COMPLIANCE TO THE NATIONAL CORE STANDARDS BY PRIMARY HEALTHCARE FACILITIES AS PART OF THE ‘ADOPT A CLINIC’ PROJECT IN LIMPOPO PROVINCE

A dissertation submitted by

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in partial fulfilment of the requirements for the degree of

Master of Pharmacy

in the

School of Pharmacy

at the

Sefako Makgatho Health Sciences University

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2018
DECLARATION

I declare that this dissertation hereby submitted to the Sefako Makgatho Health Sciences University, for the degree of Master of Pharmacy, in the School of Pharmacy has not previously been submitted by me for a degree at this or any other university; that it is my work in design and execution, and that all material contained herein has been duly acknowledged.

__________________________________    ________________
Segolela, TA (Ms)       15 March 2019

Date
DEDICATION

To my late beloved husband, Mmachuene Michael Segolela, and our three kids, Khutso, Tshephang and Kgothlang, because of you I did not give up.

To my late parents, Moja and Skati Ramahuta, who raised me with love and never neglected their responsibilities.

Lastly, but not least, to the almighty Father for giving me the strength to satisfy my desires. His word says in Proverbs 13:4, “A sluggard’s appetite is never filled, but the desires of a diligent are fully satisfied.”
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“The greatest good you can do for another is not just share your riches but to reveal to him his own”. Benjamin Disraeli.

I hereby would like to acknowledge the following people, who contributed to this project:

- My supervisor, Prof JC Meyer, co-supervisors Mrs E Helberg and Mr M Makhado, for providing mentorship and above all for helping me realise my potential. It was a big privilege working with unselfish people like you.

- Prof HS Schoeman the statistician, for assisting with the data analysis.

- To all the data collectors who assisted me with data collection.

- To family and friends for the support and being there throughout this long challenging journey.

- Lastly to the Limpopo Department of Health, for granting me permission to collect data from the 49 primary health care facilities.
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<th>Description</th>
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<tr>
<td>ATC</td>
<td>Anatomical Therapeutic Chemical</td>
</tr>
<tr>
<td>BCG</td>
<td>Bacillus Calmette-Guerin</td>
</tr>
<tr>
<td>CCM</td>
<td>Community Case Management</td>
</tr>
<tr>
<td>CHC</td>
<td>Community Health Centre</td>
</tr>
<tr>
<td>CHW</td>
<td>Community Health Worker</td>
</tr>
<tr>
<td>COHSASA</td>
<td>Council for Health Service Accreditation of Southern Africa</td>
</tr>
<tr>
<td>CSPs</td>
<td>Community Service Pharmacists</td>
</tr>
<tr>
<td>DHS</td>
<td>District Health System</td>
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<tr>
<td>DoH</td>
<td>Department of Health</td>
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<tr>
<td>EML</td>
<td>Essential Medicines List</td>
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<tr>
<td>HST</td>
<td>Health Systems Trust</td>
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<tr>
<td>KZN</td>
<td>KwaZulu-Natal</td>
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<tr>
<td>LDoH</td>
<td>Limpopo Department of Health</td>
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<tr>
<td>MEC</td>
<td>Member of Executive Council</td>
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<tr>
<td>MoH</td>
<td>Minister of Health</td>
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<tr>
<td>MSH</td>
<td>Management Sciences for Health</td>
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<tr>
<td>NCDs</td>
<td>Non-Communicable Diseases</td>
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<tr>
<td>NCS</td>
<td>National Core Standards</td>
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<td>NDoH</td>
<td>National Department of Health</td>
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<tr>
<td>NDP</td>
<td>National Drug Policy</td>
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<tr>
<td>NHC</td>
<td>National Health Council</td>
</tr>
<tr>
<td>NHI</td>
<td>National Health Insurance</td>
</tr>
<tr>
<td>OHSC</td>
<td>Office of Health Standards and Compliance</td>
</tr>
<tr>
<td>PBPA</td>
<td>Post Basic Pharmacist Assistants</td>
</tr>
<tr>
<td>PFMA</td>
<td>Public Finance Management Act</td>
</tr>
<tr>
<td>PHC</td>
<td>Primary Health Care</td>
</tr>
<tr>
<td>SIAPS</td>
<td>Systems for Improved Access to Pharmaceutical and Services</td>
</tr>
<tr>
<td>SMUREC</td>
<td>Sefako Makgatho University Research Ethics Committee</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
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<tr>
<td>UHC</td>
<td>Universal Health Coverage</td>
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ABSTRACT

Introduction: In 2012, the National Department of Health (NDoH) and Limpopo Department of Health (LDoH) conducted audits to determine medicines availability in each facility and to assess amongst others compliance of medicine storerooms to National Core Standards (NCS) elements. In response to the audit findings, the NDoH introduced the Ideal Clinic programme to address identified gaps in addition to ensuring compliance to NCS. In addition, Pharmaceutical Services in Limpopo Province introduced the ‘Adopt a Clinic’ project led by Community Service Pharmacists (CSPs) to ensure compliance to standards and improve medicines availability. This study aimed to investigate the effect of the support provided by CSPs to selected PHC facilities, as part of the ‘Adopt a Clinic’ project in Limpopo Province, on medicines availability and compliance to the NCS and Ideal Clinic standards.

Objectives: The objectives of the study were to i) retrospectively determine compliance to the NCS and Ideal Clinic standards in PHC facilities supported by CSPs as part of the ‘Adopt a Clinic’ project prior to and after intervention by CSPs for period 01 February to 30 November of 2014 and 2015; ii) determine current compliance (2017) with the NCS and Ideal Clinic standards in PHC facilities which were supported by CSPs as part of the ‘Adopt a Clinic’ Project in 2014 and 2015; iii) retrospectively measure medicines availability in PHC facilities supported by CSPs as part of the ‘Adopt a Clinic Project’ prior to and after intervention by CSPs in 2014 and 2015; iv) measure current medicines availability (2017) in PHC facilities which were supported by CSPs as part of the ‘Adopt a Clinic Project’ between February 1st 2014 and December 31st 2015.

Method: Medicines availability, Ideal Clinic checklists and NCS checklists were used to collect data from 49 sampled facilities. Data were collected retrospectively from 2014 and 2015 records used during the ‘Adopt a Clinic’ project and prospectively in 2017 post CSPs support withdrawal. The percentage medicines availability was calculated based on a minimum of one medicine line available on the shelf, regarded as available. The percentage medicines availability was summarised per district and per Anatomical Therapeutic Classification (ATC) system. The overall percentage compliance to Ideal Clinic standards and NCS was measured for each facility as well as per indicator. Mean and median differences in medicines availability and compliance to standards at baseline, during CSPs intervention and post CSPs intervention were tested for statistical significance using the paired t-test, Wilcoxon signed rank test or z test as appropriate. Statistical significance was set at p<0.05.
**Results:** The average percentage medicines availability measured during CSPs intervention and post CSPs intervention were 83% and 81% respectively which were all below provincial target of 90%. At the time of CSPs intervention, average compliance to Ideal Clinic standards was 77% which declined to 70% at post CSPs intervention. Performance of the PHC facilities assessed on Ideal Clinic standards declined in 64% (18/28), sustained in 11% (3/28) and improved in 25% (7/28) of facilities at post CSPs intervention. Compliance of facilities to NCS declined from 85% attained during CSPs intervention to 73% at post CSPs intervention. The decline at post CSPs intervention was observed in all facilities except for Makhushane which maintained the 77% attained during CSPs intervention. Of the 49 NCS checklist elements that were assessed, compliance was noted in 37 elements (76%) and areas where facilities performed poorly were on availability of standby generator (10%), availability of standard operating procedure(40%), record keeping(10%) and access control (30%).

**Conclusion:** Assigning of CSPs to PHC facilities impacted medicines availability and compliance to Ideal Clinic standards as well as NCS positively and this may be one of the solutions to achieve compliance which is essential for National Health Insurance (NHI) implementation. Although there was a significant decline (p value < 0.001) on what CSPs attained during their support, percentage medicines and compliance to Ideal Clinic standards and NCS were still above the baseline status and this shows that nursing personnel managed to implement some of the lessons learnt from CSPs. Most of the areas where facilities performed poorly can be corrected without any financial implications and it is the responsibility of pharmaceutical services and supporting hospitals to enforce compliance. The withdrawal of CSPs support had a significant impact on the availability of medicines at PHC facilities although the availability per grouped ATC showed improvements post CSPs intervention. Availability was however still below the 90% provincial target. Only 8% of PHC facilities obtained 90% availability when there was no longer CSPs support, compared with 33% during CSPs support.

**Recommendations:** Limpopo Province should consider assigning or appointing dedicated pharmacy personnel, such as pharmacists and pharmacist’s assistants to support PHC facilities. Medicines should furthermore only be deemed available if the quantity on hand is greater or equal to at least one week’s usage derived from previous analysis. Lessons learnt from the Vhembe district CSPs coordinator, as well as good service rendered by WF Knobel and George Masebe hospitals, should be used as a model to champion and tackle low medicines availability in the province in the future. This should be monitored in future projects.
1.1 INTRODUCTION

This chapter provides a description of the background and rationale for the study. The research question, aim and objectives are provided, followed by the importance of the study. The chapter ends with the layout of the dissertation.

1.2 BACKGROUND AND RATIONALE FOR THE STUDY

In 2011/2012, Health Systems Trust (HST) conducted a national healthcare facility baseline audit in all the healthcare facilities in the country. The emphasis of the audit was on the seven domains of the National Core Standards (NCS), including the six priority areas for fast tracking quality improvement in patient centred care. The six priority areas are: positive and caring attitudes, waiting times, cleanliness, patient safety, infection prevention and control, and availability of medicines and supplies (NDoH, 2012).

The overall audit outcome average scores on quality measures was 53% nationally with Gauteng Province scoring the highest (69%), while Limpopo Province (46%) and the Northern Cape Province scored the lowest (40%). Availability of medicines was highest in Gauteng (60%) and lowest in the Northern Cape (42%), while medicines availability in Limpopo Province was equally low (43%) (NDoH, 2012).

In response to the NCS baseline audit, the LDoH in collaboration with Management Sciences for Health (MSH) under the Systems for Improved Access to Pharmaceutical and Services (SIAPS) project conducted an audit in 2012 to assess NCS compliance in all 40 hospitals and 14 selected Primary Health Care facilities in the Mopani District. Areas where Mopani PHC facilities scored low ratings were on availability of Standard Operating Procedures (SOPs) and standby generators (0%), sufficient storage space (14%), proof of ordering records (14%) and staff aware of allocated medicine budget (14%) (LDoH, 2012).

To address the gaps identified by the NCS baseline audit, the NDoH developed an Ideal Clinic realisation programme as an internal mechanism to ensure compliance to norms and standards at PHC level (NDoH, 2016). The Ideal Clinic manual describes an Ideal Clinic as “a clinic with good infrastructure, sufficient staff, adequate medicines and supplies, good administrative processes and uses applicable clinical guidelines to ensure
Developing and sustaining an Ideal Clinic requires the following components to be in place: administration, integrated clinical services management, medicines and supplies, laboratory services, human resources for health, support services, infrastructure, health information management, communication, District Health System (DHS) support, implementing partners and stakeholders (NDoH, 2017).

Medicines availability is one of the priorities of pharmaceutical services, monitored both provincially and nationally, as outlined in the NCS document (NDoH, 2011) and ministerial priorities (NDoH, 2010). Limpopo Province has embarked on improving medicines availability at all healthcare facilities by setting a target of 95% medicines availability at hospitals and 90% at PHC facilities (LDoH, 2012). Despite all the efforts and the interventions made, medicine stock outs continued to be a challenge, as is evident from the national healthcare facilities baseline audit (NDoH, 2012) and a report entitled ‘Compliance of Limpopo Hospitals Pharmacies and Selected Mopani Clinics with the NCS’ (LDoH, 2012). The average scores for the Limpopo Province compliance study on medicines availability for hospitals and PHC facilities were 79% and 73% respectively, which was lower than provincial targets of 95% (hospital) and 90% (PHC facilities) (LDoH, 2012). The low medicines availability clearly illustrated that Limpopo Province has not achieved the National Drug Policy’s (NDP) objective of ensuring availability and accessibility of medicines for all people (NDoH, 1996).

South Africa’s White Paper on the NHI laid the basis for moving the country towards Universal Health Coverage (UHC) through the establishment of a unified health system. Preliminary activities on the NHI, comprising of PHC re-engineering, Operation Phakisa Ideal Clinic Realisation Programme, improving buildings and planning for human resources for health, were targeted at reinforcing health system and service delivery platform (NDOH, 2017).

According to the White Paper on the NHI, facility-based services offered at PHC facilities and integrative practices will conform to the Ideal Clinic model. Results will be monitored through a performance management framework in accordance with agreed upon standards. For this model to be successful, PHC settings and environment must comply with the Ideal Clinic model specifications (NDoH, 2017).

The findings from the NCS baseline audit and compliance study in Limpopo Province led to the introduction of the ‘Adopt a Clinic’ Project in the Province in 2013, where each
Community Service Pharmacist (CSP) was allocated a maximum of ten PHC facilities to provide support in improving medicines supply management practices, mentor nursing staff and prepare facilities for NHI implementation. The CSPs contract however, is for a period of one year, meaning CSPs can effectively only provide support to the adopted facilities for a period of approximately 10 months. For sustainability of the programme, nursing personnel supported by hospital pharmacy personnel were therefore expected to maintain the standards as implemented by CSPs, beyond the project.

Pharmaceutical Services in Limpopo Province introduced the ‘Adopt a Clinic’ project led by CSPs. In this project CSPs are assigned a number of PHC facilities to support, thereby ensuring compliance to standards and improved medicines availability. The results of the ‘Adopt a Clinic’ project presented by the first CSPs group showed improvement in the average medicines availability at selected PHC facilities from 70% at the beginning of the project to 73% when the project ended in October 2013 (LDoH, 2013). Based on the success of the project, LDoH management included a clause in the 2014 CSPs contract stating that it is compulsory for CSPs to participate in the ‘Adopt a Clinic’ project henceforth (LDoH, 2014).

A number of reports have been presented in different districts within the Province and pharmaceutical services forums which indicated improvements in PHC facilities compliance to the NCS following the support by CSPs within the ‘Adopt a Clinic’ project (LDOH, 2015). Although there is some anecdotal evidence of the success of the project, no formal evaluation has been done yet, to investigate the impact of CSPs support in improving medicines availability and compliance to the NCS at PHC level. This study therefore aimed to address this by determining medicines availability and compliance to the NCS by PHC facilities as part of the ‘Adopt a Clinic’ project in Limpopo Province, which is crucial for PHC re-engineering and NHI implementation.

1.3 RESEARCH QUESTION

What is the effect of the support provided by CSPs to selected PHC facilities, as part of the ‘Adopt a Clinic’ project in Limpopo Province, on medicines availability and compliance to the NCS and Ideal Clinic standards?
1.4 **AIM OF THE STUDY**

The study aimed to investigate the effect of the support provided by CSPs to selected PHC facilities, as part of the ‘Adopt a Clinic’ project in Limpopo Province, on medicines availability and compliance to the NCS and Ideal Clinic standards.

1.5 **OBJECTIVES OF THE STUDY**

The objectives of the study were as follows:

- To retrospectively determine compliance to the NCS and Ideal Clinic standards in PHC facilities supported by CSPs as part of the ‘Adopt a Clinic’ project prior to and after intervention by CSPs for the period 1 February 2014 to 31 December 2015.

- To determine current compliance (2017) with the NCS and Ideal Clinic standards in PHC facilities which were supported by CSPs as part of the ‘Adopt a Clinic Project’ for the period 1 February 2014 to 31 December 2015.

- To retrospectively measure medicines availability in PHC facilities supported by CSPs as part of the ‘Adopt a Clinic Project’ prior to and after intervention by CSPs for the period 1 February 2014 to 31 December 2015.

- To measure current medicines availability (2017) in PHC facilities which were supported by CSPs as part of the ‘Adopt a Clinic Project’ for the period 1 February 2014 to 31 December 2015.

1.6 **IMPORTANCE OF THE STUDY**

The results of this study provide a good overview of medicines availability, compliance with NCS and the Ideal Clinic standards of PHC facilities in Limpopo Province. This might assist management to develop strategies to improve compliance status in preparation for NHI implementation.

This report might serve as a reference to future CSPs or any other healthcare personnel who may be tasked to provide support to PHC facilities in terms of their medicines management.

Lessons learnt from PHC facilities that are performing better might be used as a benchmark for other facilities or contribute towards planning for quality improvement.
1.7 OUTLINE OF THE DISSERTATION

The dissertation is presented as five chapters.

Chapter 1 provides the background and rationale for the study, the research question, aim and objectives as well as the importance of the study. Chapter 2 focuses on the literature relating to the study. The methods used in this study, are described in detail in Chapter 3. In Chapter 4, the results of the study are presented and discussed in the format of two manuscripts for publication in peer-reviewed journals. Chapter 5 presents the limitations of the study, recommendations and the final conclusions. The reference list for the dissertation and appendices follow Chapter 5.
CHAPTER 2
LITERATURE REVIEW

2.1 INTRODUCTION

In this chapter, the literature review conducted on the research topic is presented. The chapter starts with a discussion of the redesigning of healthcare systems at an international level, followed by PHC re-engineering in South Africa. In the next two sections, quality healthcare delivery is described and how compliance and readiness of facilities for NHI implementation in South Africa is measured using the National Core Standards. The implementation of the Ideal Clinic realisation, as a way to improve healthcare services to all patients in the country is discussed. This is followed by medicines availability, with special attention to the objectives of the National Drug Policy, accessibility and affordability of medicines. The chapter is concluded with a brief description of the community service concept for pharmacists in South Africa.

2.2 REDESIGNING HEALTHCARE SYSTEMS

Redesigning healthcare systems has become an international preoccupation, as policy makers seek new ways to address continuing problems of variation in the quality of health care and dissatisfaction among patients, the public, and professionals. Many countries now have national healthcare quality improvement agencies which are using redesign techniques. Examples include the Institute of Healthcare Improvement in the United States, the Modernisation Agency in the United Kingdom National Health Service, the Dutch Institute for Healthcare Improvement and the Australian Council for Safety and Quality in Healthcare. There is substantial international exchange of ideas and techniques between these various bodies, and this international exchange could be seen as a form of collective policy “puzzling” as ideas are borrowed, adapted, tested, and reformulated (Locock, 2003).

Healthcare organisations are using redesign to tackle variation in the quality of care and improve public satisfaction. It is represented as a radical challenge to traditional assumptions and practices which involves thinking through the best process to achieve speedy and effective patient care, identifying delays, unnecessary steps, or potential for error, and redesigning the process to improve the quality of care (Locock, 2003).
Typical steps in a redesign initiative might include mapping the existing care process, analysing where problems exist in that process and questioning why each step is done, by whom, where, in what sequence. Furthermore, to determine whether there is a better way, imagining what an “ideal” process might look like (sometimes described in re-engineering as “visioning”), identifying practical changes to the current process to make it closer to the ideal process, testing these changes and evaluating whether they result in improvement (Locock, 2003).

As global spending on healthcare increases and service improvement is not adequately reflecting on resource consumption, many healthcare organizations therefore resolve to improving their services by implementing business process reengineering. Business process reengineering is a business strategy adopted by so many health care organisations in order to efficiently and successfully manage their business, using currently available technology (Musa & Othman, 2016).

