EXAMINING THE INVENTORY MANAGEMENT OF ANTIRETROVIRAL DRUGS AT COMMUNITY HEALTH CENTRES IN THE CAPE METROPOLE, WESTERN CAPE

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WESTERN CAPE

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A thesis submitted in partial fulfillment of the requirement for the degree of Magister

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KEY WORDS

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ABSTRACT

EXAMINING THE INVENTORY MANAGEMENT OF ANTIRETROVIRAL DRUGS AT COMMUNITY HEALTH CENTRES IN THE CAPE METROPOLE, WESTERN CAPE

Alice Mahoro

M. Pharm thesis, School of Pharmacy, University of Western Cape

South Africa is faced with a high number of people living with HIV/AIDS, and subsequently a great need to access quality medicines for improving patient therapeutic outcomes. Antiretroviral drugs (ARVs) require rigid, efficient and effective management, due to their valuable efficacy in prolonging the survival of HIV/AIDS patients, and the limited possibility of substitution. Managing their flow is vital to ensure an uninterrupted supply. Problematic inventory management was experienced by some healthcare facilities in South Africa where in recent years it resulted in stock outs and stock losses through thefts. These factors present obstacles to the availability of quality medicines, which ultimately leads to treatment failure and deterioration of the health status of patients.

The aim of this study was to characterise the inventory management practices and medicine store maintenance of ARVs in community health centres (CHCs) in the Cape Metropole, Western Cape, in order to identify specific problems associated with ARV stock management. The study used a descriptive, cross-sectional study design to examine ARV records and to highlight associated discrepancies between recorded

quantities on logistics tools used and physical counts, to assess the store maintenance, to measure the supply rate and identify factors contributing to poor stock management.

The sample comprised 15 CHCs under the Western Cape Provincial Government (WCPG) accredited to provide ARV treatment. A checklist developed by Management Sciences for Health was adapted and was used to gather quantitative information (e.g. physical stock count). Some qualitative data was collected from responsible personnel for ARV drug management at each site.

86.7% of CHCs utilised a logistics tool (either manual or electronic) to manage ARVs. The average number of adult ARV drugs with a logistics tool available in all CHCs was 82.7% of which 21.9% met the criteria for accuracy. Only 32.9% of all logistics tools had records that were up to date. The average percentage of total variation between stock records and physical counts for the ARV drugs assessed was 51.6%. No historical data on stock outs and monthly usage (monthly consumption) could be retrieved in any of the CHCs, although there were no actual stock outs on the day of the fieldwork. The order fill rate was 91.9%. Since ordering is done more often that it should, stock availability did not appear to be problematic. Standard appropriate physical dimensions were not met by 20% of the CHCs and only 66.7% of the CHCs had appropriate labeling of the shelves in the dispensary and in the storeroom.

This study demonstrated poor inventory management with respect to the general quality of record keeping, space allocation and general organisation of the medicine storeroom.

Making timely entries and recording issues on logistics tools are recommended to keep up to date inventory records and management information system. Frequent monitoring of stock status is suggested, to avoid discrepancies and to keep it to adequate levels

which will minimise multiple ordering. Regular supervision by the district pharmacist is needed to identify training and other needs. A study on general cost and delivery costs associated with poor record keeping should be carried out.

DECLARATION

I declare that *Examining the inventory management of antiretroviral drugs at community health centres in the Cape Metropole, Western Cape* is my own work, that it has not been submitted before for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged as complete references.

Alice Mahoro

November 2013

Signed……………………..

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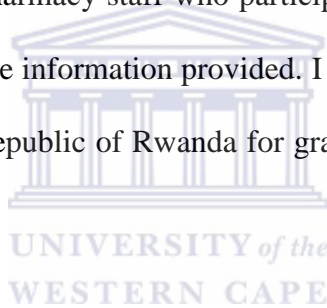
I would like express my gratitude and appreciation to my lovely husband, Antoine Bahizi, for the statistical analysis for this study, for his steady support, and for his time and valuable input as far as the statistical part of this work was concerned.

Particular thanks go to my family: my daughter, my mother and brothers for their steadfast support and encouragement, which kept me going when discouragement seemed rampant. To my faithful friends – their presence and their prayers were a large support.

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List of Acronyms

AIDS   Acquired immunodeficiency syndrome

ARV   Antiretroviral

ART   Antiretroviral therapy

CHC   Community health centre

CPA   Central Procurement Agency

CTCH   Cape Town City Health

EDs   Essential drugs

FEFO   First to expire, first out

FIFO   First in, first out

GPP   Good Pharmacy Practice

HIV   Human immunodeficiency virus

HRH   Human Resources for Health

ID   Identification

LMIS   Logistic Management Information System

MAX-MIN   Maximum-minimum

MSF   Médecin Sans Frontières

MOH   Minister of Health

MSH   Management Sciences for Health

NDOH   National Department of Health

NEMLC   National Essential Medicines List Committee

NHI   National Health Insurance

PBPA   Post Basic Pharmacist's Assistant

PHC   Primary health care

PLWHIV   Person living with HIV

PTCs   Pharmacy and Therapeutics Committees

UNAIDS   United Nations Joint Programme on HIV/AIDS

SAPC   South African Pharmacy Council

STD DEV   Standard Deviation

SOPs   Standard Operating Procedures

WCPG   Western Cape Provincial Government

WHO   World Health Organization

Chapter 1 Introduction

1.1 Global, regional and local HIV burden

Access to life-saving medicines such as ARV drugs is increasingly allowing more people to live with HIV. Approximately 34.2 million people worldwide were living with HIV in 2011. In sub-Saharan Africa more than half (56%) of the people needing treatment were receiving it in 2011, this is 1.4 million more people than in 2010 and significantly higher than the 400 000 people receiving treatment in 2003. This reveals an expansion of treatment access, especially where the need is the greatest (UNAIDS, 2012). According to UNAIDS, in 2011, 68% of the total number of people living with HIV (PLWHIV) were in sub-Saharan Africa, with South Africa at the top of the list with the greatest number of PLWHIV (5.6 million people in the country are HIV positive) (UNAIDS, 2011). In 2011, the Actuarial Society of South Africa calculated – using a computer model (ASS2008) – that the number of people who died of AIDS declined from an estimated 257 000 in 2005 to 194 000 in 2010. This declining death rate is due to antiretroviral treatment (ART) availability (Actuarial Society of South Africa, 2011). The rate of new HIV infections in highly affected countries, including South Africa, decreased by 25% between 2001 and 2009 (UNAIDS, 2011).

1.2 Importance of drugs and medical supplies in the success of ARV programmes

The availability of drugs and medical supplies is critical to the success of any healthcare programme. Drugs and medical supplies are part of the final link between patients and health services. They play a key role in prevention, treatment and care programmes, and in order to sustain these services, numerous medical commodities are required.

A reliable and consistent supply of these commodities to health facilities at all levels of the health system will determine the success of these nationwide programmes (Raja & Mohammad, 2005).

Health commodities are expensive and valuable resources in any healthcare programme. They have to be managed effectively in all the steps of the supply chain to ensure that quality commodity products are available at all times (Chandani *et al.*, 2009). Particular attention is needed when it comes to the management of ARV drugs due to their unique characteristics: their valuable efficacy in prolonging the survival of HIV/AIDS patients, and the limited possibility of therapeutic substitution (Chandani *et al.*, 2009; Deliver, 2008)

1.3 Role of primary health care in South Africa

The primary care level is a vital part of healthcare in South Africa. An integrated package of essential primary healthcare (PHC) services is available to the entire population and provides a solid foundation for a single and unified health system. The goal of PHC is to achieve greater equity in access to medical and pharmaceutical care in a way that is effective and sustainable. Against the backdrop of human resource shortages in South Africa, patients are down-referred to the primary level to involve the health workforce at lower levels, and consequently expand Human Resources for Health (HRH). Down-referral also serves to rapidly enhance access to ART and other health services, and this is done in accordance with the WHO Alma Ata Declaration of 1978 on PHC, which is to "promote the decentralization of services among communities in order improve equity in access to health care"(WHO, 2008b:1). The integrated PHC services offered include women's reproductive health, integrated management of childhood illness, adolescent and youth health, communicable diseases and non-

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communicable diseases (NDOH, 2009). South Africa embarked on the implementation of PHC re-engineering for the National Health Insurance (NHI) preparation. The continuous monitoring of the quality of health care and service delivery has been identified as an integral part of the health system strengthening strategies under the NHI, with a focus on prevention and health promotion (Matsoso & Fryatt, 2013; NDOH, 2012).

1.4 Drug supply management in South Africa

Effective drug supply management is critical to ensure the cost-effective distribution of medicines given that the cost of medicines is often high and mismanagement results in wastage and pilferage. South Africa spends about 12.3% of the public sector health funding on pharmaceuticals (NDOH, 2012). There is a need for efficient management of the drug supply cycle to prevent all types of wastage, including shrinkage and expiries (Nakyanzi *et al.*, 2010).
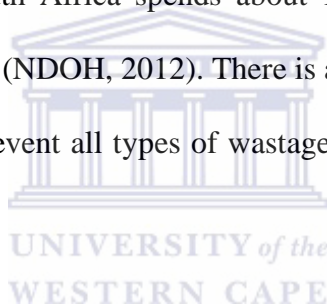
Good national policies are not enough for well-functioning drug supply. Without commitment from the district to the health facility, to ensure an organised and efficient drug supply and training to carry out responsibilities–medicines will fail to reach the medical staff at the PHC facility and the patients, who are the end users of medicines (Clark & Barraclough, 2010). The drug supply cycle is illustrated in Figure 1.
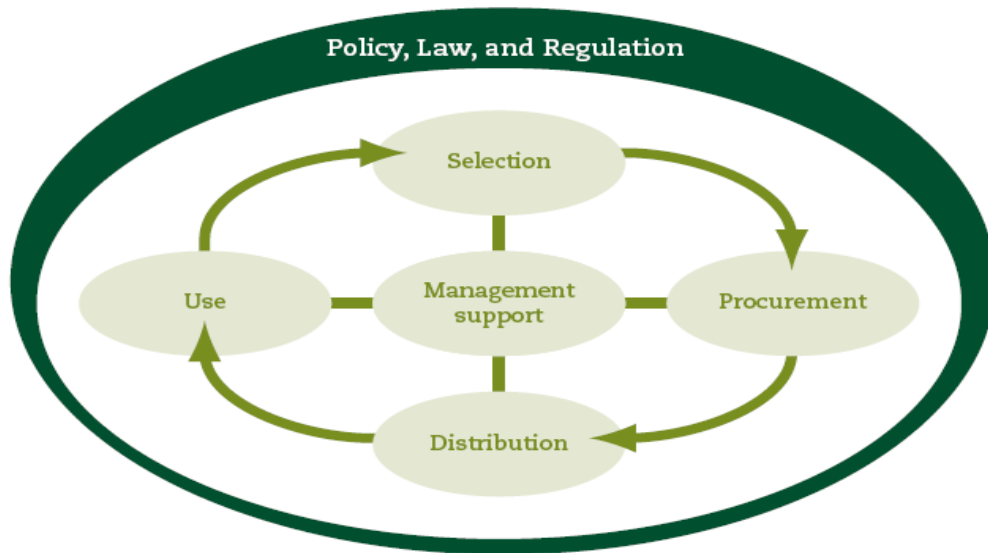
Figure 1. Drug supply cycle

(MSH, 2010)

The drug supply cycle comprises four major components that are governed by policies and regulations (WHO, 2004). With reference to South Africa's public sector, the drug supply cycle (MSH, 2010; Pharasi & Miot, 2013; SAPC, 2010) include:

i. The selection of medicines that are available for procurement in the public healthcare sector that takes place through the National Essential Medicines List Committee (NEMLC), provincial and facility-based Pharmacy and Therapeutics Committees (PTCs).

ii. Tenders that are prepared, advertised and awarded by the National Department of Health (NDOH); then procurement is done at the state's cost by the Central Procurement Agency (CPA) an agency under NDOH. It was planned that the CPA might eventually migrate out of the NDOH and become an independent public entity responsible directly to the Minister of Health (MOH).

iii. The delivery of healthcare services is a provincial competence and the distribution involves provincial depots that deliver medicines to primary health facilities.

iv. Use that focuses on diagnosis, prescribing and dispensing that is carried out in suitable space and facilities for normal dispensing activities by a pharmacist or a pharmacist's assistant – followed by and rational usage by the patient.

The inventory management at the facility level refers to the routine ordering process. It includes activities related to the process of ordering, receiving, storing, distributing, issuing, and re-ordering stock of commodities (Odinga, 2007).

1.5 Inventory management challenges in South Africa

Managing medicines to ensure a continuous supply can be challenging (Schouten *et al.*, 2011). Some of the challenges described by PHC staff in the Free State province include lack of proper storage, poor stock control, and lack of human resources (Moloto, 2005). The shortage of pharmacists leaves nursing personnel with the onerous responsibility for clinical and pharmaceutical management, often resulting in poor drug management. Other issues reported include the delivery of medicines that are prone to expire and difficulties in quantification due to fluctuation in demand (Moloto, 2005). In the Eastern Cape province, poor consumption data from facilities and lack of security of supplies were pointed out as the main challenges at the depot (WHO, 2006).

1.6 Common problems in inventory management

In many countries, poor inventory management in public health institutions results in wastage of financial resources, poor availability of some essential medicines, stock outs,

stock losses and consequently, failure to ameliorate patients' health outcomes (MSH, 2012).

Poor inventory management is evidenced by inaccurate stock records, lack of systematic monitoring of the stock, and undefined procedures on ordering frequency and quantity, which are linked to lack of knowledge of the meaning of inventory management, as well as inefficient and ineffective management (MSH, 2012). A study conducted in three countries in East Africa (Tanzania, Uganda and Rwanda) emphasised that, despite the efforts of initiatives such as the Global Fund to Fight AIDS and The President's Emergency Plan for AIDS Relief to increase the availability of and access to ARVs – the pharmaceutical supply management in the aforementioned countries was found to be deficient. The weakness was underlined by the incapacity to adequately quantify needs, place orders, and adequately keep records (Matowe *et al.*, 2008).

