THE STATUS OF VACCINE AVAILABILITY AND ASSOCIATED FACTORS IN TSHWANE GOVERNMENT CLINICS

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The Status of Vaccine Availability and Associated Factors in Tshwane Government Clinics

By

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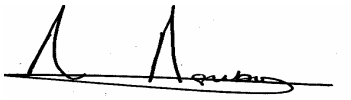
DECLARATION

I, Ntombenhle Judith Ngcobo, Student no. 210 210 869, hereby declare that the treatise for Masters' in Business Administration is my own work and it has not been previously submitted for assessment or completion of any postgraduate qualification to another University or for another qualification.



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DEDICATION

I dedicate this work to my two beloved daughters: Busi and Sinenhle; as a source of inspiration to them and that they may always draw strength from within and reach for their goals; remain focussed, no matter how daunting the challenges may be.

I also dedicate this work to my late mother, Mrs Andrina F. Ngcobo.

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Vaccines have greatly contributed to the control of vaccine preventable diseases. The adoption of the Decade of Vaccines (DoV) by the World Health Assembly in 2011 is an indication of how the global community values the benefits of vaccines. Efforts by many countries to introduce new vaccines are a significant move towards attaining this vision. However, new vaccines put strain on vaccine supply chains. The immunisation programme in South Africa has similar challenges, with indications of vaccine stock outs in clinics since the introduction of three new vaccines in 2009. This study set out to establish the status of availability of vaccines in Tshwane government clinics and associated factors.

Method

A cross-sectional study was conducted in a sample of randomly selected government clinics in Tshwane health district of Gauteng province. Data was collected using a structured measurement instrument during a visit to each of the participating clinics. Data was collated and analysed using excel based software.

Results

A total of 31 clinics participated. In the preceding 12 months, clinics experienced vaccine stock outs, especially of the 3 new vaccines: pneumococcal conjugate vaccine (PCV), rotavirus (RV) vaccine and Pentaxim ®. These were also out of stock for a long duration; for over 2 weeks in a majority of clinics. The causes of vaccine stock outs were: poor management of stock, depot out of stock, unreliable deliveries, lack of pharmacy assistants, and limited fridge capacity. Further burdening the situation is the emergency ordering system that does not function effectively.

Conclusion

Significant vaccine shortages occur in Tshwane government clinics. It is recommended that the vaccine supply chain should be restructured and overhauled with the use of advances in technology. Urgent measures should be taken to address the identified causes of stock outs including ensuring reliable deliveries of stock and emergency orders.

Key words: *vaccine shortages, vaccine stock out, supply chain management*.

CHAPTER 1. INTRODUCTION AND BACKGROUND TO THE STUDY

1.1 Introduction

Vaccines are used in the immunisation programmes for control of vaccine preventable diseases (VPDs). Vaccination is a deliberate process of inoculating a subject with an antigen (a vaccine) that closely mimics an organism that causes a natural infection to confer an immune status, a status of protection from a particular infection. The terms immunisation which means rendering one immune (often through vaccination) and vaccination are commonly used interchangeably. Vaccination is implemented in all countries through the Expanded Programme on Immunisation (EPI) which focuses mainly on children. EPI was launched by the World Health Organisation (WHO) in 1974 (WHO, UNICEF, World Bank, 2009).

Vaccination has greatly contributed to the control of vaccine preventable diseases and thus to human development. Immunisation with vaccines saves more than 2.5 million lives a year and with increased coverage and use of newer vaccines, it has the capacity save an additional 2 million deaths a year (WHO, 2009). Vaccines have made possible the realisation of major public health milestones. Vaccines helped to ensure that smallpox, a disease that killed and disfigured millions of people and caused a lot of human suffering has been eradicated from the surface of the earth. In 1979 the World Health Assembly (WHA) declared smallpox to be globally eradicated (Arita, 2011).

Vaccines are considered the most cost effective public health intervention, second only to the provision of safe water. No other intervention has had a similar impact on the control of mortality and morbidity (Plotkin, Orenstein, Offit, 2005). As the international community strongly advocates for advances in human development and the reduction of childhood mortality through the Millennium Development Goals (MDGs), efforts are intensified to reach more and more children with lifesaving vaccines. It is evident that efforts to achieve the MDG number 4 of reducing childhood mortality will be successful if centred on strengthening the immunisation programme (WHO, 2009). Recently there are more intensified efforts by the global community to reap the benefits of vaccines and extend these benefits to other age groups. In 2011 the World Health Assembly declared the period 2011 to 2020 the “Decade of Vaccines”.

For vaccination programmes to be effective and to sustain the impact made in the control of VPDs; it is crucial that there is an ongoing uninterrupted supply of quality vaccines maintained under the right cold chain conditions; right through the supply chain up to service delivery level, at facilities where children are vaccinated. There should be a good level of reliability of vaccine supply, so that when the users of health care services present to facilities, vaccines are available and the recipients (primarily children) are vaccinated according to the national schedule.

In South Africa, vaccines have a long supply chain. The supply chain starts with the manufacturer, usually an overseas based company; from manufacturer vaccines are transported to a national depot; from national depot to a provincial depot and from provincial depot to a district depot; from where they are normally transported to facilities. An interruption in the supply of vaccines can occur anywhere along the supply chain, resulting in stock outs in all levels below. An uninterrupted supply of vaccines is a pre-requisite for an effective immunisation programme. It refers to a situation where any level in the supply chain receives the ordered quantities stock of vaccines within an expected time frame.

Failure to ensure an uninterrupted supply of vaccines results in vaccine stock outs in clinics, subsequently caregivers and their children are turned away without being vaccinated. This may have serious implications for the health system, as vaccines are essential drugs and by definition should be available at all facilities that render immunisation services at all times. Furthermore, vaccine stock outs represent a failure by the Department of Health to deliver on its primary mandate of providing reliable quality health services and protection of children and communities from VPDs.

This study will use the term uninterrupted supply to refer to actual supply and ability of a certain level in the supply chain to supply and receive vaccine orders placed, whilst the term stock out refers to shortages which include running out of stock and zero quantities. Stock outs therefore mean that a certain level in the supply chain cannot meet the demands of a lower level and cannot supply a particular vaccine. At facility level it means that clients cannot be vaccinated according to schedule; they have to be turned away; much to their inconvenience, expense and opportunity cost.

1.2 The Problem of Vaccine Stock Outs - The Management Dilemma

1.2.1 The Nature of the problem

South Africa has a functional Expanded Programme on Immunisation (EPI), with 11 conditions covered by the EPI schedule. These conditions are: polio, measles, tuberculosis, diphtheria, pertussis, tetanus, haemophilus influenzae type b, hepatitis B, rotavirus and pneumococcal infection, cervical cancer. The 3 vaccines: Rotavirus Vaccine (RV), Pneumococcal Conjugate Vaccine (PCV) and DTaP-IPV//Hib, a vaccine combination of 5 antigens called Pentaxim ®; were introduced in 2009.

Anecdotal evidence points to that vaccine stock out have mainly become a serious challenge since the introduction of the 3 new vaccines in 2009. The Post New Vaccine Introduction Evaluation (PIE) conducted in 2011 by the Department of Heath with the support of WHO and UNICEF in all 9 provinces, reported on significant vaccine stock outs in all provinces (NDOH-PIE, 2011). It is important to note that DTaP-IPV//Hib, Pentaxim ® a combination of 5 vaccines (pentavalent), contains: diphtheria, pertussis, tetanus, polio (new injectable polio) and haemophilus influenzae antigens; replaced the previous Combact Hib (DPT-Hib, a 4 antigen combination) that contains the same antigens except for injectable polio. Therefore, this was not a new vaccine but merely a newer formulation of vaccine antigens that were in the schedule before the introduction of new vaccines. Any shortage or stock out of the Pentaxim ® (DTaP-IPV//Hib) would mean that children are not protected against infections that were under control for a long time. Such a situation could result in outbreaks of conditions that for a long time were under effective control, such as diphtheria and pertussis.

It is mainly these 3 new vaccines that have been commonly reported to be in short supply and it would appear that of the 3, most stock outs are of Pentaxim ®.

1.2.2 The Extent of Vaccine Stock-Outs. HOW Big is the problem?

The reports of new vaccine stock out after the new vaccines were introduced include direct complaints from the public to the national and provincial department of health offices and newspaper reports; where users of health services expressed concern and frustration at being turned away at health facilities as vaccines were out of stock.

Furthermore, reports from the national EPI programme based on facility visits and the Post Introduction Evaluation (PIE) of new vaccines have identified similar findings in more comprehensive reports. The PIE report indicated vaccine stock outs in more than 60% of facilities visited that stretched over a period of 18 months prior to July 2011.Of significance was that for the period of April 2010 to March 2011 over 221 000 children that received measles vaccine at 9 months did not get the 3rd dose of PCV for protection against pneumonia and meningitis; normally given at same time with measles vaccine at 9 months. All provinces and all districts including Tshwane District in Gauteng province had vaccine stock outs. These significant findings have implications for the delivery of Primary Health Care (PHC) services in South Africa.

Other sources of information support these claims. Figures for 2010 on the amount of vaccine stock ordered and received by provinces, indicate that provinces ordered much less vaccines than their estimated stock requirements (EPI National Office, direct communication). Therefore, these reports may partly explain why district/sub district depots and eventually facilities run out of stock ,

Other than the PIE report and media reports on vaccine stock out there seem to be very scanty specific documented reports on vaccine stock out in South Africa. The South African Health Review 2011, by the Health Systems Trust (Naledi, 2011) refers to frequent stock outs of drugs in the Essential Drug List due to poor management. They refer to the introduction of new services like antiretroviral (ARV) therapy and new vaccines, which have exposed inadequate infrastructure at facility level, resulting in poor service. There is no specification and quantification of the stock outs in this report.

Muzi (2006) on the study on Essential Drug List (EDL) in Mopani district in Limpopo province reported that up to 73% of facilities surveyed reported stock out of paracetamol (Panado®). This indicates serious drug stock out with a high proportion of facilities in this district having stock out of basic drugs in the EDL.

1.2.3 The Effects of Vaccine Stock outs

Vaccine stock outs have many far reaching implications for health managers, for the immunisation programme, for service users, for the vulnerable children and for society at large. It affects all segments of society. The users of the health services suffer significantly when there are vaccine stock outs; this is further exacerbated by the lack of effective mechanisms to communicate with parents about the vaccine stock situation.

There are also cost issues. Immunisation is a cost effective programme; even with the use of newer and more expensive vaccines. The cost of treating the targeted diseases and associated disabilities is much higher than the cost of immunisation.

When clients are turned away because of vaccine stock outs the public loses trust in the health system and government services in general. Those who were directly affected as clients share their experiences and eventually communities lose trust in the programme.

Anecdotal evidence points to the fact that stock outs are mostly due to poor management of vaccine supplies either at provincial depot, district depot or at facility level. Vaccine stock outs and consequences pose a serious management dilemma. They are a marker of poor management that results in a dysfunctional health system that fails to protect the country's citizens from deadly infections. Vaccine stock outs therefore impact on society and other segments of the health system.

1.3 Scope of the Study

This study examines the extent and factors associated with vaccine stock outs in government facilities in Tshwane Health District in Gauteng province over a period of 1 year. The assessment includes a sample of clinics in Tshwane Health District that provide immunisation services. The study did not cover private facilities and clinics that are run by Non-Governmental Organisations (NGOs).

1.4 Research Problem

For the Department of Health to deliver on its mandate of protecting children and communities from vaccine preventable diseases and to meet the Millennium Development Goal (MDG) number 4 of reducing childhood mortality, it is essential that there is an uninterrupted supply of vaccines at all levels so that children can be vaccinated. When interruption occurs there are serious negative consequences. Information is scarce within the South African context and specifically within Tshwane district, on the situation of vaccine availability, extent of probable vaccine stock out and the causes of vaccine stock outs.

1.5 Objectives and the Related Hypothesis

Primary Objective:

The study aims to establish the status of vaccine availability and associated factors in government health facilities of Tshwane Health District of Gauteng province.

Secondary Objectives

- To establish the status of vaccine availability and possible occurrence of vaccine stock out in Tshwane District health facilities.
- To determine the impact the higher levels of the supply chain have on health facilities with regard to vaccine stock levels
- To establish an association between the availability of dedicated appropriately trained Health Workers responsible for vaccines and vaccine availability.
- To determine if there is an association between vaccine stock shortages and the practices of vaccine stock management including ordering patterns.
- To determine if there is an association between cold chain capacity at district depot and lower levels and stable vaccine stock levels.
- To determine if focus supervision is associated with vaccine stock out.

The Hypothesis Testing

The Hypothesis testing is based mainly on the secondary objectives of the study. The Null Hypotheses are as follows:

- The reliability of the higher levels of supply chain on providing the stock ordered is not associated with maintenance of adequate vaccine stock at facilities
- There is no association between having dedicated, appropriately trained Health Workers responsible for vaccines and the availability of vaccines.
- There is no association between the occurrence of vaccine stock out and the practices of vaccine stock management, including ordering patterns.
- There is no association between cold chain capacity and of vaccine stock out.
- The focus of supervision has no effect on vaccine stock out.

1.6 Research Design

This is a descriptive cross-sectional study. It is a descriptive study that is quantitative in nature. It falls under the positivism research paradigm. It observed and recorded observations in an objective manner.
Facilities that participated in the study were selected randomly.

A measuring instrument was used in the study to examine the availability of vaccines in clinics and identified specific vaccines most commonly affected by stock outs. The study examined the causal relationship between the independent variable of vaccine availability and the following dependent variables: vaccine stock management, reliability of a higher level in supplying the ordered quantities, presence of dedicated and trained person for vaccine management, cold chain capacity and the focus of supervision.

Ethical clearance was sought from the Research Ethics Committee (Human) at the Nelson Mandela Metropolitan University (NMMU).

Data was collected through administration of a structured questionnaire, the measuring instrument that was administered by the principal researcher.

1.7. Definition of Key Concepts

Vaccine Stock Management: This refers to ensuring an uninterrupted supply of vaccines at different levels. It includes forecasting of vaccine needs, maintaining minimal and maximum stock levels and the potency of vaccines through maintenance of adequate cold chain.

Vaccine supply chain: The different levels in the supply of vaccines from the manufacturer, to national suppliers, to provincial depots, to district depots that supply health facilities, right up to facility level. All these have a responsibility of maintaining the cold chain as well as adequate vaccine stock including buffer (additional) stock to guard against extra and or unforeseen demands.

Cold chain: A system consisting of people, equipment which ensures that heat sensitive pharmaceuticals such as vaccines, are maintained under the right temperatures to keep them potent till they reach the intended recipients at health facilities. The prescribed temperature range for these pharmaceuticals must be maintained at all times; during storage and transportation.

Vaccine stock-outs: A situation where a point of service delivery, either a depot or a health facility does not have vaccines and clients who present for this service cannot be offered the vaccine.

Vaccination: A deliberate process of inoculating a subject with an antigen (a vaccine) that closely mimics an organism that causes a natural infection to confer an immune status, a status of protection from a particular infection.

Immunisation: A process of rendering one immune or protected against a particular infection, often through vaccination. The terms vaccination and immunisation are used interchangeably, although quite often the term vaccination is more appropriate; because not all those who are vaccinated end up immune.

Immunisation coverage: The proportion of the target population usually children who have been vaccinated, expressed as a percentage. The numerator is all those who have been vaccinated with a specific antigen (vaccine) over the denominator, all those who are targeted for vaccination. In real terms it should be vaccination coverage rather than immunisation coverage.

CHAPTER 2. LITERATURE REVIEW

2.1 Introduction

Vaccines are an important component of Primary Health Care services. As highlighted in the previous chapter, vaccines protect children ensuring they grow healthy, free from vaccine preventable diseases (VPDs) to become productive members of communities. To that extent, vaccines are an investment for the future. Furthermore, vaccines are increasingly used in other segments of the population such as pregnant women and the pre-adolescent age group.

The percentage of children vaccinated also known as the immunisation coverage is one of the basic indicators of the level of functioning of a health care system. To increase vaccine coverage and maintain it at an acceptable level, it is crucial that causes of vaccine shortages are promptly investigated and addressed.

Bearing testimony to the significant and outstanding benefits of vaccines the World Health Assembly (WHA) in 2011 adopted a resolution on a "Decade of Vaccines" (DoV) for the period of 2011 to 2020. The vision of the DoV is a world free of vaccine preventable diseases. The DoV has a mission to extend the benefits of vaccines to all people irrespective of their circumstances. This mission includes ensuring universal access to new and under-utilised vaccines, which up to now the developing less resourced countries have had and still continue to have limited access to.

To be able to achieve the vision of the DoV the WHA in 2012 adopted the Global Vaccine Action Plan (GVAP), which is road map to achieving the objectives of the DoV. As eloquently put by Thompson, Strebel, Dabbagh et al. (2013, p. 149):

> *"the Global Vaccine Action Plan aspires to create a world in which all individuals and communities enjoy lives free from vaccine preventable diseases by extending the full benefits of immunisation to all people by 2020 and beyond."*

This is progressive, but the bottom line is that if the world is to achieve universal access to life-saving vaccines as envisaged in the DoV and as elaborated in the GVAP, systems have to be in place to ensure uninterrupted supply of vaccines. There should be efficient systems for ensuring availability of vaccines; right from the manufacturer to the national depots, to regional/provincial depot, to district depots and finally to the facility level; where users, the beneficiaries of health services present.

The issues brought up by accelerated efforts to ensure universal access to lifesaving vaccines in accordance with GVAP and DoV are appropriately captured by Zaffran, Vandelaar, Kristensen et al. (2013). Zaffran and colleagues highlight the point that immunisation programmes in many countries since 2000 were already facing a situation where their vaccine portfolios (the number of vaccines in the national schedule) had increased from 6 to 12 antigens currently recommended by WHO (actual number depending on the disease epidemiology in that country and region). Humphrey (2011) concurs and points out that the first decade of this century has been most productive in vaccine development with a release of a plethora of new life saving vaccines for rotavirus diarrhoea, meningitis and human papilloma virus infection that cause cervical cancer.

Whilst the potential of the increased number of vaccines to reduce morbidity and mortality is not questioned, the point is that access to these vaccines is dependent ("hinges") on the ability of supply chains and logistic systems to receive, store, and transport the vaccines at appropriate temperatures and have them delivered to the recipients on time (Zaffran, et al., 2013). According to Humphrey (2011) the introduction of new vaccines has put unprecedented strain on the delivery and logistics systems that have not changed or have not been upgraded over a number of decades. The supply and logistics systems in many countries have not been able to keep pace with the increasing number of antigens in the national schedules (Zaffran, et al 2013).

Anecdotal evidence points to that, vaccine shortages have become problematic issues for the Expanded Programme on Immunisation (EPI) in South Africa since the introduction of the 3 new vaccines in 2009. The findings of the PIE (2011) are elaborated in this report.

2.2 The Vaccine Supply Chain

Vaccines have to reach the people they are intended for and be available for them when they present to health facilities and when vaccines are needed for other situations such as in response to outbreaks and during immunisation campaigns.

There is therefore a need for a system of vaccine supplies. According to the Strategic Advisory Group of Experts (SAGE) on Immunisation, a WHO advisory group of experts;

the success of national immunisation programmes depends a great deal on the supply chain systems for delivery of vaccines and related consumables. To be effective, an immunisation programme needs a functional supply system that meets the 6 rights. The supply system must deliver: the right vaccine, at the right quantities, at the right cost, at the right place, right time and in the right condition (WER, 2014).