2.3 PRIMARY HEALTH CARE RE-ENGINEERING

Primary health care (PHC) re-engineering is a vision that originated in 2010, following the Brazil benchmark visit by the Minister of Health (MoH) and Members of the Executive Council (MEC). The visit followed the MoH’s commitment to contribute to the overall government strategy of “A Long and Healthy Life for All South Africans”. The purpose of the visit was to learn more on how community agents from Brazil working in partnership with health professionals in selected areas contributed to improving health outcomes. Following the visit, the Minister initiated a small team to develop a South African model to strengthen PHC. The team’s first report was accepted by the National Health Council (NHC) in November 2010 and it recommended that the South African model be based on the ward system as had been started in the KwaZulu-Natal (KZN) Province (Pillay & Barron, 2011).

The NDoH embraced a three-stream approach to PHC re-engineering namely, a ward based PHC outreach team, strengthening school health services and district based clinical specialist teams (Pillay & Barron, 2011). The aim of PHC re-engineering is to uplift the state of health of the people through the provision of a need-based, equitable health care delivery system through integrated health care services, provided by a multidisciplinary health team in collaboration with non-governmental organisations and other stakeholders (Mpumalanga Department of Health, 2014).
PHC re-engineering aims to strengthen the current DHS which is the way of providing health services to local communities. It is also aimed at strengthening interaction between the health services and the end users, by reaching out to families with an emphasis on health advancement, preventative activities and identification of individuals at high risk of certain diseases or health problems. This will create a strong DHS on which the NHI can be grounded and gain its potential to achieve better health outcomes (NDoH, 2012).

During its introduction, it was envisaged that once the programme is fully implemented, hospital patients’ burdens would be addressed as a result of a strengthened referral system to PHC facilities. In the absence of a proper referral system, which is the responsibility of the referring and referral facilities, hospitals would be used inappropriately by patients who would have been seen at the first level of care according to the referral policy. This would be at the expense of other patients who are truly requiring care at either tertiary, regional and district hospitals. Once a well-functioning referral system is established, hospitals will be able to service patients who really need care at that particular level, while others are attended to at PHC facilities. It is therefore imperative that all PHC facilities are upgraded to the standards of the Ideal Clinic in order to realise the objectives of PHC re-engineering (Mohapi & Basu, 2012).

2.4 QUALITY HEALTH CARE DELIVERY

Although the government has increased accessibility of health services to those who use them on a regular basis, the quality of these services is still a concern in both public and private sectors. The poor quality of health services rendered is associated with a number of root causes which are complex e.g. shortage of staff, negative staff attitudes, poor medicines availability, poor infrastructure, and long waiting times. Resolving these challenges will require cooperation from all role players. Upgrading the quality of health services to an acceptable standard will depend on the availability of policies and legislation focusing on all dimensions of quality, standards and regulation that measure the quality of these services and institutions, as well as processes that are tailored towards quality improvement (NDoH, 2013).

A study conducted in Nigeria on assessment of PHC facilities showed poor performance on the availability of essential medicines, management of expired medicines and proper storage facilities for vaccines and mechanisms to maintain power supply (Oyekale, 2017).
In India, a study that assessed the utilisation of the services of primary health centres found that the number of patients seen in the surveyed facilities was low, which was attributed to inadequate infrastructural facilities to provide a complete package of treatment and casual attitude of the PHC staff towards patients. It was also found that shortage of required medicines contributed to poor utilization of PHC facilities in the rural villages of India (Dar, 2015).

On the other hand, in England health coverage is universal. The major funder of the National Health Services (NHS) is general taxation, while only a small portion is coming from national insurance. All England residents are automatically entitled to free NHS care as well as non-residents with an European Health Insurance Card. Other people such as non-European visitors or undocumented immigrants can only access emergency services (Thoriby & Arora, 2017).

2.5 NATIONAL CORE STANDARDS

In aligning to the NDoH legislative and policy mandates, the Office of Health Standards Compliance (OHSC) developed NCS for health establishments in South Africa that afforded a basis of quality of care against which the delivery of health services can be tracked. National Core Standards for health establishments are minimum standards which are recognized internationally and are used to measure quality of services rendered which could be used in preparation for NHI implementation (NDoH, 2011).

The NCS are structured into seven domains, of which the first three (patient rights and safety, clinical governance and care, and clinical support services) are involved directly with delivery of quality health care to patients. The third domain, clinical support services, covers the indicators for pharmaceutical service delivery in the country (NDoH, 2011).

It is very important that pharmaceutical services play its role in ensuring implementation and compliance to the NCS throughout every health care facility in the country. Through the implementation of NCS, a valuation of health facility’s conformity to service standards can be measured. These standards are known globally and used to establish minimum safety standards and desired best practice across a health facility (NDoH, 2012).

The South African Health Review 2017 stated that measurement of health outcomes is undertaken by both the (OHSC) and Council for Health Service Accreditation of Southern Africa (COHSASA). The OHSC has developed NCS as basic criteria of measuring health
outcomes for all healthcare institutions. National Core Standards are part of the monitoring process recommended in the National Health Amendment Act 59 and are assessed during obligatory inspections by the OHSC. The OHSC assessed 1427 state hospitals and clinics from 2012 to 2016 and only 89 of the facilities assessed met at least 70% compliance which is the minimum acceptable score (NDoH, 2017).

Prior to the implementation of NCS, assessment was conducted at PHC and hospitals around South Africa in 2009 with the aim of wanting to move quickly towards implementing the NHI but recognised that it could work only if facilities could provide quality services. Assessments were carried out in 2011 and 2013, to assess where the country was in terms of compliance to a number of components in the PHC facilities checklist. This had highlighted problems which ranged from: under and over-staffing, PHC facilities not have been constructed in the right places or the right size to serve the communities properly, and suffered in many cases from poor management, lack of managers, lack of facilities and equipment (NDoH, 2016).

National Healthcare Agreement of the Council of Australian government has introduced objectives which will ensures quality of health care. The objectives include improving health outcomes for all, sustainability of the system, developing performance indicators and benchmarks on which progress is assessed. Indicators and benchmarks in the agreement address issues of quality from primary to tertiary care and include disease specific targets of high priority. Australian Council on Healthcare Standards is a nongovernment agency that has been given the responsibility to accredit health institutions. The Council works collaboratively through National Registration and Accreditation Scheme to facilitate workforce mobility across jurisdictions and maintain patient protections (Glover, 2017).

2.6 IDEAL CLINIC

An Ideal Clinic is a clinic that complies with the NCS and is ready for NHI implementation. Most of the clinics are in the process of becoming ideal and structural challenges have been identified as one of the shortcomings that affect compliance of the bulk of the PHC facilities. The Ideal Clinic initiative is an approach to respond to the insufficiencies in quality of PHC services and lay a strong basis for effective implementation of NHI. The initiative is intended to allow a health authority to gain the required information, test responses and summarise the changes needed to existing systems and processes to reach and maintain the desired PHC status (HST, 2017).
The Ideal Clinic realisation programme is one of the preparatory activities towards the implementation of the National Health Insurance (NHI), which is a health care financing system, that pools funds to actively purchase and provide access to quality, affordable healthcare services for all South Africans based on their health needs irrespective of their socio-economic status. The main objective of the NHI is to ensure that the population has access to quality health services without financial hardships for individuals and their families. According to the NDoH's NHI white paper, compliance with the NCS would in future be a requirement for all healthcare facilities in South Africa, thereby ensuring the provision of quality healthcare services following the implementation of NHI programme (NDoH, 2015).

The success of an Ideal Clinic programme depends on implementing a scale-up plan, securing the required resources, continued innovation and sustaining leadership. The implementation of the initiative has its origin in the findings of a baseline audit commissioned by NDoH in 2011. The audit demonstrated poor performance on average by PHC facilities in all areas of priority (HST, 2017).

According to the South African Health Review 2017, 322 clinics achieved Ideal Clinic status and were accredited. In addition, the number of clinics scoring over 70% increased from 139 to 445 while the number that scored less than 40% dropped from 213 to 90 during the 2015/2016 financial year. Three main challenges identified must be addressed by the national and provincial departments of health in order to improve the rate of scale-up which are: poor infrastructure, inadequate staffing, and poor supply-chain systems (Hunters, Asmall, Ravhengani, Chandran, Tucker & Mogalagadi, 2017).

Kwazulu-Natal’s 2017 Service Delivery Improvement Plan revealed that only two PHC facilities namely Phatheni and Efaye achieved Ideal Clinic status during the first phase of NHI pilot. In 2014, during the provincial first baseline assessment, only 15 out of 609 facilities achieved Ideal Clinic status which was significantly below the expected performance to ensure 100% compliance by March 2020. A number of inadequacies were identified for non-achievement and slow progress, these related to structures and processes to manage the improvement process, inequitable distribution of resources, lack of ownership and accountability for improvement plans, as well as inadequate governance structures (KwaZulu-Natal DoH, 2017).
Chapter 2: Literature Review

2.7 MEDICINES AVAILABILITY

Medicines availability is one of the standards measured under the pharmacy domain of the NCS and it is also one of the six priority areas for fast tracking quality improvement in patient centred care. In South Africa, medicines are considered available when percentage availability is 80% and above at hospitals and clinics in accordance with NDoH’s annual performance plan. Other elements measured under this domain which affect medicines availability indirectly are minimum/maximum levels for each product kept at the facility, good storage conditions and management of expired medicines (NDOH, 2011).

The Government of South Africa developed and implemented the NDP. This is a comprehensive framework whereby each health component plays an important role in achieving one or more of the general objectives of the policy. The goal of the NDP is to ensure an adequate and reliable supply of safe, cost-effective medicines of acceptable quality to all citizens of South Africa and the rational use of medicines by prescribers, dispensers and consumers. When the NDP was introduced in 1996, there were a number of shortcomings in pharmaceutical services, notably the imbalances in access of essential medicines which affected quality of care (NDoH, 1996).

The NDP of South Africa states that it is important that medicines are available to satisfy the health care needs of all citizens (NDoH, 1996). The target for medicines availability in hospitals and PHC facilities in Limpopo Province is 95% and 90% respectively (LDoH, 2005). According to the study conducted by Mohale in 2016, the average medicines availability in the 40 public sector hospitals in Limpopo Province was 79% and this was below the provincial medicine’s availability target of 95%.

The national health care facilities baseline audit revealed a national compliance of 54% by facilities to the availability of medicines and supplies priority area. According to the baseline audit, a high percentage failure to the vital measure ‘Tracer medicines’ was 77% in PHC facilities and 70% in Community Health Centres (CHCs). A percentage failure of 51% and 44% was obtained for clinics and CHCs respectively on availability of SOPs which indicated how schedule 5 and 6 medicines are stored / controlled / distributed in accordance with the Medicines and Related Substances Act 101 of 1965 (NDoH, 2012).

According to the study on improving access to medicines, medicine availability is satisfied when medicines specific to the largest disease burden are in existence. Despite the vast
range of issues that affect the availability, affordability, efficacy and obtainability of medicines, other aspects like political will, capacity, policies and funding do arise. Policy approaches utilizing The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities and domestic law can greatly aid in increasing access to medicines. However, the use of flexibilities such as compulsory licensing is not welcomed by pharmaceutical companies as it jeopardizes the value of the market, decreasing potential profits. To this end, Abbott responded to the compulsory licence of an antiretroviral medicine in Thailand by announcing that it would no longer register new medicines for sale within that country (Bors, Gervais, Christie & Clayton, 2015).

Medicines are often the most important cost driver of health care expenditure on hospitals and primary Health care. Patients that have access to adequate and effective medicines at the time of need are more likely to be happy with the treatment they receive. When such medicines are not available, patients will go elsewhere, even if they have to pay high prices to private providers, to get the care they think they need. The availability of affordable and effective medicines is, therefore, one of the most visible indicators of the quality of health services. Satisfaction with the medicines received is a key determinant of utilization of health services and return visits in the public sector. Despite significant progress in increasing access to essential medicines in low- and middle income countries during the past decades, many of the health services used by the poor still lack adequate supplies of basic medicines (Attridge & Preker, 2005).

A case study on factors affecting the procurement of medicines at Narok County referral hospital in Kenya identified inadequate funding and poor quantification as main contributing factors for availability of medicines. As a result of inadequate funding, payments of service providers were delayed and this left the suppliers with no option but to suspend the accounts. Proper quantification could not be performed as source data in the form of monthly reports were provided inconsistently, which affected the supply chain processes. The poor quantification led to over or under estimations which ultimately led to expiry or shortage of medicines (Muhai, 2017).

In Sri Lanka, the national survey on availability, price and affordability of some essential medicines for non-communicable diseases (NCDs) showed a need to strengthen procurement policies and procedures in order to ensure constant supply to the public health facilities. Strengthening of policies and procedures is envisaged to better accessibility to services for the majority of the people and at the same time lessening the sickness and death rate of NCDs. The results showed that availability of surveyed
medicines was highest (>80%) in semi-government community pharmacies while public health care facilities and private pharmacies showed 50-80% availability, which is fairly high (Panthihage, 2014).

A study on assessing medicines availability at five primary and one secondary care institutions of a rural district in Sri Lanka using the national essential medicines list showed a fairly high availability with average percentage availability of 56% and 71% respectively. The study further recommended that a need based annual estimate of medicines based on essential medicines list be done as a way of improving availability (Rathish, Premarathna, Jayathilake, Kandegedara, Punchihewa, Ananda, Jayasumana & Siribaddana, 2017).

The budget of medicines is usually tight in developing countries and thus the procurement cycle should be well-monitored in order to prevent fruitless expenditure through wastage which includes pilferage, misuse and expiry. Wastage reduces medicines available to patients, thus compromising the quality of health care received (Nakyanzi, Kitutu, Oria and Kamba, 2010). With the CSPs’ ‘Adopt a Clinic’ project introduced in 2013, baseline data indicated medicines wastage through expiry in different PHC facilities, with the percentage of expired medicines in PHC facilities above the recommended limit of 0.05% of the provincial target (LDoH, 2005). The ‘Adopt a Clinic’ project therefore also aimed at improving medicines supply management practices which would indirectly reduce medicines wastage (LDoH, 2013).

According to Zambian inventory management policies for pharmacy, only past consumption is considered in determining minimum and maximum stock levels as well as demand planning which is contrary to the widely known practice of including other factors such as lead time, seasonal fluctuations, and procurement period. The reliance on one particular factor as in the Zambian policy, instead of combination of all key factors, had an impact on the availability of essential medicines in the country (Leung et al, 2016). The implementation of the inventory management policies contributed to the substantial fraction of stock-outs.

A study conducted in Ethiopia, Malawi, and Rwanda on factors affecting availability of essential medicines among CHCs, showed poor medicines availability, with majority of CHCs being out-of-stock of at least one medicine from the checklist on the day of the assessment. The findings confirmed that medicines availability was a challenge for all Community Case Management (CCM) programmes. Supply chain was found to be one of
the factors contributing to low medicines availability (Chandani, Noel, Pomeroy, Anderson, Pahl & Williams, 2012). Similarly, a study on medicines availability and affordability in 36 developing and medium income countries showed an availability that ranged from 29.4% to 54.4% (Cameron, Ewen, Ross-Degnan, Ball & Laing, 2009).

Similarly, in South Africa, a study conducted in the Free State Province revealed that medicines were inconsistently available especially in PHC facilities. The non-availability of medicines was associated with unreliable deliveries from the medical depots, poor medicines management, shortage of pharmacy personnel, unavailability of a reliable medicines management system and the fact that the depot and pharmaceutical services operate independently within the province (Zuma, 2013).

In the Limpopo Province, a number of major factors contributing to low stock availability were identified from the 2014/2015 ‘Adopt a Clinic’ project report, these included; lack of transportation to provide support visits at the PHC facilities, inaccessibility of PHC facilities as a result of poor road infrastructure, shortage of staff (both pharmacy personnel and nursing staff) and lack of accountability for stock management. The challenges identified showed the need for consistent support visits by pharmacy personnel or rather, pharmacy personnel should be permanently employed at PHC level (LDoH, 2013).

In the Eastern Cape Province of South Africa, pharmaceutical services introduced quality improvement projects which have shown positive results in some of the districts. Seven institutions from three districts (OR Tambo, Amathole and Alfred Nzo districts) showed a 14% improvement (from 70% to 84%) in compliance with the NCS relating to storage and management of medicines and a 21% improvement (from 56% to 77%) in compliance with cold chain maintenance. An overall improvement of 18% in compliance with the NCS was noted (Mlindazwe, Nkontselo, Nongauza, Magugwana, Ndlela, Mashologu & Kapay, 2012).

Similarly, Dr Kenneth Kaunda district in the North West Province conducted a quality improvement project in the five hospitals and nine PHC facilities with the aim to improve availability of tracer medicines by 5% by November 2012. Results showed a 6% increase in medicines availability at PHC facilities (from 72% to 78%) and a decrease in medicines availability of 2% (from 89% to 87%) at hospital level (Swanepoel, Motara, Degenaar & Moloisi, 2013).
In Limpopo Province, the ‘Adopt a Clinic’ project contributed to improved medicines availability in Vhembe District from 82% to 87% (Mabilo, 2014). Several studies conducted in countries like Uganda (Okiror, Onchweri, Miruka & Maniga, 2015), Kenya (Wangu & Osuga, 2014) and India (Prinja, Pankaj, Jaya & Rajesh 2015), showed medicines availability ranging from 50% to 65%, which is consistent to figures in South Africa, according to the national baseline audit conducted in all nine provinces (NDoH, 2012). These studies attributed the low medicines availability to factors such as lack of accountability, lack of transport, short supply by medical stores and funding challenges. Contributing factors were also highlighted in the previous medicines audit conducted in the Limpopo Province, thus highlighting the need to investigate the impact of assigning CSPs to PHC facilities, through an ‘Adopt a Clinic’ project initiative, on medicines availability and compliance to the NCS as well as Ideal clinic standards in the Province.

2.8 COMMUNITY SERVICE FOR PHARMACISTS

According to the Pharmacy Act No 53 of 1974 as amended, "pharmaceutical community service" means the provision of services or' the performance of one or more or all of the acts forming part of the scope of practice of a pharmacist in a public health facility or a complex of health facilities in accordance with regulations. A person who wants to perform pharmaceutical community service must apply for a post in a public health facility or a complex of health facilities appearing on a list of facilities approved for pharmaceutical community service and published by the Minister in the Government Gazette.

If a period of pharmaceutical community service is interrupted, such period must consist of periods which, when added together, including approved periods of leave, are not less than one calendar year in total, provided that pharmaceutical community service must be completed within a period of two years from the date of commencement of such service. The period of pharmaceutical community service already served shall lapse if community service is not completed within a period of two years from the date of commencement of such service. On completion of pharmaceutical community service by a pharmacist, the relevant health authority must furnish the South African Pharmacy Council and the National Department of Health with a report that such person has satisfactorily completed pharmaceutical community service in terms of the Act (Pharmacy Act No 53 of 1974 as amended).
2.9 SUMMARY

From the literature review, it was evident that compliance to medicines availability, the NCS and Ideal Clinic standards are still challenges in South Africa which needs robust intervention mechanisms more in particular in preparation for the much awaited implementation of the National Health Insurance.

The literature review that covered studies in South Africa, other African countries and the global perspective all have one thing in common. The shortage of human resources, lack of equipment, inadequate infrastructure facilities, lack of accountability by the accounting officers, poor medicines supply management practices, lack of transport, poor quantification and inadequate budget for procuring medicines were some of the factors that contributed to low medicines availability in studies reviewed. It may be prudent to explore some of the strategies to completely redesign the methods and approaches to tackle challenges on unavailability of medicines. Multi-disciplinary approach, collaboration between departments and team work had been shown to produce improved results and the same can be applied in our setting.