When South Africa started the scale-up programme of ART it faced a shortage of ARVs due to drug supply management malfunction, with the problem seemingly linked to poor inventory control (MSF, 2007; PlusNews, 2009). In an ART scale-up programme, inventory control should be one of the priority interventions for strengthening inventory management at the health facility level (Walkowiak & Keene, 2009). Adequate medicine stock levels and other medical supplies ensure not only the effectiveness of the health systems, but also contribute to improving the therapeutic outcomes of patients (MSH, 2012).

In 2013, stock outs were reported at a provincial depot in South Africa where procurement and stock control systems were rated ineffective and may have encouraged theft (Bateman, 2013). Recent stock outs have also been reported in Gauteng, Eastern

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Cape and Kwazulu Natal where PHCs have experienced stock outs of ARVs (Mapumulo, 2013; Khan, 2012).

1.7 ARV supply system in the Western Cape

The Western Cape depot delivers all ARVs to the CHCs and clinics in the province. Medicine procurement is done through the pull system. According to this system, CHCs determine their needs and send their requisitions by fax to the pharmacist in charge at the Western Cape provincial depot, where the requisitions are processed further. ARV delivery is done within three working days. The software used for this processing is called JAC (Western Cape Department of Health, 2005). The pharmacist in charge ensures that standards in the management of ARVs are maintained by health facilities. This is achieved through the development and implementation of guidelines and standard operating procedures (SOPs) (Western Cape Department of Health, 2009).

1.8 Problem statement

South Africa is faced with the greatest HIV-positive population in the world (UNAIDS, 2011). A regular supply of ARV drugs is, therefore, essential to improve the therapeutic outcomes of PLWHIV. Some issues regarding supply management have been raised in literature, *inter alia* poor management of ARV medicines and poor mechanisms for inventory tracking in some health facilities (Bateman, 2013; Summers *et al.*, 1998).

Inventory management is a key step in ensuring a continuous supply of ARVs. It is crucial to know the levels of medicines in the store in order to maintain the availability of ARVs, to avoid stock outs, overstocking and expiries. These are challenges in public sector health institutions, and are to a large extent attributed to poor inventory control

systems that do not provide an audit trail for medicines delivered from the provincial stores.

Most research in the drug supply arena, have focused on the optimisation of the supply system in terms of its efficiency through linking product selection decisions to patient needs; basing financing and procurement decisions on established quantification methodology; and improving information system that provides feedback for tracking stock movements (Chandani *et al.*, 2009; Kagashe & Massawe, 2012; Roy *et al.*, 2009). On the other hand, few studies have covered inventory management in the supply chain. Research done on the scale up of access to ARVs in South Africa explored some aspects of inventory management (e.g. ordering, distribution, continuity of ART supplies and the impact of ART delivery on other drugs and supplies) but not record keeping practice and order fill rate. The media has reported many cases of ARV stock outs in hospitals and PHC facilities but their causes are not explained (Khan, 2012). There is a need to assess inventory management in order to identify management problems in primary health facilities, and to introduce fully operational strategies to overcome these issues. Since there is no literature in the public domain on ARV inventory management in the Western Cape, this study aims to document practices at PHC level. In light of the aforementioned, this study will evaluate the inventory management practices and drug store maintenance of ARVs in primary health facilities in order to make recommendations on inventory practices in public health facilities in the Western Cape.

1.9 Study aim

This study aimed to describe the inventory management practices for ARV drugs at CHCs in the Cape Metropole of the Western Cape, and to identify and characterise specific challenges related to inventory management.

1.10 Specific objectives

Specific objectives of this study were to:

i. Identify the logistics tools used for record keeping

ii. Evaluate the quality of record keeping with respect to accuracy of stock recorded relative to physical stock count, and the completeness of information on the logistics tool to identify a particular ARV medicine

iii. Assess the store maintenance (considering stock outs and store management);

iv. Measure the supply rate of ARV drugs

v. Identify factors contributing to poor stock management

In achieving these objectives, the study sought to answer the following questions:

i. Do record-keeping practices exist in CHCs and, if so, how accurate are they?

ii. Are there any recorded ARV stock outs or actual stock outs on the day of the visit?

iii. Is the store maintained according to Good Pharmacy Practice Standards?

iv. What is the supply rate of ARV drugs (against the orders placed)?

v. What are the predictors of poor stock management?

1.11 Definition of Terms

Inventory management

Management of the routine ordering process. It includes activities related to ordering, receiving, storing, distributing and issuing, and re-ordering stock of commodities. All

these activities are tracked with appropriate documentation, thus good record-keeping is critical to the success of the all process (Odinga, 2007).

Inventory control

Systematic management of the balance on hand of inventory items, involving the supply, storage, distribution, and recording of items (Odinga, 2007).

Record-keeping

Systematic procedure by which the records of an organization are created, captured, maintained, and disposed of. This system also ensures their preservation for evidential purposes, accurate and efficient updating, timely availability, and control of access to them only by authorised personnel (De Boisdeffre, 2006).

Stock out

Depicts a situation in which the demand or requirement for an item cannot be fulfilled from the current inventory (MSH, 2010).

Stock losses

The quantity of stock removed from inventory for any reason other than consumption by clients (for example, expiry or damage) (MSH, 2010).

Order fill rate

The percentage of individual items ordered from a supplier and issued (MSH, 2012).

Pharmacist's assistant

Pharmacy staff member who works under the direct or indirect supervision of a licensed pharmacist, and performs many pharmacy-related functions as stated by the South African Pharmacy Act of 1974 (SAPC, 2011b).

1.11 Overview of chapters

This thesis is structured into six chapters: Chapter two offers a review of the relevant literature on inventory management; describing the research conducted nationally and internationally with a focus on developing countries on this subject; reviewing the facets of inventory management; elucidating the main challenges related to inventory management and describing strategies to enhance inventory management. Chapter three provides a detailed description of the methods used for data collection. Chapter four presents the results and chapter five is a discussion of the results. Chapter six provides the conclusion and useful recommendations emanating from this study.

Chapter 2 Literature review

This chapter provides a review of literature concerning drug supply management, with a focus on inventory management in developing countries, depicting facets of inventory management, associated challenges and describes strategies to optimise inventory management.

2.1 Drug supply management

Drug supply management is a key component of pharmaceutical services. The availability of medicines contributes to improved quality of pharmaceutical services. The availability of medicines is considered to be the most important quality indicator of healthcare in African settings (Jitta *et al.*, 2003), as medicines play a key role as a final link between patients and health services. Sustained supply contributes to improving the therapeutic outcomes of patients (Clark & Barraclough, 2010). Many studies have been carried out on the management of the drug supply system, particularly in developing countries (Chandani *et al.*, 2006; Jitta *et al.*, 2003; Pharasi, 2007), where strengths and weaknesses of the drug supply management system have been highlighted.

Developing countries have in recent years experienced a tremendous increase in the volume of ARV drugs, due to initiatives aimed at universal access to ART. A robust supply system is necessary to manage the massive amount of ARVs and related commodities. Unfortunately, experience gained from literature in developing countries has revealed notably fragile pharmaceutical supply in developing countries, with human resource shortages being the main contributing factor (Van Damme *et al.*, 2006; Waako *et al.*, 2009). This is the case in East African countries, such as Kenya, Uganda, Tanzania and Rwanda, where interviews with health care workers revealed that human

resources have been a major challenge in the scale up of ART programmes (Waako *et al.*, 2009). Similar human resource shortages were found in Malawi, where the supply system was found be weak and the scaling up of ART needed a new strategy (Schouten *et al.*, 2011).

Human resource shortages are common in the field of pharmaceutical management in African countries, where pharmacists and pharmacy technicians are scarce in spite of the existence of training institutions (Pharasi, 2007). This creates impediments to the smooth running of pharmaceutical services; inefficient medicine selection, drug shortages, expiries – due mainly to improper quantification – poor inventory management, and inadequate dispensing, have been found to be associated with the lack of adequate human resources in the aforementioned East African countries (Matowe *et al.*, 2008; Waako *et al.*, 2009). The lack of HRH, particularly in sub-Saharan Africa, has been identified as the main bottleneck to health services, particularly ART scale-up (Callaghan *et al.*, 2010; Ojikutu *et al.*, 2008; Van Damme *et al.*, 2006). This shortage of HRH has also affected healthcare systems in South Africa (Steyn *et al.*, 2006; Van Rensburg, 2006). Pharmacists who are chiefly responsible for drug supply management top the list of scarce skills in South Africa's public health sector especially in rural and remote areas (Van Rensburg *et al.*, 2008; Van Rensburg, 2004).

The lack of medicines in many health facilities in Africa is due to poor procurement processes and distribution practices; this is a major concern when it comes to the scale-up of ART (Harries *et al.*, 2007). A descriptive study carried out in Malawi showed that maintaining an uninterrupted supply has been a challenge in many African PHC facilities and stock-outs of ARVs have been recorded (Schouten *et al.*, 2011). Stock outs lead to treatment disruption, which increases the risk of treatment failure and the

development of drug resistance –scenarios that have been observed in sub-Saharan PHC facilities (Harries, 2005). South Africa, as with other developing countries, faces – in the scale up of ART – the "difficult tasks of ensuring uninterrupted drug supply, motivating staff, promoting drug adherence among patients, and conducting regular supervision and monitoring" (Harries, 2005:117). In spite of the expansion of ART coverage in limited-resource countries facilities are facing major challenges regarding supply chain management with reference to HIV/AIDS drugs. In 2009 the WHO reported that at least 38% of reporting countries had experienced at least one stock out in health facilities, which highlights a problem with the supply system (Schouten *et al.*, 2011). An exploratory-retrospective and cross-sectional study in India showed that not only ARV drugs are affected, but essential drugs have also run out in most supply systems in past decades; essential drugs required by various PHCs were either always in very short supply or missing in medical stores (Roy *et al.*, 2009).

Problematic drug supply management has been noticed in healthcare facilities in Gauteng, Mpumalanga and North West, where some hospitals have claimed to experience stock outs of tenofovir (Khan, 2012). There is a great need to access quality medicines in South Africa, where about 5.6 million people are HIV positive (UNAIDS, 2011).

Due to stock outs in rural facilities, patients may have to make long and expensive journeys to obtain treatment. If the availability of medicines at the secondary level is better than at the primary level, the community will lose confidence in PHC and seek hospital treatment instead (Clark & Barraclough, 2010). A loss of confidence in PHC has been observed in the Free State, where patients on chronic medication due to

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medicine stock outs have defaulted – resulting in poor disease control as revealed in an action research study in the Free State province (Moloto, 2005).

According to Clark and Barraclough (2010), improper monitoring of medicine flow can lead to wastages, including expiries and under-utilisation of medicines in health facilities, which leads to the unavailability of medicines and failure to achieve patients' therapeutic goals.

A cross-sectional survey of six public and 32 private medicine outlets in Ugandan using semi-structured questionnaires showed that medicine expiries were severe in public as well as private facilities with expired medicines being found at national medical, district and hospital stores. Contributing factors included neglect of stock monitoring and a lack of knowledge of basic expiry prevention tools. Similar cases of expiries have been reported in Botswana, India and Tanzania (Nakyanzi *et al.*, 2010). In a private setting in Malawi, 65% of drug products were found to be expired, 29.8% of which were international donations. An excess of unnecessary medications and inappropriate international donations were identified as a potential cause of expiries (Lauffenburger *et al.*, 2011). An effective drug supply management system has been reported in Zimbabwe, on the other hand, where stock management of essential drugs (EDs) at health facility level was good. An inventory control system based on applied monthly ordering was a key success to supply management. Drugs were ordered when their stocks reached the ordering point, which was set at three months' consumption. Another strategy implemented was a regular assessment of the abovementioned inventory control system (Moloto, 2005).

South Africa has a well-structured and well-managed pharmaceutical sector, built on a National Drug Policy within which the ART programme is located (Gray & Suleman, 1999). Drug prices are regulated (Gray, 2009), essential drug (ED) lists are established (Health Systems Trust, 2003), and EDs are easily accessible at the national level (Health Systems Trust, 2004; WHO, 2009). The South African government announced in November 2003, the Operational Plan for Comprehensive HIV and AIDS Care, management and treatment (henceforth referred as Comprehensive Plan) – that aimed to ensure free access to ART and in the process, to strengthen the entire national health system. To achieve the goals of improved access to treatment; increased adherence and improved management of those currently on ART; a significant number of human resources are required. To meet this need, the comprehensive plan suggested the employment of mid-level cadres namely pharmacist assistants (pharmacy personnel that received a two years in-service training course supervised by a pharmacist in drug supply management) (Foster & McIntyre, 2012; Mbewu *et al.*, 2003). The delegation of tasks to less qualified staff, known as task shifting has proven to be effective. Evidence from Medecin Sans Frontières (MSF) in Lesotho where, as in Malawi and Mozambique nurses were allowed to initiate PLWHIV on ART has shown that more facilities providing ART were established and access to treatment improved (MSF *et al.*, 2009). Extensive research in the area of HIV management has been done to evaluate models of care that can reduce demand for doctors and improve health care efficiency by delegating the provision of primary care to nurses (Laurant *et al.*, 2004; McPake & Mensah, 2008). Other models of task shifting have been explored including the delegation of tasks from doctors to physician assistants (Kruk *et al.*, 2007); from nurses

to community health workers (Wools-Kaloustian *et al.*, 2009), and a few studies refer to pharmaceutical care staff (Monteith *et al.*, 2010).

Pharmacist assistants work under direct or indirect supervision of a pharmacist. The legal framework for the indirect supervision by a pharmacist in South Africa is presented in regulation 12 of the Pharmacy Act, 1974 (Act 53 of 1974) regulations. The regulation stipulates that supervision can only be done in a PHC setting or any other facility as approved by the South African Pharmacy Council (SAPC) and that the supervising pharmacist cannot supervise more than five individuals. The supervision should be conducted at least once a month and should be documented. The pharmacist assistant cadre can only handle patient ready packs, and written and up-dated protocols and SOPs have to be available describing clearly the responsibility of the pharmacist assistant (SAPC, 2011b).

The responsibilities of the pharmacist's assistant cadres at the PHC facilities are related to inventory management and consist of ordering pharmaceuticals and related products, receiving and checking of ordered stock, storing pharmaceuticals and related products monitoring and maintaining stock. They also replenish pharmaceuticals and related products to usage areas within the facility; monitor expenditure against allocated budget; evaluating and dispensing prescriptions for schedule 0-5 (SAPC, 2010).