Important is to note the last right for vaccines, the right condition. This is an additional requirement for vaccines that is not a standard for all pharmaceuticals/ drugs. The right condition means that vaccines must be maintained under cold chain conditions at all times; right from the manufacturer, to national depots, to regional/provincial depots, to districts and eventually at health facilities (clinics), the point where vaccines are used.

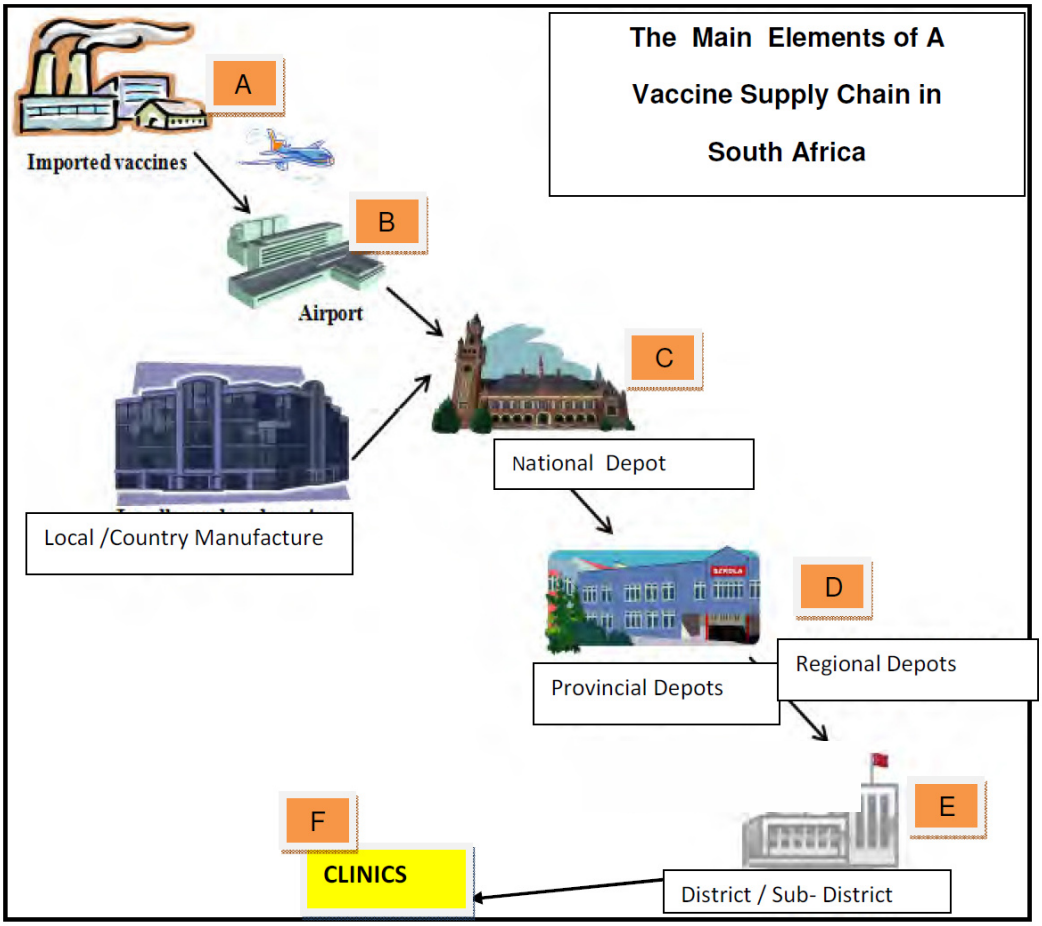
Supply systems consist of the logistics for obtaining and distributing supplies or products needed; this includes the manufacture, transportation, equipment, storage, warehousing, refrigeration and the information system used to track where the products are at a point in time (PATH and WHO 2011). The supply system for vaccines is complex; as already indicated, it is further complicated by the fact that currently all vaccines must be maintained at the appropriate temperatures, generally 2 to 8 degrees Celsius, a process referred to as cold chain maintenance.

Maintenance of the cold chain is very important with vaccines; as failure to do so results in vaccines losing their potency. This has been well documented; a diphtheria outbreak in Australia in 1993 to 1996 and a localized outbreak of measles in the United Sates in 1970 were associated with improper vaccine storage (PATH, WHO, Health Systems Research Institute Mahidol University, 2011).

The supply system, also referred to as the supply chain, may only differ slightly from country to country but generally for most developing countries it follows a similar layout. Vaccines are received at national depot from an overseas based manufacturer, they are then transported to a national warehouse; From here transported to regional/provincial stores; from regional stores to district stores and from there to health facilities/clinics. Receiving supplies from a foreign country brings up issues related to customs clearance etc. (although often there are standing working arrangements which address this). The supply chain in South Africa is similar to other countries and follows the layout as illustrated in figure below.

Figure 2.1 Vaccine Supply Chain

(Adapted from PATH, WHO, Health Systems Research Institute, Mahidol University, 2011).



It is evident that such a complex supply chain needs to be managed. Effective management at each level of the supply chain will have an impact on availability of vaccines at all levels, especially at the end-user level, the clinic. It is also important to highlight the process of information going backwards from the health facilities (clinics) on number of doses administered to the district level; the district compiles monthly reports and gives information to the province and this information goes right up to national level. Each level uses combined figures of data of administered doses for estimates of vaccine orders for the next cycle.

The importance of close to accurate forecast that are communicated to suppliers and manufacturers timely cannot be over emphasized; as this area is of particular significance in vaccine logistics for the following reasons:

- Vaccine manufacturing is complex and takes a long time; it may take 9 months to over a year, therefore orders have to be placed in time as manufacturers have to know well in advance which countries and what quantities are needed (Klein, 2006).

- Vaccine quality checks are very stringent and much more stringent than for other drugs. In addition to the WHO prequalification and approval at country of origin, local approval is required and also local batch testing is conducted. Some countries such as Vietnam and South Africa do local batch testing. The local testing of batches increases the lead time for vaccines from the time of placing an order to the time of receiving an order.

- There are few vaccine manufacturers compared to other drugs.

- Unexpected demands of an emergency nature may take up stock planned for other countries. Such demands include disease outbreaks, which require countries to conduct campaigns to prevent further outbreak, e.g. measles, polio and influenza.

- All these factors are important in considering the issues of supply chain and what can go wrong in the supply chain leading to vaccine stock outs.

2.3 Causes of Vaccine Shortages

Researchers have approached the causes of stock shortages from different angles. For simplicity, referring to the above diagram figure 2.1 is useful for understanding the possible causes of vaccine stock outs. It is best to refer to the components of the supply chain, the related logistics, systems and the processes of management at each level.

2.3.1 Manufacturing Level (Level A in figure 2.1 above)

Many things could go wrong at the first level of production. Apart from batch failures and increased in demands there are some fundamental issues which affect this level, some are unique for vaccines. Apart from other complications in manufacturing, vaccine manufacturing is quite complex and takes much longer than the manufacture of other drugs. To develop and eventually supply a successful vaccine and the final product should cover the cost of the failed product. To demonstrate this point Klein (2006) refers to pneumococcal conjugate vaccine 7 valent (PCV7), which for the 7 serotypes requires 7 separate large scale fermentation and purification. And there are 300 separate quality control tests. This complexity may explain why there are so few manufacturers of vaccines.

Klein and Meyers (2006) examined the causes of vaccine shortages, mainly addressing childhood vaccination and influenza vaccines, and categorized causes into 3 categories: financial, regulatory and liability. The regulatory environment for manufacturing of vaccines is very stringent, such that many developing countries cannot manufacture vaccines. Regulatory requirements also encompass the requirements for licensing of production plants. The requirements and quality control processes relating to both the licensing of vaccines and particularly for the licensing of vaccine manufacturing plants are very stringent in the United States and fall under the auspices of the Food and Drug Administration (FDA), (Jacobson, et al., 2006; Rodewald, et al., 2006). Furthermore, vaccine manufacturing has to first meet WHO and UNICEF standards. Even the largest manufacturers in the world have faced this challenge; Klein and Meyers (2006) highlights this issue and the frequent inspections by FDA at the manufacturing facilities. As a result many countries, especially developing countries have to import all their vaccines.

In South Africa the regulatory environment relating to registration of new vaccines is administered by the Medicines Control Council (MCC). According to MCC regulations, vaccines that are to be registered for use in South Africa must have some data to show that they are safe and effective in the local setting and will be safe and effective in accordance with the schedule according to which they should be used (Act 101 of 1961). This often means that vaccines have to undergo local clinical trials even when they have been used in other countries and are already registered in their countries of origin. Furthermore, MCC regulations stipulate that every batch of vaccines, should undergo safety test at the national control laboratory (NCL) in Bloemfontein; before the batches can be released for use. The batch testing at NCL takes between 4 to 8 weeks, occasionally longer. This has significant implications for timely distribution and delivery of vaccines, particularly when stock levels are low.

There is also the issue of legal liability and the financial implication this may have on the manufacturer, in case there is a severe adverse event that occurs from a vaccine (Klein and Meyers, 2006). The United States has a high rate of litigation and this is one area that companies are concerned about. However, the US immunisation programme has a Vaccine Injury Fund which is mandated by Law. Those who develop adverse events from the use of vaccines may not lay other legal claims to a manufacturer once their case is considered by the Vaccines Injury Fund.

Financial causes in this context refer to business decisions, which are based on economic issues. Globally, there is a decrease in the number of vaccine manufacturers as vaccine production has lower profit margins than other pharmaceuticals (Klein and Meyers, 2006; Jacobson, et al., 2006). Therefore, the manufacture of vaccines may not be a profitable business for many companies. This is further exacerbated by that governments are the biggest market for vaccines and governments expect to purchase products, especially vaccines at low prices.

In the vaccine manufacturing and supply industry the financial decision and other factors of complex regulatory and manufacturing processes mentioned result in vaccines being a single source product with only one or at most two manufacturers for most vaccines. This is further complicated by mergers amongst big companies that are also vaccine manufacturers (Ventola, 2011).

Business decisions by manufacturers may affect stock availability. “Just in time” inventory management to optimise cash flow and reduce the cost of inventory stock may be used in vaccine supply. This is critical in vaccine manufacturing; once vaccines are produced not only do they need adequate storage but even more significant is storage under appropriate cold chain conditions. Vaccine manufacturers need to have a clear understanding of the demand well in advance and use this information to draw up their production plan.

Other causes of shortages at manufacturing level are failure to meet demands and interruption of production, such as batch failures. Increased in global demand of vaccines, are fairly common. In 2013 there was an increase in global demand for measles vaccine, resulting in measles vaccine supply shortages, which affected South Africa. (Personal Communication EPI-SA) . Failure by manufacturers to meet demands may be due to higher than expected demand for increased quantities of vaccines (Hinman, Orenstein, Santoli, et al., 2006).

Unexpected high demands may occur when countries or group of countries face an epidemic and have to respond to it by vaccination, as with measles outbreak. Other increases in demand may be due to accelerated global efforts for disease control like with polio and the shortage of polio vaccine in 2013 (CDC, 2013). These situations have affected vaccine supply in SA.

A sudden increase in demand can also occur when there is a change in the vaccination schedule which requires additional doses. This happens when a national programme advisory committee recommends an additional dose in the national immunisation schedule; this leads to increase in demands (Jacobson, 2006).If such changes are not properly timed and timely communicated to suppliers; this may put strain on vaccine supplies.

Failure to meet demands may be worsened by a situation where other manufacturers discontinue production of certain vaccines which they deem not profitable.

2.3.2 Airport and Customs Clearance level – Level B in figure 1.2

Most countries already have the systems in place for customs clearance of vaccines. However, complications have arisen in situations where a new supplier has to supply a vaccine when the usual supplier cannot for some reason meet the demand. In SA this

happened in 2010 with clearance of UNICEF procured polio vaccines. Customs clearance for this kind of unusual supplies take longer than the normal supplies, resulting in stock outs lower down in the supply chain.

As vaccines are flown from the country of manufacture there may be improper transport conditions which may affect the potency of vaccines. Freeze sensitive vaccines have frozen en route whilst flying from country of manufacture, resulting in many doses being destroyed. It has happened that the whole shipment freezes. This creates an unexpected demand on the manufacturer (Personal Communication Sanofi 2011/2013).

2.3.3 National and Provincial Levels (Level C in figure 2.1)

The national and provincial levels are considered together in this section as the factors at these levels are similar. Differences relate to the size of responsibility, quantities, the need to interact with the suppliers and to send vaccines for batch testing at national level. Quite a few things can go wrong at the national depot. The main factors at this level relate to: forecasting of demands on time; stock management including ensuring adequate safety (buffer) stock; availability of equipment, including adequate cold chain capacity; human resources and governance. The importance of these factors in ensuring adequate stock at all levels within a country's supply chain is highlighted by WHO in the Effective Vaccine Management Initiative (WHO, 2010). Lack of financial resources may potentially be another factor but generally it may be less of a factor for stock shortages as countries with less resources are supported by the Global Alliance for Vaccines and Immunisation (GAVI) through UNICEF to finance and procure vaccines.

WHO recommends that the national level depot should keep vaccine stock of 3 months as part of safety stock (EVM, 2010; PIE, 2011). Complying with this requirement is dependent amongst other factors on having adequate space and cold chain capacity to store the vaccines. Cold chain capacity as a requirement for ensuring adequate vaccine stock is elaborated in the next session on the impact of new vaccines on vaccine supplies.

Forecasting and placing orders to manufacturers is important. The national depot has this responsibility; forecasts should be informed by previous consumption levels, revised

target population figures and specific demographic information on immigration. Other factors that the national procurement office should consider include risk of disease outbreak, planned immunisation campaigns, change in policies and schedule. Global disease eradication and control efforts often spearheaded by WHO and UN agencies should always be considered in developing forecasts of vaccine requirements. This means keeping up to date with international trends and WHO recommendations. For example, the current DOV and the GVAP have an impact on vaccine demands from countries. Similarly the current Polio Endgame plan with the need to include inactivated (injectable) polio vaccine and switchover to a two valent polio vaccine has an impact on demand of these vaccines (PEI, 2014).

Financial constraints and lack of resources to purchase vaccines as considered by Klein and Meyers (2006) area significant relevance for the provincial and district levels in South Africa. Each province manages its own budget and provinces settle their accounts directly with the national supplier. It is up to the suppliers to suspend provision of services when accounts are not settled. Indications are that, it is usually after long periods of time when suppliers are owed big amounts that they suspend delivery of vaccines. However, there is lack of information on this.

2.3.4 The District Level and Facility Level (Clinics), Level D

Accurate forecasting of demands and the need for adequate cold chain capacity also apply to districts and clinics. These levels have to order on time and make accurate estimates of their vaccine needs. Ordering patterns and effective stock management are equally important at these levels. How each district and each clinic manages the vaccine stock and maintains safety levels is very important in ensuring an uninterrupted supply of vaccines. Orders have to be placed in right quantities on time, taking into account the lead time for orders; the time it takes for a vaccine order placed from a clinic to reach the district level, to be processed, packed and delivered to the clinic.

Clinics normally have regular deliveries of stock, usually once a month or once in 2 weeks. Management of the quantities ordered, maintenance of information system for stock and ensuring minimum levels are maintained should be effective and used to ensure continuous availability of vaccines. This applies equally to both levels, their stock

levels do not reach zero (0) at any point in time. Management systems should ensure that before zero levels are reached measures have been instituted to address the shortage. The importance of these factors is also captured by WHO, et al. (2010) in the Effective Vaccine Management Initiative

2.3.5 Cold Chain Capacity and Transport

Cold chain capacity refers to available fridge space or cold room space to keep vaccines at appropriate temperatures. The national, provincial and district depots mainly use cold rooms and to a lesser extent fridges to store temperature sensitive pharmaceuticals including vaccines. Clinics use fridges. Cold chain capacity refers to the capacity or the available space in the cold rooms at national, to district levels and fridges at fridges at clinic level to store vaccines. There should also be adequate cooler boxes of appropriate size for each level to transport to the next level.

The transport of vaccines over long distances requires specialised vehicles fitted with cooling systems to ensure the temperatures are maintained. For local delivery within a district, normal delivery vehicles suffice.

The impact of cold chain capacity and transport in the supply chain needs special consideration. These resources should be available, functional and reliable. Cold chain capacity and transport affect availability of vaccines at all levels from national level to point of the user of vaccines or the recipients, the children.

Furthermore, the capacity of one of these resources affects the other. If there is inadequate cold chain capacity this necessitates an increased in frequency of stock deliveries and thus impacting on transport and vice versa. The impact of cold chain capacity and transport is clearly evident in relation to the introduction of new vaccines and literature points to this. (See section below: Haidari, Connor, Wateska, et al., 2013; Lee, et al., 2012).

2. 4 New Vaccines and the Impact on Supply Systems

The introduction of new vaccines has had a major impact on vaccine supply chains. It is evident that as the number of vaccines in the EPI schedule grows, their availability is highly dependent on the capacity of the supply chain to handle the increased portfolio (Zaffran, et al., 2013). As highlighted earlier, the introduction of new vaccines has put unprecedented strain on the delivery and logistics systems in developing countries that have essentially remained the same over 3 decades (Humphrey, 2011).

There are a number of factors which contribute to the impact of new vaccines on the supply chain. First, the presentation of the newer vaccines is different from that of the 6 basic antigens which have been there since EPI was launched by WHO in 1974. The 6 basic antigens normally referred to as the traditional antigens came as multiple doses, with 1 vial of 5mLs containing 10 doses. The presentation of the newer vaccines such as the pneumococcal conjugate vaccine (PCV) and rotavirus vaccine (RV) is different; they are single doses, that are prefilled in syringes (in SA, PCV and Pentaxim ® come prefilled in a syringe). Apart from this presentation the packaging in boxes of 10 doses is bulky. For example, a single dose of PCV takes up to 20 times the volume of a 10 dose vial of the traditional vaccines (Humphrey, 2011).

Consequently the impact of the increase in number of antigens with newer vaccines and the presentations is most profound on the volumes that have to be handled, stored and transported. It is not only the addition of more vaccines in the supply chain but it is the bulkiness of the presentation of these vaccines. This point is illustrated by Zaffran and colleagues (2013); that for countries introducing PCV and RV the volume increase is 143% per dose, affecting cold chain capacity of the supply chain. This increase in volume implies an increase in the cold chain requirements of these vaccines which according to Humphrey is up to 5 times the original capacity. Other sources put this figure at 11, the increase cold chain space by a factor of 11, in some countries (WER, 2014). There is a similar kind of increase in volume for transport requirements.

Zaffran and colleagues (2013) studied the potential impact of implementation of new vaccines which come in different formulations, on the supply chain and systems in 20 countries that planned to introduce PCV and RV in 2011 and 2013. They compared volume requirements with the planned introduction of new vaccines with the available cold chain storage capacity. Of the 20 countries only 2 were not going to have

increased volumes of cold chain space requirements at national level after the new vaccines. The rest were all to have a very high increase in cold chain requirements at national level. Increases were over 200% in a majority of these countries. The countries that were not going to increase their cold chain space requirements were already planning to expand their cold chain capacity and or they were about to start the use of combination vaccines, which combined 3 different vaccines into 1 product. However, even in these countries, further analysis at lower levels, at regional and district depots indicated that the capacity of the cold chain was not going to cope with the volumes of the new vaccines.