Compliance to service standards was not great in South Africa in terms of National Core Standards and Ideal Clinic initiatives. Similar compliance studies from other countries did not achieve better results either which shows that the problem is not only in South Africa but globally. Countries have to double the effort in addressing provision of health service gaps in order to achieve the universal health coverage objectives such as equity in access to health services, quality of health services and ensuring that the cost of using services does not put people at risk of financial harm.

The literature also highlighted the importance for a well-supported and sustained programme such as the ‘Adopt a Clinic’ project which would assist in improving the rendering and provision of pharmaceutical services, as it has been the case in facilities that had the constant presence of CSPs.

The quality of healthcare services which is measured by the NCS and Ideal Clinic standards remains a challenge, which requires urgent intervention from management. Poor infrastructure, shortage of staff and insufficient medicines budget are amongst the major challenges that contribute to poor quality services rendered by most of the PHC facilities. On the other hand, staff have the responsibility of improving their attitudes towards the patients and co-workers. Availability of medicines is also a problem
nationwide. A huge budget is allocated for the procurement of medicines on an annual basis, but still cannot meet the demand. The community should be educated about budget constraints, the scarcity of resources and the importance of using different levels of care appropriately.

It is important to also note that PHC re-engineering was introduced with good intentions of improving utilisation of PHC facilities and also of decanting hospitals. These objectives can be realised if PHC facilities can be provided with the necessary resources, which include human resources, medicines, out-reach programmes and support from the districts.

The methodology of the study is described in the next chapter.
3.1 INTRODUCTION

This chapter presents the methods used for this study. The study site, population, sample selection, data collection process and instruments are described. Analysis of data is discussed followed by measures taken to ensure validity and reliability of data including elimination of bias. The ethical considerations of the study conclude the chapter.

3.2 STUDY DESIGN

This was a quantitative operational study approach using an implementation evaluation research design. Both prospective and retrospective data on the NCS, Ideal Clinic standards and medicines availability were collected from PHC facilities in the Limpopo Province.

Quantitative operational approach was used as the study comprised measurable indicators from collected data on medicines availability, NCS and Ideal Clinic standards. The study conducted an evaluation and assessment on the project that was already implemented and hence the implementation evaluation approach.

3.3 STUDY SITES

The study was conducted in 49 public sector PHC facilities selected from Limpopo Province’s five districts namely Capricorn, Mopani, Sekhukhune, Vhembe and Waterberg (see Figure 3.1a). Figure 3.1b shows the distribution of the study clinics within the Province.
Figure 3.1a: Five districts of Limpopo Province

Figure 3.1b: Limpopo Province map with sampled PHC facilities
3.4 STUDY POPULATION AND SAMPLE

The target study population consisted of 286 PHC facilities which were adopted in either 2014 or 2015, as part of the ‘Adopt a Clinic’ project in Limpopo Province (Table 3.1).

Table 3.1: Number of facilities in Limpopo Province sampled per district

<table>
<thead>
<tr>
<th>Districts</th>
<th>Total number of PHC facilities</th>
<th>PHC facilities adopted in 2014 or 2015</th>
<th>PHC facilities sampled for this study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capricorn</td>
<td>105</td>
<td>66</td>
<td>17</td>
</tr>
<tr>
<td>Mopani</td>
<td>106</td>
<td>63</td>
<td>8</td>
</tr>
<tr>
<td>Sekhukhune</td>
<td>93</td>
<td>49</td>
<td>12</td>
</tr>
<tr>
<td>Vhembe</td>
<td>124</td>
<td>77</td>
<td>8</td>
</tr>
<tr>
<td>Waterberg</td>
<td>64</td>
<td>31</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>492</td>
<td>286</td>
<td>49</td>
</tr>
</tbody>
</table>

From the 286 PHC facilities adopted in 2014 or 2015, 49 were selected according to a set of inclusion and exclusion criteria, as illustrated in Figure 3.2. The list of 49 selected PHC facilities, which met the inclusion criteria, is available in Appendix 1.

Figure 3.2: Exclusion and inclusion criteria for adopted PHC facilities
3.5 DATA COLLECTION

Data collection commenced after ethical clearance for the study was granted by Sefako Makgatho University Research Ethics Committee (SMUREC) and permission obtained from the LDoH Research Committee. The five district offices were informed of the study as recommended by the LDoH, who in turn granted permission to access their facilities.

3.5.1 Data collection period

Medicines availability, Ideal Clinic standards and NCS data were collected from January to July 2017 for all 49 sampled PHC facilities.

3.5.2 Data collectors and data collection training

Data were collected by the researcher with the assistance of two pharmacists and two post-basic pharmacist assistants (PBPAs). One pharmacist was employed by MSH, an organisation that was providing technical support in the Province until 2016 when the project ended and the second one was employed at Mankweng Hospital. The two PBPAs that took part in data collection were employed at Matlala Clinic and Mphahlele Clinic in Capricorn district.

There was no need to train the pharmacist from MSH as he had previously used the tools in different settings. The pharmacist from Mankweng Hospital was taken through the tool telephonically prior to data collection and he collected data from only one clinic. The two PBPAs were trained by the researcher prior to commencement of data collection in order to ensure understanding and consistency.

3.5.3 Data collection instruments

Data collection instruments included the NCS checklists (Appendix 2), Ideal Clinic checklist (Appendix 3) and Limpopo Province medicines availability checklist for PHC facilities (Appendix 4). National Core Standards and Ideal Clinic checklists were used to collect both prospective (2017) and the retrospective (2014 and 2015) data.

The NCS checklists assessed medicines store rooms including cold chain management, record keeping and medicines in consulting rooms. The Ideal Clinic checklist consisted of 35 questions which assessed inventory management and the stock management system. Each NCS and Ideal Clinic question was scored for compliance where “Yes” denoted compliance and “No” not yet compliant. The percentage NCS and Ideal Clinic compliance
was calculated by adding all “Yes” scores and dividing by the total number of applicable facility checklist items.

Limpopo Province PHC medicines availability checklist (updated in 2016 as a result of changes in the Essential Medicines List (EML)) was used to collect prospective (2017) and retrospective data (2014 and 2015). Percentage medicines availability was measured by counting all products where stock on hand was greater than zero (numerator), dividing by total number of items on the clinic list (denominator). The availability was retrospectively measured before the CSP intervention at baseline and post-intervention in 2014 and 2015, and prospectively in 2017.

A pilot study to test the tools was not necessary since they have been used extensively in the past to collect data on the NCS, Ideal Clinic standards and medicines availability.

3.5.4 Data collection

Following ethical clearance and permission from the Province, the Districts’ PHC Management was informed of the study in writing, who in turn informed the operational managers of the selected facilities. On the day of data collection, the researcher explained the objectives of the study and the data collection process to operational managers at the facilities who were then requested to provide written informed consent for the data to be collected.

Prospective data on current medicines availability and compliance with the NCS or Ideal Clinic standards were collected by the researcher with the assistance of two pharmacists over a period of seven months in 2017. Data were collected from the selected PHC facilities medicines store rooms using the NCS (Appendix 2) or Ideal Clinic standards (Appendix 3) and medicines availability data collection instruments (Appendix 4). Medicines were physically checked for availability as per medicines availability list and number ‘1’ was captured to denote availability of an item and ‘0’ denoted out of stock. Compliance to NSC and Ideal Clinic standards was measured through observation of medicine supply practises and ‘Yes’ was captured on the tools to denoted compliance and ‘No’ not yet compliant.

Retrospective data were collected through document review from 2014 and 2015 ‘Adopt a Clinic’ project records of the 49 PHC facilities sampled. These records included a summary of baseline (pre-intervention) and post-intervention assessment findings on medicines availability and the NCS or Ideal Clinic standards for each facility. Similar to the prospective data, data from these already completed records were entered onto a Microsoft Excel™
spreadsheet to reflect data at baseline (before the CSP intervention) and post-intervention results.

3.6 DATA ENTRY AND ANALYSIS

Data entry by the data collectors was verified by the researcher for correctness and completeness and any discrepancies were rectified immediately prior to data capturing. Data were captured by the researcher with the assistance of the pharmacist from MSH, using Microsoft Excel™ spreadsheets. Completeness and accuracy of the entered data were confirmed and verified.

Medicines availability was measured by counting all products where stock on hand was greater than zero (numerator), dividing by total number of applicable items on the PHC list (denominator) to get percentage availability. The availability was retrospectively measured at baseline before the CSP intervention (2014 or 2015) and directly after the CSP intervention (2014 or 2015) and prospectively after the CSP intervention in 2017.

On each NCS and Ideal Clinic checklist, all “Yes” answers were counted and divided by total number of applicable items to obtain percentage compliance. Results at baseline, CSP intervention and post CSP intervention were compared to establish the impact of the interventions. The method used tracked changes from baseline to CSP intervention and to post CSP intervention where a “+” denoted a change from non-compliance to compliance status, “-” denoted a change from compliance to non-compliance status, “1” signified positive no change compliance status and “0” denoting negative no change non-compliance status.

For the purpose of percentage medicines availability calculations per programme, medicines on the PHC list were further classified according to Anatomical Therapeutic classification (ATC) system. Mean and median percentage medicines availability per identified ATC group were then calculated.

The z test (normal approximation of the binomial distribution) has been used to test the significance of a percentage of positive changes, namely by testing the null hypothesis of 50% positive changes against the alternative hypothesis of more than 50%. As such the test effectively tested whether an observed percentage of positive change is better than a chance outcome.

The prospective data on the NCS, Ideal Clinic standards and medicines availability were compared with the available retrospective data. Mean and median differences in medicines
availability and compliance to standards at baseline, during CSP intervention and post CSP intervention were tested for statistical significance using the paired t-test, Wilcoxon signed rank test or z test as appropriate. Statistical significance was set at p<0.05.

All statistical procedures were performed using SAS Release 9.4, and also in consultation with the statistician.

3.7 RELIABILITY AND VALIDITY

The validity of the study was enhanced by the fact that the data collection instruments for NCS and Ideal Clinic have already been tested extensively during their development process. The development process of both NCS and Ideal Clinic tools contributed to the content validity. The same applied to the medicine’s availability monitoring tool, as it has been approved and used by the Province for weekly reporting, since 2013.

All the data were collected by pharmacists and PBPA who were experienced or trained on the NCS assessment tools, the Ideal Clinic checklists and the medicines availability tools used in the Province. The researcher recognizes the fact that this study was conducted in selected PHC facilities in Limpopo Province which present a threat to the external validity of the data. This was taken into consideration during the interpretation of the results and the findings were not generalized to all PHC facilities in the Province.

The researcher acknowledged that bias exists in all research (Struwig & Stead, 2007). Sampling bias was minimised by including all the PHC facilities that met the inclusion criteria of the study. Response bias in terms of the retrospective data cannot be ruled out as the data were collected by the CSPs who also implemented the interventions, based on their baseline findings. The prospective data however were collected objectively by external data collectors.

3.8 ETHICAL CONSIDERATIONS

Ethical clearance for the study was obtained from the SMUREC (SMUREC/H/247/2016:PG) (Appendix 5). Permission to conduct the study were obtained from the LDoH Research Committee (Appendix 6) and the five District Offices (Appendix 7). The PHC facilities sampled were informed of the study before commencement of data collection through the pharmacy managers of the hospitals supporting the selected PHC facilities and through their respective District Offices. Operational managers or supervisors were requested to provide written informed consent (Appendix 8) for assistance with the completion of the data
collection tools. All signed informed consent forms, completed data collection tools and other study documentation were scanned and will be kept in a protected secure place for a period of five years.

3.9 SUMMARY

This was a quantitative operational study using an implementation evaluation research design. Two sets of data; prospective (2017) and retrospective (2014 or 2015) data on the medicine’s availability, Ideal Clinic standards and NCS, were collected from all the 49 PHC facilities. Each data set was collected on three separate checklists for medicines availability, Ideal Clinic standards and NCS. Prospective data were collected through observation and document review while retrospective data was collected from 2014 or 2015 ‘Adopt a Clinic’ project records. Data collected was verified by the researcher for correctness and completeness and any discrepancies were rectified immediately prior to data capturing using Microsoft Excel™ spreadsheets. Completeness and accuracy of the captured data was confirmed, verified and then imported into SAS Release 9.4 for statistical analysis in consultation with the statistician. Ethical clearance and permission for the study were obtained from the SMUREC, LDoH Research Committee and the five District Offices.

In Chapter 4 the results of the study and discussion thereof are presented in the format of two manuscripts, which will be submitted for publication to peer-reviewed journals.
CHAPTER 4
RESULTS AND DISCUSSION

4.1 INTRODUCTION

The results of the study are presented and discussed in this chapter in the format of two manuscripts, which will be submitted for publication to peer-reviewed journals. The manuscripts are presented in the format required by the respective journals, according to author guidelines.

Manuscript 1 will be submitted to the South African Medical Journal (SAMJ) for publication under the title ‘Medicines availability in Limpopo Province primary health care facilities during and beyond an ‘Adopt a Clinic’ community service pharmacist project’. The author guidelines appear in Appendix 9 and can be accessed electronically at: http://www.samj.org.za/index.php/samj/about/submissions#authorGuidelines.

Manuscript 2 will be submitted to the African Journal of Primary Health Care & Family Medicine under the title ‘Compliance to quality standards by Limpopo Province Primary Health Care facilities as part of an ‘Adopt a Clinic’ community service pharmacist project’. The author guidelines appear in Appendix 10 and can be accessed electronically at: https://phcfm.org/index.php/phcfm/pages/view/submission-guidelines.

Each manuscript is preceded by a letter to the editor of the particular journal. For the purpose of the dissertation, tables are embedded in the text within the manuscripts using single line spacing.

4.2 MANUSCRIPT 1

4.2.1 Manuscript 1: Letter to the editor

This section contains the letter to the editor of the SAMJ, which will accompany the submission of the manuscript to the journal.
Dr Bridget Farham  
Deputy Editor: South African Medical Journal  
Private Bag x 1  
Pinelands  
Cape Town  

Dear Dr Farham  

**RE: SUBMISSION OF MANUSCRIPT: Medicines availability in Limpopo Province primary health care facilities during and beyond an ‘Adopt a Clinic’ community service pharmacist project**

We are pleased to submit the abovementioned original research article authored by Thabang Segolela, Johanna C Meyer, Mulatedzi Makhado, Brian Godman and Elvera Helberg for consideration of publication in the South African Medical Journal.

In this manuscript, it was noted that medicines availability at primary healthcare facilities improved during ‘Adopt a Clinic’ project when there were community service pharmacists delegated to support selected primary healthcare facilities on medicine supply management practices. We believe that this manuscript is appropriate for publication by South African Medical Journal because it shows that medicines availability which is an integral part of the healthcare management system is a major problem at the first level of care. The study revealed that problems of medicines availability can be corrected through a multidisciplinary approach including medical practitioners, nursing personnel and finance.

We consider SAMJ the journal of choice for publishing this manuscript because it is open-access and widely read by South Africans working in the public healthcare sector.

This manuscript has not been published or under consideration for publication elsewhere. The authors have no conflict of interest to disclose.

Yours faithfully,

__________________________________________________________________________  
Thabang Segolela  
15 March 2019  
Date
4.2.2 Manuscript 1 for publication

Medicines availability in Limpopo Province primary health care facilities during and beyond an ‘Adopt a Clinic’ community service pharmacist project

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Abstract

Background. Medicines availability is a key priority for both the National and Provincial Departments of Health in South Africa when implementing a number of health system strengthening reforms. In view of this, Limpopo Province introduced the ‘Adopt a Clinic’ project managed by Community Service Pharmacists (CSPs) from 2013 to identify service gaps and improve medicines availability, targeted at 90%, at primary health care (PHC) facilities.

Objective. To compare medicines availability at PHC facilities in Limpopo Province during an ‘Adopt a Clinic’ project supported by CSPs in 2014 and 2015 with medicines availability in 2017 (beyond the project) based on the approved provincial medicines list.

Methods. Operational study using an implementation evaluation research design conducted in 49 sampled PHC facilities in Limpopo Province. Data on availability of medicines was collected retrospectively for 2014 and 2015 and prospectively in 2017. A minimum of one medicine line available on the shelf was regarded as available. The percentage medicines availability was summarised per district and per anatomical therapeutic chemical (ATC) classification.

Results. Average medicines availability was 83.0% in 2014 and 2015 with CSP support and 80.6% post support, all below the 90% target. Medicines availability improved further in 2017 following withdrawal of CSP support for certain ATC classes, with the highest availability (96%) for medicines used in diabetes (A10) and medicines for obstructive airway diseases (R03). Antianemic preparations (B03) had the lowest availability (41%) and showed a decrease post CSP support.

Conclusion. There was an increase in medicines availability during the CSP intervention, which decreased when the support was withdrawn. However, even with CSPs’ support, the average percentage availability was below provincial targets. Pharmaceutical services together with districts should develop additional strategies to reach agreed performance levels and improve future care.
Chapter 4: Results and Discussion

Introduction

Medicines availability is a problem in many low and middle income countries (LMICs),\(^1,2\) which was the case in the Limpopo Province in South Africa.\(^3\) In several studies conducted among LMICs, medicines availability ranged between 50% and 65%.\(^4,5,6,7\) Similar trends were observed in Ethiopia, Malawi and Rwanda where more than half of Community Health Centres (CHCs) were out-of-stock of at least one tracer medicine on the day of the assessment.\(^8\) A baseline study conducted in all nine provinces of South Africa in 2012 also reported low average medicines availability at 54%.\(^9\) There were many factors that contributed to this poor performance. In South Africa, inconsistent and part delivery of medicines by medical depots, poor medicines management, shortage of pharmacists and pharmacist assistants as well as lack of electronic medicines management systems have been identified as key factors leading to poor performance.\(^10\) In the Tshwane District, causes of vaccine stock-outs included poor management of stock, district depots out of stock, unreliable deliveries, lack of pharmacist assistants, limited fridge capacity and the ineffective emergency ordering system.\(^11\)

In South Africa, National Health Insurance (NHI) is intended to move the country towards universal health coverage by ensuring that the population has access to quality health services and that the full range of essential medicines and other medical supplies are available in all public health facilities.\(^12\) Medicines availability is one of the pharmaceutical services priorities, monitored at provincial and national levels, with the aim of improving medicines supply management practices and ensuring zero stock-out rates for essential medicines.\(^13,14\) Compliance to the National Core Standards (NCS) for health establishments is enforced by legislation through the Office of the Health Standards Compliance while providing a benchmark of quality of care against which the delivery of health services can be monitored. In future, all health care facilities will have to comply with the standards to deliver services within the NHI.\(^15\)

In preparation of NHI implementation, the National Department of Health (NDoH) in South Africa has implemented a number of health system strengthening reforms such as the Ideal Clinic initiative, which is defined as a clinic with good infrastructure, adequate staff, adequate medicines and supplies, and one that uses pertinent clinical policies and guidelines to ensure the provision of quality health services to the community enhanced by guidelines readily available as APPs.\(^16,17\) Another initiative is the stock visibility solution, called a clinic dashboard, aimed at showing online medicine availability among facilities across South Africa. With the direct delivery strategy, selected facilities obtain their medicines directly from suppliers without passing via provincial pharmaceutical depots. These reforms also aim to achieve a continued dependable supply and reliable payment for goods and services, as well as improved process efficiencies and governance. These changes will assist South Africa in meeting the growing patient needs with the implementation of NHI in a responsive manner.\(^17\)

Since 2007, the Department of Health (DoH) in Limpopo Province embarked on improving medicines availability by setting a target of 90% at primary health care (PHC) facilities.\(^14\) Currently, the NDoH’s annual performance plan requires that all facilities attain 90% medicines availability as a standard.\(^13\) In addition, in 2006 the staff establishment for pharmaceutical services in to address human resource constraints.\(^14\) Medicines stock-outs continued to be a problem provincially and nationally as reported by two audits conducted in the province in 2012, which showed an average medicines
availability of 54% and 73% respectively.\textsuperscript{[3,9]} At the same time, the Limpopo Province initiated a quality improvement project called ‘Adopt a Clinic’. This project was led by Community Service Pharmacists (CSPs), who were expected during their service year to visit their adopted facilities at least once a month. The roles of CSPs included implementing medicines supply management practises to improve medicines availability as well as ensuring compliance to the NCS. Due to the limited number of CSPs, not all PHC facilities were adopted by CSPs and the duration of adoption is limited to one year. This study aimed to compare medicines availability at PHC facilities during the ‘Adopt a Clinic’ project in 2014 or 2015, with the post project medicines availability status in 2017 to provide direction for the future especially if the 90% target is not being reached.