Notwithstanding the creation of a mid-level worker for drug supply management , human resource constraints remain singled out to be a major cause of medicines supply related challenges (Odoi-adome & Matowe, 2010). The HRH shortage in the developing world presents a huge challenge with little evidence that things will improve in the near future.

Of the 12,460 pharmacists working in South Africa in 2011, only 29% worked in the public sector which serves about 80% of the population. The ratio of pharmacists to population in South Africa is 25.5:100 000 (SAPC, 2011a) relative to a minimum of 45:100 000 recommended by WHO (SAPC, 2011a). Unfortunately the use of the existing workforce to optimise good inventory management in South Africa has not been sufficiently addressed in literature (Schneider *et al.*, 2006). Existing literature focuses on various constituents of ARV supply management including ordering, distribution, continuity of ART supplies and the impact of ART delivery on other drugs and supplies (Steyn *et al.*, 2009). Little attention is given to order fill rate of the supplier and record keeping in inventory management as a crucial component in ensuring that accurate information is available for decision making (Kagashe & Massawe, 2012).

2.2 Inventory management

It is essential to review inventory management indicators and to monitor them regularly for the success of drug supply management. Poor inventory management mechanisms affect the availability of medicines, as proven by the poor availability of ARVs reported in Tanzania, where stock outs have been recorded in hospitals that depended on the Medical Stores Department (MSD) for their supply – lack of logistics skills in ordering was associated with observed stock outs. In Lesotho stock outs have been associated with poor record-keeping practice (Kagashe & Massawe, 2012).

The availability of ARVs as a global recommendation by many international organisations and initiatives, including the WHO, UNAIDS, the Global Fund to Fight AIDS, and the President's Emergency Plan for AIDS Relief, constitutes the importance of inventory management (Matowe *et al.*, 2008).

Although cases of lack of ARVs in full supply have been observed; hospitals and PHC facilities in Lesotho had 80% of the essential ARVs. This unfortunate situation is exacerbated by the fact that nurses in charge of inventory management do not have sufficient knowledge regarding safe drug substitution and they generally lack guidance to deal with ARV shortages because there are not enough pharmacists and pharmacist's assistants to conduct supervision at PHC facilities (Pharasi, 2007). Other African facilities are facing a challenge in the scale up of ART, which is maintaining ARV drug supplies (Harries *et al.*, 2007).

Weaknesses in inventory management are due, on the one hand to human resource challenges, as argued by Pasquet *et al*. (2010) and Waako *et al*. (2009), and on the other hand to undefined procedures and a lack of systematic monitoring of the stock (MSH, 2012).

Inventory control is one of the elements underpinning inventory management; a failure to monitor stock levels regularly could have fatal consequences; disruption of or delay in a course of treatment may worsen a patient's condition and lead to death if a lifesaving medicine is out of stock (Clark & Barraclough, 2010). The lack of a standardised inventory control system with procedures for monitoring and managing stock levels of ARV drugs is a challenge to emerging logistic systems; as is the case in Lesotho where stock levels were not monitored, resulting in over-stocking of certain medicines (Pharasi, 2007). In the scale up of ARV drugs, monitoring stock level has to be enhanced.

The scaling up of ART provision in sub-Saharan African countries has improved the availability of ARVs and extended access to life-saving medicines. The start of the ART

scale-up programme encountered problems relating to ARV shortage, largely due to drug supply management malfunction at the depots on the national scale. Countries that suffered from a shortage included South Africa, and Malawi (PlusNews, 2009; Raja & Durgavich, 2008)

To maintain confidence in the health system, a sustained supply of ARVs is required (Deliver, 2006). Standardised procedures to forecast the correct amount of medicines needed has to be based on information; i.e. the stock on hand has to be established; pre-determined stock levels have to be set to control fluctuations in demand, and the monthly consumption needs to be calculated. The lack of such information handicaps ordering procedures. Lack of consumption data at facilities in Sierra Leone resulted in emergency orders (Allers *et al.*, 2007). The requirements for medicine quantification are not estimated according to actual hospital needs in Jordan, where inadequate recordings on stock cards have been noticed in some hospitals (Talafha, 2006).

Successful inventory management is based on good record keeping. Paper-based record keeping is found in most drug supply systems, where stock cards or bin cards are used for that purpose (Pharasi, 2007; Talafha, 2006). In a descriptive cross-sectional study carried out in Tanzania, using Inventory Management Assessment Tool (IMAT) – inaccurate records were found in the Mwananyamala and Temeke hospitals while at the Muhimbili national hospital a computerised system was in place besides bin cards. This contributed to the accuracy of the records found (Kagashe & Massawe, 2012). Non-existent computerised systems add to already overworked personnel, exacerbated inaccurate stock recordings practices in MOH hospitals in Jordan (Talafha, 2006).

A study carried out in Zimbabwean PHC facilities – where drug supply management is carried out by nurses under the supervision of pharmacy technicians – showed that the introduction of a record keeping system allowed for improved quantification resulting in more readily available pharmaceuticals. The study reported that inventory management improved with on-the-job training and with more frequent supervisory visits by pharmacy technicians who assisted with stock management – the organisation of drugs in storerooms– checking of stock records and help in setting stock levels (Moloto, 2005).

2.2.1 The purpose of inventory management

An inventory management system aims to assist in determining when and how much stock to order or issue. Orders that are placed timely allow drugs to be available at the right time (Odinga, 2007). Timeous delivery forms an integral part of large-scale roll out of ART (Steyn *et al.*, 2009). For a proper quantification it is critical to take into account the data on actual drug consumption at health facility level (Talafha, 2006). When medication quantification requirements are not estimated according to real needs, it could lead to misquantification and may tie up a portion of the medicine budget – leaving insufficient funds for other important and perhaps life-saving medicines (Clark & Barraclough, 2010). Maintaining enough stock to avoid shortages, to confront fluctuation and to avoid oversupply also constitutes the aim of successful inventory management (Deliver, 2008; Odinga, 2007).

2.2.2 Inventory control system

Inventory control deals with the physical control of product quantities in the store to ensure a balance on hand.

It helps to decide what, when and how much to keep in the store to avoid shortages and pilferages and to minimise ineffective stock (Odinga, 2007; Roy *et al.*, 2009). In a study done in Zimbabwe, the WHO (cited in Moloto, 2005) highlighted the importance of inventory control – as it influenced the effective management of EDs at health facilities. This system is based on monthly ordering, where a drug is ordered when stock on hand reaches the ordering point, which is set at the three months' consumption.

A number of strategies are adopted in inventory control: maximum-minimum, rationing system, ABC and VED (Deliver, 2006; Kagashe & Massawe, 2012). In Deliver's experience, the maximum-minimum inventory control is the best to implement (Deliver, 2006). In this system, inventory levels are based on past consumption; this prevents stock imbalances by managing the risk of expiries due to overstock, and minimises emergency orders caused by inadequate stock. The maximum-minimum inventory control system permits resupply based on needs, and takes into account safety stock, with the ultimate goal of having ARVs available whenever they are needed (Allers *et al.*, 2007; Chandani *et al.*, 2009). However, this system may not be adequate for every supply system. In the scale up of ART in Malawi, the maximum-minimum system based on monthly consumption normally used in supply management was not applied to the supply of ARVs due to increasing numbers of new patients starting ART and hence an increase in consumption rate. The ordering was done based on remaining stock levels at all PHC facilities; when the aforementioned level was assumed to cover two months, a six-months' supply was distributed to ART sites (Schouten *et al.*, 2011).

A lack of awareness of the methods of inventory control was found in public hospitals in Tanzania; most of the staff (65%) in Dar es Salaam hospitals did not know any of the inventory control methods used in inventory management.

Consequently, there was a poor estimation of needs resulting in over-stocking of medicines (Kagashe & Massawe, 2012). A study conducted in Darbhanga district in India found that no inventory control techniques were used for the maintenance of the stock in public hospitals, resulting in frequent stock-outs (Roy *et al.*, 2009).

2.2.3 Physical count

Matching the stock on hand with stock-keeping records by physically counting the number of each type of product in the store at a given time is required for functioning inventory management (WHO, 2004). Products are counted separately by generic names, dosage forms and strength. There are two general types of physical inventory: a complete physical inventory and a cyclic or perpetual physical inventory (Clark & Barraclough, 2010).

According to Kang and Gershwin (2005), stock control should be carried out at least once a year for financial reporting purposes and stock status reports. The accuracy of the inventory can be calculated for comparison between the inventory records and the physical count; if there is a match between inventory records of the stock and the actual stock, it is defined as the perfect inventory accuracy of a store. When a facility relies on inventory records in decision-making, the impact of inaccurate inventory records on performance can be severe. Maintaining perfect inventory records is difficult to achieve in practice (Kang & Gershwin, 2005; Odinga, 2007). In a study carried out in Lejweleputswa district in the Free State province, inventory control was found to be poor as stock cards at most facilities were not completed with all the necessary and accurate information. Poor inventory management and inaccuracy of records meant that procurement and budgeting was based on unreliable information.

The consequences of such practices are poor planning, stock outs, and shrinkage of purchased drugs (Moloto, 2005). The physical stock count must be tracked by appropriate documentation stating the status of the stock. Any discrepancy must be recorded correctly and turned into a report to be transmitted to the managers concerned (MSH, 2012). In a study on medicine stock outs and inventory management in Tanzanian public hospitals, Kagashe and Massawe (2012) reported discrepancies between recorded quantities on stock cards and physical count. Mwananyamala hospital had 72% of recorded balance on stock cards that was greater than the physical count, while Mwananyamala hospital had 8% of recorded balance on stock cards that was less than the physical count. These discrepancies were due to poor logistics skills. Pharmacists were responsible for the inventory management at both hospitals. Accurate information obtained during the stock-taking will not only help in maintaining adequate stock levels of medicines, but also in establishing the basic information needed for ordering (Chandani *et al.*, 2006).

2.3 Ordering practice

A full supply of medicines like ARVs is a goal that must be achieved in any ART programme. The concept of 'full supply' is used to describe the supply status that must exist in the supply chain to ensure regular availability of medicines like ARV drugs at all delivery points, in order to ensure that there is no interruption in patient treatment (Raja & Mohammad, 2005). The ordering process involves assumptions based on monthly consumption, lead time, safety stock, re-order levels, stock on hand and the procurement period (Allers *et al.*, 2007; MSH, 2012). A supply chain assessment for ARVs done in Sierra Leone showed that estimates did not take into account the aforementioned factors, when ordering quantities of ARV drugs needed for adults,

paediatric ART and ARV prophylaxis during pregnancy, post-partum, and for post-exposure prophylaxis – the ordering process did not clearly describe the sources of data, the basis for the assumptions, or how the actual quantities of product were arrived at. However, the study suggested that the forecasting methodology should include assumptions about the number of patients expected to continue treatment during the forecast period; the expected rates of drug substitution within regimens and switches from first- to second-line regimens, and the number of new patients expected to initiate treatment during the forecast period according to scale-up plans and service delivery capacity (Allers *et al.*, 2007).

In the Darbhanga district in India, it was found that demand estimations were not following consumption patterns and re-order and buffer stock levels were not maintained at any of the PHC facilities. The lack of basic reordering skills at all levels; like not knowing how to calculate monthly stock available or how to calculate orders on maximum and minimum quantities was found to be a factor contributing to this mismanagement (Muyingo *et al.*, 2000; Roy *et al.*, 2009). Allocation to regional stores in Malawi was found to ignore the available historical consumption data and was population-based instead (Raja & Durgavich, 2008). A push system is favored rather than a pull one in the Nigerian supply system. Drug allocation to PHC facilities follows that trend, however, this results in overstocking, and facilities are receiving drugs that do not meet their needs (FMOH, 2003).

2.4 Supplier order fill rate

The supply level of a medicine affects its availability greatly. An audit of Malawian PHC facilities showed that 4% of requested quantities of benzyl penicillin were found to have been received, corresponding to the observed stock out at PHC facilities.

Interviews with the nurses in charge of medicines at the PHC facilities revealed that insufficient deliveries from the regional depot constituted the main reason for the observed shortages at the PHC facilities. The median fraction of the ordered drugs received by the health centres was a mere 18% (Lufesi *et al.*, 2007). A full supply is required to maintain confidence in the supply system.

2.5 Efficient store management

The availability of quality medicines and medical supplies at health units contributes significantly to health service utilisation and to the overall public health outcomes. Given the limited resources, especially in developing countries it is important to minimise resource wastage by ensuring that procured medicines and medical supplies are appropriately received, stored and distributed while maintaining their quality. This contributes to the timely access to health services by those in need (Foster, 1991; Kagashe & Massawe, 2012).
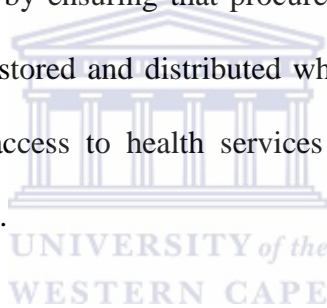
2.5.1 Security of drug storage

Medicines are very expensive and avoiding pilferage through theft or any other spoilage saves costs (Foster, 1991). The storage site should be a secured area that allows protection of medicines against contamination and deterioration, and permits the maintenance of the integrity of the packaging and quality. Foster (1991) indicated that, during storage and distribution, drugs deteriorate due to poor storage conditions like heat, moisture and excessive light. She added that theft and expiration were other ways in which drugs were wasted and that this can be prevented. Protection with a lock and limiting access to authorised staff prevent theft and pilferage (Laeiddee, 2010; WHO, 2004). Theft has been reported in the Eastern Cape and Gauteng provincial depots and hospitals in 2013 (BBC News, 2013; Mgaqelwa, 2013).

2.5.2 Storage Environment

It is vital that the storage of medicines is managed efficiently and effectively to ensure that medicines are kept properly, as the shelf life of medicines depends on their storage conditions (Dawson, 1994). The storage area must be dry and well-ventilated, out of direct sunlight and maintained within acceptable temperature limits. The presence of an air conditioner is necessary to allow the correct temperature. The inventory must be protected from excessive humidity according to product specifications, and the presence of sufficient lighting is necessary. Fire safety equipment must be available and the staff should be trained to use it. Furthermore, the storage must meet physical dimension standards (MSH, 2012). Storage conditions were found to be generally acceptable in PHC facilities in Nigeria where a situation assessment found that 84% and 92% of the facilities met more than 50% of ARV storage requirements in their dispensaries and stores respectively (FMOH, 2003). However, some facilities struggled to meet storage conditions; in Uganda, public hospitals and PHC facilties were found to have low quality of storage. Only one out of nine (11.1%) hospitals, and two out of 60 (3.33%) PHC facilities were rated as having good storage conditions (Muyingo *et al.*, 2000).