Considering other effects of the new vaccines, a concern has been raised that the vaccine management systems recommended by WHO and donors seem to put too much emphasis on improving the capacity of stationary cold chain resources such as cold rooms and the fridges; yet little attention is given to improving transport capacity. This brings about challenges; neglecting the need to augment transport capacity may make the situation worse and increases bottlenecks, leading to vaccine shortages at different levels (Haidari, et al., 2013). Haidari and co-authors emphasise that the interplay between cold storage capacity and transport is crucial and the supply chain does not benefit by strengthening one without the other.

The impact of introducing new vaccines and the resultant stock outs has been experienced by a number of countries. For example the introduction of rotavirus vaccine in Latin American countries (such as Brazil, Ecuador, El Salvador, Venezuela, etc.) in 2006/7 resulted in frequent vaccine stock outs in clinics as the clinics did not have enough refrigerator capacity to store the large volumes of vaccines. Subsequently, when clients visited the clinics, there were no vaccines.

An important fact to consider is that the newer vaccines are much more expensive than the traditional vaccines. Therefore, there are a lot of complexities around these vaccines: they are expensive, they are bulky, come differently packaged and put strain on the supply chain systems. Yet, they still need to be stored at the right temperatures like other vaccines. Because of these complexities they pose a challenge in that the risk of their damage, like exposure to heat and freezing is high and very costly.

According to Zaffran (2013) WHO estimates that 50% of vaccine doses are wasted either before or after a vial is opened. This wastage can either be due to vaccines

destroyed by: freezing, changes in the vaccine vial monitor (VVM), breakage of vials or expiry. Therefore, destroyed vaccines which is a wastage, result in stock out. This is an unfortunate situation because high rates of vaccine wastage could be tolerated somehow in the past when vaccines were much cheaper, some at a cost of few cents per dose; however, vaccines are now up to 50 times more expensive than previously (Sabot, Yadav, Zaffran; 2011). Wastage, even of limited quantities puts a serious strain on financial resources.

The importance of upgrading and establishing efficient supply chains for new vaccines to ensure access to lifesaving vaccines is well captured by Sabot, Yadal and Zaffran (2011, p 3).

> *"We thus need a paradigm shift in our approach to the delivery of new vaccines. Maximising the value we get from every dollar that we invest in immunisation and every vaccine vial we procure, must be an equal priority to expanding coverage and accelerating new vaccine introduction, within the design and execution of delivery systems, correspondingly receiving as much attention as the development of new vaccines and technologies. If the hundreds of millions of dollars invested in vaccine development are to be translated to the desired transformation in disease burden, vaccine delivery systems must themselves be transformed."*

There is also the need for an advanced information system to manage stock that is more costly and be able to make realistic forecast in distribution (Zaffran, et al., 2013).

2.5 The Effects of Vaccine Shortages

Vaccine stock shortages have many far-reaching implications for: the health system, the health managers, the immunisation programme, public (parents and children as users of the service), and for society at large. The major benefits of vaccines and their important role in the control of vaccine preventable diseases have been outlined, it is nevertheless important to further highlight that vaccination does not only directly protect those who are vaccinated but it also protects many who have not been unvaccinated. This indirect protection is referred to as "herd immunity" (Fine, Eames, Heymann., 2011). Through herd immunity, vaccination protects more people, even those that were not vaccinated, as it becomes difficult for the infectious agent to find those who are not immune. This herd immunity effect helps to prevent outbreaks of infectious conditions. The impact of vaccination on the control of vaccine preventable diseases (VPDs); the key status of vaccination coverage as an indicator of a strength of a health system; the concept of herd immunity and its role in prevention of outbreaks; form the basis for an understanding of the implications of vaccine stock outs which have far reaching consequences.

2.5.1 Effects on the Users of Health Services, Society and Other Sectors

One of the first outcomes is that when facilities face shortages of vaccines, clients are turned away. The doses that are supposed to be given to children are delayed and some doses are altogether missed (Smith, Nuorti, Singleton, et al., 2007, Groom, 2006). When users of health facilities are turned away, it means they have wasted their money (taxi or bus fare to the clinic), there is also an opportunity cost for their time. This is certainly more in areas where child care–givers, parents and children have to walk or travel long distances to access health services (Humphrey, 2011).

Should shortages occur frequently this subsequently leads to the users of the health services losing confidence in the health system. When they are told to come back after a period of time, which may be two to three weeks when the clinic believes there will be enough stock, when that time comes they may not be certain whether to go back to the clinic or not. It thus causes a dilemma for them. At times they do go back and may find that even if the vaccines were available a few days ago, by the time they get there the

vaccines are again out of stock. If this happens frequently it builds anger and frustration and eventually a complete lack of trust in the health system

The main effect on the users and mainly the children who are beneficiaries of the health services, is that vaccine doses are delayed or missed during shortages; consequently children are not protected against preventable infections (Lipworth and Kerridge, 2013; Rodewald, et al., 2006). This is a serious effect as they become prone to diseases that they should be protected from. They run the risk of succumbing to infections, hospitalization, disability and death. Furthermore, when shortages of those vaccines that the users pay for occur such as influenza vaccine, the prices are likely to go up and this directly affects the users (Hinman, et al., 2006).

At the level of society the effects are that communities are not protected from vaccine preventable diseases. Society may face the devastating effects of outbreaks of conditions that should be under control or the re-emergence of previously controlled infections, like measles. Therefore societal good is not realized and society also loses confidence in the health system of the country (Jacobson, Sewell and Proano, 2006; Rodewald, et al., 2006).

Society carries a big burden when children are not vaccinated for any reason including being turned away for lack of vaccines. Vaccination of children helps to protect many including those very young to be vaccinated and the old people who are not targeted by vaccination but who are at risk of the infections children may suffer from or that children commonly carry without falling sick.

In countries where vaccination is part of school entry requirements and these are enforced, vaccine shortages may mean that such requirements are not enforceable and this requirement has to be withdrawn (Jacobson et al., 2006). This defeats the purpose of these requirements as they are meant to protect children and prevent disease outbreaks. This is also disruptive to other sectors of society as such requirements have to be suspended for a period of time and reinstated when vaccine supplies are normal.

2.5.2 Programme Effects

Effects of vaccine shortages on the immunisation programme are also profound. Vaccine supply shortages may necessitate that policies and vaccination schedule be

revised so as to prioritize those at risk and to manage with limited stock. This has been the case in the USA when shortages were faced with routine EPI vaccines as with influenza vaccine, between 2001 and 2005. When pneumococcal conjugate vaccine (PCV) shortages were experienced in 2001 in the USA soon after introduction in 2000, the Advisory Committee for Immunization Practices (ACIP) recommended that the fourth dose be delayed. In 2003, with indications that supplies would be inadequate, the Centers for Disease Control and Prevention recommended that both the 3rd and 4th dose be suspended (Smith et. al., 2007). Similarly influenza vaccine shortages have meant that the available doses be used for only those at high risk.

This has significant implications for the programme. A sudden change in policy of vaccine administration is disruptive and causes confusion. It may also take time for the information to be communicated clearly to all service providers to understand the need and to adjust the schedule. Furthermore, when the vaccine supplies are restored it needs further communication for health care providers to follow the original schedule.

When vaccine shortages occur at clinics (with no short term change in guidelines) means that health professionals must be able to deal with the situation. First they need to communicate with the care-givers about the vaccine shortage and inform them when to come back. Smith et al. (2007) highlights this point that vaccinators need to communicate effectively so that doses that are missed or not given during shortages are given when stock is available. Therefore, there should be a level of certainty as to when the stock will be available. Secondly vaccinators should be confident as to how to give missed doses when vaccines are available. Indications are that different vaccines are out of stock at different times, therefore vaccinators should be able to catch up (give missed doses) for each vaccine. They also need to record the doses appropriately on the clinic held records and also on the Road to Health Card. Failure to do this correctly has serious implications for EPI as incorrectly recorded doses result in wrong, invalid or difficult to interpret coverage figures. Incorrectly recorded doses on the patient held records will yield false results when coverage surveys are conducted.

When vaccine shortages occur and doses are delayed or missed, this affects immunisation coverage. EPI cannot be an effective programme if coverage is low mainly because clients are often turned away. This means individuals are not protected and the common good of herd protection, of protecting the entire community due to herd

immunity is lost. When vaccination coverage is low this means more and more people are at risk of vaccine preventable diseases and preventable outbreaks occur. It has been clearly documented that where immunisation coverage falls even in instances where diseases have been previously controlled, a drop in coverage results in resurgence of diseases. Communities that object to immunisation have provided good examples of this (Salmon, Teret, Mc Intyre, et al., 2006).

2.5.3 Health Systems Effects

The main effect for the health system is that it fails to deliver on its key objective and mandate; to protect citizens from vaccine preventable diseases. Vaccine shortages that occur at clinic level reflect on areas of management failure and inability to fully manage a priority public health programme. As immunisation coverage is a basic indicator for measuring health systems functioning; this means that low vaccination coverage contributes to a country's poor rating on global reports such as the Global Competitiveness Report.

An important aspect that has not been adequately covered in literature is the legal and ethical duty that government agencies such as the Department of Heath have to protect children and the duty to provide health services in relation to failure to ensure adequate stock levels of vaccines at facilities at all times. Children have a right to health services. According to the South African Constitution, children have a "right to health services" and not a "right to access to health services" that adults have (Constitution, 1996). Therefore, the government has a legal duty to ensure the realization of this right. Vaccine shortages represent the government's failure to ensure the realisation of this right.

Lipworth and Kerridge (2013) have brought up the ethical issue of drug shortages including vaccines. They assert that to view drug shortages as merely a technical issue related to production and an economic issues related to business decisions of major companies is to miss the point; drug (including vaccine) shortages are a moral, political and an ethical issue and should be considered as such by those who have the responsibility to address shortages. The issues raised are that when drug shortages occur they impair and threaten the capacity of governments and health professionals to fulfil their moral obligations to patients and society; to provide health benefits and

prevent harm. The point is that the principles of beneficence and non-maleficence are not fulfilled. Harm may indeed result to individuals if they succumb to infection and to society if disease outbreaks occur.

Another important argument raised by these authors is that when supply shortages occur, they are easily explained by these factors such as: regulatory environment which is strict, economics and profit margins etc. However, these conditions (regulatory, economic etc.) which lead to supply shortages originate from the values that we as society uphold. Supply shortages are just mere outcomes of what we have chosen to expect from the: pharmaceutical industry, biotechnology industry, regulatory mechanism and health system. This is an interesting point of view. It has been noted that the vaccine industry is one industry where profit margins are limited especially as governments are the main market, and this happens all over the world generally even for developed countries like the USA. Rodewald et al. (2006) bring up the issue of CDC and price capping of vaccines and its potential effect on vaccine supply shortages; however they did not appreciate the ethical and moral implications as brought up by Lipworth and Kerridge (2013).

There is a call for those responsible for responding to drug shortages to broaden their analysis and include the ethical obligations to society (Lipworth and Kerridge, 2013). If in South Africa most of the vaccine shortages that occur at clinics and are not due to failures of the suppliers to meet demands, then the situation is of grave concern. Anecdotal evidence points to that the majority of stock shortages are due to poor management of vaccine supplies either at provincial or district depot or at facility level. This has grave moral, ethical and legal implications for the Healt**h** System as such a situation contravenes the Constitution.

It is apparent that should stock shortages be frequent, random and unexpected or when facilities are not pre warned of shortages the situation is worse. This certainly has serious implications for service users, the programme and society at large.

This study aims to investigate the status of vaccine availability at the selected district and associated factors, concentrating at facility level. As illustrated by WHO and the approach to vaccine management there are many factors at each level that impact on vaccine supply. It is hypothesized that there may be management failure to ensure an uninterrupted supply of vaccines at clinic level.

CHAPTER 3. MODEL DESIGN

This chapter provides a theoretical model of the vaccine supply chain, with its different components. It demonstrates the linkages within the different levels of the supply chain, indicating the dependability of one level on the other level as well as some of the factors that operate at each level. It highlights the management principles that apply to vaccine supply chain which are the same as those that relate to Operations Management and Supply Chain Management in general. It then specifically unpacks the core criteria of effective vaccine management that are used by WHO is assessing vaccine supply management. Based on the literature review in the previous chapter and specific literature on supply chain the vaccine supply chain model is constructed and related aspects that form the basis for different independent variables are identified, which may have an impact on the availability of vaccines; the focus of the study.

3.1 Introduction to Supply Chain and Its Definition

The Vaccine Supply chain has been described in Chapter 2. The objective of this chapter is to look at the generic concepts and principles of supply chain; supply chain and logistics management to see how these apply to the logistics of vaccine supply. This chapter also identifies the different levels of the supply chain, the linkages between these levels and the requirements at each level that ensure optimal functioning and eventually ensure uninterrupted supply of vaccines. With this basic understanding it then constructs a model of the vaccine supply chain that outlines the factors at each level that can cause vaccine shortages.

First the supply chain should be defined. Many definitions of the supply chain have been proposed by writers. In essence these definitions refer to supply chain as a process of the manufacture of goods, and value adding, the transportation through distributors and retailers, and the final transfer of finished products to customers. Janvier-James and Mbang (2012) has made a collection of many definitions of supply chain and supply chain management. An important aspect is the extended view of the supply chain. The extended view includes the information and flow of information, logistics and management services, and the links of all the different elements of both internal and external elements to the organisation. The extended view is most appropriate for understanding of business operations and applies to the vaccine supply chain.

3.2 Supply Chain Management

Operations of a supply chain do not function in isolation; they are part of the business, they are used to implement strategies, support strategies and in the case of a health system, operations ensure the rendering of health services (Pycraft, Sing, Phihlela, et al., 2010). In the case of vaccine supplies, operations of a supply chain are core to the existence of this priority public health programme, the immunisation programme. A supply chain has to be managed; its management is strategic in that it may enhance the competitive position of an organisation and in public service it determines whether a government programme is effective or not in rendering the services.

Supply Chain Management has been defined as:

> *"the designing and management of all activities involved in sourcing and purchasing, transformation and all logistics management activities. Principally it also includes coordination and partnership with network partners who can be suppliers, mediators, third party service providers and customers. Supply Chain management coordinates supply and demand within and across corporates*" (Janvier- James and Mbang, 2012, p 196)

Supply Chain Management (SCM) draws from the areas of operations management, logistics, procurement and information technology but it strives for integration. The primary objective of managing an operations or logistics is to ensure: quality, speed, dependability, flexibility and cost (Pycraft, et al., 2010). These apply equally to government structures as they apply to business in general. All of these 5 performance areas are important in the vaccine supply chain as they will result in clients receiving immunisation services of an expected standard.

SCM is about providing the right good or services to the right place in the right quantities and at the right time. The fundamentals of SCM are that it must be: fast, trustworthy, cost–effective and flexible to meet customer needs. Therefore there is convergence of the objectives of SCM and Operations management as viewed by different writers (Janvier-James and Mbang, 2012; Pycraft, et al.,2010). Furthermore, for vaccine SCM one should consider the 6 rights highlighted earlier, of the right: vaccine, quantities, place, time, condition and cost.

As supply chain and logistics are core to the existence of a business or programme and to business strategy, there are important strategic decisions to be made for the supply chain. These decisions relate to, but are not limited to: outsourcing, which has to do with how much the organisation will do and how much it will buy, either services or goods; location, where will that component of the network be located; transportation between different levels and capacity, how big should each component be, this has to do with how big should the warehouse should be at each level and also related to long-term plans. These decisions are based on assumptions pertaining to forecasted demands.

3.3 Vaccines Supply Chain

Provision of immunisation services and the responsibility to ensure an uninterrupted supply of vaccines provide a perfect example of how the principles of Logistics and Supply Chain Management apply to the vaccine supply chain and how they should be used to effectively manage a functional vaccine supply chain.

Similar to other pharmaceuticals, the supply of vaccines, right through the chain from manufacturer up to clinic level where a child is vaccinated, uses a “pull” control system (Windisch, Waiswa, Neuhann et al., 2011). Clinics place orders with the district depot based on their forecasts of utilisation. The district depots, in turn place orders with the provincial depots, which in turn also place orders with the national depot. The national depot will place orders with the manufacturers. A “push” system, whereby a manufacturer produces goods and as soon as they are ready, the goods are put in the supply chain, is generally not possible for most vaccines as there are limited manufacturers, complicated regulatory mechanisms and there are cold chain requirements for vaccines, as discussed in the previous chapter. The manufacturers usually have long-term production plans by country, group of countries or for big agencies that purchase in big quantities like UNICEF and the Global Alliance for Vaccines and Immunisation (GAVI).

The demands for vaccines that are used in a national immunisation programme are relatively easy to forecast. A national Expanded Programme on Immunisation (EPI) has the responsibility to vaccinate all children of a certain age group. The forecasts of vaccine demand should thus be based on demographics and projected population

growth. Demand can thus, be said to be dependent as it is based and is dependent on population figures; hence a national immunisation programme should vaccinate all children in a targeted age group. It is in a set-up of private providers that demand for immunisation services can be said to be similar to operations with independent demand, where uptake cannot be predicted and is merely influenced by market factors.

According to WHO (2010), based on the Effective Vaccine Management (EVM) Initiative, there are 9 criteria that will enable effective uninterrupted supply of vaccines. These 9 criteria are: (i) Pre-shipment and arrival procedure, from the manufacturer to ensure vaccines arrive in good condition (ii) Cold storage capacity including buildings, (iii) Transport capacity, (iv) stock management systems (v) Maintenance of buildings, vehicles and cold chain equipment (vi) Appropriate EVM policies adopted and implemented, (vii) Information system (viii) Supportive management functions (ix) Distribution between each level in the supply chain should be effective. With this set of criteria WHO and the other United Nations (UN) agencies developed the EVM Assessment tool to help countries assess the functioning of their Vaccine Supply Chain at different levels. The EVM tool is based on assessment using the 9 criteria and emanates from many years of work and earlier versions of tools for assessment of vaccine stock management.

Literature has indicated that each level, each link in the supply chain is critical for effective functioning of the chain (Janvier-James and Mbang, 2012; Pycraft, et al., 2010). Factors related to the cold chain capacity, transport and it's reliability, availability of human resources and their training, the management systems including means of forecasting future demands, the use of information system, maintenance of equipment, as well as management at all levels is crucial to ensure an efficient supply chain. The introduction of new vaccines which present additional demands on the system has been highlighted.

The figure 3.1 below presents a model of the different components and levels of the Vaccine Supply Chain in South Africa, the factors and elements that impact on the supply chain at different levels, the relationship of the different levels and the effect of one level on the next level and the whole supply network. The factors that impact on

each level are based on literature, including the WHO criteria for Effective Vaccine Management (EVM). Of essence is to note the existence of a chain, should a weakness occur at any level, the whole system is compromised; subsequently there is interruption in the supply of vaccines. Eventually the objectives of the EPI are not achieved.