Methods

**Study setting and design**

An operational study using an implementation evaluation research design was conducted in the 49 PHC facilities from five districts of the Limpopo Province. Medicines availability data collected during an ‘Adopt a Clinic’ project for period 01 February 2014 to 30 November 2015 was compared with the after project status in 2017.

**Sampling**

The study population consisted of 286 PHC facilities from Limpopo Province which were adopted in 2014 or 2015 as part of the ‘Adopt a Clinic’ project. The sample consisted of 49 PHC facilities which met the selection criteria. Exclusion criteria were PHC facilities with incomplete ‘Adopt a Clinic’ project reports for 2014 or 2015, PHC facilities meeting the criteria but having been re-adopted in 2016 and those that had a permanent post-basic pharmacist assistant (PBPA) appointed.

**Data collection and analysis**

Medicines availability data were collected retrospectively from the 2014 or 2015 ‘Adopt a Clinic’ project reports and prospectively in 2017. Retrospective data consisted of two sets of data which were collected at the beginning of the project in 2014 or 2015 referred to as baseline, and at the end of the project in 2014 or 2015 referred to as CSP intervention. Prospective data referred to as CSP post-intervention were collected in 2017 over a period of three months by one of the authors assisted by two pharmacists and two PBPA\textregistered s using Limpopo Province’s PHC medicines list. CSPs post-intervention data were collected by physically checking medicines availability in storage bin locations where a minimum of one pack per medicine line seen on the shelf was regarded as available.

Data were checked, sorted and arranged in Microsoft Excel\textsuperscript{®} before statistical analysis using SAS Release 9.4. Percentage medicines availability was calculated for each facility and grouped per district to obtain a district mean and median. Data were tested for significance, with the paired t-test being used to determine difference in means and the Wilcoxon signed rank test to measure difference in medians. Percentage medicines stock out was calculated from CSPs post-intervention data and a cut-off point was for products that were out of stock in at least 30% of facilities. Medicines for all clinics were classified by their international non-proprietary name (INN) as well as grouped by Anatomical Therapeutic classification (ATC) system\textsuperscript{[18]} to determine medicines availability for different diseases.
Ethical considerations
Ethical clearance for the study was granted by the Sefako Makgatho University Research Ethics Committee (SMUREC/H/247/2016:PG) and permission to conduct the study was obtained from the Limpopo Province Department of Health Research Ethics Committee (Ref 4/2/2).

Results
Table 1 shows a summary of the mean and the median medicines availability values per district. The mean and median procedures were evaluated to determine if there was a significant change from the period involving CSPs to post CSP intervention. The average medicines availability was higher during CSP intervention; however, none of the districts reached the 90% target.

Table 1: Mean and median medicines availability at baseline, with CSP intervention and post CSP intervention

<table>
<thead>
<tr>
<th>Districts</th>
<th>Mean % (Standard Deviation)</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Capricorn</td>
<td>Vhembe</td>
</tr>
<tr>
<td>Baseline (2014 or 2015)</td>
<td>85.4 (6.8)</td>
<td>66.5 (12.6)</td>
</tr>
<tr>
<td>CSP Intervention (2014 or 2015)</td>
<td>88.3 (6.0)</td>
<td>82.5 (7.3)</td>
</tr>
<tr>
<td>Change from Baseline to CSP Intervention</td>
<td>2.9 (5.5)</td>
<td>16.0 (14.6)</td>
</tr>
<tr>
<td>P (Paired t-test)</td>
<td>0.045</td>
<td>0.017</td>
</tr>
<tr>
<td>Post CSP Intervention (2017)</td>
<td>79.7 (6.7)</td>
<td>84.6 (3.6)</td>
</tr>
<tr>
<td>Change from CSP Intervention to Post CSP Intervention</td>
<td>-8.6 (8.3)</td>
<td>2.1 (8.9)</td>
</tr>
<tr>
<td>P (Paired t-test)</td>
<td>0.001</td>
<td>0.52</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Districts</th>
<th>Median % (Quartile 1, Quartile 3)</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Capricorn</td>
<td>Vhembe</td>
</tr>
<tr>
<td>Baseline (2014 or 2015)</td>
<td>88.4 (81, 90.2)</td>
<td>66.9 (59.2, 76.1)</td>
</tr>
<tr>
<td>CSP Intervention (2014 or 2015)</td>
<td>89.2 (86.6, 91.1)</td>
<td>83 (75.5, 89.4)</td>
</tr>
<tr>
<td>Change from Baseline to CSP Intervention</td>
<td>1.7 (-2.2, 8.1)</td>
<td>18.6 (17.3, 30.1)</td>
</tr>
<tr>
<td>P (Wilcoxon signed rank test)</td>
<td>0.072</td>
<td>0.039</td>
</tr>
<tr>
<td>Post CSP Intervention (2017)</td>
<td>80.4 (75, 81.3)</td>
<td>86 (81.2, 87.5)</td>
</tr>
<tr>
<td>Change from CSP Intervention to Post CSP Intervention</td>
<td>-5.9 (-15.2, -4.5)</td>
<td>3 (-5.8, 9.9)</td>
</tr>
<tr>
<td>P (Wilcoxon signed rank test)</td>
<td>0.001</td>
<td>0.547</td>
</tr>
</tbody>
</table>

Figure 1 illustrates the 10 specific facilities (20%) where medicines availability improved during the CSP intervention period and continued post CSP intervention.
Chapter 4: Results and Discussion

Figure 1: PHC facilities that showed constant improvement in medicines availability across all study phases (n=49)

Figure 2 depicts individual medicine lines which were out of stock in most PHC facilities during the post CSP intervention measurement, arranged in descending order.
Table 2 shows medicines availability for commonly treated diseases at PHC level arranged per ATC class at baseline, during CSP intervention and post CSP intervention.
### Table 2: Medicines availability per ATC class at baseline, during CSP intervention and post CSP intervention

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A07</td>
<td>Antidiarrheals, intestinals, antiinflammatory/antiinfective agents</td>
<td>64%</td>
<td>62%</td>
<td>57%</td>
</tr>
<tr>
<td>A10</td>
<td>Medicines used in Diabetes</td>
<td>71%</td>
<td>59%</td>
<td>96%</td>
</tr>
<tr>
<td>A11</td>
<td>Vitamins</td>
<td>64%</td>
<td>60%</td>
<td>89%</td>
</tr>
<tr>
<td>A12</td>
<td>Mineral Supplements</td>
<td>49%</td>
<td>59%</td>
<td>81%</td>
</tr>
<tr>
<td>B02</td>
<td>Antibiotics, antiinfective agents</td>
<td>58%</td>
<td>61%</td>
<td>90%</td>
</tr>
<tr>
<td>B03</td>
<td>Antianemic preparations</td>
<td>31%</td>
<td>47%</td>
<td>41%</td>
</tr>
<tr>
<td>B05</td>
<td>Blood substitutes and perfusion solutions</td>
<td>63%</td>
<td>61%</td>
<td>64%</td>
</tr>
<tr>
<td>C01</td>
<td>Cardiac Therapy</td>
<td>70%</td>
<td>68%</td>
<td>92%</td>
</tr>
<tr>
<td>C03</td>
<td>Diuretics</td>
<td>69%</td>
<td>63%</td>
<td>88%</td>
</tr>
<tr>
<td>D07</td>
<td>Corticosteroids, Dermatological preparations</td>
<td>67%</td>
<td>51%</td>
<td>71%</td>
</tr>
<tr>
<td>D08</td>
<td>Antiseptics and Disinfectants</td>
<td>76%</td>
<td>68%</td>
<td>86%</td>
</tr>
<tr>
<td>G01</td>
<td>Gynecological antiinfectives and antiseptics</td>
<td>71%</td>
<td>69%</td>
<td>90%</td>
</tr>
<tr>
<td>G02</td>
<td>Other gynecologicals</td>
<td>67%</td>
<td>67%</td>
<td>90%</td>
</tr>
<tr>
<td>G03</td>
<td>Sex hormones and modulators of the genital system</td>
<td>73%</td>
<td>66%</td>
<td>89%</td>
</tr>
<tr>
<td>H02</td>
<td>Corticosteroids for systemic use</td>
<td>59%</td>
<td>60%</td>
<td>66%</td>
</tr>
<tr>
<td>J01</td>
<td>Antibacterials for systemic use</td>
<td>57%</td>
<td>59%</td>
<td>62%</td>
</tr>
<tr>
<td>J04</td>
<td>Antimycobacterials</td>
<td>64%</td>
<td>59%</td>
<td>77%</td>
</tr>
<tr>
<td>J05</td>
<td>Antivirals for systemic use</td>
<td>64%</td>
<td>62%</td>
<td>89%</td>
</tr>
<tr>
<td>J07</td>
<td>Vaccines</td>
<td>70%</td>
<td>62%</td>
<td>85%</td>
</tr>
<tr>
<td>M01</td>
<td>Antiinflammatory and antirheumatic products</td>
<td>67%</td>
<td>63%</td>
<td>78%</td>
</tr>
<tr>
<td>M02</td>
<td>Topical products for joint and muscular pains</td>
<td>76%</td>
<td>69%</td>
<td>92%</td>
</tr>
<tr>
<td>N02</td>
<td>Analgesics</td>
<td>63%</td>
<td>59%</td>
<td>93%</td>
</tr>
<tr>
<td>N05</td>
<td>Psycholeptics</td>
<td>33%</td>
<td>37%</td>
<td>46%</td>
</tr>
<tr>
<td>P01</td>
<td>Antiprotozoals</td>
<td>46%</td>
<td>42%</td>
<td>69%</td>
</tr>
<tr>
<td>R03</td>
<td>Medicines for Obstructive Airway Diseases</td>
<td>65%</td>
<td>53%</td>
<td>96%</td>
</tr>
<tr>
<td>R06</td>
<td>Antihistamines for Systematic Use</td>
<td>61%</td>
<td>48%</td>
<td>85%</td>
</tr>
<tr>
<td>S01</td>
<td>Ophthalmologicals</td>
<td>57%</td>
<td>53%</td>
<td>65%</td>
</tr>
<tr>
<td>V04</td>
<td>Diagnostic Agents</td>
<td>73%</td>
<td>67%</td>
<td>75%</td>
</tr>
<tr>
<td>V07</td>
<td>All other non-therapeutic products</td>
<td>67%</td>
<td>67%</td>
<td>89%</td>
</tr>
</tbody>
</table>

### Discussion

Medicines availability calculated per district showed an average improvement from 76% at baseline to 83% during the CSP intervention. This was certainly an improvement on the 54% reported among the nine South African Provinces in 2012,\(^7\) however, below approved targets.

According to the project scope, CSPs were expected to visit the adopted PHC facilities at least once a month to provide support on implementation of medicines supply management practices. The continuous presence of CSPs could have contributed to a significant improvement in medicines availability. This was further demonstrated by a significant decline in medicines availability post CSP interventions (Table 1), which could be due to a...
lack of dedicated pharmacy personnel to coordinate all activities that were performed by CSPs during the project. In the absence of CSPs, nursing personnel are expected to take care of all pharmaceutical activities in addition to other programmes they manage on a daily basis. The additional responsibilities for nursing personnel might have resulted in pharmacy activities being compromised. This will be explored further in future research projects given concerns with the lack of essential medicines availability.

The average change in medicines availability from baseline to CSP intervention showed a mean increase of 7.1%, and a median increase of 8.0%, although not statistically significant. On the other hand, the change from the CSP intervention to post CSP intervention showed a mean decrease of -2.4% and a median decrease of -0.96% in medicines availability, although in both cases also not statistically significant (Table 1).

Vhembe and Waterberg were the only districts that consistently improved in average medicines availability throughout the study period (Table 1). Vhembe had a pharmacist appointed at Makhado CHC whose responsibilities were to mentor and train CSPs, pharmacist assistants and nursing personnel on medicines supply management practices. Lessons learnt from the Vhembe district in having an appointed pharmacist at the CHC level to coordinate pharmacy activities at PHC facilities could inspire other districts to fill the vacant pharmacists’ posts at CHC level. This is again something that will be investigated in future.

All four Waterberg district PHC facilities are supported by George Masebe hospital, which was among the top performers in the 2016 Limpopo Pharmaceutical Services Awards. The hospital had also reported an average of 80% medicines availability on the NDoH hospital dashboard in the 2016/2017 financial year, which may explain why all four PHC facilities performed well following withdrawal of CSPs support [19].

Lonsdale and Matlala clinics supported by WF Knobel hospital were the only two PHC facilities in the Capricorn district which showed improvement in medicines availability throughout the study period. WF Knobel, like George Masebe, has been a constant performer both in the province and at national level [19]. It has also been noted that Matlala clinic appointed a PBPA after the sample had been finalized, which could well have contributed to its good performance.

At PHC facilities, only nursing personnel specialised in psychiatry can prescribe antipsychotic medicines. Due to shortage of staff with this speciality, most facilities did not keep these medicines as observed at the time of data collection (Figure 2). Chronic psychiatric patients managed at PHC level are mostly referred from the hospitals, which typically dispense medicines on a monthly basis in line with the individual prescription. Haloperidol injection and zuclopenthixol acetate are part of the emergency product list and they were expected to be available at all times, which was not the case in the study. This will be explored further.

Removal of cefixime tablets and doxycycline capsules from the sexually transmitted infections protocol affected their use. These two medicines were however included in the monitoring list as the provincial medicines list had not yet been updated at the time of data collection. However as expected, their availability would be low as depicted in Figure 2.
The availability of ferrous sulphate tablets has always been a problem in South Africa. An audit conducted in 2016 showed shortages in all nine provinces, with shortages of raw materials at the manufacturer level as the main reason for supply problems. To rectify this, Pharmaceutical Services could advocate the use of alternatives such as the combination of folic acid and ferrous sulphate tablets as an additional item on the PHC list. The fact that ferrous sulphate was not available in many facilities is a serious concern, especially for pregnant women, and this needs to be urgently addressed.

In 2012, Sanofi had problems with the production of Bacillus Calmette-Guérin (BCG) vaccine which led to its withdrawal in 2015. The other main manufacturer, MSD, also experienced BCG vaccine production problems. Additional reasons for BCG vaccine shortages were attributed to supply constraints linked to production, quality assurance and the fact that the Medicines Control Council (current South African Health Products Regulatory Authority) delayed approval of the release of the batches. The shortage of the vaccine has been countrywide since 2012 and hence the low availability noted in some of the PHC facilities in Limpopo Province. In response, the country sourced Biovac as an alternative supplier from 2015 and the situation has improved.

Encouragingly, whilst medicines availability dropped post CSP intervention, the availability per grouped ATC classification showed most improvements post CSP intervention. Here at least 43% (48/112) of medicines had attained availability of at least 90% (Table 2). However, the reasons for improved availability per ATC class at post CSP intervention could though not be fully established in our research.

None of the ATC sub-class medicines though reached 90% availability at baseline and at CSP intervention, and this might well mean that there are additional factors contributing to medicines availability, other than human resources, among PHCs in this Province and wider. Some of the factors contributing to low medicines availability could be challenges with delivery from medical depots, delivery of medicines after lead times have elapsed and part delivery of stock.

With SA being the main consumer of antiretroviral medicines, expectations were that availability of these products would be at 100% at all times as compared to 89% recorded in the post CSP intervention phase. In moving towards NHI implementation, low medicines availability would negatively affect the quality of good services expected to be provided to all citizens and it is therefore very important that all contributory factors be dealt with accordingly. Generally, our results showed better medicines availability during the ‘Adopt a Clinic’ project when PHC facilities were supported by CSPs. However, there are areas for improvement and these will be monitored in the future.

We are aware that there are limitations with the study. Medicine lines with a positive balance on hand were counted as available, which could give the wrong impression of medicines being available but not sufficient to treat all patients. The date of data collection did not take into consideration supplier delivery dates and this would have favoured their availability at PHC facilities visited immediately after supply. Medicines availability data analysis excluded non-pharmaceutical products and there were some that are essential including syringes and needles. The study also did not focus on factors that contributed to low medicines availability. However, we believe our findings are robust providing future direction.
Conclusion and recommendations
The withdrawal of CSP support had a significant impact on the availability of medicines at ambulatory care facilities although the availability per grouped ATC classification showed improvements post CSP intervention. Only 8% of PHC facilities obtained 90% availability when there were no longer CSP support, compared with 33% during CSPs support. Consequently, the province should consider assigning or appointing dedicated pharmacy personnel to support PHC facilities. They could also be used to counsel patients to improve adherence to medicines, which is also a concern in South Africa.

Medicines should furthermore only be deemed available if the quantity on hand is greater or equal to at least one week’s usage derived from previous analysis. Lessons learnt from the Vhembe district CSP coordinator, as well as good service rendered by WF Knobel and George Masebe hospitals, should be used as a model to champion and tackle low medicines availability in the province in the future. This will be monitored in future projects.

Acknowledgements
Special acknowledgements go to Prof H Schoeman who assisted with the statistical analysis of data.

Funding
No funding was provided for this project.

Conflict of interest
The authors declare no conflict of interest.

References
Chapter 4: Results and Discussion


4.3 MANUSCRIPT 2

4.3.1 Manuscript 2: Letter to the editor

This section contains the letter to the editor of the African Journal of Primary Health Care & Family Medicine, which will accompany the submission of the manuscript to the journal.
Editor in Chief  
African Journal of Primary Health Care & Family Medicine

Dear Sir/Madam

RE: SUBMISSION OF MANUSCRIPT: Compliance to quality standards by Limpopo Province Primary Health Care facilities as part of an ‘Adopt a Clinic’ community service pharmacist project

We are pleased to submit an original research article entitled ‘Compliance to National Core Standards and Ideal Clinic standards by Limpopo Province Primary Health Care facilities as part of Adopt a Clinic’ Project by Thabang Segolela, Johanna Meyer, Elvera Helberg and Mulatedzi Makhado for consideration to be published in African Journal of Primary Health Care & Family Medicine.