2.5.3 Storage arrangement

The inventory must be well labeled and arranged in an accessible manner for counting and general management (Raja & Mohammad, 2005). A good store management system is built in a way that allows the tracking of medicine movement in the store and ensures proper stock rotation so as to allow medicines with the earliest date to be used first. Two techniques are used for this purpose, namely FEFO and FIFO (Clark & Barraclough, 2010; MSH, 2012).

2.5.3.1 Use of FEFO/FIFO

The use of the FEFO (first expiry, first out) system is one of the techniques of inventory management, where the products with the closest date of expiry are the first to be issued, despite the order in which they were received. This helps in preventing loss through expiries. The manufacturer labels products with an expiry date to indicate the date until which the quality and efficacy of the medicine is still guaranteed (WHO, 2003). In the case that there are no expiry dates on products, one should arrange items according to the date of arrival, using the FIFO method (first in, first out). Units bought earliest are used first, and products that arrived first are placed at the front of the shelves. FIFO uses the same process as FEFO, except that the date of reception is used instead of the date of expiry (Clark & Barraclough, 2010; Waters, 2003). The lack of a stock rotation system in Ugandan outlets was identified as a factor contributing to the expiries experienced: only 5.3% of medicines were stocked using neither FIFO nor FEFO, and this contributed largely to their expiration (Nakyanzi *et al.*, 2010).

2.6 Record keeping in inventory management

Records are produced and maintained in the context of professional responsibilities that are necessary to the running of business activities (De Boisdeffre, 2006). Emerson (cited in Yusof and Chell, 1998) defines records as documents that arise from the activities, process and transactions of an organisation and that constitute facts upon which to base future decisions. In inventory management they serve as the basis of the information needed in ordering new stocks of medicines and other supplies, and provide an audit trail. They are crucial in inventory management as they help in ensuring balanced levels of stock and are the basis for decision-making. They also constitute an important source of data used to compile various reports (MSH, 2012; Yusof & Chell, 1998).

Difficulties of complying with record-keeping practices have been identified in many PHC facilities in Lesotho; challenges pinpointed in ART scale up included scarce reliable records, characterised by poor record-keeping practices and late reporting of consumption data. The staff were not sufficiently trained and motivated at every level to use the LMIS (Logistic Management Information System), a tool used in order to prevent stock-outs (Pharasi, 2007). In Jordan, the lack of proper stock-recording practice in some hospitals contributed to information inaccuracy during the quantification of the hospital needs (Talafha, 2006).

Documenting all activities in inventory management is critical. Creating accurate records reduces the likelihood of discrepancies that may occur in many activities that take place in the store room. In this way, the pharmacy staff and the administration have information necessary for decision making. Access to quality data is also necessary for the forecasting and quantification process, the outcome of which is used by the facility and the provincial health information system. A proper information system allows for the identification of bottlenecks in the facility system (Ombaka, 2009). Kagashe and Massawe (2012) identified discrepancies in records during a study carried out in Tanzanian public hospitals: at one hospital (Temeke), records showed that recorded balances were greater than physical count, indicating that the recording of issuing of supplies was very poor. One of the contributing factors was that there were many record books to be filled out, in such a way that a person issuing the medicines does not record directly on the bin card. Some tracer items at the aforementioned hospital had no bin cards (Kagashe & Massawe, 2012).

2.7 Inventory management: experience in South Africa

Skilled human resources are the backbone of any health-care system. Various authors (Kober & Van Damme, 2004; Kovsted, 2005; Steyn *et al.*, 2009; Steyn *et al.*, 2006) state that the shortage of HRH is in all likelihood the greatest challenge facing the implementation and scaling up of ART programmes in developing and low resourced countries. The HRH shortage has affected South Africa's public health sector, where, with respect to pharmaceutical services, it was estimated that an additional 661 pharmacists were needed to implement the comprehensive plan (Mbewu *et al.*, 2003) and approach the difficult task of ensuring uninterrupted supply of ARV. In 2013, the media reported shortages of ARVs in many PHCs; in Gauteng, KwaZulu-Natal and the Eastern Cape patients have missed their ARV doses for several weeks due to supply shortage, which could result in the development of resistance for some of these patients (Mapumulo, 2013; SHARE, 2013). Reasons for these shortages are not explained in literature (Steyn *et al.*, 2009). There is a need to identify and document ARV management issues at the PHC level.

2.8 Summary insight on African countries inventory management assessments results

Various countries carried out in depth assessment of the drug inventory management for the situation analysis of its strengths and weaknesses. In Tanzania, not all facilities provide ART; only 48% reported to manage ARVs. Consumption or distribution patterns were methods used to determine needs. Poor inventory management with regards to storage space, record availability and accuracy, medicines stock out, and a serious lack of pharmaceutical human resources at health facilities was observed (WHO, 2008a). In Namibia, inventory management was characterized by scarce record keeping;

most of the facilities had limited access to computers and limited knowledge of their use. Although, stock cards were used they were not adequately maintained. Staff lacked training and skills in accurate recording procedures. Monitoring and evaluation systems for pharmacies were inadequate, particularly in regions that do not have a regional pharmacist. Poor storage conditions, with lack of stock access security and air conditioning were also observed. There were no uniform methods for quantification of drug needs in the facilities assessed (Aboagye *et al.*, 2003). In Nigeria storage of ARVs was generally satisfactory in all PHCs, as 84% and 92% scored above the 50% required for adequacy of storage in the dispensary and the facility store respectively. Most of the facilities also had special clinic days dedicated to PLWHAs. One episode of stock out of more than three months since the inception of ARV programme was experienced (FMOH, 2003). The detailed findings of a recent South African health facility audit report were unfortunately never put in the public domain (K. Ward, personal communication, October 30, 2013). The true picture of inventory management in this country is not provided in the literature.

Chapter 3. Methodology

This chapter describes the study design, study population, sample and instruments used in data collection. Furthermore, it describes mechanisms to enhance validity and reliability of the study findings, the statistical tests and proposed presentation of qualitative data and the ethical considerations to safeguard study participants.

3.1 Study design

For the purpose of this study both a descriptive, cross-sectional design and a retrospective record review was used. Cross-sectional studies are carried out at one time point or over a short period. They are used to estimate the prevalence of an outcome of interest for a given population, providing a snapshot of the outcome and characteristics associated with it, at a specific point in time. In our study, we used an observational method to check for stock availability, stock discrepancies and store management at one specific point in time. However, the cross-sectional design gives no indication of the sequence of events and does not allow for inferring causality (Levin, 2006).

Descriptive studies collect information without changing the environment. They are only used to describe the existing distribution of variables without regard to causal or other hypotheses. They reveal patterns and connections that might otherwise go unnoticed, and often use qualitative and quantitative research methods (Grimes & Schulz, 2002). Qualitative research methods are defined by Strauss and Corbin (1997:17) as "any type of research that produces findings not arrived at by statistical procedures or other means of quantification". They can refer to research about many aspects of life, such as life experiences, behaviours and organisational functioning. In our study we asked study participants open-ended questions to elaborate on some of the

quantitative data. Quantitative research is "explaining phenomena by collecting numerical data that are analysed using mathematically based methods (in particular statistics)" (Aliaga & Gunderson, 1999:1). This study used retrospective data to allow the researcher to answer questions on completeness of stock records, order fill rates and historical stock outs.

3.2 Study area

The study was carried out in the Cape Metropole in the Western Cape province of South Africa; it is one of six districts in the province and is divided into eight sub-districts.

The Cape Metropole was selected for its close proximity to the University of the Western Cape, where the researcher was based to limit study costs.

The public sector PHC facilities in this district are either under the Western Cape Provincial Government (WCPG) or Cape Town City Health (CTCH). CHCs are governed by the WCPG and were selected for this study since these facilities are accredited to provide ART (Mbewu *et al.*, 2003; Steyn *et al.*, 2009). The average number of ART patients per site is provided in Table 1.

Table 1. Average number of ART patients at each CHC

Sites	Patients number
Site 1	720
Site 2	233
Site 3	597
Site 4	200
Site 5	- *
Site 6	4673
Site 7	875
Site 8	904
Site 9	3753

Site 10	1500
Site 11	1300
Site 12	258
Site 13	1500
Site 14	300
Site 15	1000

*: unavailable data

There are 23 WCPG PHC-accredited facilities in total, but only 15 consented to participate in the study, which made up the study sample. These entities comprise pharmacies with responsible pharmacist managing drug supply management. These CHCs are distributed over eight sub-districts (Figure 2).
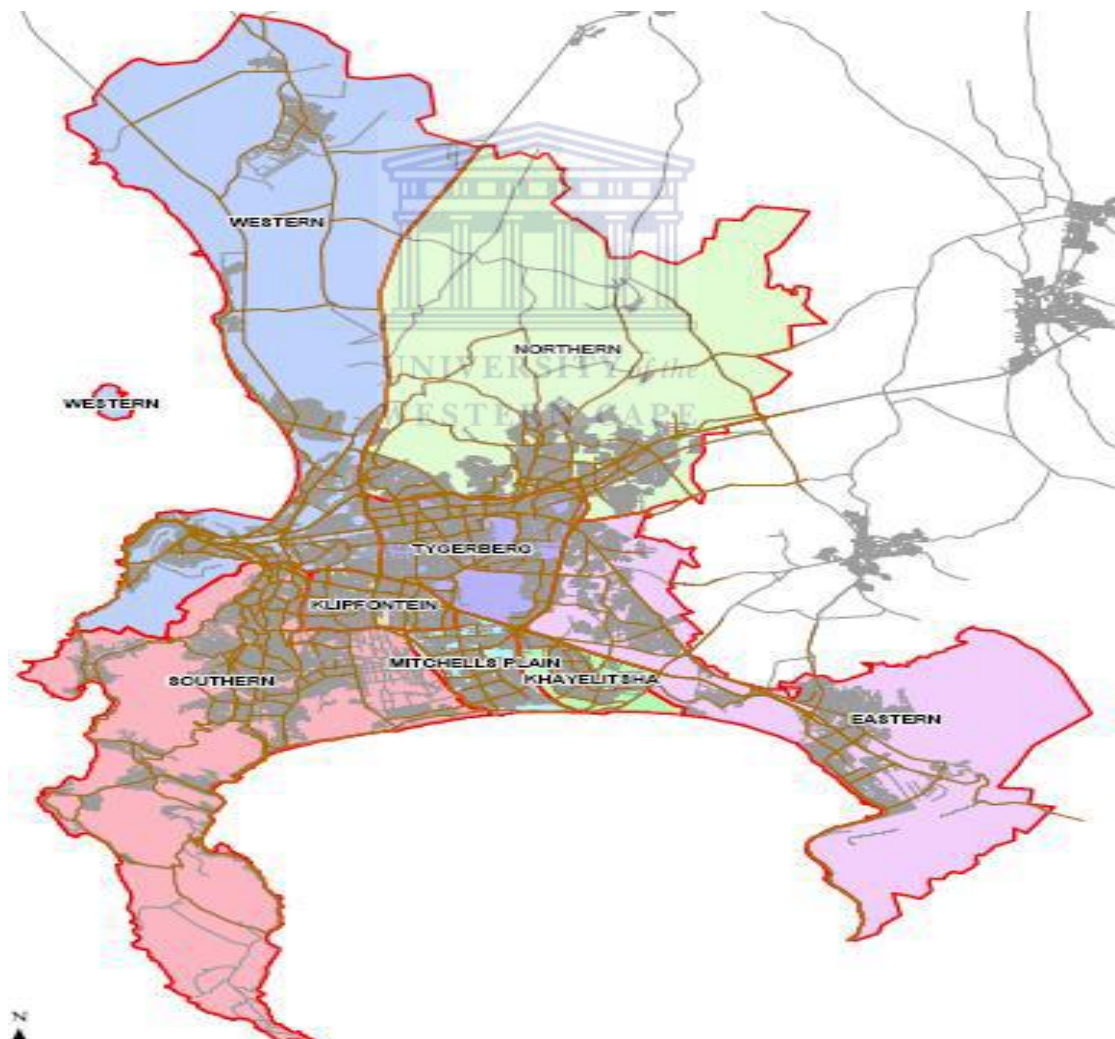
Figure 2. Geographical location of the Cape Metropole sub-districts

(Departement of Health, 2007)

3.3 Study population

Twenty-three CHCs under the Western Cape Provincial Government (WCPG), accredited to provide antiretroviral treatment comprised the population. The personnel in charge of ARV inventory management on the day of the visit was interviewed at each facility to provide qualitative information that supplemented the quantitative data. The personnel in charge of ARV inventory management was either a pharmacist or a Post-Basic Pharmacist's Assistant (PBPA).

3.4 Selection criteria

This section indicates the inclusion and exclusion criteria used to select the facilities to include in the study.

3.4.1 Inclusion criteria

Inclusion criteria included all CHCs located in the Cape Metropole, Western Cape that are accredited to provide ARVs.

3.4.2 Exclusion criteria

There were no exclusion criteria.

3.5 Data collection

3.5.1 Data collection tool

This section explains the data collection tools used in this study. They include:

1. Inventory management questionnaire

2. Managerial questionnaire

3. Observational check list

3.5.1.1 Inventory management questionnaire

This tool, adopted from literature (Shieshia M. *et al.*, 2010) and adapted for this study
aimed to describe various aspect of inventory management such as responsibility in
antiretroviral management, stocktaking time, ordering practice, logistics tools used and
how they are used, and the lead time, information management and open-ended
questions (See Appendix II). Some qualitative data were also used to gain a better
understanding of the statistical findings.

3.5.1.2 Managerial questionnaire

This questionnaire elicited general experiences of personnel in ARV management and
was targeted at pharmacists or PBPAs in charge of inventory management. The
questionnaire described various aspects of inventory management, which included: i)
the type of personnel in charge of the management; ii) years of experience in ARV
management; iii) training received; and iv) the patient head count at each facility. These
independent variables were assessed for association with the outcome variables, viz., the
quality of record keeping and errors found in records (see APPENDIX III).