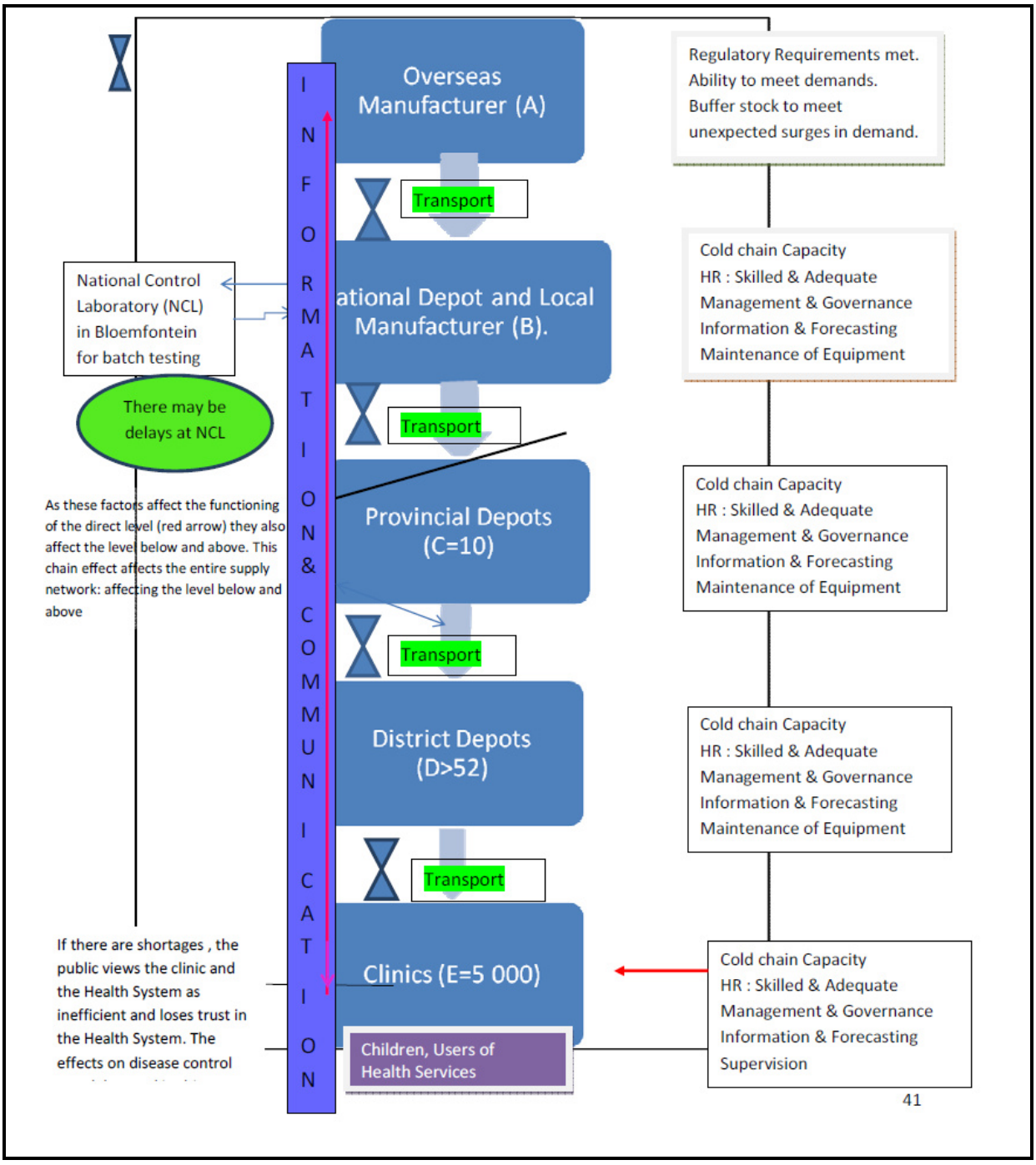
The objectives of the vaccine supply chain are the same as for other businesses as highlighted above, to ensure: quality, dependable, speedy, flexible services to users of health facilities, at a reasonable cost. Furthermore, the design, management and monitoring of the performance of this network is the responsibility of health managers at appropriate levels who have the authority to take decisions and the responsibility to address bottlenecks, and where necessary completely overhaul the entire system to ensure delivery of services; thereby fulfilling the responsibilities of the Department of Health.

Senior Health managers should decide where necessary to review the location of the depot; the size of the depot and the cold chain capacity for vaccines; the transport used to deliver, the size of delivery vehicles, maintenance, the frequency of deliveries; the equipment used to monitor cold chain; human resources, the skills of health workers in the supply chain, number at each level and their training; information system used at each level and their integration across levels as well as management and governance mechanisms. Management can also decide to outsource operations either of the entire supply chain or at a certain level. Senior managers have these choices and decisions to make regarding how the vaccine supply chain is designed and how it functions.

When one has to look at functioning of an operation in this case vaccination at clinic level and availability of vaccines at clinics one has to look at all the relevant components that interact and impact on vaccine availability at clinics.

3.4 The Model of Vaccine Supply Chain and Causes of Stock Outs

Figure 3.1



The figure 3.1 above clearly indicates that each level is dependent on the level above it and the level above also depend on the level below as it needs to receive orders and information on number of doses used and similar information.

3.4.1 Some Key Issues on the Model

 = This represents the “Pull System” for the supply of vaccines.

T**ransport and Frequency of Deliveries**

Transport requirements between the levels are crucial. There are a few dimensions relating to effective provision of transport in the vaccine supply chain as highlighted by WHO in the EVM Initiative. There should be adequate number of vehicles of a certain capacity that meet the cold chain requirements. These vehicles should be well maintained and serviced with back up mechanism in case of break down.
Transport should be well managed and should deliver according to schedule agreed upon by the two levels. The frequency of deliveries should take into consideration factors such as capacity of cold chain at the level being supplied, head counts and the number of doses per vaccine consumed over a period of time.

Information and Communication: The flow of information between different levels and different elements is critical for optimal functioning of the supply chain. This flow of information is in both directions, up and down. Effective information system, using technology that informs each level of the consumption of vaccine doses over a period of time is important for each level to forecast future needs and timely place vaccine orders. Should there be a sudden increase in demand for vaccines, such as in the case of disease outbreak, this should be timely communicated up the supply chain, to the manufacturers so they can increase production.

Communication should be effective on areas that matter. Each level must inform the level above and below; should there be batch failures or should there be stock that has been destroyed by freezing or should there be equipment failure, breakdown of fridges or vehicles which affect delivery and availability of vaccines at the next level or which affect the capacity of that level to handle the normal quantities often delivered.

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Communication should be effective on areas that matter. Each level must inform the level above and below; should there be batch failures or should there be stock that has been destroyed by freezing or should there be equipment failure, breakdown of fridges or vehicles which affect delivery and availability of vaccines at the next level or which affect the capacity of that level to handle the normal quantities often delivered.

3.4.2 Complexity of the Model

Although this model is represented by one box at each level it should be highlighted that it is much more complex than it seems. In SA, there is one national depot which supplies 10 provincial depots. There are 2 provincial depots in Eastern Cape: one in Port Elizabeth and the other in Umthatha. Each of these provincial depots supplies district depots. The structure may be slightly different for some provinces that use sub-district structures of regional hospitals to act as district depots. Each district or sub-district depot has a number of facilities to supply. It is not a one to one relationship. Thus the information that flows up and down comes from a network of locations.

Similarly, for the manufacturers the situation is complex. A few vaccine manufacturers have to meet the demands of virtually the whole world for reasons elaborated upon earlier. South Africa is just one customer amongst many customers in an industry that has sophisticated purchase mechanisms; Latin America has a pooled system of vaccine purchasing which Africa does not have. Therefore, self-financing (not supported by UNICEF and GAVI) countries like South Africa, have to put individual orders for small volumes; a small value compared to big countries with pooled financing and supply mechanisms.

3.5 The Dependent and Independent Variables and Interaction

The dependent variable in this model is the availability of vaccines at each level. However, the study focuses on factors that operate at the clinic level. A number of factors that will affect the overseas manufacture and the issues related to international flow of goods (vaccines) are not the subject of this study. It is evident that most of the factors are the same at each level from national to the clinic level. However, of significance is that the process is a chain process; each level is affected by the level above it in its endeavour to maintain adequate vaccine stock at all times and each level affects the level above it in terms of information flow and demands placed. This is particularly important in view of the fact that the system is that of a ”pull” mechanism which theoretically has less build-up of inventories.

The main factors that have a causal relationship at clinic level are the following:

Management and Governance. Management of stock refers to the use of a stock management system that is regularly checked if up to date in this case the use of stock cards to manage stock and the setting of minimum and maximum levels. The minimum level of stock is the lowest stock quantity that a facility may have; stock quantities should not drop below this level as it results in stock outs. Maximum levels are the opposite, stock quantities should not go above maximum levels as this result in over stocking and vaccines may expire or lose potency through other means. Management of stock also relates to timely orders of right quantities of vaccines. There should be standard operating procedures (SOP) and understanding of how and how many orders are placed for each vaccine, taking into account the different doses required per child under 2 years for each vaccine.

Human Resources and Training

There should be adequate manpower to manage vaccines. At a clinic level there should be a dedicated person with the responsibility of managing vaccine stock, ideally a Pharmacist/Assistant in all Community Health Centres (CHCs). These health workers should be trained in stock management with special focus on Vaccine Management.

Cold Chain Capacity: There should be adequate cold chain capacity to store vaccines. Literature has highlighted to lengths the issue of limited cold chain capacity which inevitably becomes a challenge when new bulky vaccines are introduced.

Information and Forecasting. At clinic level information is generated by the activities of vaccinating children who come at different ages and the number of activities is affected by the general head count of children. Different levels should be linked and share such information and the doses of vaccines given.

Supervision and Support. This may be considered to fall under Management and Governance but it needs specific mention seeing that supervisors as supporters of facilities have a duty to prevent stock outs, promptly manage them if they should occur.

The performance of a higher level and Transport is critical in the chain system. The higher level may be out of vaccines, may cut down on quantities and may not be delivering on time. Very few facilities have access to transport that can be used in situations where deliveries are not as scheduled.

CHAPTER 4. THE BASIS OF THE STUDY RESEARCH METHODOLOGY

This chapter gives an overview of the philosophical basis and assumptions of the study, which have guided the study methodology. It then proceeds to outline the study methodology, the process followed for ethical approval. It ends by introducing the measuring instrument and the process used for data collection.

4.1 The Research Paradigms

A research paradigm is a philosophical framework that guides how scientific research is conducted (Collis and Hussey, 2009). It forms the basis for an approach to research and is considered by Bunniss and Kelly (2010) to be set of beliefs and practices that are used by communities of researchers to regulate research. The term philosophy is defined by thesaurus as logical and rational. The New Shorter English Dictionary describes philosophy as the pursuit of truth and knowledge through argument and reason. Paradigm is defined as; a model, a pattern, a standard. Therefore a research paradigm is a standard based on accepted reasoning at that time by a group of researchers as the best way to approach research (Collis and Hussey, 2009).

For simplicity it can be considered that there are two research paradigms: the positivist and interpretivism. The positivist is the traditional approach to research, primarily used by scientists. The interpretivism was developed to address needs of social research, which could not be addressed by measurements, experiments and statistical calculations. The two paradigms have significant differences which relate to their: origins, assumptions about the nature of reality and what constitutes the truth, assumptions about what forms the basis of knowledge, the research methodology and the type of data commonly used (Collis and Hussey, 2009).

Over a long period of time it was considered that the two research paradigms hold different and opposing standpoints. Those who were proponents of one paradigm were harshly critical of the other paradigm (Bunniss and Kelly, 2010). It is now considered there is a continuum of paradigms which range from a purely positivist approach to interpretivism (Bunniss and Kelly 2010; Collis and Hussey, 2009). Furthermore, some researchers find it more useful to simply combine the 2 approaches so that valuable information is not lost (Bunniss 2010; Onwuegbuzie and Leech, 2005).

4.2 Positivism

Positivism is based on the belief that reality is independent of influence by human subjects (including researchers). The belief is that social reality is singular and objective. According to Mc Nabb (2013) the positivist approach holds that something or an idea or a concept can only be meaningful and real if it can be seen or measured.

Measurement, numbers and experiment are important aspect of positivism, and are part of a requisite for scientific enquiry. Proponents of the positivist approach have tended to harshly criticize the interpretivism approach which seemed to be based on faith alone and thus metaphysical (Mc Nabb, 2013). According to positivists, the interpretative approach poses a challenge in that the use of qualitative data and related methods cannot be verified.

Positivism aims to discover theories based on empirical research, through observation and experiment. The premise is that knowledge is derived from positive information and generalization that are time and context free are possible and desirable (Johnson and Onwuegbuzie, 2004). With positivism, theories provide explanation, permit anticipation of phenomena and therefore allow them to be controlled.

This approach is mainly used by natural scientists in research such as experiments, longitudinal studies and surveys. The methodological approach is that of deductive reasoning, which enables generalizing from specific. Results should be accurate and reliable and experiments should be repeated with the same results, and thus should be valid.

The research paradigm a researcher decides to adopt is an important factor as it generally dictates the research methodology used. The positivism approach with the need for empirical observation dictates the collection of quantitative data. Experiments and numbers are used to describe things. The use of numbers also involves statistical analysis which varies from simple analyses like measures of central tendencies as with averages to complex statistical analysis like multivariate analysis and other relationships.

4.3 Interpretivism and Qualitative Research

Interpretivism emerged as a realization that the positivist approach cannot fully apply to social sciences (Collis and Hussey, 2009; Onwegbuzie and Leech, 2007). Interpretivism has thus been defined by Blaikie (2004) as:

> *".. a term used to identify approaches to social science that share a particular ontological and epistemiological assumptions. The central tenet is that because there is a fundamental difference in the subject matters of the social sciences, the methods of the natural sciences cannot be used in the social sciences."*

The basis of interpretivism which other authors refer to as phenomenology is based on the premise that social reality is not objective, but is highly subjective as there are multiple construed realities . In social sciences research has to identify means of understanding the situation and many complex views on the subject matter rather than a narrow meaning; these different meanings are shaped by society, experience and history (Creswell, 2013). Interpretivism maintains that research and reality occur in a certain context, within certain values at a certain time and becomes a product of these; time and context free generalization is not possible. Therefore social research has to deal with how a researcher interprets a situation, interacts with participants, draws from the views of participants and reflects on the different meanings. Consequently, phenomelogical reduction allows for examination of things as perceived, and according to experience (Thompson and Zahavi; 2006).

The methodological process of reasoning is inductive from the specific to the general (Johnson and Onwuegbuzie, 2004). According to this approach, the researcher interacts with that being researched because it is impossible to separate what exists in social world from what is in the researchers mind. This approach was developed in response to main challenges faced by social scientist with limitations of positivism.

Creswell (2013) describes 5 approaches to Qualitative research which is based on the interpretivism philosophy and these are: Narrative, Phenomelogical, Ground theory, Ethnographic and Case Study. He further describes the 4 philosophical assumptions discussed in the section below.

4.4 The Relevance and Meaning of the Research Paradigms

It is worth reviewing the question of why these research paradigms and their relevance to one's research. The research paradigms are fundamental to approaching research and in developing the research methodology. The research methodology is based on the one's philosophical standpoint, which is the research paradigm selected.

To understand this, reference is made to the different philosophical assumptions of these 2 opposing research paradigms. Creswell (2013) based on his earlier work and quoted by a number of authors including Collis and Hussey (2009) outlines 4 assumptions of the 2 paradigms which are different for each paradigm. The philosophical assumptions are: (i) Ontological assumption, the nature of reality. According to positivism, reality is singular and objective and according to interpretivism it is subjective and multiple. (ii) Epistomological assumption, what is valid knowledge. According to positivism, research is independent of what is being researched and with interpretivism a researcher interacts with what is being researched. (iii) Axiological assumption, the role of values. Positivism maintains that research is value free and interpretivism accepts that research is value laden and biases are present. (iv) Methodological assumptions, the process of research. This is one of the major differences that has to do with how one proceeds in designing research. As outlined earlier, positivism approach is about measurements, statistical analysis and predictions; whereas qualitative studies are influenced by the context in which the study is conducted and reasoning is inductive.

It can be seen that the chosen paradigm and the philosophical assumptions give a basis for approaching a study and choosing a research method.

4.5 Paradigm of the Study and Research Method

The study was based on the positivist, quantitative paradigm. It was an objective measure of the availability of vaccines in health facilities. The research process and the researcher should not influence the reality of vaccine stock levels. Quantitative data was collected and submitted for statistical analysis to examine the level of stock availability and a relationship between the different variables. The type of data was primary data as it was collected direct from the population studied.

It examined the relationships between certain independent variables and the dependent variable of vaccine shortages. The process of reasoning and drawing conclusion was deductive. Generalisation and inferences was made from the sample collected to the conclusion that the results of the sample are a reflection of the situation with population from which the sample came, i.e. other clinics in this district as the sample is representative of the population from which it came.

The study design was quantitative, in the form of a survey that used a questionnaire as a measuring tool. The study was both descriptive and analytical as it established the level of stock out of vaccines and further examined the underlying causes of the shortages. It did this by examining the relationship between the independent variables and the dependent variable of vaccine stock out.

4.6 Sampling, Sampling Frame and Sample Size

The District Health Information System (DHIS) was the sampling frame for this study. DHIS is excel based computer software with a database of all government health facilities. It is used to collect health data from health facilities all over the country has a list of health facilities, including clinics and hospitals for each province, and by district.

A list of Primary Health Care facilities (clinics) in Tshwane District was obtained from the DHIS. It indicates that there are 136 government healthcare facilities in Tshwane, which includes clinics, national central hospitals, district and specialised hospitals. Seventy five (75) of the 136are primary health care facilities, the clinics of interest for this study.

A sample of clinics was selected using simple random sampling technique. Each facility was allocated a number using the table of random numbers. With each clinic having a number, a sample was then collected selecting the random numbers.

A sample size is important as it determines the degree to which one can generalise from the sample. A sample of 32 clinics was drawn from the 75 in the sampling frame of Tshwane Government clinics. This sample enabled relevant statistical analysis.

4.7 Statistical Analysis

Data were captured by the Principal Researcher into an Excel spreadsheet provided by the NMMU Unit for Statistical Consultation (USC). Data cleaning was conducted by the Principal Researcher twice using original instruments for all clinics, checking for outliers and double checking information entered. The data collection software was designed by a USC consultant to have integrity checks which allowed only responses from the pre-selected possible categories.

The captured data was analysed by the NMMU Unit for Statistical Consultation (USC) using in-house statistical software developed on an Excel platform. Analysis was in two stages: the first stage consisted of descriptive statistics for the variables such as the position of interviewed participants, occurrence of stock out by vaccine and its duration. The second stage analysed the association amongst variables and performed the student t-Test and Chi squared tests where appropriate. Hypothesis tests were used to examine an association between the dependent and the independent categorical variables; using nominal and interval scaled data.

Data is presented in the form of tables, graphs, bar charts and pie graphs.

To decide whether to accept or reject the Null Hypothesis, the level of significance for the p value is set at 0.05. Qualitative responses were analysed for themes and the main themes that emerged from qualitative responses were critically evaluated.

4.8 Ethics and Ethics Clearance

This study received ethical approval from the Human Research Ethics Committee of Nelson Mandela Metropolitan University and from the Tshwane Health District Committee on Research. The process of ethical clearance involved 3 stages:

- 1st stage was a pre-approval from Tshwane District Committee on Research. The study proposal was submitted this committee for preview and for an approval letter to be sent to the NMMU RECH to indicate that Tshwane will in principle allow the study to go ahead once ethics approval granted by the University

- 2nd stage was application for ethical approval from the NMMU Research Ethics Committee on Human Subjects

- 3rd stage was submission of the NMMU ethics approval to Tshwane to grant permission for the study and allow the investigator access to health facilities.