The research topic covered various aspects of quality standards in healthcare delivery at primary health care level. We therefore consider it appropriate for publication by African Journal of Primary Health Care & Family Medicine. In this manuscript, the results showed that NCS compliance in the medicines storeroom, which is one of the requirements for delivering services within the National Health Insurance, is dependent on the availability of human resources.

This manuscript has not been published and is not under consideration for publication elsewhere. We have no conflicts of interest to disclose.

Yours faithfully,

Thabang Segolela

15 March 2019

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4.3.2 Manuscript 2 for publication

Compliance to quality standards by Limpopo Province Primary Health Care facilities as part of an ‘Adopt a Clinic’ community service pharmacist project

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Keywords: National Core Standards; Ideal Clinic; National Health Insurance; Primary Health Care; Community Service Pharmacists
Abstract

Background: Two health facility audits were conducted to assess compliance to National Core Standards (NCS) in 2012 and the identified shortcomings led to the introduction of the Ideal Clinic initiative and an ‘Adopt a Clinic’ community service pharmacist (CSP) quality improvement project.

Aim: The aim was to compare compliance to NCS and Ideal Clinic standards at baseline and during the ‘Adopt a Clinic’ project in 2014 and 2015 with the post-project compliance status in 2017.

Setting: Primary health care (PHC) facilities from the five districts of Limpopo Province.

Methods: An operational quantitative study using observation and document review data collection techniques. Retrospective (2014 and 2015) and prospective (2017) data were collected from the 49 sampled PHC facilities using NCS or Ideal Clinic checklists.

Results: Compliance to NCS and Ideal Clinic indicators improved significantly at the time of CSP intervention which on average declined following withdrawal of CSP support. The non-compliance was most notable in areas such as: availability of standard operating procedures and standby generators, record keeping and control of medicines in the consulting room.

Conclusion: The improved compliance status attained during CSP support demonstrated the need to either sustain the ‘Adopt a Clinic’ project or permanently appoint pharmacy personnel at PHC level.
Chapter 4: Results and Discussion

Introduction
In South Africa, poor quality of health services is a challenge that affects the regular users of the health system negatively. Long waiting times, unhygienic conditions, discourteous staff, unavailability of essential medicines and dilapidated facilities are among the most common challenges faced by the public sector[1]. Similar non-compliant challenges were observed during the National Core Standards (NCS) baseline audit[2] of the National Department of Health (NDoH) and the Limpopo Province facilities audit, which included selected Mopani district primary health care (PHC) facilities’ medicines storerooms[3]. The other problem areas identified by the two audits were insufficient storage space, poor records management, poor inventory management, low medicines availability, expired medicines and lack of accountability[2, 3]. Several countries have introduced health standards to measure compliance of their health facilities aimed at improving the quality of services rendered to patients and meeting the requirements of Universal Health Coverage to ensure that all citizens can access essential quality health services[1, 4].

The South African government led by the Minister of Health visited Brazil to learn lessons about mechanisms used to improve PHC services which eventually led to the Re-engineering PHC in South Africa[5]. In addressing the challenges encountered through the re-engineering of PHC facilities, a set of ‘Core Standards for Health Establishments’ was published in 2011. Subsequently, the Office of Health Standards Compliance (OHSC) was established to monitor healthcare service delivery and enforce compliance to quality standards for all health establishments in South Africa[1]. Like in South Africa, the Indian and Egyptian Ministry of Health have successfully developed and implemented an accreditation programme including standards for PHC centres. An accreditation would be awarded to facilities that complied with the standards for a specific period depending on the level of performance [6, 7].

Shortcomings identified during a NDoH baseline audit led to the introduction of the Ideal Clinic initiative which is a quality improvement strategy, aimed at uplifting the standards of healthcare services rendered by PHC facilities. Furthermore, it also lays a strong foundation for the successful implementation of National Health Insurance (NHI) as South Africa is progressing with universal health coverage for all people of South Africa regardless of their socioeconomic status [4, 8]. An Ideal Clinic is defined as a clinic “with good infrastructure, adequate staff, adequate medicines and supplies, good administrative processes and sufficient bulk supplies, that uses applicable clinical policies, protocols, guidelines as well as partner and stakeholder support, to ensure the provision of quality health services to the community”[8].
In addition to the two audits\(^2,^3\) the OHSC further assessed NCS compliance of 1,427 public hospitals and PHC facilities over a 4-year period ending 31 March 2016, with results showing that only 6% (89/1427) of all facilities achieved the minimum requirement of 70% compliance\(^9\). In response to the findings from NCS compliance audit in Limpopo Province, the ‘Adopt a Clinic’ Project was introduced in 2013. Within this project community service pharmacists (CSPs) provide support to PHC facilities by ‘adopting’ the facility, in most cases a clinic, for a 12-month period. The aim of the programme is to support PHC facilities on any matter related to medicines supply management practices and compliance to quality standards, in preparation for NHI implementation\(^10\). This study aimed at comparing compliance to quality standards at baseline and during the CSP interventions in 2014 or 2015 with the post CSP intervention project status in 2017.

**Research methods and design**

**Study design and setting**

An operational study using an implementation evaluation research design was conducted in 49 selected PHC facilities from the five districts in the Limpopo Province. Figure 1 shows the distribution of sampled PHC facilities within the Province.

![Limpopo Province map with sampled PHC facilities](image)
Study population and sampling strategy

The study population consisted of 286 PHC facilities from Limpopo Province which were adopted in 2014 or 2015 as part of the ‘Adopt a Clinic’ project. The sample consisted of 49 PHC facilities which met the selection criteria. Exclusion criteria were PHC facilities with incomplete ‘Adopt a Clinic’ project reports for 2014 or 2015, PHC facilities meeting criteria but having been re-adopted in 2016 and those that had a permanent Post Basic Pharmacist Assistant (PBPA) appointed.

Data collection and analysis

National Core Standards and Ideal Clinic checklists were used to collect retrospective data from 2014 or 2015 ‘Adopt a Clinic’ project reports and prospectively in 2017. Retrospective data consisted of two sets of data which were collected at the beginning of the project in 2014 or 2015, referred to as baseline, and at the end of the project in 2014 or 2015 referred to as CSP intervention. Prospective data, referred to as the post CSP intervention, were collected from January to July 2017. Post CSP intervention data were collected by physically observing the status of compliance per checklist item.

Data were checked, sorted and cleaned in Microsoft Excel® followed by statistical analysis using SAS Release 9.4. Data from 11 PHC facilities could not be analysed, as three and eight clinics respectively did not have complete retrospective data on the NCS and the Ideal Clinic standards. Overall, data for 38 facilities were analysed, 10 on the NCS and 28 on the Ideal Clinic standards. Percentage compliance with standards was calculated for each facility, based on the number of compliant items divided by the maximum number of possible items on the particular checklist. Results were grouped per district to obtain a district mean and median compliance. Compliance at baseline before the intervention, at the CSP intervention and post CSP intervention were compared to establish the impact of the CSP interventions. Differences were tested for significance, using the paired t-test for means and the Wilcoxon signed rank test for medians.

Changes from baseline to CSP intervention and post CSP intervention were tracked to assess the impact of CSPs on PHC facilities compliance. These included a change from non-compliance to compliance status, and a change from compliance to non-compliance. The z test was used to test the significance of a percentage of positive changes, namely by testing the null hypothesis of 50% positive changes against the alternative hypothesis of more than 50%.


**Ethical Considerations**

Ethical clearance for the study was granted by Sefako Makgatho University Research Ethics Committee (SMUREC/H/247/2016: PG) and permission to conduct the study was obtained from Limpopo Department of Health Research Ethics Committee (Ref:4/2/2).

**Results**

The performance of 28 PHC facilities assessed on the Ideal Clinic indicators are presented in Figure 2. From the assessed PHC facilities, performance declined in 64% (18/28), sustained in 11% (3/28) and improved in 25% (7/28) of facilities post CSP intervention.

![Figure 2: Performance of PHC facilities on Ideal Clinic indicators](image)

Table 1 shows a summary of the mean and the median percentage compliance with Ideal Clinic standards in Capricorn and Sekhukhune districts. The mean and median compliance percentages were compared to determine if there was a significant change from baseline to the period during the CSP intervention, and to the period post CSP intervention.
Table 1: Mean and median compliance with Ideal Clinic standards at baseline, CSP intervention and at post CSP intervention

<table>
<thead>
<tr>
<th>Districts</th>
<th>Mean % (Standard Deviation)</th>
<th>Median % (Quartile 1, Quartile 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Capricorn</td>
<td>Sekhukhune</td>
</tr>
<tr>
<td>Mean Compliance at Baseline (2014 or 2015)</td>
<td>19.1 (8.1)</td>
<td>19.9 (3.0)</td>
</tr>
<tr>
<td>Mean Compliance at CSP Intervention (2014 or 2015)</td>
<td>27.6 (4.9)</td>
<td>27.6 (2.7)</td>
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<td>Mean Change from Baseline to CSP Intervention</td>
<td>8.5 (7.6)</td>
<td>7.7 (2.8)</td>
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<tr>
<td>P (Paired t-test)</td>
<td>0.001</td>
<td>0.001</td>
</tr>
<tr>
<td>Mean Compliance at Post CSP Intervention (2017)</td>
<td>23.4 (4.6)</td>
<td>25.6 (2.6)</td>
</tr>
<tr>
<td>Mean Change from CSP Intervention to Post CSP Intervention</td>
<td>-4.2 (4.9)</td>
<td>-2.0 (3.3)</td>
</tr>
<tr>
<td>P (Paired t-test)</td>
<td>0.004</td>
<td>0.069</td>
</tr>
</tbody>
</table>

The summary of the average percentage compliance with the NCS for the 10 assessed PHC facilities are shown in Figure 3. At post CSP intervention, all PHC facilities’ compliance declined except for Makhushane clinic which maintained the 77% compliance attained during the CSP intervention.
Figure 3: Summary of NCS compliance for assessed PHC facilities

Figure 4 presents the percentage compliance with the NCS on storage area, access control and cold chain management for the 10 PHC facilities. The results showed that 60% of PHC facilities improved compliance post CSP intervention.
Figure 5 presents the summary results of performance on documentation and record keeping as part of NCS compliance. Makhushane was the only PHC facility that improved in this category at post CSP intervention.

Table 2 shows a summary of the mean and the median percentage compliance with NCS on storage area, access control and cold chain management for the 10 PHC facilities. The mean and median compliance percentages were compared to determine if there was a significant change from baseline to the period during the CSP intervention, and to the period post CSP intervention.

Figure 5: Percentage compliance to NCS on documentation and record keeping per facility

Table 2 shows a summary of the mean and the median percentage compliance with NCS on storage area, access control and cold chain management for the 10 PHC facilities. The mean and median compliance percentages were compared to determine if there was a significant change from baseline to the period during the CSP intervention, and to the period post CSP intervention.
### Table 2: Mean and median percentage compliance with NCS at baseline, CSP intervention and post CSP intervention

<table>
<thead>
<tr>
<th>Checklists</th>
<th>Mean % (Standard Deviation)</th>
<th>Median % (Quartile 1, Quartile 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Medicine storage and cold chain management</td>
<td>Record keeping and expiry of medicines</td>
</tr>
<tr>
<td>Baseline (2014 or 2015)</td>
<td>12.1 (3.07)</td>
<td>3.5 (2.12)</td>
</tr>
<tr>
<td>CSP Intervention (2014 or 2015)</td>
<td>15.7 (1.42)</td>
<td>6.4 (0.97)</td>
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<tr>
<td>Change from Baseline to CSP Intervention</td>
<td>3.6 (2.84)</td>
<td>2.9 (2.69)</td>
</tr>
<tr>
<td>P (Paired t-test)</td>
<td>0.003</td>
<td>0.008</td>
</tr>
<tr>
<td>Post CSP Intervention (2017)</td>
<td>15.9 (1.79)</td>
<td>5.6 (0.97)</td>
</tr>
<tr>
<td>Change from CSP Intervention to Post CSP Intervention</td>
<td>0.2 (1.99)</td>
<td>-0.8 (1.14)</td>
</tr>
<tr>
<td>P (Paired t-test)</td>
<td>0.758</td>
<td>0.053</td>
</tr>
</tbody>
</table>

### Discussion

#### Ideal Clinic Standards

At the time of CSP intervention, 89% (25/28) of facilities improved on compliance to Ideal Clinic indicators from baseline status and 50% (14/28) reached the 80% Ideal Clinic compliance target\[8\]. Although 50% of facilities reached the 80% Ideal Clinic target during the CSP intervention, it could not be concluded that they have attained Ideal Clinic status as the study only focused on the pharmacy, which is one of the sections in a facility. Following the withdrawal of the CSP support, a decline of 64% (16/25) was observed, 12% (3/25) remained unchanged and an improvement was noted in 24% (6/25) of facilities. Even though there was a major decline at post CSP intervention, 29% (8/28) of facilities reached the 80% Ideal Clinic target or above.

The absence of CSP oversight meant that there was no longer dedicated personnel to maintain what was attained by the CSPs, hence the decline. Experience has shown that participatory evaluation improves programme performance\[11\], meaning that personnel will
generally perform well under constant monitoring. For instance, SOPs were distributed to all PHC facilities in the province during the 2014/2015 financial year and each PHC facility was expected to have a copy. The fact that copies of SOPs were no longer available in some facilities at the time of data collection, highlights non-prioritisation of certain indicators as they were no longer constantly monitored.

Amongst the three districts that were assessed on the Ideal Clinic standards, Vhembe District was a top performer. The presence of dedicated pharmacists for the day to day clinic activities contributed towards strengthening services and improvement of compliance in the district beyond the CSP intervention. PBPAs in the Vhembe District were roped in to be part of the CSP team that visited and supported the clinics, which effectively translate to building capacity and ensuring sustainability.

Section 38(1) (d) of the Public Finance Management Act (PFMA) states that it is the duty of an accounting officer of an institution to take full responsibility and ensure that proper control systems exist for assets and that (a) preventative mechanisms are in place to eliminate theft, losses, wastage and misuse; and (b) stock levels are at an optimum and economical level. The accounting officer must ensure that processes (whether manual or electronic) and procedures are in place for the effective, efficient, economical and transparent use of the institution’s assets\[^{12}\]. In contrary to what the PFMA requires, the status achieved by CSPs could not be maintained.

Facilities can use an expiry dates analysis to determine if they can use all of their short-dated medicines before the expiry date\[^{13}\]. A number of mechanisms are available to guide facilities on prevention and management of expiry of medicines. For instance, special conditions of pharmaceutical contracts empower facilities to take appropriate action and it stipulates that a supplier should furnish a guarantee letter that would allow a facility to return excess unused expired medicines if the expiry date of the product at the time of issue was below 18 months of expiry\[^{14}\]. It was expected that PHC facilities would be furnished with guaranteed letters from the supplier for products issued with an expiry date of less than 18 months but it was not the case in most of facilities.

The average change in Ideal Clinic standards compliance from baseline to CSP intervention showed a mean (8.5%) and median (8.0%) increase in the Capricorn District and a mean (7.7%) and median (8.0%) increase in Sekhukhune District, of which all were statistically significant (p<0.001).
Chapter 4: Results and Discussion

National Core Standards

National Core Standards compliance status showed improvement or sustainability from all 10 PHC facilities during the CSP intervention in comparison with the status at baseline. The CSP interventions in 80% (8/10) of facilities exceeded the minimum NCS compliance status of 80%. The compliance status declined in 90% (9/10) of facilities after withdrawal of the CSP support but the level of decline did not reach the baseline status, except for Chalema clinic. The decline clearly indicates the importance of having pharmacy personnel constantly supporting PHC facilities. Without pharmacy personnel support, it may be difficult for nursing personnel to attain the compliance status achieved during the CSP intervention and this may be a challenge in moving towards NHI implementation.

Most clinics (60%) performed well even at post CSP intervention on medicines storage, access control and cold chain management. At the time of data collection, medicines storerooms were locked when not in use, which is a good practice to ensure that stock is not accessed by unauthorised personnel. Since all PHC facilities in the Province are required to comply with Ideal Clinic standards, the installation of burglar bars that were seen in some of the facilities at the time of data collection, could be an indication that the Province has started addressing Ideal Clinic gaps in preparation for NHI.

Good performance was also observed in cold chain management, which could be attributed to cold chain management and medicine supply management training conducted throughout the Province by Management Sciences for Health (MSH) and LDoH. It has also been noted that cold chain management is regularly monitored by the clinic supervisors as part of the Expanded Programme on Immunization indicators and hence the high level of compliance.

All records must be managed in accordance with state law. The principal task of records management and records managers is to help employees manage the records in their facilities. This includes helping employees to know how to organize materials so that those who need them can find them; which records are vital and valuable; how to preserve records; and how and when to dispose of records or to identify non-records that can be disposed of immediately\(^{15,16}\). According to Good Pharmacy Practice of South Africa, a facility should ensure the correct and effective record keeping of the purchase, sale, possession, storage, safekeeping and return of medicines or scheduled substances\(^{17}\). Section 40(1)(a) of the PFMA states that accounting officers of institutions must, subject to the provisions of the National Archives of South Africa Act (Act 43 of
1996), retain all financial information in its original form. Limpopo Province Pharmaceutical Services in collaboration with MSH developed manuals for SOPs, which were distributed to all clinics in 2014 but more than half of facilities neither had the copy nor knowing the existence of such documents at the time of data collection. This has highlighted challenges of record keeping that facilities are encountering which need to be addressed more in particular in preparation towards implementing NHI.

There was a statistically significant increase in the mean percentage compliance from baseline to CSP intervention on medicine storage and cold chain management (3.6%; \( p=0.003 \)), record keeping and expiry of medicines (2.9%; \( p=0.008 \)) and medicine storage in consulting rooms (3.3%; \( p=0.002 \)). Similarly, the statistically significant increase in median values were on medicine storage and cold chain management (3.0%; \( p=0.004 \)), record keeping and expiry of medicines (2.5%; \( p=0.016 \)) and medicine storage in consulting rooms (3.5%; \( p=0.008 \)).

The period from CSP intervention to post CSP intervention, showed a statistically significant increase in the mean (0.2%) and median (1.0%) on medicines storage and cold chain management. In contrast, the statistically insignificant decrease in mean (0.8%) and median (1.0%) values on record keeping and expiry of medicines were noted. The mean and median percentage compliance on medicine storage in consulting rooms decreased significantly by 2.0% (\( p=0.017 \)) and 2.0% (\( p=0.031 \)) respectively.

In summary, there was a significant improvement in all focus areas in terms of the NCS and Ideal Clinic standards during the CSP intervention. This means that CSPs support to PHC facilities resulted in a vast improvement on compliance to standards which could serve as a foundation in scaling up PHC pharmacy readiness for NHI implementation. On the contrary, all focus areas showed a decline in compliance post CSP intervention. It is therefore very clear that the presence of CSPs aided PHC facilities to improve compliance with quality standards.

It is recommended that pharmacy documents be stored in the medicine room where they can be accessed, that nursing personnel be trained on record keeping and documentation, and that the Pharmaceutical Services budget should make provision to fill vacant PBPA positions at PHC facilities.
Conclusion
The impact made by CSPs was very evident as the compliance levels to quality standards was high in almost every aspect, which later declined following the withdrawal of CSP support to PHC facilities in 2017. Although some positive changes were noted which were attributed to support from the pharmacy department, pharmacy personnel alone may not change the status of compliance to NCS and Ideal Clinic standards without team work, collaboration and involvement of all other key stakeholders. In preparation for NHI implementation, the Pharmaceutical Services Directorate has an important role to play in ensuring that pharmaceutical services rendered are of good quality in line with defined standards.