3.5.1.3 Observational checklist

This checklist contained three sections evaluating the stock status by way of the stock
card (or any other logistics tool used), the order fill rate as well as storage practices (see
Appendix IV, Appendix V, and Appendix VI).

A. Stock status

A tool developed by Management Sciences for Health was adapted for this study and was used to gather quantitative information on ARV inventory management at CHC level (MSH, 1997).

The checklist consists of quantitative information used to determine the effectiveness of ARV drug stock management, with reference to ARV drugs for adult first and second line regimens: current stock recorded, discrepancies between stock recorded and physical stock count, number of days of stock out (we considered information on both manual and electronic logistics tools) (Appendix IV). Information on ordered quantities and received quantities are found on Appendix V (Last order placed and delivery note were analysed). Details of the checklist are tabulated and explained below (Table 2).

Table 2. Variables on the Check list and their details

Record keeping variables	Descriptions
1. Presence of logistics tool	Logistics tool availability was expressed for each facility as a percentage of ARV drugs having a logistics tool out of the total number of ARV drugs used at the facility.
2. Correctness of information filled on the logistics tool	This included drug name, dosage form, and unit of issue. This was also expressed as a percentage of ARV drug logistics tool having all these fields filled in out of the total number of logistics tool available.
3. Updated logistics tool	The updating of logistics tool was determined

	by checking if the current recorded balance on the logistic tool matched the physical stock count. This data was then expressed as a percentage of ARV drugs having updated logistics tool out of the total number of ARV drug logistics tools.
4. Record discrepancies	Imbalances between stock recorded and physical stock count were measured and classified into positive and negative discrepancies. They are positive when recorded quantities on the logistics tool are greater than the physical count and they are expressed as a percentage of positive discrepancy cases out of the total number of ARVs stocked at the CHC. They are negative when the recorded quantities are less than the physical count and they are expressed as a percentage of negative discrepancy cases out the total number of ARVs.
5. Inventory variation of ARVs assessed	The total inventory variation measures the degree to which systems accurately record the real status of drugs in stock. It is calculated by subtracting the total value of the physical count from the total value of the recorded amount of all ARVs assessed, in absolute values, multiplied by 100, and divided by the

	total value of physical count. The average of total inventory variation is obtained by summing the results of each CHC divided by the total number of CHCs.
6. Individual variation of ARVs assessed	The individual variation for a set of ARV drugs assessed characterises the magnitude of discrepancy between records and the real stock levels of each individual ARV drug. It is calculated by subtracting the physical count value of each ARV assessed from its recorded value, multiplied by 100, and dividing the resulted value by the records count. Then, the total result values for all indicator drugs are summed and divided by the number of indicator drugs, to obtain the average for each CHC. The average for all CHCs is obtained by summing the results of each CHC divided by the total number of CHCs.
7. Records accuracy	Three aspects were taken into consideration in the examination of records accuracy: logistics tool existence; filled in with all information on the ARV drug identification; with updated quantities. Frequency of records fulfilling these criteria was calculated.
8. Days of stock out	Number of days that ARVs have been out of stock during the three months preceding the

	data collection was recorded. It was expressed as a percentage that measures the capacity of CHCs to maintain a constant and sustainable availability of ARVs during the period evaluated. The percentage of time ARVs have been out of stock was calculated by dividing the total number of stock-out days during three months for all ARVs held at CHCs, multiplied by 100, and dividing the result by 90 days multiplied by the total number of ARVs assessed. The average for all facilities was calculated by summing the average percentages of each CHC divided by the total number of CHCs.
9. Months of stock	This variable aimed to determine how many months would be covered by the available quantities of ARVs at the facility. This was determined by dividing the available quantities by the average monthly consumption for each ARV held at the CHC. Average months of stock for each ARV for all CHCs were calculated by summing all months obtained divided by the total number of CHCs.

B. Order fill rate

To measure the order fill rate, order and receipt forms were used to calculate the difference between ordered and received quantities. The difference was considered when the facility received less quantity than ordered, and the difference was expressed as a percentage of received quantities out of total ordered quantities (Appendix V).

C. Storage conditions

The checklist was used to evaluate the storage conditions of ARVs in the storage room and dispensing room against standards of Good Pharmacy Practice (GPP) (SAPC, 2010). Thirteen aspects were verified, *inter alia* security of the storage room, protection of medicines, the arrangement of medicines as well as the storage itself. These can be seen in Appendix VI. Details of the checklist are tabulated below (Table 3).

Table 3. Storage conditions according to GPP

Storage condition aspects	Descriptions
1. Security of access	Storage site can be securely locked; access to storage and pharmacy limited to authorised personnel only
2. Conditions of storage site as well as pharmacy	Storeroom was maintained in good condition: clean, all trash removed, sturdy shelves, and organised boxes
3. Temperature conditions	Inventory was protected from harmful temperatures according to product specifications. The room temperature is around 25 degrees Celsius and for the fridge items at 2 to 8 degrees

4. Inventory protection	Inventory is protected from excessive humidity, harmful light sources and corrosive materials according to product specifications.
5. Physical dimensions	Physical dimensions of the storage site meet appropriate standards: at least 30 cm above the floor, no medicines stored on the floor, and there is sufficient space for the stock
6. Inventory availability	Sufficient inventory is present at the site, based on facility's indicated criteria
7. Labelling	Inventory is appropriately labelled on the shelves and in the storeroom.
8. Arrangement	Inventory is arranged in manner that is accessible for counting and general management.
9. Use of FEFO	Inventory is arranged in manner that is accessible for first to expire, first out (FEFO)
10. Package status	Packages and containers are closed.
11. Package cleanliness	Packages are clean in both pharmacy and storeroom
12. Package conditions	Packages and boxes are not crushed
13. Expiry date	Inventory is within expiry date

3.6 Data collection logistics

Data collection was carried out between March and May 2013. Appointments were made telephonically with the facility managers to provide the go-ahead to access the

facility on the data collection day. Subsequent to this, the pharmacy manager was called for an appointment and to provide a brief overview of the study; if telephonic contact was unsuccessful after three attempts, an unannounced visit to the facility for scheduling an appointment was made. On the appointment date, the researcher visited the CHCs to provide more study information, elicit consent and then proceeded to conduct face-to-face interviews and to perform the observational assessments. One of the main challenges encountered in the data collection was the cancellation of the appointments by some pharmacists without notifying the researcher.

3.7 Validity

To ensure data validity, the following strategies were employed:

- A pilot study was carried out at 5 random CHCs to pre-test the tool for its content, and the ambiguity of the questions. Changes were made to get more information i.e.: managerial questions were added to get sight on responsibility in inventory management, questions on how tools were used were added.
- Data entry was done the same day as data collection to avoid errors
- Busy days at the facility were excluded from days of data collection to avoid errors due to unrecorded data as a result of high workload.

3.8 Reliability

To ensure reliability or generalizability of the study, clearly defined measurements and a well-detailed questionnaire were used. Use of adapted data collection tool also improved reliability. Use of only one researcher for data collection and entry improved reproducibility since inter-researcher variability is nullified.

3.9 Ethical considerations

Confidentiality and anonymity were the primary ethical issues taken into consideration. Ethical clearance was obtained from the University of the Western Cape, Research and International Relations Committee, and approval from the Western Cape provincial health research committee was obtained before the study was conducted. No names of respondents or names of health facilities were used on either the questionnaires or in the final results of this study. Only codes were assigned to each facility (Appendix I). Filled data forms were locked in a cupboard at the University where the key was kept by the researcher. Informed consent forms were signed by the participants after they agreed to participate in the study. The research findings will be presented to the academic audience and in the stakeholders meeting. The result will also be made available through publication and electronically available in the university library for the academic community.
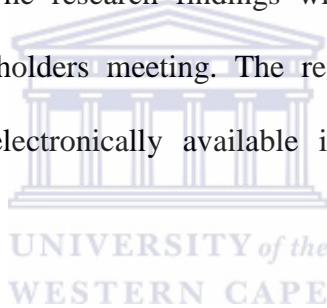
3.10 Data analysis

All data was entered onto an Excel spread sheet and analysed using STATISTICA 11 (StatSoft, 2012).

3.10.1 Hypotheses

3.10.1.1 Null hypotheses

I. There is no association between updated logistics tools and patient head count

II. There is no association between inventory variation and frequency of stock taking

III. There is no association between positive discrepancies and years of experience

IV. There is no association between negative discrepancies and type of personnel

3.10.1.2 Alternative Hypotheses (two-tailed)

I. There is an association between updated logistics tools and patient head count

II. There is an association between inventory variation and frequency of stock taking

III. There is an association between positive discrepancies and years of experience

IV. There is an association between negative discrepancies and type of personnel

3.10.2 Descriptive statistics

Continuous variables were described in terms of medians and percentiles while categorical variables were expressed as frequencies.

3.10.3 Inferential statistics

Normality tests were carried out on the continuous variables, using Kolmogorov-Smirnov test. The threshold level of significance (p value) was fixed at 0.05.

Based on the skewness (Appendix VII) of the outcome measures, non-parametric tests were deemed appropriate. The associations between dependent and independent continuous variables are measured by Spearman's Rank Correlation and group (sets of data grouped by one of the independent variables) means are compared using the Wilcoxon Rank Sum test (for only 2 groups) and the Kruskal-Wallis test (for 3 or more groups).

Table 4. Outcome variables and their hypothesised predictor variables

ID	Outcome variables	Outcome variable measurements	Predictor variable	Predictor variable measurements
1	Updated stock card	Continuous	Head count	Continuous
2	Total inventory variation	Continuous	Frequency of stock taking	Categorical
3	Positive discrepancies	Continuous	Type of personnel managing ARVs	Continuous
4	Negative discrepancies	Continuous	Years of experience	Categorical

In order to investigate the overall change in the updated logistics tools variable, a primary analysis using Spearman's Rank Correlation was carried out with one specific predictor variable, head count. To examine if the frequency of stocktaking affects the inventory variation, Kruskal-Wallis test was used. To investigate whether the positive discrepancies are affected by the type of responsible personnel, Wilcoxon Rank Sum test was used, and to investigate whether the negative discrepancies are affected by the years of experience, Spearman's Rank Correlation was used. For bivariate analysis a p value of less than 0.05 was considered significant.

3.10.4 Qualitative data analysis

Qualitative data were analysed using content analysis. It is a method used to examine artifacts of social communication. Typically, these are written documents or transcriptions of recorded verbal communications. It is broadly defined as "any technique for making inferences by systematically and objectively identifying special characteristics of messages" (Holsti, 1968: 598).

Texts (from interviews) were used to develop a theme that helped to explain certain quantitative data.

Chapter 4. Results

In this chapter the findings of the study are described. The findings are interpreted following the interpretation scheme developed in the methodology section. They give a descriptive summary of CHC inventory and store management practices as well as associated challenges. Finally the bivariate statistical test results used to evaluate associations between dependent and independent continuous variables are presented and interpreted.

4.1 Descriptive analysis

Permission was received to conduct the study at 15 out of the 23 eligible sites. The remaining facilities fell under 2 sub-districts where sub-district managers refused to participate in the study.

4.1.1 Responsibility for ARV drug management and workload

ARV drug management was assigned to pharmacists in 53.3% of CHCs and PBPAs in 46.7% of CHCs. Regarding their years of experience, 40% of the respondents had more than five years of experience with ARV drug management, while 60% had less than or equal to five years of experience in this area. All staff responsible for ARV drug management, in addition to their formal qualification, received at least one training workshop in ARV drug management. ARV drugs are mostly dispensed in combination with other medicines at 14 (93.3%) of the CHCs and one (6.7%) CHC had a dispensing unit reserved for ARVs and other chronic medicines (Table 5). The ARV manager at the facility with separate dispensing units mentioned, "*managing ARVs and chronic medications alone, is easy compared to managing all medicines altogether, we only*

deal with a number of items which makes medicine management easy". On average, each facility received 1 272 patients (SD 1334.6) on ARV treatment monthly.

Table 5. Characteristics of CHCs as it relates to ARV management (N=15)

Features of sample	Number and percentage of CHCs n (%)

Type of personnel
    Pharmacists
    PBPAs
	
	8 (53.30)
	7 (46.70)

Years of experience
    ≤5years
    >5years
	
	9 (60)
	6 (40)

Dispensing integration
    ARVs alone
    ARVs and other medicines
	
	1 (6.7)
	14 (93.3)

4.1.2 Inventory control

The stocktaking was done once a month in 66.7% of cases. In 26.7% of cases it was done once every six months, and in 6.7% of cases it was done every week. Stock taking involved all medicines, including ARVs. According to staff responsible for ARV management, the methods used to determine the needed quantities include: use of consumption patterns, the maximum-minimum concept and quantities automatically generated by the software based on consumption patterns. The first and second methods are used equally by CHCs (40 %), and automation was used at 20% of the CHCs (Table 6).

Table 6. Characteristics of CHCs related to the inventory control (N=15)

Features of sample	Number and percentage of CHCs n (%)
Frequency of stock taking	
Once a week	1 (6.7)
Once a month	10 (66.7)
Twice a year	4 (26.7)
Stock needs assessment method	
Consumption patterns	6 (40)
Maximum-minimum	6 (40)
Electronically generated	3 (20)

4.1.3 Logistics tools use

The logistics system used by CHCs includes manual forms and electronic software. The manual logistics tools are stock cards, while the electronic software is JAC. 69.3% of CHCs currently only use stock cards, while 33.3% are in the process of initiating an electronic system (Table 7). An ARV manager said "s*tock cards are rarely used because we have no store room, the stock in use is kept on shelves and now that we are starting to use JAC and there is no need even to keep stock cards"*. About the recent introduction of JAC, one manager explained,*"I am not familiar with the new system JAC, I am not sure how I can track dispensed quantities, last ordered quantities or monthly consumption. The system has according to me, too many unnecessary steps in dispensing medicines"*. It was also explained, *"for different unit packs for the same ARV, JAC does not show on which pack you took doses. It is confusing"*.