Ethical approval and clearance related to the 3 stages are attached as Annexure 9.2.

In line with ethical approval and with code of research practices, the study respected ethical principles, including: confidentiality, beneficence, justice and non-malefecence. The ethical process of obtaining written informed consent was followed. The signed consent forms were filed and stored in a locked cupboard.

During data capture and analysis, the identity of respondents was protected. No names of respondents were entered on the questionnaire. Facility names were coded to further ensure confidentiality. However, in order to support the Health System and provide relief to facilities, health workers and the users of health services; where there were serious challenges that need urgent intervention, the authorities were given the relevant information to allow them to address specific challenges.

Each questionnaire had a covering information letter to the respondent explaining the nature and the objective of the study. This letter explained that, whilst participation is valued, it is voluntary. There was no reimbursement for participants.

Written informed consent was obtained from each participant interviewed. The participants were first informed about the study based on information on the letter, then they were requested to participate. The voluntary nature of their participation was again highlighted. This section was signed by the participant and by the researcher. (Annexure 9.1, Informed consent form and information for participants).

4.9 Measuring Instrument

The measuring instrument was a questionnaire. The questionnaire was based on the objectives of study and directed at ensuring that the study objectives are addressed.

Questions were mainly either closed questions or used the Likert scale. There were 5 independent variables; each with specific questions. The independent variables correspond to each sub-objective. Few open ended questions allowed for comments on opinion and experiences. Themes were looked for in analysing open ended questions.

There are two sections of the questionnaire: administrative and information section.
The information section gathers information on stock availability, and each independent variable and related factors. The independent variables correspond to the sub-objectives. There are 3-5 questions per independent variable.

The tool gathered the information as outlined below. For each question different possible responses were provided to choose from. See measuring instrument in Annexure 9.3.

Dependent Variable: Availability of vaccine stock – the dependent variable.

- Is there currently any vaccine stock shortage?
- In the last 12 months were there vaccine stock shortages?
- Which vaccines were out of stock?
- Duration of stock?

Independent variables and Related Questions.

a. Vaccine Stock Management

- Are there vaccine stock cards available and up to date?
- Are the minimum stock levels reflected on the stock cards?
- Are the maximum stock levels reflected on the stock cards?
- How does the clinic decide how much to order?

b. Supervision

- How often is supervision conducted?
- Is there specific supervision for EPI?
- Does the supervisor interact with the vaccinator?
- Does the supervisor specifically check on vaccine stock levels?

c. Cold Chain Capacity

- Is there enough fridge capacity in this clinic?
- Has the clinic reduced vaccines ordered due to constraints in fridge capacity?
- Has the clinic requested nearby hospitals and clinics to help store their vaccines?
- Did the new vaccines: Pentaxim ®, PCV, RV affect fridge capacity?

d. Human Resources

- Is there dedicated health worker responsible for vaccine stock management?
- Who is the responsible person, by job category?
- Has this person been trained in vaccine stock management?
- Is there support from the district office to the clinic pharmacy on stock control.

e. Impact of a Higher Level

- What were the causes of stock outs reported? Was the depot out of stock?
- Does the depot reduce quantities of vaccines ordered and supply less?
- Which vaccines are affected by such cuts?
- How soon is an emergency order received?
- Are routine orders received on time?
- Has the higher level warned in advance of impeding vaccine stock shortages?

f. Other Factors; Transport, Budget

- Are there budgetary constraints?
- Are there constraints faced with paying the suppliers?
- Are there transport problems?

Systems for responding to Stock Out.

- Is there an emergency toll free number for reporting vaccine stock outs?
- Does such a system if available work?
- Would the clinic benefit from a toll free number to report stock out that will report at 3 different levels: district, province and national office.
- Would you be willing to use your cell phone to report stock shortages to such a toll free (no pay) number.

4. 10 Data Management

Data was collected by the Principal Researcher. Clinic managers or acting managers were phoned in advance to set up appointments for the clinic visits. The structured questionnaire was administered to participants who were either a: Vaccinator, Pharmacist, Pharmacy Assistants, or Facility Manager.

Before the collection of data the investigator introduced herself, produced the permission letter from the District Office and explained the purpose of the study. Participants were informed of the voluntary nature of their participation and their right to refuse participation or withdraw from participation at any time with no penalty. After this session they were requested to participate and if willing to sign the consent form which also was explained.

Out of 32 facilities visited 31 agreed to participate and the respondents signed the consent form. The 1 facility that did not participate, the Professional Nurse claimed she was busy and had not been properly informed about the visit; she indicated that an appointment could be set up for 2 months later.

Data was collected over a 2 week period from 9 December 2013 to 21 December 2013. Data was captured by the Principal Researcher into an excel spread sheet provided by the Statistics division of NMMU. Data cleaning was conducted by the Researcher twice using original instruments for all clinics, checking for outliers and double checking information entered. The data collection software was designed by the Statistician to have integrity checks, entry fields in the spread sheet were preset to allow only the responses from the pre-selected possible categories.

The captured data was analysed by the Statistics division of NMMU using an excel based statistical software. Analysis was in 2 stages; the first stage analysed the simple variables including the position of interviewed participants, occurrence of stock out by vaccine and its duration. The second stage analysed the association amongst variables and performed the student t-Test and Chi Squared test where appropriate.

CHAPTER 5. RESULTS

5.1 Overview of Clinics and the Respondents

Of the 75 government clinics in Tshwane, a total of 32 clinics were selected to participate in the study. Informed written consent was obtained from participants in 31 of the 32 clinics giving a 97% response rate.

The clinics were classified by geographical region subdivided into 3 sub-regions: North, East and Central. The distribution of sampled and interviewed clinics by sub-region is indicated in the table below.

Table 5.1. The Distribution of participating clinics by sub-region.

Sub-region	No. of Clinics Visited	Percentage
North	19	61%
East	7	23%
Central	5	16%
Total	31	100%

The position of interviewed health workers is displayed in the pie chart below. In 23 (74%) of clinics the vaccinator was interviewed. There were some clinics where two individuals, a vaccinator and assistant pharmacist were interviewed separately.

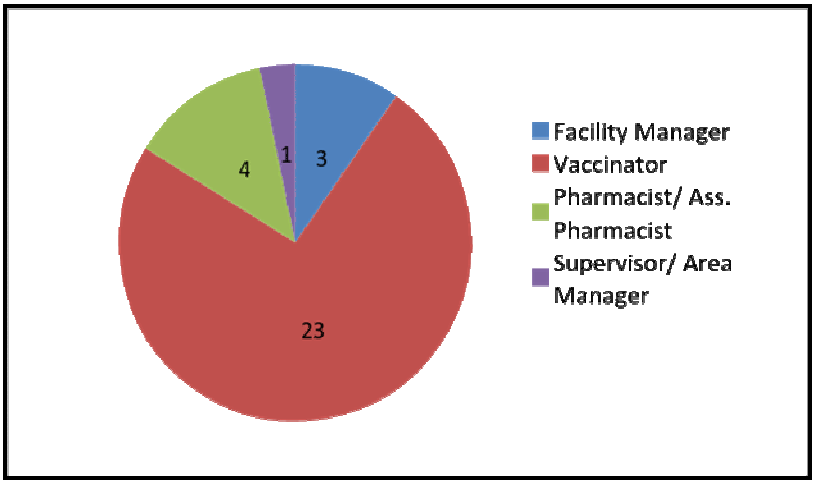

Figure 5.1.The frequency distribution of the position of the interviewed health workers.

5.2 Vaccine Availability

5.2.1 Current Stock situation.

On the day that the clinics were visited a total of 11 items were found to be out of stock in at least 9 clinics. All clinics visited had pneumococcal conjugate vaccine (PCV) in stock on the date of the interview. Rotavirus vaccine (RV) and measles vaccines were out of stock on the day of the interview in 2 (6.5%) of the 31 clinics visited. DTaP-IPV//Hib (Pentaxim®) was out of stock on the day of the interview in 3 (10%) of the clinics visited. Measles diluent, tetanus and low strength diphtheria (Td) and syringes were out of stock in 6 (19%) of the 31 clinics visited on the day of the interview. The availability of BCG is not analysed as it is mainly those facilities with maternity delivery services that mainly need BCG, as BCG is given at birth.

5.2.2 Stock availability in the previous 12 months (year)

All the vaccines (except Td) had been out of stock in clinics visited. The number of clinics experiencing stock out in the last year per vaccine ranged from 5 clinics that had been out of stock of measles to 23 clinics that had experienced stock outs of Pentaxim® in the previous 12 months.

Table 5.2. The Frequency of vaccine stock outs in the preceding 12 months by vaccine and the number of clinics.

Vaccine	No. (%) of Clinics with stock out N=31
Pentaxim ®	23 (74%)
PCV	20 (65%)
Rotavirus	18 (58%)
Hepatitis. B	16 (52%)
Other	15 (48)
Measles	5 (16%)

Note: The Category “Other” in table above refers to other vaccines like polio, BCG, Td and diluents of BCG and measles vaccine

The duration of stock outs for all vaccines considered lasted from 2 days or less to more than two weeks.

Figures5.2 –5.5 below represent the frequency distribution of the duration of stock out per vaccine and the number of clinics experiencing the stock out of particular vaccine.

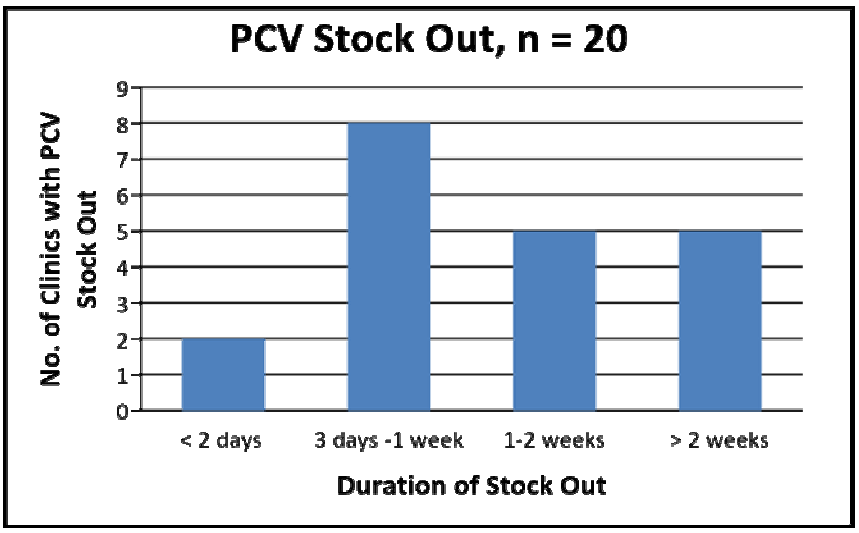

Figure 5.2. Frequency distribution of the duration of PCV stock outs in 20 clinics experiencing stock out in the previous 12 months.

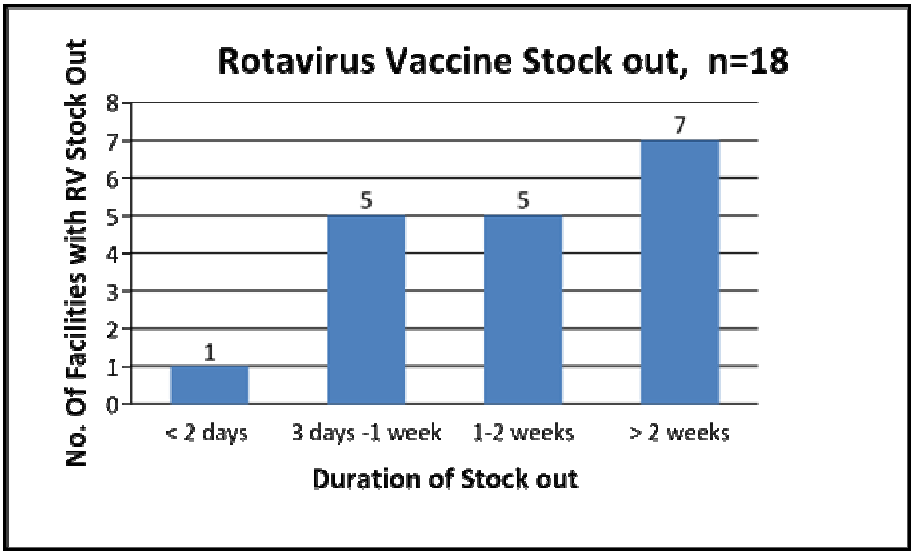

Figure 5.3. Frequency distribution of the duration of RV stock outs in 18 clinics experiencing stock out in the previous 12 months.

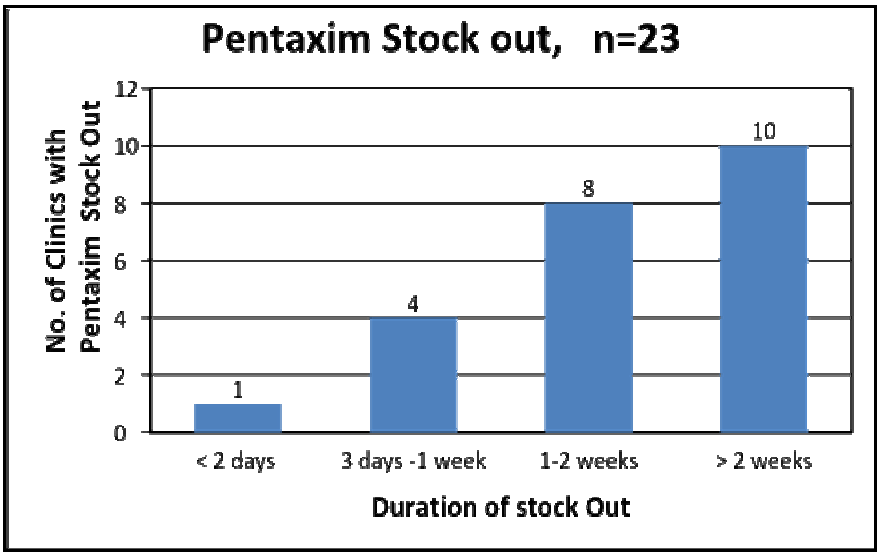

Figure 5.4. Frequency distribution of the duration of Pentaxim ® stock outs in 23 clinics experiencing stock out in the previous 12 months.

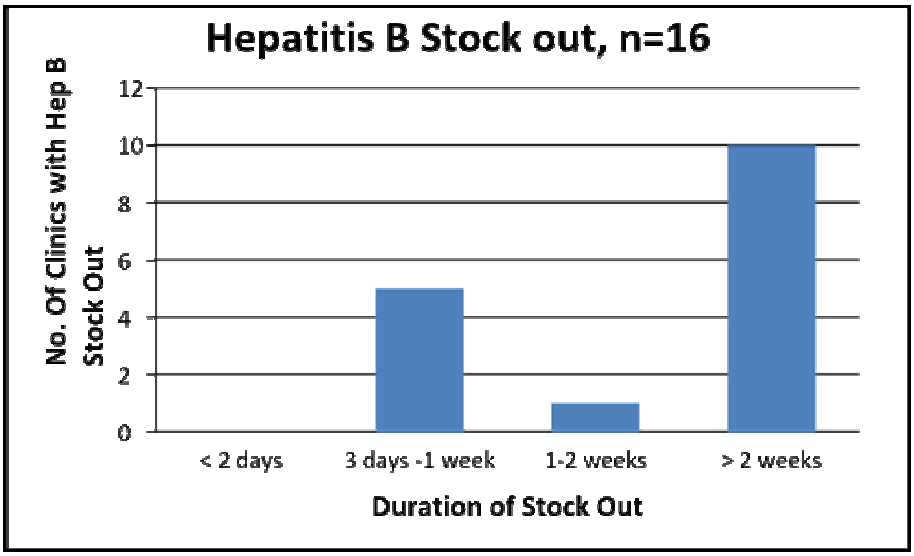

Figure 5.5. Frequency distribution of the duration of Hepatitis B stock outs in 16 clinics experiencing stock out in the previous 12 months.

5.3 Reasons for Vaccine Stock Outs

A number of reasons for vaccines being out of stock were given. The reasons for stock out are not mutually exclusive per clinic. More than 1 reason per clinic was reported for vaccine stock outs. Reasons included: delays in delivery, depot being out of stock, orders that are reduced by the district depot and shortage of vehicles. Some clinics perceived that not having a vehicle in their clinic or for a group of neighbouring clinics to collect stock from the depot, contributed to the clinics being out of stock or that it was shortage of vehicles at the district depot that resulted in stock out. This reason is categorised as transport in table 3 below. For each vaccine the reason for stock out was elicited.

Table 5.3: Reasons given for stock outs per vaccine (n=31)

Vaccine	Depot Out of stock	Late Orders	Delayed Delivery	Orders Reduced	Transport
PCV	15 (48%)	6 (19%)	18 (58%)	1 (3%)	17 (55%)
RV	17 (55%)	7 (23 %)	19 (61%)	2 (6%)	17 (55%)
Penta	20 (65%)	7 (23%)	20 (65%)	3 (10%)	19 (61%)
Measles	5 (16%)	1 (3%)	5 (16%)	2 (6%)	3 (10%)
Hep B	18 (58%)	1 (3%)	6 (19%)	1 (3%)	5 (16%)
Other	15 (48%)	2 (6%)	9 (29%)	3 (10%)	10 (32%)

- Depot out of stock means that the district depot did not have the particular vaccine in stock and therefore could not supply the clinics.
- Late orders means that the clinic accepted that it had been late in placing orders as a result they were out of stock.
- Delayed deliveries refers to that stock was not delivered according to schedule as expected.

- Orders reduced means that the district depot would supply fewer quantities than ordered.
- Transport was given as a reason for those clinics that brought up that it was lack of transport that contributed to stock outs. This issue was brought up as some clinics thought that if they had their own transport or there was transport dedicated for a group of clinics they could collect orders that were either late or in case of emergency.
- Other refers to stock out of other essential items like syringes or measles vaccine diluent.

Figure 5.6 below shows the frequency of the different reasons; depot out of stock accounted for 44% of all reasons followed by delayed deliveries at 38%.