Acknowledgements
The authors thank the Limpopo Department of Health for making their facilities available to conduct the study. The data collectors are appreciated for their role in the data collection. District Managers, Operational Managers, Pharmacy Managers and nursing staff are thanked for their time and support in providing information. Prof HS Schoeman is acknowledged for his contribution towards the statistical analysis of the data.

Competing Interests
The authors declare that there has been no financial or personal relationship(s) that may have inappropriately influenced the writing of this article.

Author’s Contributions
TA Segolela, JC Meyer and E Helberg developed the concept and designed the study. TA Segolela and B Godman conducted the literature review. TA Segolela collected the data, which were supervised by JC Meyer and E Helberg. TA Segolela and M Makhado analysed the data and wrote the first draft of the manuscript. All the authors participated in the interpretation of the data, critical review of subsequent versions of the manuscript as well as contributed significantly to its content. All the authors approved the final version of the manuscript.

Funding
None.

Disclaimer
The views expressed in this manuscript represent those of the authors.
References


Chapter 4: Results and Discussion


CHAPTER 5
LIMITATIONS, RECOMMENDATIONS AND CONCLUSIONS

5.1 INTRODUCTION

In this chapter, the limitations of the study are outlined and recommendations are suggested based on the results. The chapter ends with the final conclusion to the study.

5.2 LIMITATIONS OF THE STUDY

A limitation of the study was that medicine lines with a positive balance on hand were considered as available, which could give the wrong impression of medicines being available but not enough to treat all patients.

The date of data collection did not take into consideration supplier delivery dates and this would have favoured the medicines availability at PHC facilities visited immediately after supply and the reverse for PHC facilities visited much longer after supply.

Medicines availability data analysis excluded non-pharmaceutical products, although there are certain lines that are essentially needed like syringes and needles in order to administer an injection.

The study did not focus on factors that contributed to low medicines availability or poor compliance to NCS or Ideal Clinic standards.

5.3 RECOMMENDATIONS

The following are recommendations of the study:

- Medicines should be deemed available if the quantity on hand is greater or equal to at least one-week usage quantity derived from the past six months usage patterns.

- Lessons learnt from the Vhembe District CSP coordinator, as well as good service rendered by WF Knobel and George Masebe hospitals, should be used as a model to champion and tackle low medicines availability in the province.

- Pharmacy documents should be well protected and stored properly in the medicine store rooms where they can be accessed as appropriate.

- Training of nursing personnel on record keeping and documentations.
• Vacant PBPAs posts in PHC facilities should be filled as a priority to continue providing the type of support provided by CSPs in terms of pharmaceutical services.

5.4 CONCLUSIONS

The impact made by CSPs was very evident as the medicine's availability and compliance to quality standards improved; however, it later declined following the withdrawal of their support to PHC facilities in 2017. In the facilities although some positive changes were noted which were attributed to support from the pharmacy department, pharmacy personnel alone may not change the status of medicines availability and compliance to NCS as well as Ideal Clinic standards without team work, collaboration and involvement of all other key stakeholders.

Factors that contributed to low medicines availability and poor compliance to quality standards were not investigated but they can be attributed to poor implementation of SOPs, vacant PBPA posts, dysfunctional or lack of equipment such as air conditioners and standby generators, insufficient storage space, etc. as found in this study. These attributes should be addressed as a matter of urgency as they are key in facilitating NHI implementation.

Pharmaceutical Services Directorate has an important role to play in ensuring that pharmaceutical services rendered are of good quality in line with defined standards by providing proper management and improved inventory management practices. Primary Health Care facilities are managed by nursing personnel and it is very important that pharmaceutical services collaborate with all other departments within health to identify service delivery gaps, motivate money to address gaps and devise plan of action to improve quality of health services provided to the patients.

Although most of the deficiencies identified can be addressed through mobilization of resources and capacitating health personnel through training and development, these methods alone would not bring the significant improvements unless supported by mentorship and good governance. Exploring mechanisms to retain skilled personnel, gradual introduction of electronic medicines management systems and new supply chain innovations in PHC facilities may provide solution to some of the medicines management practice challenges.
REFERENCES


References


References


References


References


## APPENDICES

### Appendix 1: List of 49 PHC Facilities sampled for the study

<table>
<thead>
<tr>
<th>No</th>
<th>District</th>
<th>Clinic</th>
<th>Status</th>
<th>Adopted with no Pharmacist Assistants</th>
<th>Either NCS or Ideal</th>
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<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>30</td>
<td>Sekhukhune</td>
<td>Marishane</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>31</td>
<td>Sekhukhune</td>
<td>Nchabeleng</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>32</td>
<td>Sekhukhune</td>
<td>Nkoana</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>33</td>
<td>Sekhukhune</td>
<td>Paulus Masha</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>34</td>
<td>Sekhukhune</td>
<td>Philadelphia Gateway</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>35</td>
<td>Sekhukhune</td>
<td>Selepe</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>36</td>
<td>Sekhukhune</td>
<td>Spitzpunt</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>37</td>
<td>Sekhukhune</td>
<td>Witfontein</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>District</td>
<td>Clinic</td>
<td>Status</td>
<td>Adopted with no Pharmacist Assistants</td>
<td>Either NCS or Ideal</td>
</tr>
<tr>
<td>----</td>
<td>-----------</td>
<td>--------------</td>
<td>--------</td>
<td>---------------------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>38</td>
<td>Vhembe</td>
<td>Damani</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>39</td>
<td>Vhembe</td>
<td>Davhana</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>40</td>
<td>Vhembe</td>
<td>Guyuni</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>41</td>
<td>Vhembe</td>
<td>Masisi</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>42</td>
<td>Vhembe</td>
<td>Mbilwi</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>43</td>
<td>Vhembe</td>
<td>Shingwedzi</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>44</td>
<td>Vhembe</td>
<td>Sibasa</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>45</td>
<td>Vhembe</td>
<td>Tshiungani</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>46</td>
<td>Waterberg</td>
<td>Bakenberg</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>47</td>
<td>Waterberg</td>
<td>Chalema</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>48</td>
<td>Waterberg</td>
<td>Mokamole</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
<tr>
<td>49</td>
<td>Waterberg</td>
<td>Segole</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Appendices

Appendix 2: National Core Standards Assessment Questionnaire for PHC facilities

CHECKLIST DOMAIN 3 – CLINICAL SUPPORT SERVICES,

3.1 Pharmaceutical services
Medicines and medical supplies are managed in compliance with relevant legislation and principles of medicine supply management

<table>
<thead>
<tr>
<th>Number of checklist</th>
<th>Criterion</th>
<th>Checklist reference</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1.3.1.1</td>
<td>Medicines are stored and managed in compliance with the Pharmacy Act 53 of 1974, Medicines and Related Substances Act 101 of 1965 and relevant rules and regulations</td>
<td>Good Pharmacy Practice Medicine storage</td>
<td>Medicine is stored correctly as per Good Pharmacy Practice</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of questions</th>
<th>Planned number of responses</th>
<th>Unit where assessed</th>
<th>Type of assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>19</td>
<td>19</td>
<td>Medicine room C04</td>
<td>C04 C04 C04</td>
</tr>
</tbody>
</table>

**Instructions:** In the medicine storage area (pharmacy/pharmacy store in hospitals and some CHCs and medicine rooms in PHC clinics) observe whether there is compliance with each of the aspects listed below. Tick in the Yes column if they are compliant and in the No column if not compliant.

<table>
<thead>
<tr>
<th>No.</th>
<th>Question / Aspect</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Medicines are stored in a secure pharmacy store (hospitals &amp; CHCs) or medicine room (PHC clinics)</td>
</tr>
<tr>
<td>2</td>
<td>The pharmacy, pharmacy store or medicine room is fitted with burglar bars</td>
</tr>
<tr>
<td>3</td>
<td>There is sufficient space in the pharmacy, pharmacy store or medicine room for orderly arrangement of stock and proper stock rotation</td>
</tr>
<tr>
<td>4</td>
<td>The pharmacy, pharmacy store or medicine room is kept locked.</td>
</tr>
<tr>
<td>5</td>
<td>There are no cracks, holes or signs of water damage in the pharmacy, pharmacy store or medicine room. (Yes if no cracks etc. and No if there is)</td>
</tr>
<tr>
<td>6</td>
<td>The storage area is clean and tidy (shelves are dusted, floor is swept, and walls are clean)</td>
</tr>
<tr>
<td>7</td>
<td>Medicines are stored neatly on shelves according to a classification system</td>
</tr>
<tr>
<td>8</td>
<td>There are no medicines stored in direct contact with the floor. (Yes if not stored on floor and No if stored on floor)</td>
</tr>
<tr>
<td>9</td>
<td>There is no evidence of pests in the pharmacy, pharmacy store or medicine room. (Yes if no evidence of pests and No if evidence)</td>
</tr>
<tr>
<td>10</td>
<td>Control of access to pharmacy, pharmacy store or medicine room is of such a nature that only authorized persons have access to the medicine</td>
</tr>
<tr>
<td>Maintenance of the cold chain</td>
<td></td>
</tr>
<tr>
<td>------------------------------</td>
<td></td>
</tr>
<tr>
<td>11 Each refrigerator has a working dial/digital thermometer or alcohol/mercury thermometer (Not a minimum/maximum thermometer)</td>
<td></td>
</tr>
<tr>
<td>12 The temperature in the refrigerator is between 2 and 8°C</td>
<td></td>
</tr>
<tr>
<td>13 The temperature inside the refrigerator is measured twice a day and recorded on a chart</td>
<td></td>
</tr>
<tr>
<td>14 No medicines or vaccines are stored in the refrigerator door. (Yes if no storage in door and No if stored in door)</td>
<td></td>
</tr>
<tr>
<td>15 No food is stored in the refrigerator. (Yes if no food are stored and No if food are stored)</td>
<td></td>
</tr>
<tr>
<td>16 The ice in the refrigerator is less than 10mm thick</td>
<td></td>
</tr>
<tr>
<td>17 A backup system is available for storage of medicines when defrosting the refrigerator</td>
<td></td>
</tr>
<tr>
<td>18 There a standby generator or other emergency power system for use in case of a power failure.</td>
<td></td>
</tr>
<tr>
<td>19 A system is in place to ensure the cold chain is maintained from the time of dispensing to the time of receipt by the end-user (patient)</td>
<td></td>
</tr>
</tbody>
</table>

**Actual Score (Sum of positive responses)**

**Maximum possible score (Sum of all questions minus the not applicable responses)**
CHECKLIST DOMAIN 3 – CLINICAL SUPPORT SERVICES,

3.1 Pharmaceutical services
Medicines and medical supplies are managed in compliance with relevant legislation and principles of medicine supply management

<table>
<thead>
<tr>
<th>Number of checklist</th>
<th>Criterion</th>
<th>Checklist reference</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1.3.1.2</td>
<td>Medicines are stored and managed in compliance with the Pharmacy Act 53 of 1974, Medicines and Related Substances Act 101 of 1965 and relevant rules and regulations</td>
<td>Good Pharmacy Practice Medicine supply management principles</td>
<td>Procedures relating to the management of medicine as required by Good Pharmacy Practice are followed in the pharmacy</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of questions</th>
<th>Planned number of responses</th>
<th>Unit where assessed</th>
<th>Type of assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>8</td>
<td>C04</td>
<td>CC04</td>
</tr>
</tbody>
</table>

Instructions: In the area used for medicine storage (pharmacy/pharmacy store in hospitals and some CHCs and medicine rooms in clinics) observe whether there is compliance with each of the aspects listed below. Tick in the Yes column if they are compliant and in the No column if not compliant

<table>
<thead>
<tr>
<th>No.</th>
<th>Question / Aspect</th>
<th>Yes</th>
<th>No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Standard operating procedures are available for procurement of medicine, receiving of medicine, storage of medicine, issuing of medicine and cold chain management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Documentation showing proof of ordering of stocks of medicine is available</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Documentation showing proof of receipt of stocks of medicine is available</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>A system is in place to ensure packing and issuing of medicine according to FEFO and FIFO principles (as applicable)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>A system is in place to check expiry dates on medicine in the pharmacy and pharmacy store (hospitals and CHCs) or in the medicine room (PHC clinics)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>No expired medicines are observed in the pharmacy or pharmacy store or medicine room (Yes if no expired medicines are observed and No if observed)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>A system is in place to write off any expired medicine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>The member of staff responsible for the stocks of medicine in the health establishment is aware what the budget is for the current financial year</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Actual Score (Sum of positive responses)
Maximum possible score (Sum of all questions minus the not applicable responses)

Final Draft 29 May 2012
# CHECKLIST DOMAIN 3 – CLINICAL SUPPORT SERVICES, PHARMACEUTICAL SERVICES

**3.1 Pharmaceutical services**

Medicines and medical supplies are managed in compliance with relevant legislation and principles of medicine supply management

<table>
<thead>
<tr>
<th>Number of checklist</th>
<th>Criterion</th>
<th>Checklist reference</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1.3.1.3</td>
<td>Medicines are stored and managed in compliance with the Pharmacy Act 53 of 1974, Medicines and Related Substances Act 101 of 1965 and relevant rules and regulations</td>
<td>Medicines storage Good Pharmacy Practice</td>
<td>CHECKLIST - Medicines in the wards or consultation rooms are appropriately stored and managed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of questions</th>
<th>Planned number of responses</th>
<th>Unit where assessed</th>
<th>Type of assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>1</td>
<td>P07 P01 P09 CC04 PC01 PX01 PX03 PX04 PX05 PX06 PX09</td>
<td>OBS</td>
</tr>
</tbody>
</table>

**Instructions:** Observe the listed aspects below in the cupboards or medicine trolleys where medicines are kept in the ward/consulting room. Tick in the Yes column if they are compliant and in the No column if not. Some degree of professional judgment is required to decide if there is compliance or not.

<table>
<thead>
<tr>
<th>No.</th>
<th>Question / Aspect</th>
<th>Yes</th>
<th>No</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Medicines are stored in a secure cupboard or medicine trolley</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>There is sufficient space in the cupboard or medicine trolley for orderly arrangement of medicines and proper stock rotation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>The cupboard or medicine trolley is kept locked.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>The cupboard or medicine trolley is clean and tidy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Medicines are stored neatly according to a classification system</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>There are no medicines stored in direct contact with the floor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>There is no evidence of pests in the cupboard or medicine trolley</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Control of access to cupboard or medicine trolley is of such a nature that only authorized persons have access to the medicine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Documentation showing proof of ordering of stocks of medicine is available</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Documentation showing proof of receipt of stocks of medicine is available</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Description</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>-------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>A system is in place to ensure packing and issuing of medicine according to FEFO and FIFO principles (as applicable)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>A system is in place to check expiry dates of medicine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>No expired medicines are observed</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Actual Score (Sum of positive responses)**

**Maximum possible score (Sum of all questions minus the not applicable responses)**
CHECKLIST DOMAIN 3 – CLINICAL SUPPORT SERVICES,

3.1 Pharmaceutical services
Medicines and medical supplies are managed in compliance with relevant legislation and principles of medicine supply management

<table>
<thead>
<tr>
<th>Number of checklist</th>
<th>Criterion</th>
<th>Checklist reference</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1.3.4.2</td>
<td>Medical supplies are stored and managed in compliance with medicine supply management principles</td>
<td>Medicines storage Good Pharmacy Practice</td>
<td>Medical supplies are stored correctly.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of questions</th>
<th>Planned number of responses</th>
<th>Unit where assessed</th>
<th>Type of assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>9</td>
<td>C04</td>
<td>S14</td>
</tr>
</tbody>
</table>

**Instructions:** In the medical supplies storage area observe whether there is compliance with each of the aspects listed below. Tick in the Yes column if they are compliant and in the No column if not.

<table>
<thead>
<tr>
<th>No.</th>
<th>Question / Aspect</th>
<th>Yes</th>
<th>No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Medical supplies are stored in a secure storage area</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>There is sufficient space in the storage area for orderly arrangement of stock and proper stock rotation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>The storage area is kept locked.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>There are no cracks, holes or signs of water damage in the storage area.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>The storage area is clean and tidy (shelves are dusted, floor is swept, and walls are clean)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Medical supplies are stored neatly on shelves according to a classification system</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>There are no medical supplies stored in direct contact with the floor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>There is no evidence of pests in the storage area</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Control of access to the storage area of such a nature that only authorized persons have access to the medical supplies</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Actual Score (Sum of positive responses)**

**Maximum possible score (Sum of all questions minus the not applicable responses)**
### Appendix 3: Ideal Clinic Checklist

<table>
<thead>
<tr>
<th>No</th>
<th>Inventory Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Inventory Management System for medicines and supplies in place</td>
</tr>
<tr>
<td>2</td>
<td>A system to monitor the stock levels and availability of medicines and supplies</td>
</tr>
<tr>
<td>3</td>
<td>Stock files and orders medicines according to these stock files</td>
</tr>
<tr>
<td>4</td>
<td>Dispensary Room temperature is appropriately controlled</td>
</tr>
<tr>
<td>5</td>
<td>Medicine Store kept locked at all times</td>
</tr>
<tr>
<td>6</td>
<td>A controlled refrigerator to store all temperature sensitive items</td>
</tr>
<tr>
<td>7</td>
<td>Implemented, and use, the Essential Medicines List and STGs for prescriptions</td>
</tr>
<tr>
<td>8</td>
<td>The Standard Operating Procedures for Medical Depots available on site</td>
</tr>
<tr>
<td>9</td>
<td>ART drugs available on site</td>
</tr>
<tr>
<td>10</td>
<td>TB drugs available on site</td>
</tr>
<tr>
<td>11</td>
<td>Vaccines available on site</td>
</tr>
<tr>
<td>12</td>
<td>Vit A available on site</td>
</tr>
<tr>
<td>13</td>
<td>ANC drugs available on site</td>
</tr>
<tr>
<td>14</td>
<td>STI drugs available on site</td>
</tr>
<tr>
<td>15</td>
<td>Chronic drugs available on site</td>
</tr>
<tr>
<td>16</td>
<td>Contraceptives available on site</td>
</tr>
<tr>
<td>17</td>
<td>Mental health drugs available on site</td>
</tr>
<tr>
<td>18</td>
<td>Physical stock correspond with stock on bin cards</td>
</tr>
<tr>
<td>19</td>
<td>Min/Max stock levels are in place for all products</td>
</tr>
<tr>
<td>20</td>
<td>Adequate medication issuing procedures</td>
</tr>
<tr>
<td>21</td>
<td>Pharmacy room temperature is monitored as required</td>
</tr>
<tr>
<td>22</td>
<td>There is a system to monitor and manage short-dated stock received</td>
</tr>
<tr>
<td>23</td>
<td>There are no expired stock on shelves</td>
</tr>
<tr>
<td>24</td>
<td>Supplier provides guaranteed letters for short-dated stock</td>
</tr>
<tr>
<td>25</td>
<td>There is a record of expired medicines and medical suppliers.</td>
</tr>
<tr>
<td>26</td>
<td>Professional nurses dispensing medication are registered with SAPC</td>
</tr>
<tr>
<td>27</td>
<td>Medicine rooms are properly and uniformly labelled in line with Good Pharmacy Practice requirements</td>
</tr>
<tr>
<td>28</td>
<td>All stock cards transactions are recorded and usage figures are totalled per month to inform calculation of stock levels</td>
</tr>
<tr>
<td>29</td>
<td>There are systems in place to manage discrepancies (Facility to provide example of latest discrepancy)</td>
</tr>
<tr>
<td>30</td>
<td>An air conditioner is installed that is in good working order.</td>
</tr>
<tr>
<td>No</td>
<td>Stock Management System</td>
</tr>
<tr>
<td>----</td>
<td>-------------------------</td>
</tr>
<tr>
<td>1</td>
<td>There is a stock card for each item in the storage area.</td>
</tr>
<tr>
<td>2</td>
<td>All information on the stock card is up to date and accurate.</td>
</tr>
<tr>
<td>3</td>
<td>Information is recorded on the stock card at the time of stock movement.</td>
</tr>
<tr>
<td>4</td>
<td>There is an accurate running tally kept in the Balance column.</td>
</tr>
<tr>
<td>5</td>
<td>A physical count is made at regular intervals, such as once a month.</td>
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### Appendix 4: Revised Limpopo Province PHC Medicines Availability Tool