One CHC was using manual and electronic systems (6.7%) as mentioned by one participant *"we use stock cards concomitantly with the JAC just to double-check record,… it helps us to keep records up to date.* 13.3% of the CHCs used none of the aforementioned logistics (Table 7). At one facility using none of the logistics tools, it was explained that *"the fact that we have no storage room, all ARV drugs are stored on*

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shelves, we do not need stock cards". Another said: "*we are in transition from manual to electronic system; we are no longer using stock cards*".

Stock cards or any other logistics tool for ARVs were present at 86.7% of all CHCs (Table 7). A total of 76.9% of the CHCs were compliant with the logistics tools of all adult ARV drugs stocked. The average number of adult ARV drugs with logistics tools available in all CHCs was 82.7% (Table 8). The completeness of basic information on the identification of the medicine (drug name and dosage form) was 100% in CHCs using any type of logistics tool. However, only 84.6% of the CHCs filled in the information regarding the unit of issue (Table 7). According to one participant, "*different pack sizes are received so we do not mention unit of issue to keep it easy*". Facilities using JAC had all information completed. The average record-keeping accuracy was 21.9% (Table 8).

Regarding the practice of updating stock information, on average 32.9% of the logistics tools were up to date in all CHCs (Table 8). One responsible personnel explained *"we update stock card generally once a month, although because medicines are all kept in the pharmacy and not the store room we do not really care much on updating stock cards. With the store room it is easy to maintain stock card updated because stock cards are updated every time an item is taken from the store room...now that there is an electronic system coming, it will help us to keep up to date records easily"*. Another explained *"we update the quantities on JAC, when a quick check is done and the system is displaying fewer quantities than those on the shelves"*.

No facility had all logistics tools updated on the day of the visit (Table 7). It was explained that "*because of many patients we receive, we do not have enough time to*

update stock cards". Another staff explained *"stock cards are not often updated, as ARVs are kept on the shelves there is no need to update stock cards". "We order every two weeks and every time it is needed, it makes difficult to get time to make entries and to update stock cards"* said another responsible personnel for ARV management. Some ARVs were stored and had no associated records.

Table 7. Logistics tools use

Features of sample	Number and percentage of CHCs n (%)
Type of logistics system (N=15)	
Manual	9 (69.3)
Electronic	5 (33.3)
Both system	1(6.7)
How the logistics tools are used	
Presence of any logistics tool (N=15)	13 (86.7)
No logistics tool (N=15)	2 (13.3)
Compliance on logistics tool (for every ARV stored N= 13)	10 (76.9)
All logistics updated (N=13)	0 (0.0)
Information completed for identification of ARV on logistics tool (N=15)	
Generic name	
Strength	15 (100)
Unit of issue	15 (100)
	11(84.6)
Stock out information	
Logistics tools with stock out (N=13)	13 (6.1)
Stock out on the day of the visit (N=13)	0 (0.0)

Table 8. Calculated averages related to logistics tool use

Average number of ARVs with logistics tools (percentage)	82.7
Stock information updated (percentage)	32.9
Record keeping accuracy (percentage)	21.9

4.1.4 Discrepancies found in records

The percentage of total inventory variation between stock records and physical counts for the ARV drugs assessed was 51.7%, while the percentage of individual variation for ARV drugs was calculated and found to be 36.8%. The frequency of negative discrepancies was on average 25.2%, while the frequency of positive discrepancies was 36.6% (Table 9). One of the participants gave the following explanation: *"because of frequent ordering, you may find that receipts are not yet entered onto stock cards, we may do it later when we have time"*.

Table 9. Logistics tool updates and discrepancies

Logistics tools	N	Average percentage (%) of logistics tools per facility for ARVs	Median	Percentiles (25)	Percentiles (75)
Positive Discrepancies	12	36.6	32.1	27.3	42.9
Negative discrepancies	12	25.2	14.3	8.5	41.3
Individual variation	12	36.8	21.4	12	72.4
Inventory variation	12	51.7	31.3	14.6	258.6

4.1.5 Stock out and months of stock

Few facilities recorded information on stock outs; only 6.1% of observed logistics tools contained any information on stock outs. However it was explained that *"in any case of shortage we borrow ARVs from the nearest facilities"*. There was no stock out on the day of the visit (Table 7). The paucity of data recorded on the logistics tools precluded any estimation of months of stock held at the CHCs. Furthermore, due to incomplete month-end reports required to calculate months of stock of ARVs held at CHCs, it was not possible to estimate the months of stock held at the CHCs.

4.1.6 Order fill rate

Respondents reported that all quantities of stock ordered are usually received, however upon observation, only 60% of the CHCs had a full supply of the last order placed. Still, the average order fill rate was relatively high at 91.9%. The duration for ordered ARV drugs to reach the facility was reported to be three days for 66.7% of facilities. Seven days were reported by 13.3% of the respondents, two days by 13.3% and one day by 6.7% of the respondents (Table 10).

Table 10. CHC ARV supply status

Features of sample	Number and percentage of CHCs n (%)
Supply rate Full supply received Full supply not received	9 (60) 6 (40)
Lead time Three days Seven days Two days One day	10 (66.7) 2 (13.3) 2 (13.3) 1 (6.7)

4.1.7 Store management

The percentage of CHCs adhering to storage conditions as established in the GPP manual are shown in Table 11. None of the facilities adhered to the principle of storing medicines according to FEFO. One pharmacy staff member explained that ARVs are fast moving items, and as such, are consumed before expiry regardless of the manner in which they are stored. 20% of CHCs did not meet the appropriate standards for the physical dimensions of the pharmacy storage site. Appropriate labelling of the shelves in the dispensary and in the storeroom was only done at 66.7% of the CHCs. One participant commented: *"the pharmacy is in a small space that makes medicine management in general a difficult task; labelling and arrangement in general cannot be done correctly in such a small space"*. Another said *"labelling is difficult because we do*

receive different brands with different pack sizes, when a delivery arrives with different brand and quantities, it becomes necessary to change the label and we do not have enough time for that". However, the arrangement of stock in a manner accessible for counting and general management was only observed at 46.7% of CHCs. All remaining GPP requirements for storage conditions were adhered to by all facilities.

Table 11. CHC adherence to Good Pharmacy Practice Standards for the storage of medicine (N= 15)

Description	Compliant CHCs %(n)
Storage room is securely locked, and access limited to authorised personnel	100 (15)
Storeroom is maintained in good condition: clean, all trash removed, sturdy shelves, and organised boxes	100 (15)
Inventory is protected from harmful temperatures according to product specifications. The room temperature is around 25 degrees Celsius and for the fridge items at 2 to 8 degrees	100 (15)
Inventory is protected from excessive humidity, harmful light sources and corrosive materials according to product specifications	100 (15)
Physical dimensions of the storage site meet appropriate standards: at least 30 cm above the floor, no medicines stored on the floor, and there is sufficient space for the stock	80 (12)
Sufficient inventory is present at the site, based on facility's indicated criteria	100 (15)
Inventory is appropriately labeled on the shelves and in the storeroom	66.7 (10)
Inventory is arranged in manner that is accessible for counting and general management	46.7 (7)
Inventory is arranged in manner that is accessible for first to expire, first out (FEFO)	0 (0)
Packages and containers are closed	100 (15)

Packages are clean in both pharmacy and storeroom	100 (15)
Packages and boxes are not crushed	100 (15)
Inventory is within expiry date	100 (15)

4.2 Inferential analysis

4.2.1 Normality test

Normality tests carried out on continuous variables showed that updated stock cards, positive discrepancies and the years of experience variables were normally distributed (Table 12).

Table 12. Normality test results

	Kolmogorov-Smirnov[a]		
	Statistic	df	P value
Stock card use	0.441	12	0.000
Updated stock cards	0.225	12	0.094
Positive discrepancies	0.208	12	0.158
Negative discrepancies	0.256	12	0.029
Head count	0.263	12	0.021
Years of experience	0.179	12	0.200[*]
Inventory variation	0.354	12	0.000
Individual variation	0.279	12	0.010

*. This is a lower bound of the true significance.
a. Lilliefors Significance Correction

4.2.2 Predictors of poor stock management

4.2.2.1 Bivariate analysis

4.2.2.1.1 Primary analysis

The Spearman correlation between updated logistics tools and head count is 0.1931 which is not significantly different from zero (p=0.5694). This result supports the null hypotheses that stock updated is not affected by head count. A scatter plot for this pair is shown below in Figure 3. Likewise the correlation between negative discrepancies and experience is not significantly different from zero (r=0.4003, p =0.1972) and the null hypotheses of non-association between negative discrepancies and years of experience is accepted (Figure 4).

Figure 3. Scatter plot for the association between updated stock card and head count
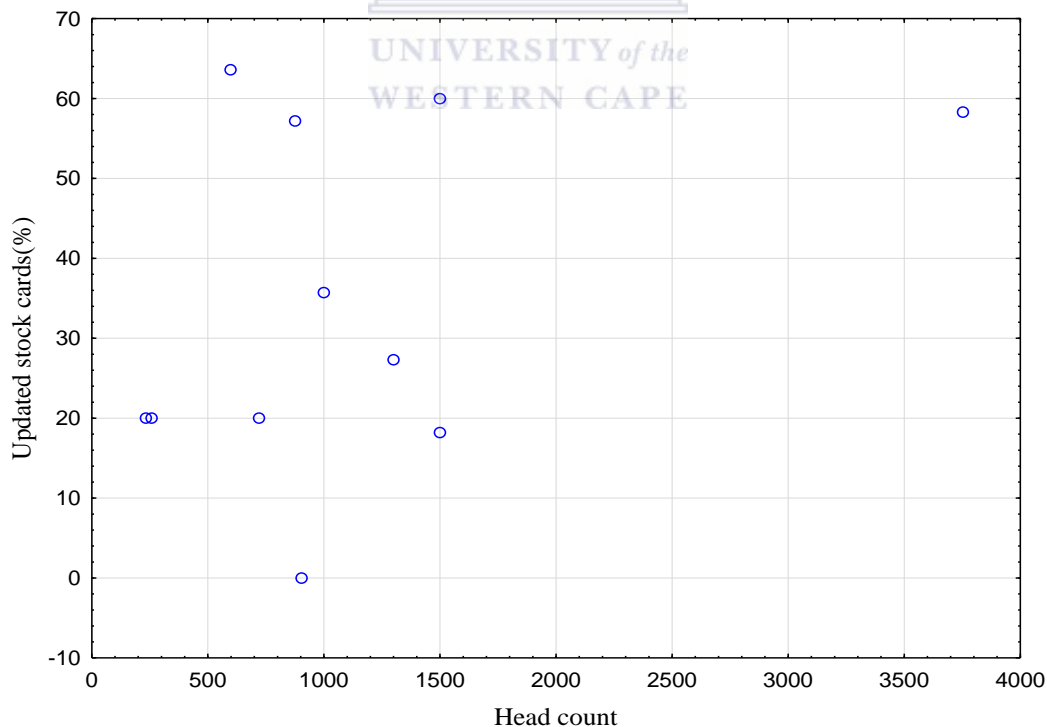
Figure 4. Scatter plot for the association between negative discrepancies and years of experience
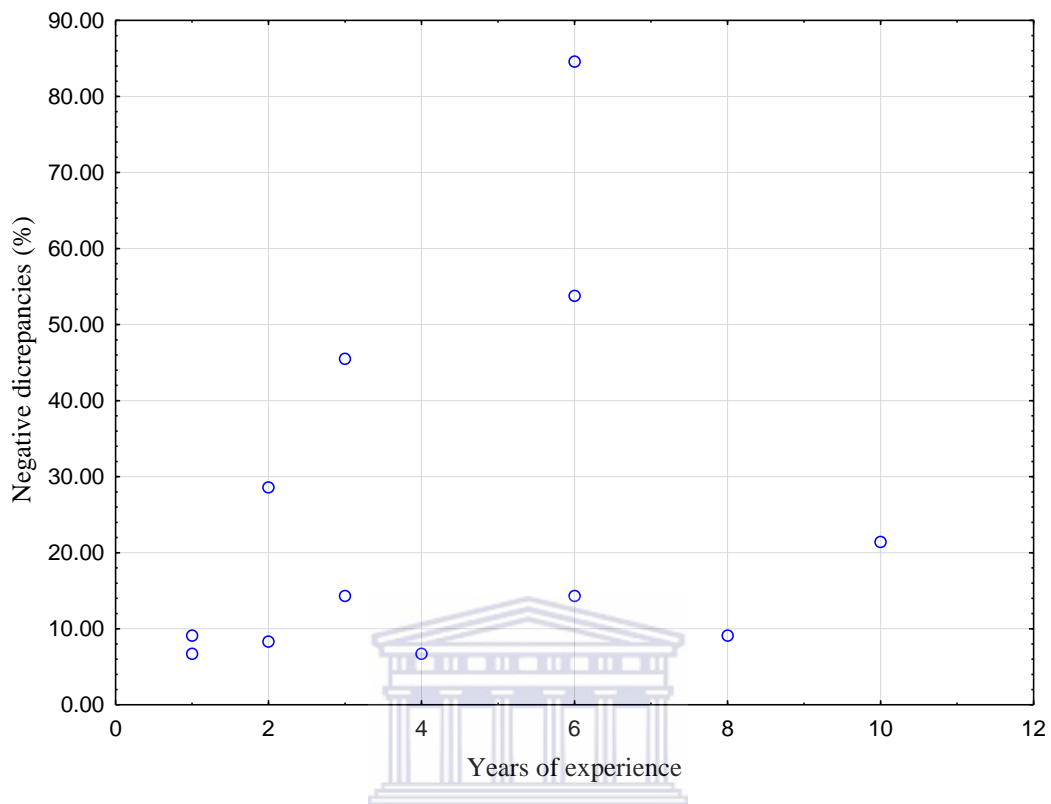
Based on the Kruskal-Wallis test, there is a significant difference among the stock taking frequencies groups for inventory variation (χ=6.8045, p=0.0091). The result shows that there is enough evidence to reject the null hypothesis; there is an association between inventory variation and the stock taking frequencies (Figure 5).