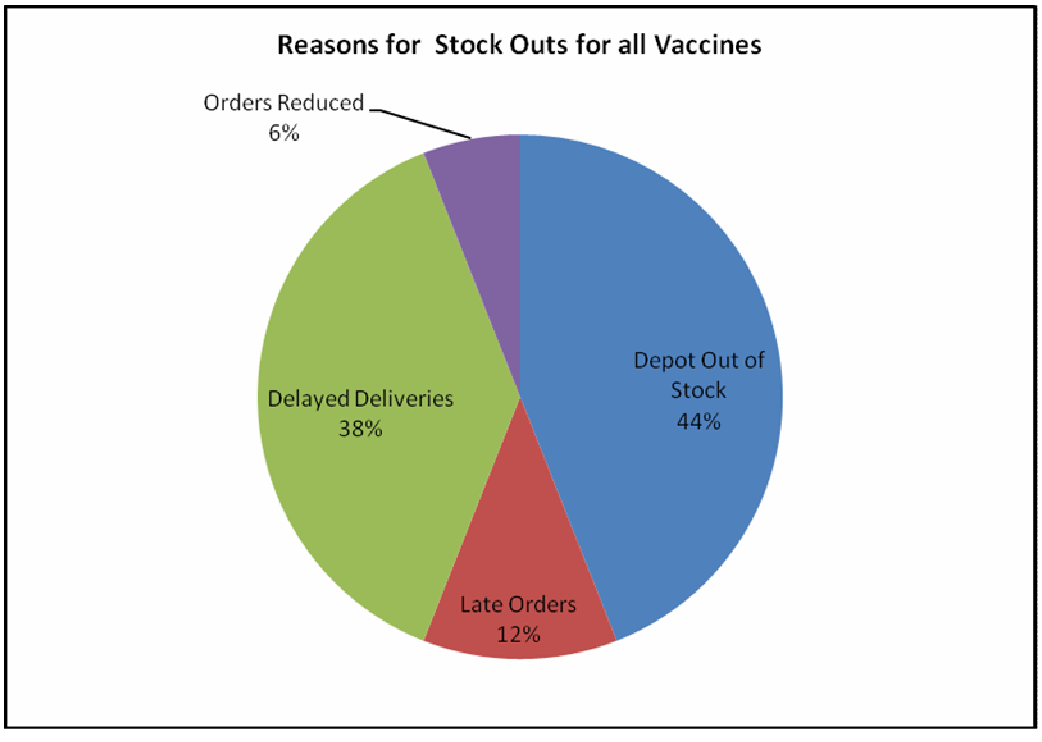

Figure 5.6. The distribution of the causes of vaccine stock out

5.4 Stock Management

Stock cards are used in clinics to manage stock and to indicate stock balance allowing for those responsible for stock management to detect when levels are low and to place orders. All clinics visited reported that they were using stock cards, except for 1 clinic that uses computer software. The facility using computer software to manage stock had an up to date system which accurately indicated stock on hand.

Stock cards were observed in 27 (87%) of the 31 clinics. One clinic reported that the stock cards were with the rest of their vaccines in another clinic due to cold chain capacity issues. Two clinics failed to produce the stock cards even though they claimed they had. Of the clinics that had stock cards, when reviewing the use of the stock cards and if they were up to date or not, only 16 (52%) clinics had up to date stock cards.

Orders are placed monthly in 29 (94%) of the clinics. Only 2 clinics indicated that they placed orders every 2 weeks. The clinics with limited fridge capacity did not report an increase in frequency of orders or increased in frequency of deliveries.

5.4.1 Zero Balance

Stock cards were examined to see if in the previous 12 months there were any zero (0) balances, that is when the stock card indicated no stock of vaccines. Table 3 below shows the result per vaccine.

Table 5.4. The clinics that had zero balances on the vaccine stock cards (n=31)

Vaccine	No. of Clinics with a Balance of zero (0)
PCV	20 (65%)
RV	20 (65%)
Pentaxim ®	23 (74%)
Measles	5 (16%)
Hep. B	16 (52%)
Other	15 (48%)

5.4.2 Minimum and Maximum Stock levels

Minimum level is the minimum quantities clinics stock should reach, it should not go below this level. It is often also used as a reorder level, so when the minimum level is about to be reached an order is placed. As a standard at clinic level minimum quantities should approximate quantities used over a 2 weeks period.

Maximum level refers to largest quantities of stock that a clinic should keep in order to avoid overstocking and the risk of vaccine wastage.

Minimum levels were on the stock cards in 17 (55%) of the clinics. Maximum levels were on stock cards in 12 (39 %) of clinics. There was no variation per vaccine, if a clinic had minimum stock levels it would have it for all vaccines and if there were none all vaccines would not have. This was the same with maximum levels.

Some clinics had minimum or maximum stock levels on the previous sheets of stock cards but cards of recent dates did not have these stock levels. This raised questions about the use of the minimum and maximum levels. There was no meaningful variation of the minimum stock levels according to the number of doses per type of vaccine. For example, Pentaxim® with 4 doses required for a child below 2 years should have the highest minimum level compared to RV with only 2 doses required for the same child.

5.4.3 Methods used to Calculate Quantities to order

The system used to decide how much to order was either: previous quantities ordered, average consumption of the previous months and stock on hand with consideration of the minimum/re-order stock levels. The clinics that had cold chain (fridge) capacity constraints were further limited by fridge space, some of these indicated that their orders were according to fridge space and they tended to order stock based on the minimum quantities they should have. Some clinics used a combination of methods as shown in table 4, thus the distribution of the methods used does not add up to 100%. In 3 clinics the respondents did not know what methods were used to estimate orders. This was mainly because the respondent was not the one responsible for placing orders.

Table 5.5. Methods used by clinics to decide on vaccine quantities to order

Method for Estimating Orders	No. (%)
Previous Quantities ordered	6 (19%)
Average consumption of like past 3 months	12 (39%)
Stock on hand and or Minimum/Re-order level	23 (74%)
Did not know	3 (10%)

5.5 Performance of a Higher Level

5.5.1 Delays in Deliveries

Delay in delivery refers to a situation when vaccines are delivered later than expected and not delivered according to scheduled delivery dates. A question was asked if there were delays in deliveries and if so how likely was it for any delivery to be delayed. Of the 31 clinics, 30 (97%) reported delays in deliveries of vaccine stock. The responses were put on a scale of frequency of delays from almost always, often, sometimes and never. Table 5 below shows the distribution of the responses.

Table 5.6 . The likelihood of experiencing delays with the delivery of stock at clinics

Likelihood of Delivery Delays	No. (%), n= 31
Always	6 (19)
Often	15 (48)
Sometimes	9 (29)
Never	1 (3)

5.5.2 Emergency Orders

All clinics indicated they had a system for placing emergency orders in case they ran out of vaccines or other essential drugs unexpectedly. It was further enquired how long it took for the clinics to receive an emergency order.

Table below shows the participants response on the period it takes for an emergency order to be delivered.

Table 5.7. The period it takes from placing to receiving an emergency order.

Period	No. of Clinics, n=31
1 day	5 (16%)
2-3 days	12 (39%)
1 week	9 (29%)
>1 week	5 (16%)
Total	31 (100%)

5.5.3 Reduced Quantities Ordered

This refers to the depot reducing the quantities ordered or not supplying the quantities as ordered but cutting down and supplying fewer quantities than ordered. This can occur in a situation where the depot itself is receiving less than expected quantities of vaccines from the higher depot or when the vaccine is expensive and there are budgetary constraints or possibly when the depot is of the opinion that the clinic/s are over ordering.

Six (19%) of the 31 clinics indicated that they had not had any of their vaccine quantities reduced compared to orders placed. There were 9 (29%) clinics which indicated that orders were often reduced for some vaccines whilst 16 (52%) indicated that orders were sometimes reduced.

The table below shows the number of clinics that reported the vaccines are reduced per vaccine antigen.

Table 5.8. The clinics that had stock quantities supplied reduced.

Vaccine	No. of Clinics that had orders reduced
PCV	19 (61%)
RV	11 (35%)
Pentaxim ®	23 (74%)
Other	1 (3%)

No clinic indicated that they were supplied more quantities of any vaccine than ordered. The depot did not supply more quantities than required for all vaccines.

5.5.4 Response to Stock Out

On the response of the supervisor and or the district office on stock outs, 2 (6%) clinics indicated that they always responded in satisfactory manner once stock outs were reported, 12 (39%) indicated that often the response was not satisfactory and 16 (52%) indicated that sometimes the response from the supervisor and the district was satisfactory. One facility indicated that there never was a satisfactory response.

5.6 Cold Chain Capacity

Respondents had to indicate if there was adequate fridge capacity in their clinics, if they had had to reduce quantities ordered and if they had to request other clinics or hospital to store the vaccines due to limited fridge space. Nineteen (19) clinics, 61% of the total 31 clinics indicated that they had limited fridge capacity. Table below shows the measures used by these clinics to cope with limited fridge capacity.

Table 5.9. Fridge capacity constraints and the effects, n = 19

Cold Chain Capacity -Element	No. of Clinics
Limited Fridge Capacity	19 (100%)
Returned Stock	6 (32%)
Reduced Stock Ordered	18 (95%)
Requested other Clinics to help	5 (26%)

A statistical analysis test Chi squared (Ch^2) was used to check for association between the limited fridge capacity and the likelihood of a longer duration of vaccine stock out.

Table5.10: Contigency table: Fridge capacity constraints and Vaccine Stock Out, n = 31

Adequate Fridge Space	Stock Out Duration < 2 weeks	Stock Out Duration >2 weeks	Total
No	9 (47%)	10 (53%)	19(100%)
Yes	5 (42%)	7 (58%)	12 (100%)
Total	14 (45%)	17 (55%)	31 (100%)

Chi2 (d.f. =1, n=31, p =0,76). Odds Ratio = 1.26

Table 5.11: t-Test on Vaccine Stock Out no. of days by Fridge Capacity

Adequate Fridge Space	n	Mean	SD	Difference	t	d.f.	p	d
No	19	21.42	15.06	1.37	0.26	29	0.800	0.09
Yes	12	20.06	13.48					

The stock out duration at the facilities was categorised into two: those with stock outs for a period of less than two weeks and those with stock outs for a period of greater than two weeks. According to results reported on Table 5.10, there was no significant association between adequacy of fridge space and whether there would be a stock out

of greater than or less than two weeks. This finding was further supported by the analysis in Table 5.11 which indicates that there is no association between these 2 variables (p> 0.5). The clinics with limited cold chain capacity were not any more likely to be out of stock of vaccines for longer periods than clinics with adequate cold chain capacity.

Respondents were asked if they were of the opinion or if their experiences were that the 3 new vaccines (PCV, RV and Pentaxim®) had contributed to limiting fridge capacity. Out of 31 29 (94%) indicated that yes, the new vaccines because of the sizes of vials had contributed to limiting cold chain capacity.

5.7 Human Resources

Of the 31 clinics, 18 (58%) had a health worker dedicated for management of pharmaceuticals including vaccine stock. The person responsible for the vaccine stock was: a pharmacist or pharmacy assistant, Vaccinator, an enrolled nurse or another professional nurse. A differentiation was not made between a pharmacist or pharmacy assistant. The figure below shows the distribution of the health workers that are responsible for vaccine stock management in the 31 clinics.

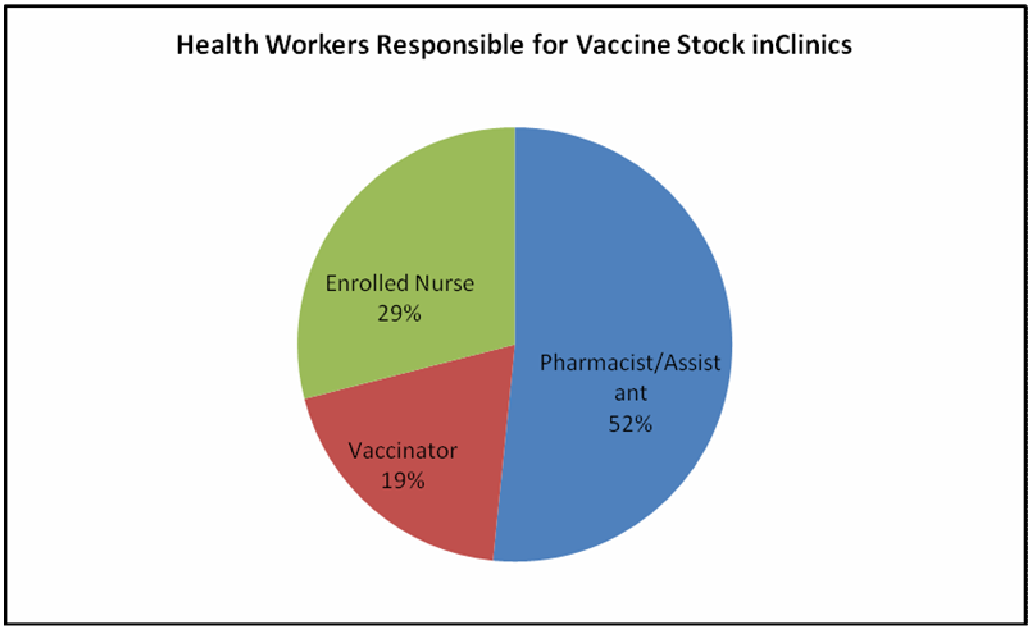

Figure 5.8 . The Health Workers responsible for vaccine stock management

In the 6 clinics where the Vaccinators were responsible for vaccine stock, the assistant pharmacists were available, but the vaccinator had the responsibility of vaccine stock. This included keeping stock cards up to date, the cold chain and placing orders through the pharmacist or pharmacy assistant.

Table 5.12: t-Test on Stock Out and Availability of Pharmacists and Pharmacy Assistants

Pharmacist/ P Assistant	n	Mean Number of stock out days	S.D	Difference	t	d.f.	p	d
Yes	16	15.64	12.61	1-10.86	-2.26	29	0.031	0.81 Large
No	15	26.50	14.12					

According to result of this test there is a significant association between these 2 variables. The clinics without Pharmacists and or Pharmacy Assistants were more likely to be out of stock of vaccines for longer periods than clinics that had Pharmacists/Pharmacy Assistants.

Twenty eight (28) clinics, which is 90% of the 31 including the 6 where the Vaccinator was also responsible for vaccine stock reported that the Vaccinator gave inputs on the quantities of vaccines that were ordered.

None of the health workers responsible for vaccines including pharmacists had specific training on vaccine stock management. Fifteen of the clinics had the person responsible trained in pharmaceutical stock management, not vaccine management.

None of the 8 enrolled nurses who accounted for 29% of the health workers responsible for stock management had been trained in management of pharmaceuticals. Enrolled Nurses reported that it was often the Facility Manager or other Professional Nurses who attended training with no further passing of the skills they learnt to the Enrolled Nurse.

On support from the District Depot or District Pharmacist provided to clinics, 17 (55%) clinics reported that they received support visits from the District depot. However, more than half of these reported that the visit from the District Pharmacist did not amount to meaningful support as in many cases the pharmacist from the depot used a tick list to tick on certain indicators like the use of stock cards with no onsite training. Statistical analysis similar to the one on the association between availability of Pharmacy

Assistant and vaccine stock out was conducted for the support received from the district depot or District Pharmacist. No association was found between the two, therefore there is no evidence from this study that clinics that received support from the district depot were less likely to be out of stock or to have a lesser duration of stock out.

Two assistant pharmacists indicated that these visits would serve a more meaningful purpose if they were used to help review systems and support the clinic improve stock management systems and review what works and what does not. They further mentioned that the visits could be used to check what the areas of weakness in stock management were and how they could be supported.

Most of the 8 Enrolled Nurses expressed frustration and even anger at having the responsibility for pharmaceuticals; which is not their original responsibility, they are not trained and often not supported. They particularly resented the job of unpacking the drugs and packing it in shelves. Two clinics volunteered information that at times the vaccine cooler box containers from the depot would be left over weekends without unpacking and would only be unpacked the following Monday as they had staff shortages and at times the stock arrives late on a Friday or on a Thursday.

5.8 Supervision

Supervision is conducted monthly in 24 (77%) of clinics, quarterly in 6 (19%) of clinics and weekly in 1 clinic (3%). All 31clinics indicated that specific EPI supervision was conducted. Thirty (30) of 31 clinics reported that the supervisor visits the area where vaccination is conducted. On the likelihood that the Supervisor checks the vaccine fridge and stock cards to establish the stock levels: 23 (74%) reported that Supervisor always checks these, 7 (23%) often and 1 (3%) reported that the Supervisor sometimes. All clinics reported that the Supervisor checks the stock levels either in the fridge or by checking the vaccine stock card.

5.9 Finance and Other

Only 2 clinics reported financial constraints as a possible cause of vaccine shortages. Nineteen (61%) indicated there were no financial or budgetary issues. Ten (32%) admitted that they did not know if financial constraints affected vaccine stock outs.

5.10 Response and Communication on Stock Outs

In response to stock outs 23 (74%) of the clinics reported that the first thing they did was to borrow vaccines from the nearest clinics when faced with stock outs. Fourteen (45%) reported to the supervisor and only 3 (10%) contacted the depot directly. The clinics that borrowed from the nearest facility indicated that this response worked well and was prompt in addressing stock outs if the neighbouring clinics had adequate stock.

Only 3 clinics reported that the depot had warned them of existing vaccine sock shortages that the depot was experiencing or communicated from the national suppliers. The other 28 (90%) had not been told of existing or pending shortages, not in the previous 12 months. None of the clinics had been able to warn users of health services in advance of expected stock outs.

When there are stock outs clients are informed when they are at the clinics. They are not given a specific date but asked to come after a week or two or on the next visit the when it is the clinic believes the stock will be available. Users of the health services are told which vaccines are out of stock that the child/children did not get but only 2 clinics volunteered the information that the clients are told what conditions the vaccine/s that is/are out of stock protect against.

Twenty five (81%) clinics had no system for calling back clients once the vaccines were in stock. Six (19%) indicated that there was a system for calling back clients once stock was available. However, only 2 clinics had clearly spelled out means of calling back clients which involved the receptionist phoning clients.

Five (16%) reported that Community Care Givers were asked to inform the community when stock was available. This information could not be verified. None of the clinics indicated that the Clinic Committee was used to inform the community either of stock shortages or when vaccines were available.

5.11 Willingness to Participate in a Dedicated Toll Free System

Out of the 31 clinics only 6 (19%) indicated that there is a system for reporting of stock out of pharmaceuticals including vaccines. This was not necessarily a toll free system. Of the 6 that reported existence of such system only 1 clinic indicated that the toll free system was effective, the rest thought that it was not effective.

Respondents were presented with a possibility of a toll free short messaging system (sms) or phone system that would report stock outs to the depot and to another high level/s like report to deport and at same time record the report at provincial office and at national office. They were asked if they would be willing to use such a system and would be willing to use their own cell phones for the toll free numbers.

All 31 supported the idea of a system that reports to more than 1 level. Out of 31, 30 indicated that they would be willing to use their own cell phones to report vaccine stock shortages.

CHAPTER 6. DISCUSSION

Vaccines are essential drugs. This means that they should be available in all facilities providing the immunisation services at all times. Furthermore, according to the National EPI, guidelines “Every Day is an Immunisation Day” and “Every Child that is well enough to go home, should go home immunised” (Vaccinators Manual, 2008). These policy guiding statements imply that there are at all times in clinics and some other health facilities such as hospitals enough quantities of vaccines for children when they present to health facilities. However, the findings of this study points to significant shortages of vaccines in government clinics in Tshwane district.

The study focussed on the factors that operate at clinic (primary health care facility) level and impact on the status of vaccine stock availability in clinics. There was no focus on factors that operate from national to district level; these were only considered so far as they lead to stock out at clinics and as reported by the clinics.

6.1 Availability of Vaccines in the Previous 12 months

On the day that the clinics were visited a total of 11 items were found to be out of stock in at least 9 clinics. The study also found that not only were vaccines out of stock, but necessary consumables such as syringes and measles diluent were out of stock in some facilities, even though this was not primary focus of the study. Vaccinators may not be able vaccinate children with vaccines like measles, hepatitis B, and Td if there are no 2mL syringes; and cannot use measles vaccine if the measles diluent is not available.