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<td>0136</td>
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<td>22</td>
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<td>2867</td>
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<td>0015</td>
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### Appendices

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<td>PHC</td>
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<td>VS</td>
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<td>PHC</td>
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<td>50</td>
<td>Y2</td>
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<tr>
<td>0277</td>
<td>PHC</td>
<td>Vaccine B C G 20 Dose Vial + Diluent</td>
<td>53</td>
<td>Y2</td>
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<td>0281</td>
<td>PHC</td>
<td>Vaccine Hepatitis B Paed 10 Dose Vial(multidose)</td>
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<td>0280</td>
<td>PHC</td>
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<td>Y2</td>
<td>1</td>
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<td>0282</td>
<td>PHC</td>
<td>Vaccine Oral Polio Trivalent 10 Dose 10</td>
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<td>Y2</td>
<td>1</td>
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<td>PHC</td>
<td>Vaccine Pentaxim Single Dose</td>
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<td>1</td>
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<td>Y2</td>
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<td>ARV</td>
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<td>146</td>
<td>DIS</td>
<td>Abacavir 20mg/ml Oral Sol – 240ml</td>
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<td>ARV</td>
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<td>3515</td>
<td>DIS</td>
<td>Lopinavir / Ritonavir Liq 80/20mg/ml - (5X60ml)</td>
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<td></td>
<td>ARV</td>
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<tr>
<td>3518</td>
<td>DIS</td>
<td>Lopinavir / Ritonavir Caps 200 / 50mg (120’S)</td>
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<td></td>
<td>ARV</td>
</tr>
<tr>
<td>2480</td>
<td>DIS</td>
<td>Tenofovir Emitrici Efavirenz 300/200/600mg Tablets</td>
<td></td>
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<td>ARV</td>
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</table>
Appendices

Appendix 5: SMUREC Clearance Certificate

Sefako Makgatho Health Sciences University
Research & Postgraduate Studies Directorate
Sefako Makgatho University Research Ethics Committee
(SMUREC)

Molotlegi Street, Ga-Rankuwa 0208
Tel: (012) 521 5617/3698 | fax: (012) 521 3749
Email: lorato.phiri@smu.ac.za
P.O. Box 163 Medunsisa 0204

APPROVAL NOTICE - NEW APPLICATION

06 October 2016
Ms TA Segoele
Department of Pharmacy
P.O Box 218
Medunsisa, 0204

MEETING: 08/2016
SMUREC Ethics Reference Number: SMURECH/247/2016: PG

The New Application received on 09 September 2016, was reviewed by members of Sefako Makgatho University Research Ethics Committee 06 October 2016 and was approved on 06 October 2016.

Title: Compliance to the national core standards by primary healthcare facilities as part of the ‘adopt a clinic project’ in Limpopo Province

Researcher: Ms TA Segoele
Supervisor: Prof JC Meyer
Co-supervisor: Ms EA Heberg
Mr M Makhado
Department: Pharmacy
School: Health Care Sciences
Degree: Master of Pharmacy

Please note the following information about your approved research protocol:

Protocol Approval Period: 06 October 2016 – 06 October 2017

Please remember to use your protocol number (SMURECH/247/2016: PG) on any documents or correspondence with the REC concerning your research protocol.

Please note that the REC has the prerogative and authority to ask further questions, seek additional information, require further modification, or monitor the conduct of your research and the consent process.

After Ethical Review: Please note a template of the progress report is obtainable in the Research Office and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit. Translation of the consent document in the language applicable to the study participants should be submitted.

International Organisation (ICRG0008691), Institutional Review Board (IRB000010336) Expiry date: 09 December 2018, Federal Wide Assurance (FWA000023943) Expiry date: 31 August 2017 and NHREC No: REC 210403-003

Sincerely

[Signature]
DR C BAKER
DEPUTY CHAIRPERSON SMUREC
Appendix 6: Limpopo Department of Health Permission Letter

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH

Enquiries: Latif Shamilla (015 293 6650) Ref: 4/2/2

Segolela TA
Sefako Makgatho Health Sciences University
Ga-Rankuwa
0208

Greetings,

RE: Compliance to the National Core Standards by Primary Healthcare facilities as part of the ‘adopt a clinic project’ in Limpopo Province

The above matter refers.

1. Permission to conduct the above mentioned study is hereby granted.
2. Kindly be informed that:-
   - Research must be loaded on the NHRD site (http://nhrd.hst.org.za) by the researcher.
   - Further arrangement should be made with the targeted institutions, after consultation with the District Executive Manager.
   - In the course of your study there should be no action that disrupts the services.
   - After completion of the study, it is mandatory that the findings should be submitted to the Department to serve as a resource.
   - The researcher should be prepared to assist in the interpretation and implementation of the study recommendation where possible.
   - The above approval is valid for a 3 year period.
   - If the proposal has been amended, a new approval should be sought from the Department of Health.
   - Kindly note, that the Department can withdraw the approval at any time.

Your cooperation will be highly appreciated.

Head of Department

[Signature]

Date /4/2/2016

18 College Street, Polokwane, 0700, Private Bag x9302, POLOLKWINTE, 0700
Tel: (015) 293 6000, Fax: (015) 293 6211/20 Website: http://www.limpopo.gov.za
Appendix 7: District Permission Letters

DEPARTMENT OF HEALTH
CAPRICORN DISTRICT

Enq : Malema DMM
Tel : 015 290 9266
From : Primary Health Care
Date : 20 January 2017
To : Segolela TA
Sefako Makgato Health Science University
Ga – Rankuwa
0208

Subject : Compliance to the National Core standards by Primary Health Care facilities as part of the ‘adopt a clinic project’ in Limpopo Province

The above matter refers

1. Permission to conduct the above mentioned study is hereby granted.

2. Kindly be informed that :

   • In the course of your research there should be no action that disrupts the services.
   • After completion of the study, it is mandatory that the findings should be submitted to the Department of serve as a resource.
   • The researcher should be prepared to assist in the interpretation and implementation of the study recommendation where possible.
   • Kindly note, that the Department can withdraw the approval at any time.

Your cooperation will be highly appreciated.

Acting Director PHC

2017/01/20
Appendices

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH
MOPANI DISTRICT

Ref: S4/2/2
Enq: Mohatli IE
Tel: 015 811 6543

To
Seholela T.A
Sefako Makgato Health Sciences University
Ga-Rankuwa
0208

Re: PERMISSION TO CONDUCT RESEARCH IN MOPANI HEALTH FACILITIES: YOURSELF

1. The matter cited above bears reference

2. This serves to respond to the request submitted to research on the topic: “Compliance to the national core standards by Primary Healthcare facilities as part of the ‘adopt a clinic project’ in Limpopo Province, South Africa”.

3. It is with pleasure to inform you about the decision to permit you to conduct research in the facilities within Mopani District.

4. You will be required to furnish Primary Healthcare authorities with this letter for purposes of access and assistance.

5. You are further advised to observe ethical standards necessary to keep the integrity of the facilities.

6. The Mopani District wishes you well in your endeavour to generate knowledge.

[Signature]
District Executive Manager
Date: 2017/02/17
Appendices

DEPARTMENT OF HEALTH
SEKHUKHUNE DISTRICT

Ref: S4/2/2
Enq: Phahlamohlaka MA
Tel: 015 633 2352
E-mail: Phillistus.Mashiane@dhsh.limpopo.gov.za
Date: 2017.01.25

To: Sub-District Managers
Fetakgomo
Ellias Motsoaledi
Ephraim Mogale
Greater Tubatse
Makhuduthamaga

FROM: HUMAN RESOURCE UTILIZATION AND CAPACITY DEVELOPMENT

SUBJECT: APPROVAL FOR PERMISSION TO CONDUCT RESEARCH: COLLECTION OF CLINIC PHARMACY DATA

1. The above matter bears reference.

2. The Head of Department has granted approval for Segolela TA from Sefako Makgatho Health Sciences University to conduct the above mentioned study at selected PHC facilities. Data will be collected in the medicine store room using the medicine availability and the national core standards tools.

3. Please note that on the day of data collection the Operational Manager will be requested to sign a consent form. All collected information will be kept confidential in line with the departmental policy.

4. Take note that the approval will be valid for a 3 year period.

5. Hope the matter is clear and understandable.

District Executive Manager
Mrs. Maepa M.L

Date: 2017

Private Bag X04
Chuenespoort 0745. Tel: 015 633 2300. Fax 015 633 7927. Website: http://www.limpopo.gov.za
The heartland of southern Africa – development is about people
Ref: S5/6
Enq: Muvari MME
Date: 25 MAY 2017

Mr /Ms. Secolela TA

Dear Sir/Madam

PERMISSION TO CONDUCT A STUDY: COLLECTION OF CLINIC PHARMACY DATA FOR RESEARCH PROJECT

1. The above matter bears reference

2. Your letter received on the 25/05/2017 requesting for permission to conduct Clinic Pharmacy data for Research Project is hereby acknowledged

3. The District has no objection to your request.

4. Permission is therefore granted for the request to be conducted within Vhembe District.

5. You are however advised to make the necessary arrangements with the facilities concerned.


DISTRICT CHIEF DIRECTOR

DATE: 25/5/2017
DEPARTMENT OF HEALTH
WATERBERG DISTRICT

REF: 4/3/3
ENQ: NKGODI D.R (PA TO THE DISTRICT EXECUTIVE MANAGER)
CELL NO: 079 791 4966.
DATE: 14/02/2017

SEGOLELA T.A
SEFAKO MAKGATHO HEALTH SCIENCE UNIVERSITY
GA-RANKUWA
0208

RE: PERMISSION TO CONDUCT RESEARCH: YOURSELF.

The above bear’s reference:-

1. The office of the Acting District Executive Manager, hereby confirms receipt of your request to conduct a research on compliance to the National Core Standard by Primary Health Care facilities as part of the adopt project in Limpopo Province, South Africa.

2. Permission is hereby granted as per approval by the HOD.

3. You are further requested to notify this office on when you are going to start with the research and make sure that there is no action that disturbs service delivery.

Your support and cooperation in terms of the above will be highly appreciated.

[Signature]

ACTING DISTRICT EXECUTIVE MANAGER
WATERBERG DISTRICT

[Date]
SEFAKO MAKGATHO HEALTH SCIENCES UNIVERSITY ENGLISH CONSENT FORM

Statement concerning participation in a Research Project.

Name of Research Project

COMPLIANCE TO THE NATIONAL CORE STANDARDS BY PRIMARY HEALTHCARE FACILITIES AS PART OF THE ‘ADOPT A CLINIC PROJECT’ IN LIMPOPO PROVINCE

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

I know that this project has been approved by the Limpopo Province Department of Health Ethics Committee and that data will only be collected from facility records and also through observation. The researcher made the permission letter available to me.

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

I hereby give consent for the facility I manage, to participate in this Project.

.................................................................................................  ........................................................
Name of operations manager                                    Signature of operations manager

.................................................................................................  ........................................................
Place.                              Date.                                  Witness____________

Statement by the Researcher

I provided written information regarding this Project.

I agree to answer any future questions concerning the Research Project as best as I am able.

I will adhere to the approved protocol.

.................................................................................................  ........................................................
Name of Researcher                 Signature                         Date                           Place____________
Appendices

Appendix 9: SAMJ Author Guidelines

Author Guidelines

Publication Fees

All articles published in the South African Medical Journal are open access and freely available online upon publication. This is made possible by applying a business model to offset the costs of peer review management, copyediting, design and production, by charging a publication fee of R5 250 (ex vat) for each research article published. The charge applies only to Research articles submitted after 1 March 2017. The publication fee is standard and does not vary based on length, colour, figures, or other elements.

When submitting a Research article to the SAMJ, the submitting author must agree to pay the publication fee should the article be accepted for publication. The publication fee is payable when your manuscript is editorially accepted and before production commences for publication. The submitting author will be notified that payment is due and given details on the available methods of payment. Prompt payment is advised; the article will not enter into production until payment is received.

Queries can be directed to claudian@hmpg.co.za.

Please refer to the section on ‘Sponsored Supplements’ regarding the publication of supplements, where a charge is applicable. Queries can be directed to dianes@hmpg.co.za or claudian@hmpg.co.za

Authorship

Named authors must consent to publication. Authorship should be based on: (i) substantial contribution to conceptualisation, design, analysis and interpretation of data; (ii) drafting or critical revision of important scientific content; or (iii) approval of the version to be published. These conditions must all be met (uniform requirements for manuscripts submitted to biomedical journals; refer to www.icmje.org)

If authors’ names are added or deleted after submission of an article, or the order of the names is changed, all authors must agree to this in writing.

Please note that co-authors will be requested to verify their contribution upon submission. Non-verification may lead to delays in the processing of submissions. Author contributions should be listed/described in the manuscript.

Conflicts of interest

Conflicts of interest can derive from any kind of relationship or association that may influence authors’ or reviewers’ opinions about the subject matter of a paper. The existence of a conflict – whether actual, perceived or potential – does not preclude publication of an article. However, we aim to ensure that, in such cases, readers have all the information they need to enable them to make an informed assessment about a publication’s message and conclusions. We require that both authors and reviewers declare all sources of support for their research, any personal or financial relationships (including honoraria, speaking fees, gifts received, etc) with relevant individuals or organisations connected to the topic of the paper, and any association with a product or subject that may constitute a real, perceived or potential conflict of interest. If you are unsure whether a specific relationship constitutes a conflict, please contact the editorial team for advice. If a conflict remains undisclosed and is later brought to the attention of the editorial team, it will be considered a serious issue prompting an investigation with the possibility of retraction.

Research ethics committee approval

Authors must provide evidence of Research Ethics Committee approval of the research where relevant. Ensure the correct, full ethics committee name and reference number is included in the manuscript.

If the study was carried out using data from provincial healthcare facilities, or required active data collection through facility visits or staff interviews, approval should be sought from the relevant provincial authorities. For South African authors, please refer to the guidelines for submission to the National Health Research Database. Research involving human subjects must be conducted according to the principles outlined in the Declaration of Helsinki. Please refer to the National
Appendices

Department of Health’s guideline on Ethics in Health research: principles, processes and structures to ensure that the appropriate requirements for conducting research have been met, and that the HPCSA’s General Ethical Guidelines for Health Researchers have been adhered to.

Protection of rights to privacy

**Patient**

Information that would enable identification of individual patients should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) has given informed written consent for publication and distribution. We further recommend that the published article is disseminated not only to the involved researchers but also to the patients/participants from whom the data was drawn. Refer to Protection of Research Participants. The signed consent form should be submitted with the manuscript to enable verification by the editorial team.

**Other individuals**

Any individual who is identifiable in an image must provide written agreement that the image may be used in that context in the SAMJ.

Copyright notice

Copyright remains in the Author’s name. The work is licensed under a Creative Commons Attribution - Noncommercial Works License. Authors are required to complete and sign an Author Agreement form that outlines Author and Publisher rights and terms of publication. The Author Agreement form should be uploaded along with other submissions files and any submission will be considered incomplete without it.

Material submitted for publication in the SAMJ is accepted provided it has not been published or submitted for publication elsewhere. Please inform the editorial team if the main findings of your paper have been presented at a conference and published in abstract form, to avoid copyright infringement. The SAMJ does not hold itself responsible for statements made by the authors.

**Previously published images**

If an image/figure has been previously published, permission to reproduce or alter it must be obtained by the authors from the original publisher and the figure legend must give full credit to the original source. This credit should be accompanied by a letter indicating that permission to reproduce the image has been granted to the author/s. This letter should be uploaded as a supplementary file during submission.

Privacy statement

The SAMJ is committed to protecting the privacy of its website and submission system users. The names, personal particulars and email addresses entered in the website or submission system will not be made available to third parties without the user’s permission or due process. By registering to use the website or submission system, users consent to receive communication from the SAMJ or its publisher HMPG on matters relating to the journal or associated publications. Queries with regard to privacy may be directed to publishing@hmpg.co.za.

**Ethnic/race classification**

Use of racial or ethnicity classifications in research is fraught with problems. If you choose to use a research design that involves classification of participants based on race or ethnicity, or discuss issues with reference to such classifications, please ensure that you include a detailed rationale for doing so, ensure that the categories you describe are carefully defined, and that socioeconomic, cultural and lifestyle variables that may underlie perceived racial disparities are appropriately controlled for. Please also clearly specify whether race or ethnicity is classified as reported by the patient (self-identifying) or as perceived by the investigators. Please note that it is not appropriate to use self-reported or investigator-assigned racial or ethnic categories for genetic studies.

**Continuing Professional Development (CPD)**

SAMJ is an HPCSA-accredited service provider of CPD materials. Principal authors can earn up to 15 CPD continuing education units (CEUs) for publishing an article; co-authors are eligible to earn up to 5 CEUs; and reviewers of articles can earn 3 CEUs. Each month, SAMJ also publishes a CPD-accredited questionnaire relating to the academic content of the journal. Successful completion of the questionnaire with a pass rate of 70% will earn the reader 3 CEUs. Administration of our CPD
programme is managed by Medical Practice Consulting. To complete questionnaires and obtain certificates, please visit MRP Consulting.

Manuscript preparation

Preparing an article for anonymous review

To ensure a fair and unbiased review process, all submissions are to include an anonymised version of the manuscript. The exceptions to this are Correspondence, Book reviews and Obituary submissions.

Submitting a manuscript that needs additional blinding can slow down your review process, so please be sure to follow these simple guidelines as much as possible:

• An anonymous version should not contain any author, affiliation or particular institutional details that will enable identification.
• Please remove title page, acknowledgements, contact details, funding grants to a named person, and any running headers of author names.
• Mask self-citations by referring to your own work in third person.

General article format/layout

Accepted manuscripts that are not in the correct format specified in these guidelines will be returned to the author(s) for correction, which will delay publication.

General:

• Manuscripts must be written in UK English.
• The manuscript must be in Microsoft Word format. Text must be single-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes).
• Please make your article concise, even if it is below the word limit.
• Qualifications, full affiliation (department, school/faculty, institution, city, country) and contact details of ALL authors must be provided in the manuscript and in the online submission process.
• Abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.
• Include sections on Acknowledgements, Conflict of Interest, Author Contributions and Funding sources. If none is applicable, please state 'none'.
• Scientific measurements must be expressed in SI units except: blood pressure (mmHg) and haemoglobin (g/dL).
• Litres is denoted with an uppercase L e.g. 'mL' for millilitres).
• Units should be preceded by a space (except for % and ºC), e.g. '40 kg' and '20 cm' but '50%' and '19ºC'.
• Please be sure to insert proper symbols e.g. µ not u for micro, a not α for alpha, b not B for beta, etc.
• Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160.
• Quotes should be placed in single quotation marks: i.e. The respondent stated: ‘...’
• Round brackets (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.
• If you wish material to be in a box, simply indicate this in the text. You may use the table format –this is the only exception. Please DO NOT use fill, format lines and so on.