Figure 5. Box plot for the association between inventory variation and stock taking frequency
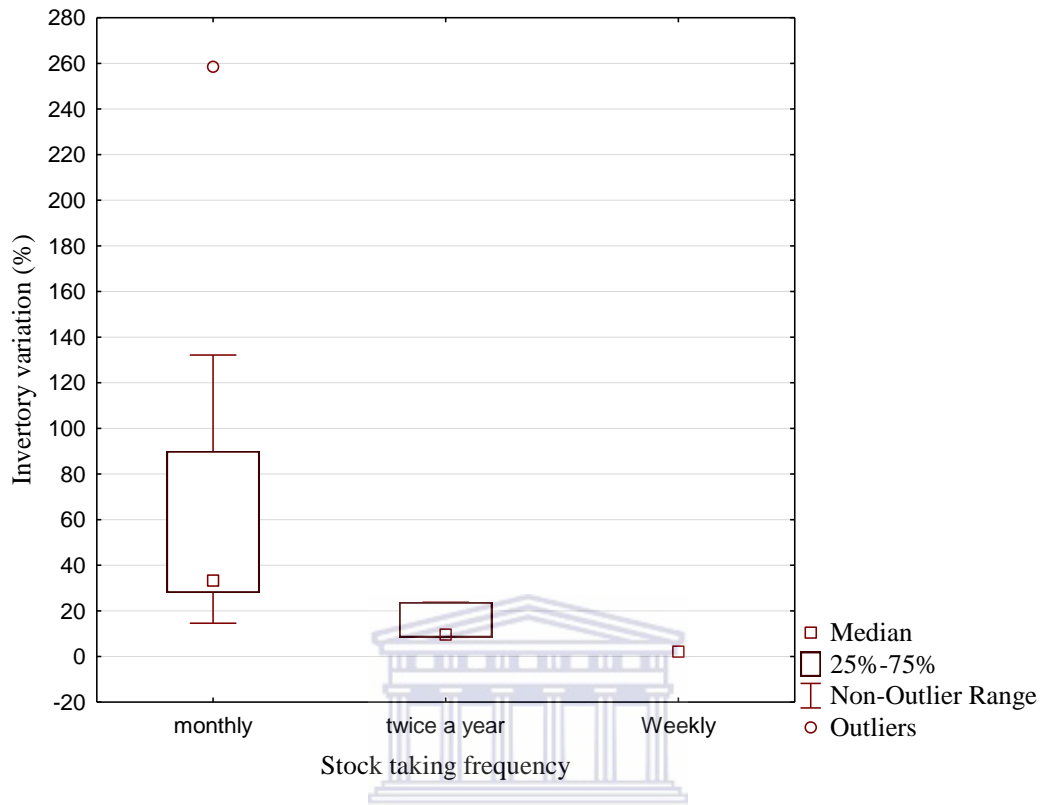
Wilcoxon Scores (Rank Sums) for positive discrepancies showed that there is not a significant difference between medians for positive discrepancies (S= 30.5000, p = 0.7790). In other words the null hypothesis is accepted; there is no association between positive discrepancies and type of personnel involved in ARV management (Figure 6).

Figure 6. Box plot for the association of positive discrepancies and type of personnel
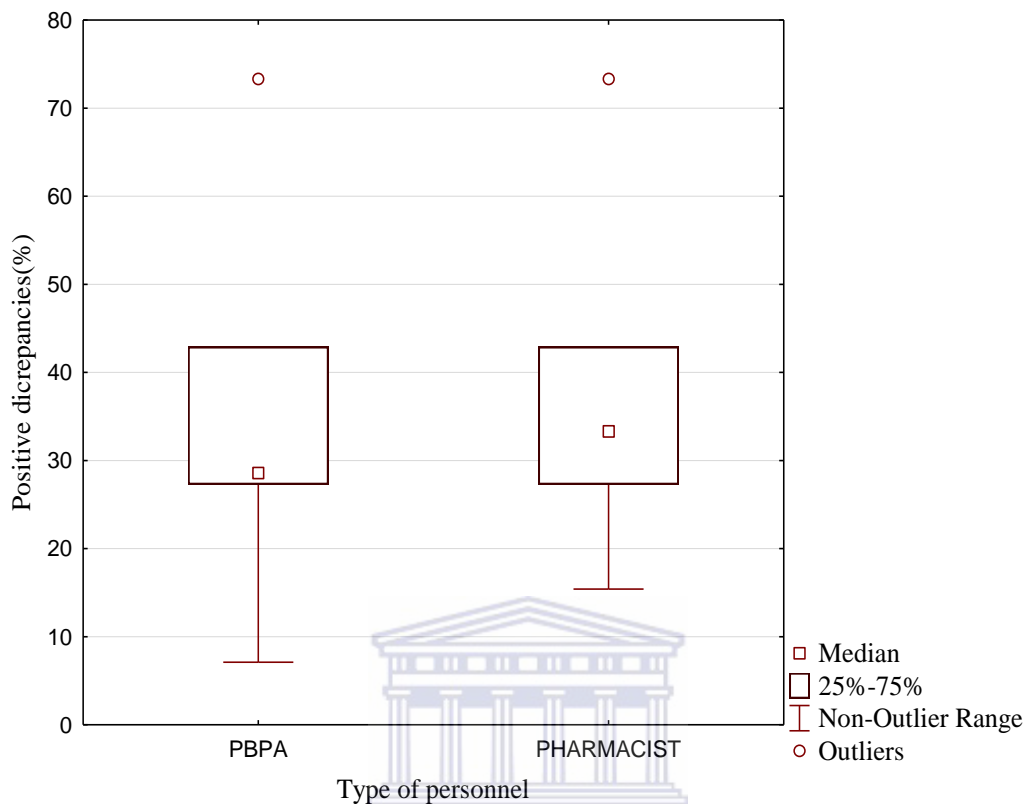
4.2.1.1.2 Secondary analyses

Other individual relationships were investigated in order to look for correlations. The Spearman correlation coefficients between head count and other outcome variables namely; inventory variation, positive discrepancies and negative discrepancies are not significantly different from zero (Table 13). There are no association between head count and the aforementioned outcome variables. Likewise the correlation coefficients between years of experience and updated stock cards, inventory variation and positive discrepancies are not significantly different from zero see Table 13, the null hypotheses of non-association between years of experience and aforementioned outcome variables is accepted.

Table 13. Spearman Correlation Coefficients for head count and years of experience as independent variables

	Updated stock card	Inventory variation	Positive discrepancies	Negative discrepancies
Head count	r=0.19311* p=0.5694	r=-0.63781 p=0.0347	r=-0.30734 p=0.3579	r=0.26316 p=0.4343
Years of experience	r =-0.24956 p= 0.4341	r =-0.59828 p=0.0399	r =-0.11744 p=0.7162	r =0.4003* p=0.1972

* Indicates that this was considered in the primary analyses

Based on the Kruskal-Wallis test, relationships between stock taking frequencies and remaining outcome variables namely, updated stock cards, positive discrepancies and negative discrepancies, are not significant (p ≥0.44 in each case). The results show that the null hypotheses should be accepted, i.e. there are no associations between the stock taking frequencies and remaining outcome variables. Equally, for responsible personnel type, none of the three remaining relationships are significant (p ≥0.41 in each case). The null hypotheses are, therefore, accepted (Table 14).

Table 14. Relationship between stock taking period, type of personnel and remaining outcome variables

	Updated stock card	Inventory variation	Positive discrepancies	Negative discrepancies
Stock taking frequencies	p=0.4429	p=0.0091*	p=0.5611	p=0.7253
Type of personnel	p= 0.6376	p=0.8763	p=0.7790*	p=0.4066

Chapter 5. Discussion

This chapter attempts to rationalise the findings obtained in this study relative to the local context and literature.

5.1 Responsibility in ARV management

Pharmacists and PBPAs were found to be the key players in ARV drug inventory management in the Cape Metropole, Western Cape. A total of 53.3% of the respondents were pharmacists, and PBPAs represented 46.7%. Where PBPA were assigned the task of managing ARVs, this was under the direct supervision of a pharmacist. Contrary to our findings, a recent country-wide audit of PHC facilities in SA revealed that 40% of CHCs in the country have no pharmacist or PBPA, indicating that pharmacy personnel at this level of care are more readily available in the Western Cape province (NDOH, 2012). This corroborates findings of the SAPC on human resources; at the end of 2010, there were 12, 813 registered pharmacists with the SAPC; with 2075 of these practicing in the Western Cape province compared to 464 in Mpumalanga or 143 practicing in the Northern Cape province. This shows that pharmacists are unevenly distributed across provinces, with the Western Cape considered to be the one of the better resourced provinces with respect to pharmacist availability (SAPC, 2011a). In this audit, the national level of compliance to the core standards for medicine availability was poor (47%) relative to Western Cape levels of compliance (60%) and the paucity of human resources was identified as a contributing factor to the differences in vital measures across the different provinces (NDOH, 2012).

5.2 Record-keeping quality

In inventory management, poor information quality is an indicator of poor stock management. Proper stock recording contributes largely to the accuracy of the information on which future decisions can be based. From the results, poor record keeping was generally observed; the accuracy of records was low. A total of only 21.9% of the records were found to be accurate. Low level of accuracy highlights a weak inventory management; which can be associated with the lack of knowledge of the importance and appreciation of what inventory management is. This results in ad hoc decisions about ordering frequency and quantities, as ordering decisions is based on weak ground information and this has cost implications. Lack of task prioritisation is also associated with this low level observed; as confirmed by some ARV managers who did not consider it important to keep records up to date records.

As alluded to earlier, poor medicine availability was found to be linked to human resource shortages for pharmacy (Matsoso & Fryatt, 2013; NDOH, 2012). However, our study shows that the presence of pharmacists and PBPAs alone does not guarantee proper inventory management and good record-keeping. Other strategies are needed for optimal inventory management.

Continuous monitoring of the quality of health care and service delivery has been identified as an integral part of the health system strengthening strategies under the impending NHI (NDOH, 2012) and as such, an effective set of information systems is required (Matsoso & Fryatt, 2013). Consequently, information management needs to be upgraded to comply with the NHI.

Logistics tools were largely available and used; 86.7% of the CHCs were using at least one logistics tool to manage ARVs. The integration of the new system was challenging for some of the staff managing ARVs. In the transition from manual to electronic logistics systems, there is a need for a phase-out period of stock cards until ARV managers are fully conversant with the new system. In our study, many facilities that migrated to electronic logistics tools and abandoned stock cards entirely were not able to generate the necessary outputs for interpretation (i.e. consumption data for stock monitoring) since they were not yet fully trained. Few facilities were not using any of the tools and, therefore, had no means to follow the stock flow – except through medicine entries that were recorded on delivery notes – and to identify anomalies such as stock leakage (Clark & Barraclough, 2010). In the interim, these facilities should utilize the manual system while waiting for the JAC integration.

 There were no stock outs recorded in any facilities on the day of the visit. Frequent orders may have contributed to the absence of stock outs. The fact that there had been only one visit to each facility could have impacted observed figures.

As far as the practice of updating stock information was concerned, on average 32.9% of the logistics tools were up to date in all the CHCs. No facility had all stock cards updated on the day of the visit. Most facilities did not update the logistics tools used and the reasons cited by the responsible personnel for ARV management included high workload and frequent ordering cycle. Keeping up-to-date records is found to be a daunting task; fewer than 40% of health facilities in Kenya were found to have stock card records that tallied with physical counts on the day of the assessment when assessed on malaria medicines (Shieshia M. *et al.*, 2010).

Keeping up to date records of all activities provides the basis for decision-making, in this case ordering and general stock management. Experience in Kenyan PHC facilities has shown that proper drug inventory, monitoring and control can identify bottlenecks in the facility system beyond the pharmacy (Ombaka, 2009).

5.3 Discrepancies in records

From the results it was clear that 33% of the recorded balances were greater than the physical counts, meaning that the recording of supplies was very poor. One of the contributing factors was that some facilities had a high patient attendance, as pointed out by one responsible personnel for ARV management, but inferential statistics have not proven high workload to be a predictor of positive discrepancies. Recorded balances that were less than the physical counts were 30.5%; this means that receipts were not correctly recorded. Among the factors contributing to this, as explained by the staff, are frequent ordering cycle and the high work load. Responsible personnel for ARV management did not have enough time to make the entries directly onto stock cards.

The results showed that the average percentage of total variation between stock records and physical counts for the ARV drugs assessed was 51.6%, which is relatively high compared to the international variation of 21% cited in literature (Talafha, 2006). The real status of ARVs in stock is not accurately recorded and this indicates that the practice of updating records is scarce. The average percentage of individual variation for the ARV drugs was 36.8%, slightly above the international figure of 31.3% cited in literature (Talafha, 2006). The reflection of the real status of ARVs in stock is inaccurate. Inaccurate record-keeping systems are of limited use for monitoring current inventory, estimating future needs and controlling the usage of pharmaceuticals.

When a delivery arrives at the health centre, the received quantities and the date of the delivery should be entered on the respective logistic tools to update the stock status. The same procedure should be followed when drugs are issued from the CHC store room to the dispensary, with the date of issue and quantity issued being recorded on the available logistics tool (Lufesi *et al.*, 2007). Timely entries on the logistics tools that are used are essential for the availability of good and updated records, which will increase the stock management efficiency and ease data collection for reporting and monitoring purposes.

Discrepancies can encourage thefts as losses will not be noticed. ARV drug thefts have been reported in some provinces in South Africa – in the Eastern Cape and Gauteng in 2013, where ARVs have been stolen from state depots by officials (Mgaqelwa, 2013). Accurate records can help to prevent this, as obvious discrepancies can raise suspicion and inspection can reveal their causes. Concomitant use of electronic software and manual stock cards can prevent stock imbalances, by updating both sources of data and cross checking their content.

5.4 Stock availability

Availability of ARVs is critical in ART programme success. While no stock outs were observed at CHCs on the day of the visit, there was no information on historical stock outs due to a lack of data. Findings show that different methods were used to determine the quantities to order. This was a challenging issue for most of the facilities assessed in Africa, where some PHCs use no formal method for inventory control; maximum-minimum and consumption methods were found to be used by between 10 and 30% of the PHCs in reported studies. A study done on medicine stock outs and inventory

management in Tanzanian hospitals showed that 16.7% mentioned maximum-minimum as the method they used to determine needed quantities while most participants (65%) were unable to mention the method they were using to determine the quantities needed. Of the remaining 35%, about 22% of the respondents mentioned the consumption method, while 27% said they quantified the amounts of medicines depending on the funds available (Kagashe & Massawe, 2012). Muyingo *et al*. (2000) found in their study carried out in Uganda, that PHC facility staffs did not know any inventory control method resulting in holding unnecessary stock. The maximum-minimum inventory control method is recommended by Deliver. Experience from the field has proven its effectiveness in the supply management of ARVs and HIV tests (Deliver, 2006). Methods used for inventory control were found to be well known by the respondents in this study, as proven by the responses obtained. For example, when a few respondents were asked to show their calculations for the maximum-minimum values of their stock, they could do so correctly.