Stock availability over the previous 12 months pointed a serious picture with 20 (65%) of clinics had PCV, 23 (74%) had Pentaxim ® and 17 (55%) had RV stock out in the previous 12 months. These findings point to a situation that has not much changed since the findings of the Post Introduction Evaluation of new vaccines in 2011 (PIE Report 2011). Of serious concern is that the study findings indicate that there is some truth in some of the media reports of vaccine stock outs which may appear to exaggerate the situation (health-e, 2014).

The findings are in keeping with the understanding that the new vaccines: Pentaxim ®, PCV and RV which come packed in bulky pre-packed single dose presentations are more likely to be out of stock. The study also found out that the new vaccines were likely to have a longer duration of stock out than that of other vaccines, 1 to 2 weeks or more in duration. This seems to confirm that these vaccines take up too much cold chain capacity, overwhelm the supply chains and lead to stock outs (Zaffran, et al.,2011; Lee, et al., 2012; Lee, et al., 2011). Measles vaccine was only out of stock in 5 clinics, hepatitis B vaccine was out of stock in 16 clinics despite the national shortages of hepatitis B and measles vaccine which were announced by the national suppliers. It is reasonable to assume that the stock outs of hepatitis B were due to shortages faced by the national supplier. This was not the case with the newer vaccines.

6.2 Reasons for Vaccine Stock Outs

There is no single factor that causes vaccine stock out; many factors contribute. Rodewald et al. (2006) came to a similar conclusion in ascertaining the causes of vaccine supply problems in the US. This finding also applies to stock outs of drugs in general as highlighted by Ventola (2011). However, the impact of new vaccines need special consideration as a cause for the vaccine stock outs within the EPI in South Africa. So significant is the impact of new vaccines on supply chains and vaccine availability that in Niger, changing just measles vaccine vial from a 10 dose vial to 5 dose, 2 dose and 1 dose vials would decrease vaccine availability for clients at clinics from 83% to 82%, 81% and 78% respectively (Assi, Brown, Djibo et al. 2011).

Whilst accepting that new vaccines have played a role in stock outs experienced in clinics, but the main question is what specifically causes the stock outs. The causes were reported as follows: depot was out of stock, deliveries were late, transport challenge, late orders, and orders are reduced by the depot. Late deliveries and transport issues are essentially related causes and are also related to functioning of the system for emergency orders. These findings indicate that the depot and transport account for significant proportion of stock outs in clinics. Therefore, factors higher up in the supply chain are the main causes of stock outs in clinics. Interventions to address stock out challenges need to focus on factors related to the district depot.

6.3 Independent Variables and Statistical Association

6.3.1 Stock management and Information System

The management of stock deserves specific consideration not only from the point of view of clinics complying with the currently expected standard but also considering the systems that are in place. Whilst the use of the stock card is in compliance with the current expected standard, it is certainly out-dated. Therefore, although all clinics were using stock cards and these were available in 87% of them, the use of stock cards cannot be said to be a system that adds value to the supply chain in the current era of technological advancement. Only one clinic in the sample uses computer software to manage pharmaceutical stock including vaccines.

Furthermore, the use of the stock cards was found to fall short of the actual expected standard. Their use cannot be said to be an effective tool to manage vaccine stock. This is indicated by the stock cards that were not a true reflection of the level of stock on hand and also that the minimum and maximum levels did not appear to be consistently and meaningfully used. The minimum levels were the same for vaccines that are required in different numbers for children below 1 year. For instance the minimum and maximum stock levels for Pentaxim ® and RV were the same, yet a child below 1 year needs only 2 doses of RV and 3 doses of Pentaxim ®; a further Pentaxim ® dose is required at 18 months, no additional doses of RV are required. Another observation was that additional pages on the stock cards did not in many instances reflect the maximum and minimum stock levels. These are indications that stock cards are not meaningfully used. However, one could understand the frustration of the many Enrolled Nurses responsible for pharmaceuticals that are not trained in stock management, having to use this cumbersome and out dated system.

The use of information technology to support supply chains is a more effective way used by many successful businesses. Literature strongly supports this view, for supply chains to be effective; it has to be supported by the use of updated information technology. Advances in technology allow linking of the various levels of the supply chain, allow tracing of products as to where they are in the supply chain and even have set up systems that can generate automatic orders and put alarms when critical stock levels are reached.

An information technology system is urgently needed for the vaccine supply chain in Tshwane district, that can link information on doses used in each facility with the depot, allow the depot to continuously monitor stock levels of each clinic and generate orders as soon as re-order levels are reached. Such a system will simplify things especially in view of serious shortages of pharmacy assistants and will appease the distraught enrolled nurses who manage stock. Current advances in technology should be explored for the benefit of the vaccine supply chain.

This situation of out-dated cold chain systems of the developing countries in the current era of new vaccines and a large portfolio of vaccines in the schedule has been appropriately highlighted by Humphrey (2011) and Zaffran, et al., (2013).

According to EPI Cold Chain Manual 2003, clinics are expected to use previous consumption and reorder levels taking into account the stock on hand to estimate their needs and place orders. Whilst 23 (74%) clinics indicated the use of re-order level and stock on hand, only 12 (39%) indicated the use of previous consumption. Others also indicated the use of previous orders without taking into consideration the consumption. A practice of basing orders on previous orders is an indicator of poor stock management because it may mean that if previous orders ended up with the clinic having stock shortages, the stock outs will continue in such a setting.

6.3.2 Cold Chain Capacity

Cold Chain capacity constraint is evidently a significant factor that impacts on the vaccine supply chain and vaccine stock availability at clinic level. With 19 (61%) of clinics having fridge capacity constraints this situation is a serious cause for concern. It is of interest to note that there was no statistical association between the duration of stock out and the clinics that reported fridge capacity constraints. This may mean clinics with fridge capacity constraints make an effort to place orders more frequently to mitigate stock out. Nevertheless, cold chain capacity constraints should be addressed, as Community Health Centres and other clinics with large numbers of headcounts reported limitations of their fridge capacity.

6.3.3 The Depot and Systems for Deliveries of Routine and Emergency Orders

The findings related to the depot and systems for deliveries of routine and emergency stock are an important aspect as they relate to factors that are generally outside the control of the management at health facility level. When a clinic does not receive vaccines because the depot is out of stock or because deliveries are delayed, this results in poor health service delivery. Apart from borrowing from other clinics there is not much a clinic manager can do. When the depot is out of stock and deliveries are delayed, it is likely that other clinics in the surrounding area experience the same, by virtue of the origin of these factors, borrowing cannot be an option. This is illustrated by the finding of depot being out of stock and delays in deliveries of routine stock reported by an overwhelming majority of facilities, with only 1 facility reporting that it never had delays in deliveries.

Furthermore, in a situation where other clinics have some stock, once they have shared their stock with the other clinics they may in turn run out of stock. This is a serious situation as supervisors do not effectively address urgent stock out challenges.

Further complicating the stock out challenge is the system for placing emergency orders that does not seem to function; so much so that some clinics thought that the delays of the emergency orders were worse than those of routine stock. This leaves the Clinic Manager in a difficult position with absolutely no alternative to intervene, except for the couple of clinics which have access to their own transport. This is an issue that needs management of the supply chain at higher level.

These findings are in keeping with the focus of the Vaccine Management Initiative and the concerns raised by Haidari, et al., (2013) emphasising the need to augment transport and not just increase cold chain capacity when introducing new vaccines.

The district depot was reported to be mainly out of stock for vaccines such as Pentaxim ®, PCV and RV. Similarly the claims by clinics that the depot reduced orders and supplied less quantities than ordered were mostly for these 3 vaccines.

6.3.4 Human Resources

The challenge faced with the scarcity of pharmacists and pharmacy assistants is an issue of grave concern, not just for the EPI and the vaccines but for the whole pharmaceutical services in government facilities and is a threat to the health system. This was illustrated by the finding that stock is at times kept for days at times even weeks in boxes unpacked. Vaccines were left over weekends in the delivery containers in some clinics, with no temperature monitoring and without checking if the vaccines are received: in the right condition, in correct quantities, with the correct diluents where appropriate. This may have serious consequences and may lead to some vaccines losing their potency.

Health workers, mostly enrolled nurses who are not pharmacist nor pharmacy assistants expressed frustration and even anger at having to do the job which they claimed was not their original job. They also are also aggrieved by that they are not trained. It was reported that if there is any training on pharmaceuticals it is not the enrolled nurse who attends but rather a professional nurse, yet the work is done by the enrolled nurse in most clinics without a pharmacist/pharmacy assistant.

None of the health workers responsible for vaccines have had any training in Vaccine Stock Management (VSM); this includes pharmacists and pharmacy assistants. Pharmacy Assistants were trained in pharmaceuticals but not in vaccine stock management. There is a special need for Pharmacist and Pharmacy Assistants to have VSM special training, as vaccines are special biologicals that have special requirements often not shared with other pharmaceuticals and biologicals. It is evident that the issues related to training of pharmacy assistants have to be addressed by the directorate of pharmaceutical services.

6.3.5 Supervision

The supervision report was very good and specific EPI supervision is conducted. Further enquiry on the supervisor visiting the vaccinator and checking the stock card, the vaccine fridge for vaccine stock levels yielded positive reports. Such positive responses on supervision do not concur well with main findings of significant stock outs and the state of the stock cards. If supervision is good as reported and if supervisors took measures to address stock issues identified, there should not be as much shortages as found.

According to the supervision checklist, stock outs for essential drugs that are in the essential drug list (EDL) including vaccines are to be checked in the red flag which means such shortages will affect basic service delivery and should be addressed immediately. The study findings on supervision may mean that either the clinics do not want to report on supervisors not checking the stock cards and fridge for stock levels or the clinics report correctly, the supervisors check these areas each time a clinic is visited but simply do not follow up on findings. It may mean that once a clinic is found to be out of stock or running low on stock, the supervisor does not see this as an imperative to act and ensure that intervention measures are pursued for clinics to get the required stock.

Both scenarios are of equal serious concern, because there is no point in supervision if that is the way it is conducted. Senior managers have to address this for supervision to serve its intended purpose. Supervision in this current form is simply of little value to the health system. This is also reflected by poor response of supervisors once stock out has been reported to them.

The findings of high supervisory rate are in keeping with those of the District Health Barometer 2012 which reported supervision coverage rate per month of approximately 70% for Tshwane (Smith, 2009). The focus should go beyond supervision coverage, rather it should be on what the supervision achieves how basic “RED FLAG” areas are addressed by supervision.

6.4 Responses to Stock Out and Communication

Clinics do the most sensible thing in response to stock out, as the first thing most (74%) clinics do, is to borrow from neighbouring clinics and continue to provide immunisation services. However, it has been highlighted earlier in this discussion that the situation that prevails often affects clinics in the same area and thus precludes borrowing. If deliveries are delayed or if the depot is out of stock clinics in a surrounding area will often share the same challenge.

Borrowing is crisis management that clinics resort to, but this cannot be an efficient means of dealing with stock outs, besides one does not know when this is resorted to. Indications are that they only start borrowing when zero levels are reached.

Furthermore as indicated earlier borrowing compromises the capacity of the clinic that borrows to provide immunisation services to its own clients, especially in view of the depot reducing orders.

Communication about stock out from depot to clinics and between clinics and clients is a cause for concern. There is evidence of communication from the national suppliers to provinces informing on shortages of hepatitis B and measles vaccines in July 2013 (personal Communication National EPI and Sanofi Aventis). This information does not seem to have filtered to health facility level as only 3 clinics reported of being warned by the depot of looming measles and hepatitis B stock out. When clinics are not aware of pending stock shortages, this compromises service delivery. Many clinics usually overstock Hepatitis B and measles vaccines. This due to the fact that Hepatitis B vaccine comes in small vials that are 10 doses each, each vial once opened can be used for 28 days. Measles come in similar vials of 10 doses, although measles must be used within 6 hours once opened. Therefore, in a small box of 10 vials there is 100 doses and 100 vials gives 1000 doses. Furthermore, there was a measles and polio national immunisation campaign in 2013 and many clinics had leftover stock. The point is, had clinics been informed appropriately of the pending stock shortages there were intervention measures that could have been pursued to alleviate stock outs as clinics could have borrowed from those that had adequate or had overstocked these vaccines. The issues related to measles and Hepatitis B vaccines are unlike those of the 3 new vaccines. These are bulky, expensive, with no overstocking, subsequently reduced orders and delays in deliveries result in stock outs.

The anticipated stock outs of measles and Hepatitis B vaccines called for intervention at a higher level, at least at district level. Once the district management was aware that these vaccines were out of stock at national level, an audit of the quantities of vaccines available in each clinic should have been conducted. This should have been followed by the redistribution of vaccines amongst clinics. This exercise would have addressed the challenges and if conducted in time, no clinic in the district would have experienced stock out of these vaccines. This would have also prevented some vaccines like measles expiring which might have happened in some facilities,

Communication with clients once stock outs are faced is not adequate and not standardised. This may also be due to the fact that clinics will not be certain as to when stock will be available. The finding is that mostly clients are told there are shortages and the child will get the missing vaccine when the child next presents to the clinic for next dose of vaccine. There were only 2 clinics with means of calling back clients once the vaccine was in stock. Other than this there is no evidence of attempts to bring the child back earlier. This is unfortunate and relates to out-dated means of communication and systems; all clients now have cell phones or someone else in the family has it. It should be easy to set up a system of calling back clients for missed doses when stock arrives. Cost implications of setting up such a system should be quite minimal and much less than the cost of responding to disease outbreaks and treating children who have succumbed to preventable infections.

Furthermore, because clients are generally not formally called back when stock arrives, this means that many children may miss their doses and more will get their doses later than prescribed by the schedule. This affects immunisation coverage which drops and leaves many children unprotected from vaccine preventable diseases. Subsequently vaccine preventable disease outbreaks like those of measles occur with serious outcomes including fatality and complications.

The findings of this study have thrown some light on the status of vaccine availability and helped to gain an understanding on the serious management challenge of a dysfunctional supply chain that results in vaccine shortages in clinics and subsequently leads to children not being vaccinated. It points to significant shortages of vaccines in clinics. The causal factors are stock management and human resource challenges at clinic level, but of significance is that factors related to the higher level, the district depot and to out-dated supply chain management systems are important factors contributing to interrupted supply of vaccines in clinics. Intervention measures should therefore address all these factors.

CHAPTER 7. CONCLUSION AND RECOMMENDATIONS

7.1 Conclusion

Significant vaccine shortages occur in Tshwane government clinics and last for significantly long periods; of a week up to more than 2 weeks in a majority of cases. The vaccine shortages predominantly affect the 3 relatively new vaccines: Pentaxim®, PCV and RV. Of serious concern is that the vaccine shortages occur without any stock challenges at national level or with the suppliers.

The causes of vaccine shortages in clinics are many but can be grossly classified into 2 subcategories: (i) supply chain problems and higher level (ii) factors at clinic level including: stock management practices, cold chain capacity constraints and lack pharmacy assistants. The major causes relating to the higher level and supply chain are: the district depot running out of stock, the delayed delivery of stock and the emergency ordering system that is ineffective. At facility level the main factors are poor stock management practices, lack of pharmacist/pharmacy assistants and cold chain capacity constraints.

A closer look at these findings clearly point to management failure at different levels. Managers from national level up to district level have maintained the same vaccine supply system that has over years been loaded with more products, not only from the EPI but also from programmes such as TB and HIV/ AIDS, with the accelerated provision of antiretroviral (ARV) treatment. The structure of the vaccine supply system has not been updated, the different stages and location of depots remains as it was more than 15 - 20 years ago. The information system between the different levels of the supply chain, certainly between the district depot and clinics and between the clinics and users of health services is out-dated. The manual submission of orders to depot, the depot with no electronic link with the clinics to indicate doses used and no background data per clinic, on population served such as headcounts for the under 1 year population. Similarly the clinics have no electronic record of the users of the health services, the caregivers who bring children for vaccination and do not have this information to communicate with clients. Therefore, currently information technology is not used to support effective vaccine management.

Furthermore even this out-dated system is not used properly, like failure to notify facilities of supply challenges reported by national suppliers. Failure at higher level, to institute measures to address national supply shortages is another example of management failure.

Managers do not seem to have developed and implemented intervention measures to address these challenges. This includes the supervisors and health facility managers, as well as district and provincial managers. Supervisors do not identify vaccine stock shortages or imminent stock shortages and respond to them. At lower level and closer to the challenges; clinic managers do not seem to have their systems in order. This was indicated by poor stock management practices and some admitting to placing orders late. However, there are some aspects that are beyond the Clinic Managers, such as delays in deliveries and when depots run out of stock.

All the above issues clearly point to the need to actively manage the vaccine supply chain. The findings also point to a pressing need for managers at all levels of the supply chain and of the Expanded Programme on Immunisation (EP) to view vaccine shortages as a failure on their part as managers. There are clear indications that the vaccine supply chain is not viewed by managers as one system with different levels that are interlinked, that requires to be actively managed as a single system. The vaccine supply chain needs a logistician to oversee its functioning over two or even more different levels, a person who will monitor and address issues that happen at district depot and follow the process up to clinic level.

7.2 Some Management Principles Brought Up in this Study

A number of important management principles that apply and have been highlighted in this report. These include the following:

- The management dilemma was outlined, relating to ensuring continuous uninterrupted availability of vaccines in clinics at all times, so that when clients present to clinics they can receive the expected services.
- The fundamental objective of operations and supply chain, to be viewed in context of strategy; in this case the health strategy is the prevention of diseases through immunisation. Operations management and supply chain management do not function in isolation; they are part of an overall corporate strategy and it's purpose to implement the strategy
- The principles of Operations Management were brought and specifically as they relate to Supply Chain Management, which are: quality, speed, cost flexibility and dependability.
- The "push" and "pull" concepts in managing supply were referred to in the model of vaccine supply.
- The concept and areas relating to certainty and uncertainty of demand is highlighted. It is indicated that demand for vaccines represents the dependent demand as there is no uncertainty since estimates can be easily made based on target population figures.
- This thesis highlights the complex inter-linkage between: the capacity and skill of human resources, their availability, motivation and how this impacts on the success of a corporate. Although this was not the focus of this study, it demonstrated the crucial role human resources can play in gaining competitive advantage and in this case human resources have a pivotal role in ensuring continuous availability of essential medicines like vaccines.
- The issues of operations design as part of an overall strategy and to be approached such that operations achieve business objectives are highlighted in relation to: placing, capacity, equipment, use of information technology, etc.

7.3 Recommendations

The study recommendations relate to Tshwane health district, however managers of other districts may benefit from reviewing these recommendations and taking those deemed relevant especially if an assessment of vaccine stock availability or of essential drugs has not been done in the last 2 to 3 years. The study recommends the following:

1. A formal assessment of vaccine stock and essential drug management is highly recommended as a matter of urgency. This will help to examine issues relating to the district depot and deliveries of stock which were not part of the scope of this study. Use of a tool adapted from the Effective Vaccine Management (EVM) tool by WHO will be appropriate.

2. The vaccine supply chain and related systems urgently need an overhaul. This specifically relates to installing an information system that is in keeping with advances in technology. The revised information system will cover the use of information at different levels and allow linkage of the information system for the different levels. Another area that requires overhaul in the vaccine supply chain is management of and location delivery points; the frequency of deliveries and possible direct supply to some facilities from the provincial depot. How the supply chain is revised can be informed by the assessment recommended above.