**NB: Copyeditors cannot be expected to pick up and correct errors wrt the above, although they will raise queries where concerned.
- Define all genes, proteins and related shorthand terms at first mention, e.g. ‘188del11’ can be glossed as ‘an 11 bp deletion at nucleotide 188.’
- Use the latest approved gene or protein symbol as appropriate:
  • Human Gene Mapping Workshop (HGMW): genetic notations and symbols
  • HUGO Gene Nomenclature Committee: approved gene symbols and nomenclature
  • OMIM: Online Mendelian Inheritance in Man (MIM) nomenclature and instructions
Preparation notes by article type

Research
Guideline word limit: 4 000 words

Research articles describe the background, methods, results and conclusions of an original research study. The article should contain the following sections: introduction, methods, results, discussion and conclusion, and should include a structured abstract (see below). The introduction should be concise – no more than three paragraphs – on the background to the research question, and must include references to other relevant published studies that clearly lay out the rationale for conducting the study. Some common reasons for conducting a study are: to fill a gap in the literature, a logical extension of previous work, or to answer an important clinical question. If other papers related to the same study have been published previously, please make sure to refer to them specifically. Describe the study methods in as much detail as possible so that others would be able to replicate the study should they need to. Results should describe the study sample as well as the findings from the study itself, but all interpretation of findings must be kept in the discussion section, which should consider primary outcomes first before any secondary or tertiary findings or post-hoc analyses. The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

Select figures and tables for your paper carefully and sparingly. Use only those figures that provided added value to the paper, over and above what is written in the text. Do not replicate data in tables and in text.

Structured abstract
- This should be 250-400 words, with the following recommended headings:
  - Background: why the study is being done and how it relates to other published work.
  - Objectives: what the study intends to find out
  - Methods: must include study design, number of participants, description of the intervention, primary and secondary outcomes, any specific analyses that were done on the data.
  - Results: first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.
  - Conclusion: must be supported by the data, include recommendations for further study/actions.
- Please ensure that the structured abstract is complete, accurate and clear and has been approved by all authors.
- Do not include any references in the abstracts.

Here is an example of a good abstract.

Main article
All articles are to include the following main sections: Introduction/Background, Methods, Results, Discussion, Conclusions.
The following are additional heading or section options that may appear within these:
- Objectives (within Introduction/Background): a clear statement of the main aim of the study and the major hypothesis tested or research question posed
- Design (within Methods): including factors such as prospective, randomisation, blinding, placebo control, case control, crossover, criterion standards for diagnostic tests, etc.
- Setting (within Methods): level of care, e.g. primary, secondary, number of participating centres.
- Participants (instead of patients or subjects; within Methods): numbers entering and completing the study, sex, age and any other biological, behavioural, social or cultural factors (e.g. smoking status, socioeconomic group, educational attainment, co-existing disease indicators, etc) that may have an impact on the study results. Clearly define how participants were enrolled, and describe selection and exclusion criteria.
- Interventions (within Methods): what, how, when and for how long. Typically for randomised controlled trials, crossover trials, and before and after studies.
- Main outcome measures (within Methods): those as planned in the protocol, and those ultimately measured. Explain differences, if any.

Results
- Start with description of the population and sample. Include key characteristics of comparison groups.
Appendices

- Main results with (for quantitative studies) 95% confidence intervals and, where appropriate, the exact level of statistical significance and the number need to treat/harm. Whenever possible, state absolute rather than relative risks.
- Do not replicate data in tables and in text.
- If presenting mean and standard deviations, specify this clearly. Our house style is to present this as follows:
  - E.g.: The mean (SD) birth weight was 2 500 (1 210) g. Do not use the ± symbol for mean (SD).
- Leave interpretation to the Discussion section. The Results section should just report the findings as per the Methods section.

Discussion
Please ensure that the discussion is concise and follows this overall structure – sub-headings are not needed:
- Statement of principal findings
- Strengths and weaknesses of the study
- Contribution to the body of knowledge
- Strengths and weaknesses in relation to other studies
- The meaning of the study – e.g. what this study means to clinicians and policymakers
- Unanswered questions and recommendations for future research

Conclusions
This may be the only section readers look at, therefore write it carefully. Include primary conclusions and their implications, suggesting areas for further research if appropriate. Do not go beyond the data in the article.

Guidelines
Guidelines should always be discussed with the Editor prior to submission.

Because of the intensive review process required to ensure Guidelines are independent, evidence-based and free from commercial bias, they are usually published as a supplement to the SAMJ, the costs of which must be covered by sponsorship, advertising or payment by the guideline authors/association. We will provide a quote based on the expected length of the guideline and whether it is to appear online only, or in print, which must be accepted by the body putting the guidelines together before submitting the work to the SAMJ.

The Editor reserves the right to determine the scheduling of supplements. Understandably, a delay in publication must be anticipated dependent upon editorial workflow. All guidelines should include a clear, transparent statement about all sources of funding and an explicit, clear statement of conflicts of interest of any of the participants in the guidelines about industry funding for lectures, research, conference participation etc.

All guidelines should be structured according to Agree II. Please access this website before putting the guidelines together, download the Agree 11 instrument and use this to put the guidelines together. All submitted guidelines will be sent to the local Agree II appraisal committee for review and must be endorsed by an appropriate body prior to consideration and all conflicts of interest expressed.

A structured abstract not exceeding 400 words (recommended sub-headings: Background, Recommendations, Conclusion) is required. Sections and sub-sections must be numbered consecutively (e.g. 1. Introduction; 1.1 Definitions; 2. etc.) and summarised in a Table of Contents.

Illustrations/photos/scans
- If illustrations submitted have been published elsewhere, the author(s) should provide consent to republication obtained from the copyright holder.
- Figures must be numbered in Arabic numerals and referred to in the text e.g. '(Fig. 1)'.
- Each figure must have a caption/legend: Fig. 1. Description (any abbreviations in full).
- All images must be of high enough resolution/quality for print.
- All illustrations (graphs, diagrams, charts, etc.) must be in PDF or jpeg form.
- Ensure all graph axes are labelled appropriately, with a heading/description and units (as necessary) indicated. Do not include decimal places if not necessary e.g. 0; 1.0; 2.0; 3.0; 4.0 etc.
Appendices

- Scans/photos showing a specific feature e.g. Intermediate magnification micrograph of a low malignant potential (LMP) mucinous ovarian tumour. (H&E stain). – include an arrow to show the tumour.
- Each image must be attached individually as a 'supplementary file' upon submission (not solely embedded in the accompanying manuscript) and named Fig. 1, Fig. 2, etc.

Tables

- Tables should be constructed carefully and simply for intelligible data representation. Unnecessarily complicated tables are strongly discouraged.
- Large tables will generally not be accepted for publication in their entirety. Please consider shortening and using the text to highlight specific important sections, or offer a large table as an addendum to the publication, but available in full on request from the author.
- Embed/include each table in the manuscript Word file - do not provide separately as supplementary files.
- Number each table in Arabic numerals (Table 1, Table 2, etc.) and refer to consecutively in the text.
- Tables must be cell-based (i.e. not constructed with text boxes or tabs) and editable.
- Ensure each table has a concise title and column headings, and include units where necessary.
- Footnotes must be indicated with consecutive use of the following symbols: * † ‡ § ¶ || then ** †† ‡‡ etc.

Do not: Use [Enter] within a row to make 'new rows':
Rather: Each row of data must have its own proper row:

Do not: use separate columns for n and %:
Rather: Combine into one column, n (%):

Do not: have overlapping categories, e.g.:
Rather: Use <> symbols or numbers that don’t overlap:

References

**NB:** Only complete, correctly formatted reference lists in Vancouver style will be accepted. Reference lists must be generated manually and not with the use of reference manager software. Endnotes must **not** be used.

- Authors must verify references from original sources.
- Citations should be inserted in the text as superscript numbers between square brackets, e.g. These regulations are endorsed by the World Health Organization[2] and others.[3,4-6]
- All references should be listed at the end of the article in numerical order of appearance in the Vancouver style (not alphabetical order).
- Approved abbreviations of journal titles must be used; see the List of Journals in Index Medicus.
- Names and initials of all authors should be given; if there are more than six authors, the first three names should be given followed by et al.
- Volume and issue numbers should be given.
- First and last page, in full, should be given e.g.: 1215-1217 not 1215-17.
- Wherever possible, references must be accompanied by a digital object identifier (DOI) link.
  Authors are encouraged to use the DOI lookup service offered by CrossRef:
  - On the Crossref homepage, paste the article title into the ‘Metadata search’ box.
  - Look for the correct, matching article in the list of results.
  - Click Actions > Cite
  - Alongside ‘url =’ copy the URL between { }.
  - Provide as follows, e.g.: [https://doi.org/10.7196/07294.937.98x](https://doi.org/10.7196/07294.937.98x)

Some examples:

Appendices

- Legal references
- Government Gazettes:
  In this example, 17507 is the Gazette Number. This is followed by :1514 - this is the notice number in this Gazette.
  Provincial Gazettes:
  Acts:
  Regulations to an Act:
  Bills:
  Green/white papers:
  Case law:
  Rex v Jopp and Another 1949 (4) SA 11 (N)
  Rex v Jopp and Another: Name of the parties concerned
  1949: Date of decision (or when the case was heard)
  (4): Volume number
  SA: SA Law Reports
  11: Page or section number
  (N): In this case Natal - where the case was heard. Similarly, (C) woud indicate Cape, (G) Gauteng, and so on.
  NOTE: no . after the v
  Other references (e.g. reports) should follow the same format: Author(s). Title. Publisher place: Publisher name, year; pages.
  Cited manuscripts that have been accepted but not yet published can be included as references followed by '(in press)'.
  Unpublished observations and personal communications in the text must not appear in the reference list. The full name of the source person must be provided for personal communications e.g. '...(Prof. Michael Jones, personal communication)'.

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Appendix 10: African Journal of Primary Health Care & Family Medicine Author Guidelines

Overview

The author guidelines include information about the types of articles received for publication and preparing a manuscript for submission. Other relevant information about the journal's policies and the reviewing process can be found under the about section. The compulsory cover letter form part of a submission and is on the first page of the manuscript. It should always be presented in English. See full structure of cover letter below. After the cover letter the manuscript body starts.

An original article provides an overview of innovative research in a particular field within or related to the focus and scope of the journal, presented according to a clear and well-structured format. Systematic reviews should follow the same basic structure as other original research articles. The aim and objectives should focus on a clinical question that will be addressed in the review. The methods section should describe in detail the search strategy, criteria used to select or reject articles, attempts made to obtain all important and relevant studies and deal with publication bias (including grey and unpublished literature), how the quality of included studies was appraised, the methodology used to extract and/or analyse data. Results should describe the homogeneity of the different findings, clearly present the overall results and any meta-analysis.

<table>
<thead>
<tr>
<th>Word limit</th>
<th>3500-7000 words (excluding the structured abstract and references)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structured abstract</td>
<td>250 words to cover a Background, Aim, Setting, Methods, Results and Conclusion</td>
</tr>
<tr>
<td>References</td>
<td>60 or less</td>
</tr>
<tr>
<td>Tables/Figures</td>
<td>no more than 7 Tables/Figure</td>
</tr>
<tr>
<td>Ethical statement</td>
<td>should be included in the manuscript</td>
</tr>
<tr>
<td>Compulsory supplementary file</td>
<td>ethical clearance letter/certificate</td>
</tr>
<tr>
<td>Language</td>
<td>only manuscripts presented in English or French will be considered</td>
</tr>
</tbody>
</table>

Cover Letter

The format of the compulsory cover letter forms part of your submission. It is located on the first page of your manuscript and should always be presented in English. You should provide the following elements:

- Full title: Specific, descriptive, concise, and comprehensible to readers outside the field, max 95 characters (including spaces).
- Tweet for the journal Twitter profile: This will be used on the journal Twitter profile to promote your published article. Max 101 characters (including spaces). If you have a Twitter profile, please provide us your Twitter @ name. We will tag you to the Tweet
- Full author details: The title(s), full name(s), position(s), affiliation(s) and contact details (postal address, email, telephone, highest academic degree, Open Researcher and Contributor Identification (ORCID) and cell phone number) of each author.
Appendices

- Corresponding author: Identify to whom all correspondence should be addressed.
- Authors’ contributions: Briefly summarise the nature of the contribution made by each of the authors listed.
- Disclaimer: A statement that the views expressed in the submitted article are his or her own and not an official position of the institution or funder.
- Source(s) of support: These include grants, equipment, drugs, and/or other support that facilitated conduct of the work described in the article or the writing of the article itself.
- Summary: Lastly, a list containing the number of words, pages, tables, figures and/or other supplementary material should accompany the submission.

Anyone that has made a significant contribution to the research and the paper must be listed as an author in your cover letter. Contributions that fall short of meeting the criteria as stipulated in our policy should rather be mentioned in the ‘Acknowledgements’ section of the manuscript. Read our authorship guidelines and author contribution statement policies.

Original Research Article full structure

Title: The article’s full title should contain a maximum of 95 characters (including spaces).

Abstract: The abstract, written in English, should be no longer than 250 words and must be written in the past tense. The abstract should give a succinct account of the objectives, methods, results and significance of the matter. The structured abstract for an Original Research article should consist of six paragraphs labelled Background, Aim, Setting, Methods, Results and Conclusion.

- Background: Summarise the social value (importance, relevance) and scientific value (knowledge gap) that your study addresses.
- Aim: State the overall aim of the study.
- Setting: State the setting for the study.
- Methods: Clearly express the basic design of the study, and name or briefly describe the methods used without going into excessive detail.
- Results: State the main findings.
- Conclusion: State your conclusion and any key implications or recommendations.

Do not cite references and do not use abbreviations excessively in the abstract.

Introduction: The introduction must contain your argument for the social and scientific value of the study, as well as the aim and objectives:

- Social value: The first part of the introduction should make a clear and logical argument for the importance or relevance of the study. Your argument should be supported by use of evidence from the literature.
• Scientific value: The second part of the introduction should make a clear and logical argument for the originality of the study. This should include a summary of what is already known about the research question or specific topic, and should clarify the knowledge gap that this study will address. Your argument should be supported by use of evidence from the literature.

• Conceptual framework: In some research articles it will also be important to describe the underlying theoretical basis for the research and how these theories are linked together in a conceptual framework. The theoretical evidence used to construct the conceptual framework should be referenced from the literature.

• Aim and objectives: The introduction should conclude with a clear summary of the aim and objectives of this study.

Research methods and design: This must address the following:

• Study design: An outline of the type of study design.

• Setting: A description of the setting for the study; for example, the type of community from which the participants came or the nature of the health system and services in which the study is conducted.

• Study population and sampling strategy: Describe the study population and any inclusion or exclusion criteria. Describe the intended sample size and your sample size calculation or justification. Describe the sampling strategy used. Describe in practical terms how this was implemented.

• Intervention (if appropriate): If there were intervention and comparison groups, describe the intervention in detail and what happened to the comparison groups.

• Data collection: Define the data collection tools that were used and their validity. Describe in practical terms how data were collected and any key issues involved, e.g. language barriers.

• Data analysis: Describe how data were captured, checked and cleaned. Describe the analysis process, for example, the statistical tests used or steps followed in qualitative data analysis.

• Ethical considerations: Approval must have been obtained for all studies from the author's institution or other relevant ethics committee and the institution's name and permit numbers should be stated here.

Results: Present the results of your study in a logical sequence that addresses the aim and objectives of your study. Use tables and figures as required to present your findings. Use quotations as required to establish your interpretation of qualitative data. All units should conform to the SI convention and be abbreviated accordingly. Metric units and their international symbols are used throughout, as is the decimal point (not the decimal comma).

Discussion: The discussion section should address the following four elements:

• Key findings: Summarise the key findings without reiterating details of the results.

• Discussion of key findings: Explain how the key findings relate to previous research or to existing knowledge, practice or policy.
Appendices

- **Strengths and limitations:** Describe the strengths and limitations of your methods and what the reader should take into account when interpreting your results.

- **Implications or recommendations:** State the implications of your study or recommendations for future research (questions that remain unanswered), policy or practice. Make sure that the recommendations flow directly from your findings.

**Conclusion:** Provide a brief conclusion that summarises the results and their meaning or significance in relation to each objective of the study.

**Acknowledgements:** Those who contributed to the work but do not meet our authorship criteria should be listed in the Acknowledgments with a description of the contribution. Authors are responsible for ensuring that anyone named in the Acknowledgments agrees to be named.

Also provide the following, each under their own heading:

- **Competing interests:** This section should list specific competing interests associated with any of the authors. If authors declare that no competing interests exist, the article will include a statement to this effect: *The authors declare that they have no financial or personal relationship(s) that may have inappropriately influenced them in writing this article.* Read our [policy on competing interests](#).

- **Author contributions:** All authors must meet the criteria for authorship as outlined in the [authorship](#) policy and [author contribution](#) statement policies.

- **Funding:** Provide information on funding if relevant

- **Disclaimer:** A statement that the views expressed in the submitted article are his or her own and not an official position of the institution or funder.

**References:** Authors should provide direct references to original research sources whenever possible. References should not be used by authors, editors, or peer reviewers to promote self-interests. Refer to the journal referencing style downloadable on our [Formatting Requirements](#) page.
Appendices

Appendix 11: Letter of discontinuation of fluphenazine deaconate injection

Bristol-Myers Squibb (Pty) Limited
Woodmead North Office Park, 54 Maxwell Drive, Woodmead, 2191
P.O. Box 227, Northwold, 2126
Tel: 011 808 5900; Fax: 011 808 3301

Date: 24 February 2017

Dear Valued Customer

Notification of Product Discontinuation:
MODECATE® (fluphenazine decanoate) 25 mg/ml injection

<table>
<thead>
<tr>
<th>Product</th>
<th>Presentation</th>
<th>Pack size</th>
<th>Registration number</th>
<th>Nappi Code</th>
<th>Anticipated end sales date</th>
</tr>
</thead>
<tbody>
<tr>
<td>MODECATE® 25 mg/ml</td>
<td>1 ml ampoule</td>
<td>3</td>
<td>C/2.6.1/35</td>
<td>744301-009</td>
<td>Sep-2017</td>
</tr>
<tr>
<td>MODECATE® 25 mg/ml</td>
<td>1 ml ampoule</td>
<td>1</td>
<td>C/2.6.1/35</td>
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<tr>
<td>MODECATE® 25 mg/ml</td>
<td>10 ml vial</td>
<td>1</td>
<td>C/2.6.1/35</td>
<td>744344-018</td>
<td>Mar-2017</td>
</tr>
</tbody>
</table>

Bristol-Myers hereby wishes to inform you that the products listed above will be discontinued.

We anticipate that the current inventory levels for MODECATE® will be depleted as per the dates provided in the table above, after which the product will no longer be available.

We would appreciate your understanding in this matter, and ask that your databases be adjusted according to the timeframes provided above.

Should you have any questions or require additional information regarding the use of MODECATE®, please contact 0800 444423 or e-mail Medinfo.SouthAfrica@bms.com.

Yours sincerely,

Dr. Abrie Hanekom
Country Manager - South Africa