5.5 Store maintenance

Storage conditions for medicines are critical and it is, therefore, important to maintain the temperature at the required levels (Foster, 1991; SAPC, 2010). All the CHCs with a store room had well-functioning air conditioners, and refrigerators for storing heat-sensitive ARVs. CHCs did not, however, respect the FIFO/FEFO principle; contributing factors were that all the ARVs are fast-moving items as explained by the personnel managing ARVs. The fact that delivered ARVs had a long shelf life (two years at most) may also have contributed to this.

The findings showed that 20% of the CHCs did not meet the standards for appropriate physical dimensions for the pharmacy; rooms were too small to hold the available inventory. This finding corroborates the PHC facility audit report which found the state of the general physical infrastructure to be inadequate with a need for expansion of existing general infrastructure (NDOH, 2012). In a study carried out by Muyingo *et al*. (2000) in Uganda, it was found that major challenges in store management at the PHC facilities, were a lack of adequate space, shelves, ventilation and sanitation. At one PHC there was no separate space for the storage of medicines, and at some centres medicines were found scattered around the table in the storeroom.

The inventory must be well labeled and arranged in a manner accessible for counting and general management (Raja & Mohammad, 2005). Labeling of the shelves in the dispensary and in the store room was found to be appropriate in 66.7% of the CHCs. Remaining CHCs were storing inventory inappropriately, with missing or misplaced labels. At one CHC, a respondent explained that ARVs delivered are from different suppliers hence contained in boxes with different pack sizes and brand, which makes labeling a daunting task as it becomes necessary to change labels every time there is a new delivery. Our study suggests the creation of different labels (with different pack size indication and brand) for the same ARV and to store ARVs accordingly. Small space was also stated by managing personnel as a cause of lack of adequate labeling.

5.6 Resupply level

The supply level of a medicine correlates closely to its availability. Shortages have been found to be linked to a low supply rate. Lufesi *et al*. (2007) found that a shortage of benzyl penicillin in Malawi PHCs was caused by a low supply level from the state

depot. An excellent order fill rate was found in this study – 91.9% of ordered items had been received in time. The lead time that indicates the time between the initiation of an order and receipt of the delivery at the facility (MSH, 2012) was found to be 3 days, which coincides with the mode reported by the responsible personnel for ARV management. This short lead time contributes to the timely delivery and availability of ARVs. The median delay between ordering and supply was 37 days in Malawian health centres, and may have contributed to the shortages of drugs at these facilities (Lufesi *et al.*, 2007).

5.7 Predictors of poor stock management

Significant differences among the stock taking times for inventory variation was observed. Inventory variation was significantly associated to the frequency of stock taking. The inventory variation was higher at the CHC carrying out stocktaking twice a year compared to the CHC carrying out a weekly stocktaking. It means that more frequent stocktaking minimises inventory variation. Other suggested predictors of poor stock management did not show significant statistical difference.

5.8 Study limitations

Eight CHCs were not accessed due to lack of access approval by the Western Cape province health research committee. This resulted in a small sample size with the following limitations: i) we cannot generalise our findings to all Cape Metropole CHCs because CHCs that did not participate in this study could have produced different results; ii) in some of the bivariate analyses conducted it may be that this small sample size did not provide sufficient power to detect statistically significant differences that were being investigated, and iii) no multivariate analysis was possible.

During the course of the study some facilities received JAC (electronic software) and this could have affected our results, as the logistics tool used at the time we designed this study was stock cards. JAC relies on a different approach in ARV management. Nevertheless, this intervention was relatively new and stock cards should have been fairly up-to-date until JAC was fully operational.

Appointment cancellation at the last minute by the contact person resulting in rescheduling, affected the period for the data collection (March - May) and this could have coincided with the introduction of JAC at some CHCs. The existence of only one CHC with an ARV dispensing unit (dedicated to ARVs only), limited our investigation into relationship between workload as hypothetical predictors for poor stock management. Due to poor record-keeping practice, data on stock outs could not be analysed.
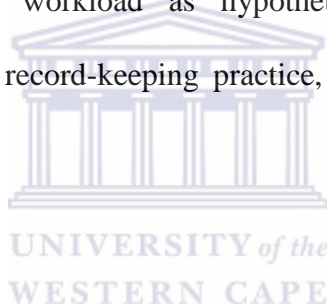
Chapter 6. Conclusion

The object of this closing chapter is to reconcile the findings of this study with the research questions. In addition, a list of recommendations for follow-up studies is provided.

6.1 Summary

The findings of this study reveal that the inventory management of ARV drugs was poor in terms of general quality of record keeping, and the store maintenance.

Poor stock management, specifically in updating and ensuring accuracy in record keeping, was found to be a major issue in ARV drug inventory management at the CHCs. Incorrect stock status, characterised by a lack of timely entries and issues on the logistics tools, was the key culprit in the lack of correspondence between the records and a physical stock count. Lack of information on stock out and monthly usage was observed in some CHCs, making it impossible to determine the extent to which the stock outs had been experienced and to estimate months of stock held at each facility. As far as storage conditions were concerned, labeling was found to be a daunting task as different labels were necessary for the same ARV drug.

The order fill rate was at 91.9% which is an excellent finding contributing to timely availability of ARV drugs. Even though good availability of ARV drugs was observed in this study drugs despite poor record keeping, it is because of good supply rate and short lead time, the real impact of poor record keeping could be in terms of costs to the State for multiple ordering and associated delivery costs. Future study could investigate into this matter.

6.2 Recommendations

The following recommendations are made in order to improve ARV drug inventory management:

- Making timely entries and recording issues on logistics tools will contribute to an up-to-date inventory and management information system. After manual inventory verification, found quantities should be compared to the stock quantities in the inventory records, and the records should be updated to produce a perfect match with actual stock quantities. The need to create logistics tools for each ARV drug in the store should be emphasised.

- The use of manual records may have contributed largely to the discrepancies found. Human error can be reduced and data processing improved by using computer technologies, e.g. JAC, which should be introduced at all CHCs.

- Manual records should still be used where the electronic system is not fully operational

- There is a need of frequent monitoring of stock status in order to keep it at the required levels, by carring out frequent stock taking to reduce discrepancies.

- Improvements in storage conditions should be promoted with regard to labeling, by creating (if space is available), a label for every brand/pack quantities and to store ARV drugs accordingly. Physical conditions in the store should be improved at the facilities concerned by the expansion of store room as it is included in PHC re-engineering plan.

- Internal organization should be improved to allow enough time for stock monitoring.

- Regular supervision by the district pharmacist is needed, regular monitoring and evaluation of all cadres in order to identify training and other needs should be consolidated.

- Association between predictors and outcome variables, should be explored in a longitudinal study

- A study on general cost and delivery costs associated with poor record keeping should be carried out.

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Appendix I

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CONSENT FORM TO PARTICIPATE IN RESEARCH

Examining the inventory management of antiretroviral drugs at community health centres in Cape Metropole, Western Cape

Purpose and Background

A master's students in pharmacy Mrs. Alice Mahoro and Dr. Kim Ward (Ph.D.) from the University of the Western Cape, School of Pharmacy, are conducting a research study to characterize the inventory management practice of antiretroviral drugs at community health centres in Cape Metropole, Western Cape.

The drug supply management is an important key to ensure antiretroviral drugs availability. Managing their flow is vital to secure an uninterrupted supply; inventory control is vital to indicate how the stock is managed, the stock keeping, distribution and resupply. Some problems with the supply have been observed in some health facilities regarding the inventory management. Inventory management practices have not been documented in the Western Cape.

You have been selected as a key informant for this study because of your managerial position.

Procedures

If you agree to participate in study,

- One researcher will conduct an interview with you for approximately 10 minutes. Your responses will be recorded with a voice recorder which will later be transcribed and analyzed.
- The researcher will conduct a physical count of antiretroviral drugs.

Risks/discomforts

Your privacy will be respected and your records will be handled confidentially. No names of respondents or name of health facility will be appearing either on questionnaires or in final results or in any publication or presentation of the findings of this study.

Only researchers involved in this study will have access to the voice recordings and transcripts. These will be stored in a confidential way: all consent forms and completed check lists will be retained in locked file cabinets in a locked room of the principal investigator. Data will be entered into a research database and will be accessed only using a password known by the investigator.

Consent

All participation in this research is voluntary. You are free to decline any participation in this study, or if you so choose, you may withdraw from it at any moment without any penalty to you or the loss of any benefits to which you are entitled. If you agree to participate, you should sign below.

_____   _____

Name of study participant   Signature of study participant

_____   _____

Date   Telephone number

_____   _____

Date   Signature of student researcher

Appendix II

Site ID:			

Date of Visit:

Inventory management questionnaire

No	Questions	Code	
1.	Who is responsible for inventory management of antiretroviral drugs?	Nurse...............................1	
		Clinical Officer...............................2	
		Pharmacist Assistant (basic) …........3	
		Pharmacist Assistant (post-basic)…...............................4	
		Pharmacist 5	
		Medical Assistant............................6	
		Other (Specify)...…...…...............7	
2.	How often is a physical inventory carried out?	Once per month?.....................1	
		Once every six months?............2	
		Once a year?.............................3	
		Other……………....………....4	
3.	Do you use and fill out the following logistics tools to manage antiretroviral drugs?		
	A. stock cards	Yes 1	
		No 0	
	B. daily register	Yes 1	
		No 0	
	C. Monthly consumption record	Yes 1	
		No 0	
	D. other	Yes 1	
		No 0	
4.	Is the stock card filled with following information?	Generic name	Yes 1
			No 0
		dosage form	Yes 1
			No 0
		unity of issue	Yes 1
			No 0
5.	How do you determine the quantities you need to order?	Formula (specify)…..........1	
		Don't know 2	
		Other means....................3	
6.	On average, what is the lag time between ordering and receiving ARVs drugs?	……………..Days	
		………………..Weeks	
7.	What are the most frequent problems faced during the inventory management?	……………………….	
8.	How are stock cards used? And what issues are associated with their use?	…………………………	

Appendix III

Managerial questions

Training: personnel in charge of ARV trained on ARV management (yes/no)	
Professional in charge (pharmacist or post-basic pharmacist assistant)	
Years of experience in antiretroviral management	
Workload: ARVs dispensed alone or combined with other medicines (yes/no)	
Head count: Patients' attendance per month	

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Appendix IV

Product name	Unit of count	Logistics tool available? Y = 1 N = 0	Logistics tool updated? Y = 1 N = 0	Last stock balance recorded on logistics tools (without correcting errors)	Physical quantity (based on actual count)	Difference between recorded and physical values	Stock out within the last 3 months Y = 1 N = 0	Total days of stock out within 3 months	Stock out today? Y = 1 N = 0	Monthly usage January 2013	Monthly usage February 2013	Monthly usage March 2013

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Appendix V

Difference between quantity ordered and quantity received

Product name	Quantity ordered (last order period)	Date order were placed	Quantity received (last order period)	Date Order received

Appendix VI

Store management

0 =no, 1 = insufficient, 2 = adequate

No.	Security and Access	0	1	2	Specific comments
01.	Storage site can be securely locked. *(Check both store room and pharmacy)*				
02.	Access to storage and pharmacy is limited to authorized personnel only *(are there any locks on the doors, who has keys, who is allowed in and who authorises entry)*				
General comments:					

No.	Conditions of Storage Site as well as pharmacy	0	1	2	Specific comments
03.	Storeroom is maintained in good condition *(clean, all trash removed, sturdy shelves, organized boxes.)*				
04.	Inventory is protected from harmful temperatures according to product specifications *(is there an air conditioner in both? What temperature is it kept at? Should be around 25 degrees Celsius. For fridge items 2-8 degrees)*				
05.	Inventory is protected from excessive humidity according to product specifications. *(Look for signs of dampness on boxes and walls)*				
06.	Inventory is protected from harmful light sources according to product specifications. *(Must not be in direct sunlight)*				
07.	Inventory is protected from corrosive materials				
08.	Storage site is visibly free of dirt and pests				
09.	Physical dimensions of storage site meet appropriate standards. *(Shelves must be at least 30 cm above floor, there must be no medicines stored on the floor, there must be sufficient space for stock available)*				

General comments:

0 = no, 1 = partially, 2 = fully

No.	Availability and Organization of Medicines	0	1	2	Specific comments
10.	Sufficient inventory is present at the site, based on facility's indicated criteria *(check stock card of selected ARVs, ensure quantities are above min stock level/buffer amount)*				
11.	Inventory is appropriately labelled. *(Check that medicines are labelled by generic name, are stored under correct label station. NB some medication is labelled according to name dosage and pack size)*				
12.	Inventory is within expiry date. *(Check all packs under each label*				
13.	Inventory is arranged in manner accessible to counting and general management *(Are medicines arranged according to generic name, alphabetically as well as dosage strength and pack size)*				
14.	Inventory is arranged in manner accessible for first-to expire, first out (FEFO). *Check if medicines are arranged such that those with the shortest expiry dates are at the outermost and first to be dispensed)*				

General comments:

0 = no, 1 = yes

No.	Packaging of Medicines	0	1	Specific comments
15.	Packages and containers are closed *(Only check immediate packages and containers)*			
16.	Packages are clean in both pharmacy and store room			
17.	Packages and boxes are not crushed			

General comments:

Pharmaceutical Management Information system

18.	The facility pharmaceutical record system is	Manual……….…...1	
		Electronic……….2	
		Both manual& electronic………..3	

19.	Are the following drug related data captured in records?	**0**	**1**
	o Physical stock count		
	o Quantities received		
	o Actual consumption		
	o Quantities issued per month(total)		
	o Stock outs		

Appendix VII

Normality Probability plots for continuous variables

Normal probability plot of inventory variation

Normal probability plot of head count

Normal probability plot of negative discrepancies

Normal probability plot of experience

Normal probability plot of updated stock cards

Normal probability plot of percentage of positive discrepancies