3. There is an urgent need to appoint a dedicated logistician, specifically for the supply of vaccines, other essential drugs and consumables such as syringes (and other surgical supplies) from district depot to facilities. This person will be tasked with the responsibility of ensuring an efficient supply chain and that emergency system works.

4. Causes of delays in delivery of stock at clinics need to be urgently addressed. This should be addressed together with the system for emergency orders. District Managers should urgently address these issues and aim to have 80% of emergency orders delivered within 24hrs. When a logistician is appointed, he/she can take up this responsibility.

5. Cold chain capacity for a large number of clinics needs to be upgraded. Guidance from the national office and WHO on recommended manufacturers of fridges suitable for vaccines with good durability and long temperature holdover time, will be appropriate.
6. The human resources issues related to the allocation of enrolled nurses to the responsibilities of pharmacy assistants and their empowerment should be prioritised. The process of allocating enrolled nurses to the responsibility for pharmaceutical stock management should be formalised. Their unique position and contribution should be acknowledged. Their training and orientation to vaccine stock management should be conducted as a matter of urgency. Management at the district office and facility managers should ensure that the right people doing the job are the ones that attend the relevant training.
7. Supervision needs to be evaluated and restructured. Supervisors should be trained to understand that their role is ineffective if serious matters such as essential drug shortages including vaccines are not identified and addressed by their visits. They should be capacitated to act, to instruct the depot to effect emergency deliveries where required.
8. Vaccine stock piles should be available at district depot. Two months stock pile stock for each vaccine should always be available.
9. Manufacturers should urgently review the presentation and the packaging of the 3 new vaccines to ensure volumes that do not overburden the supply chain. This should be an on-going effort, as means of addressing supply chain issues are limited by the size of the vials, which have serious financial implications if cold chain capacity must be doubled and deliveries increased in frequency.
10. A functional toll free system backed by a short messaging system should be introduced to enable facilities to report stock out at depot without delays. Such a system can simultaneously report the same at provincial and national levels.

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9. ANNEXURES

9.1 Consent Form and Information for Participants

INFORMATION FOR PARTICIPANTS

Dear Health Professional

The research project, "The Status of Vaccine Availability and Associated Factors in Tshwane Government Clinics" is conducted by Dr Ngcobo from the Department of Health, Expanded Programme on Immunisation (EPI). She is studying with the Nelson Mandela Metropolitan University Business School (NMMU) for a Masters degree in Business Administration (MBA).

The project aims establish the situation with vaccine availability at health facilities in Tshwane and identify factors associated with vaccine shortages. It aims to develop recommendations on how best to address such challenges where they occur and work out how EPI should respond to vaccine stock out so that children do not fall behind with the immunisation schedule. Whilst a research project is a requirement for the Masters degree, the aim is that the results of this study will be used by the Department of Health EPI at Tshwane District, Provincial and at National level to address the issues of vaccine shortages.

Your participation will help provide information that will give an understanding of these factors and how best to deal with vaccine stock outs. Your response will be treated in a strictly confidential manner, and your participation will be anonymous.

Procedure: Your participation will be through an interview that uses a questionnaire to ask for information and a request to observe some selected health facility records. The interview will take about 40 minutes.

There is no risk to participants. A decision whether or not to participate will not affect my present or future employment. There is no direct individual benefits to participants; either of a financial nature or otherwise. You are free to withdraw at any stage during the interview.

Your participation in this project is highly valued.

Truly

Dr N J Ngcobo, Principal Investigator.

Date: ……..

CONSENT FORM

Title of the research Project: "The Status of Vaccine Availability and Associated Factors in Tshwane Government Clinics"

DECLARATION BY PARTICIPANT

I ……., was invited to participate in the abovementioned research project by ……

The aim of the research project has been explained to me. I understand that my participation will be through an interview, which will make use of a questionnaire to ask for the required information. Information from the study will be shared with Tshwane Department of Health with the aim of addressing challenges associated with vaccine shortages.

I further understand that there is no risk associated with my participation. My decision whether or not to participate will not affect my present or future employment

I understand that my participation is voluntary and that I can withdraw at any stage during the interview.

I give my full consent to participate.

Signed: …… Date:……

Thank you very much.

Dr N J Ngcobo

To verify the authenticity of the study, please contact Prof C A Arnolds at 041-5043825.

9.2 Ethical Approval and Permission

9.2.1 Pre –Approval from Tshwane Ethics Committee

5

Annexure 1

Declaration of intent from the clinic manager or hospital CEO

I give preliminary permission to DR. N. NGUBO (name of researcher) to do his or her research on STATUS OF VACCINE AVAILABILITY (research topic) in TSHWANE GOVERNMENT CLINICS (name of clinic) or

_____ (name of CHC) or

_____ (name of hospital).

I know that the final approval will be from the Tshwane/Metsweding Regional Research Ethics Committee and that this is only to indicate that the clinic/hospital is willing to assist.

Other comments or conditions prescribed by the clinic or CHC manager or hospital CEO:

Signature
Clinic Manager/CHC Manager/CEO

2013/02/14
Date

9.2.2 Ethical Approval from NMMU RECH

• PO Box 77000 • Nelson Mandela Metropolitan University
• Port Elizabeth • 6031 • South Africa • www.nmmu.ac.za

Nelson Mandela Metropolitan University

for tomorrow

Chairperson: Research Ethics Committee (Human)
Tel: +27 (0)41 504-2235

Ref: [H13-BES-BS-010/Approval]

RECH Secretariat: Mrs U Spies

30 July 2013

Prof C Arnolds
Faculty of BES
Graduate School of Business
Wegspring, Room 104
Bird Street Campus

Dear Prof Arnolds

THE STATUS OF VACCINE AVAILABILITY AND ASSOCIATED FACTORS IN TSHWANE GOVERNMENT CLINICS

PRP: Prof C Arnolds
PI: Dr N Ngcobo

Your above-entitled application for ethics approval served at the Research Ethics Committee (Human).

We take pleasure in informing you that the application was approved by the Committee.

The ethics clearance reference number is **H13-BES-BS-010**, and is valid for three years. Please inform the REC-H, via your faculty representative, if any changes (particularly in the methodology) occur during this time. An annual affirmation to the effect that the protocols in use are still those for which approval was granted, will be required from you. You will be reminded timeously of this responsibility, and will receive the necessary documentation well in advance of any deadline.

We wish you well with the project. Please inform your co-investigators of the outcome, and convey our best wishes.

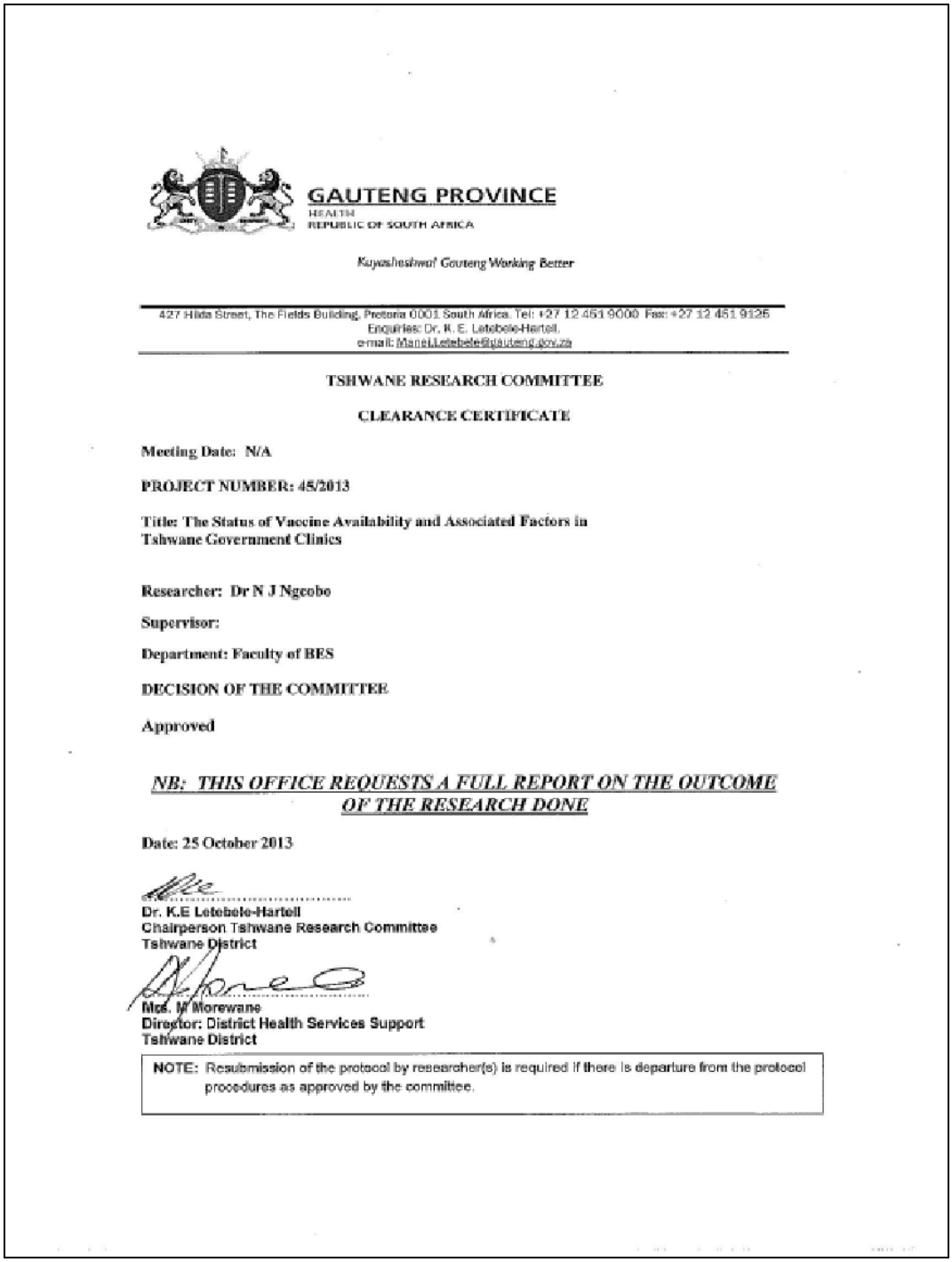
Yours sincerely

CB Cilliers

Prof CB Cilliers
Chairperson: Research Ethics Committee (Human)

cc: Department of Research Capacity Development
Faculty Officer: BES

9.2.3 Final Ethical Approval from Tshwane



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e-mail: ManeLLetebele@gauteng.gov.za

TSHWANE RESEARCH COMMITTEE

CLEARANCE CERTIFICATE

Meeting Date: N/A

PROJECT NUMBER: 45/2013

Title: The Status of Vaccine Availability and Associated Factors in Tshwane Government Clinics

Researcher: Dr N J Ngcobo

Supervisor:

Department: Faculty of BES

DECISION OF THE COMMITTEE

Approved

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

Date: 25 October 2013

Dr. K.E Letebele-Hartell
Chairperson Tshwane Research Committee
Tshwane District

Mrs. M Morewane
Director: District Health Services Support
Tshwane District

NOTE: Resubmission of the protocol by researcher(s) is required if there is departure from the protocol procedures as approved by the committee.

9.3 Measurement Tool

VACCINE STOCK AVAILABILITY QUESTIONNAIRE - FACILITY / PROGRAM MANAGER
Tshwane District - Department of Health, Expanded Programme on Immunisation and PHC

Interviewer: ……Date of Interview…..... No…

SECTION A – DEMOGRAPHICS

District: Tshwane	**Sub-district:**	**Name of Facility:**	
Respondent: (name not required	Position:		
	1. Facility Manager	2. Operations Manager	
	3. Vaccinator	4. Pharmacist/ Ass. Pharmacist	
	5. Supervisor/ Area Manager	6. Other (specify):	
	Is vaccination part of your responsibility?	Yes 1	No0

SECTION B – VACCINE STOCK OUTS

1. Current (Now) vaccine stock outs:							
Duration:	PCV	RV	Pentaxim	BCG	Measles	Hep.B	Other
No stock out.	0	0	0	0	0	0	0
2 days or less	1	1	1	1	1	1	1
3 days - 1 week	2	2	2	2	2	2	2
1 – 2 weeks	3	3	3	3	3	3	3
> 2 weeks	4	4	4	4	4	4	4

2. Vaccine stock outs during past 3 to 12 months:							
	PCV	RV	Pentaxim	BCG	Measles	Hep.B	Other
Number of times							
Maximum duration:							
No stock out	0	0	0	0	0	0	0
2 days or less	1	1	1	1	1	1	1
3 days - 1 week	2	2	2	2	2	2	2
1 – 2 weeks	3	3	3	3	3	3	3
> 2 weeks	4	4	4	4	4	4	4

3. Reasons for vaccine stock outs past 12 months (may tick more than one box per vaccine):							
	PCV	RV	Penta	BCG	Measles	Hep.B	Other
3.1 Depot is out of stock							
3.2 Orders were placed late							
3.3 Delivery is delayed							
3.4 Orders are reduced often							
3.5 Transport problems							
3.6 Don't know							
Other (specify vaccine and other reason(s):							
4. Stock cards availability and whether up to date.							
	PCV	RV	Pentaxim	BCG	Measles	Hep.B	Other
4.1 Available							
4.2 Up to date							
4.3 Comments on stock cards:							

5. Stock levels according to stock cards for last 12 months and whether recorded with data capture tools (leave blank if stock cards not available): Yes = 1, No = 0,							
	PCV	RV	Penta	BCG	Measles	Hep.B	Other
5.1 Zero (0) balance occurred							

6. To whom does this clinic and how are vaccine stock shortages reported?				
	Telephone	Email	Fax/ Form	Other
6.1Local Area Manager				
6.2 District Depot				
6.3 Supervisor				
6.4 Other (specify)				

7.1 Is there a system for Placing emergency orders.	Yes 1		No 0	
7.2 An emergency order takes how long to be delivered.	1 day	2 -3 days	1 week	>1 week
7.3 Are records of reporting stock outs/shortages kept?	Yes 1		No 0	

ORDERING PATTERNS

8. Placing And Receiving Orders				
	Weekly	2 weeks	Monthly	Other
8.1How often are vaccine orders placed?				

9 Reliability of delivery	Always	Often	Sometimes	Never
9.1 Are there delays in receiving orders?				

10. Minimum & Maximum.(Check the stock card to verify) Yes =1, No =0							
	PCV	RV	Pentaxim	BCG	Measles	Hep.B	Other
10.1Check Minimum/ Re Order Level							
10.2 Check Maximum							

11. Are there ever any instances at this facility when there is a vaccine shortage e that was not anticipated and then an order is only placed then? Check stock card to verify this information.	Yes1	No0
12. How does the clinic decide on how much quantities to order.		
12.1 Previous quantities ordered		
12.2 Average consumption for previous 3 months or so.		
12.3 Stock on hand and minimum/maximum levels		
12.4 Population (<1 year) figures are used.		
12.5 Don't know+		
12.6 Other specify		

PERFORMANCE OF HIGHER LEVEL

13 Quantities ordered versus received.	Always	Often	Sometimes	Never
13.1 Has the depot reduced quantities ordered and supplied less than ordered.				
	PCV	RV	Penta	Other
13.2 Which vaccines are often affected by cuts?				

13.3Has the Depot given you more vaccines than quantities ordered? If - Yes which vaccine? Mark Yes 1or No 0				

SUPERVISION

14 Focus and Orientation of Supervision	Weekly	Monthly	Quarterly	Not Sure/ Other
14.1 How often is supervision conducted?				

14.2 Who conducts supervision? (Manager for-)	EPI/MCWH		PHC		Other	
14.3 Is specific supervision for EPI conducted?			Yes1		No0	
14.4 Does Supervisor interact with Vaccinator or visit the Vaccination room/station?			Yes1		No0	

14.5 Does the Supervisor specifically check on vaccine stock levels.(Visit the dispensary and open the fridge and check stock cards)	Always	Often	Sometimes	Never

15. Response to Stock out	Always	Often	Sometimes	Never
15.1 Does the higher level/ supervisor respond once shortages are reported?				
15.2 Vaccines are received within what period once stock out is reported to supervisor?	1-2 days	1week	>1 week	No response

RESPONSE AND COMMUNICATION ON VACCINE STOCK OUTS

16.1 What is one of the first things the clinic does when there are stock shortages?
Reports to supervisor 1 Borrows from nearby clinics 2 ☐ Contacts the depot directly 3 ☐Other (specify) 4 ☐
Specify:

17.1 Does the Depot/supervisor warn in advance of stock shortages?	Yes		No	
17.2 Has this facility been able to warn clients in advance of possible vaccine stock shortages?	Yes		No	

17.3 What information is given to clients regarding vaccines they did not receive due to stock outs?

18.1 When stock is available is there a system to call back those who were affected by shortages?			Yes1		No0	
18.2 Do Community Health Workers inform the Community when stock is available	Yes1		No 0		D K 2	
18.3 Is there a Facility Committee informed of stock shortages	Yes1		No 0		D K 2	
18.4 if Yes - is the Committee informed of shortages	Yes1		No 0		D K 2	

COLD CHAIN CAPACITY

19. Fridge Space Capacity as a factor in vaccine stock availability		
19.1 Is there adequate fridge space for vaccines in this clinic?	Yes	No
19.2 Has this clinic returned back vaccines due to fridge space problems?	Yes	No
19.3Has the clinic had to reduce the quantities of vaccine orders due to fridge space problems?	Yes	No
19.4 Has the clinic requested nearby hospitals or other clinics to store vaccines due to fridge capacity constraints?	Yes	No

19.5 Did the f new vaccines (PCV, RV, Penta) affect fridge space?	Yes	No	D K

HUMAN RESOURCES

20. Dedicated HCW for management of pharmaceuticals including vaccines								
20.1Is there a dedicated HCW (whose only responsibility) responsible for management of drugs and vaccines?					Yes		No	
	Pharmacist or Assistant		Facility Manager	Vaccinator	Prof. or En. Nurse		Other	
20.2 Who manages Vaccine stock? Placing orders, follow up, record of stock on hand.								
20.3 Has this person been trained in Vaccine Stock Management?	Yes			NO			DK	
20.4 Does the Vaccinator give inputs on quantities ordered				Yes		No	DK	

OTHER FACTORS

21. Are there any budget / financial constraints that might have affected vaccine ordering?	Yes		No		DK	
22. Are there transport challenges, with delivery: e.g. vehicle breakdown, driver not available etc.?	Yes		No			
23. Are there any other issues / factors that in your opinion have affected vaccine stock availability?	Yes		No			
If Yes. What are these factors?						
24. Does the facility receive support from district or sub-district; like a visit by pharmacist on stock management (all drugs)?	Yes		No			

25.1 Is there a toll free system for urgent report of vaccine stock out?			Yes		No	
25.2. In your opinion is this system effective? Does it work?			Yes		No	
25.3. If yes, what is it?	Toll Free Phone. No		Toll Free sms		Other	
Specify Other.						
26. Would it be of benefit to have a dedicated toll free no. for urgent direct reporting of vaccine or EDL stock out?	Yes – Good Idea		Not sure. Can try it		No. will not work	
27. If yes, which would be better:	Toll Phone No.		Toll Free sms		Other	
28. Would you be willing to use your cell phone to call or send a stock out alert sms to a toll free no.			Yes		No	
29. Can you recommend other measures to improve vaccine stock availability in facilities and reduce stock outs						

Notes