Assessment of changes in pharmaceutical performance among primary health care health facilities that received technical assistance in a rural district of the Eastern Cape, South Africa

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A mini-thesis submitted in partial fulfilment of the requirements for the degree of Master of Public Health at the School of Public Health, University of the Western Cape

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August 2019

KEYWORDS

Assessment

Health facility

Pharmaceutical management

Pharmaceutical performance

Primary health care

Pre-test post-test

South Africa

Supportive supervision

Stockouts

Technical assistance

ABSTRACT

Background

Twenty percent of the global population receiving antiretroviral therapy (ART) reside in South Africa (UNAIDS, 2017). Demand within the public health system, already constrained by human resource scarcities and budgetary and infrastructural challenges, is expected to increase given the estimate that only 56% of an estimated 7.1 million HIV positive people in South Africa are currently on ART (UNAIDS, 2017). Technical assistance (TA) interventions are deployed to support in-house government services to optimise services, however, rigorous studies to evaluate the impact of TA strategies are scarce. In Amathole District Municipality a pharmaceutical management TA intervention was provided to 112 primary healthcare (PHC) facilities in the district by an implementing partner (IP) with the objective of ensuring "an effective supply chain for HIV and TB related commodities" (CDC, 2016: 19).

Aim

To describe and compare changes in facility-level pharmaceutical performance among PHC health facilities that received pharmaceutical management TA in a rural district of the Eastern Cape, South Africa.

Methodology

Secondary data, comprising the IP's programmatic data on 110 PHC facilities, was utilised. This included baseline and repeat assessment of facility level pharmaceutical services functioning, and TA support visit records. Analysis was conducted utilising Excel and SPSS software. Due to non-normal distribution of data, non-parametric tests were conducted. These included a pre-test post-test comparison of facility performance utilising the Wilcoxon signed rank test, and Spearman's correlation to determine the relationship between number of TA visits and changes in facility pharmaceutical functioning.

Ethics

Ethical approval from the University of the Western Cape Biomedical Research Ethics Committee was obtained. The IP and Prime consented to use of the in-house data and Department of Health, Eastern Cape granted ethical approval. Data is stored in a password protected device and folders, maintained by the primary researcher.

Results

Differences in facility support visit frequencies between the four sub-districts in Amathole District were significant (X^2 (39, n =110) = 98.5, p<0.001), suggesting that the programme was not uniformly implemented across all sub-districts. Although statistically significant improvements occurred in five facility pharmaceutical functioning domains (Guidelines and

reference materials availability, Training, Stock management, Stock monitoring, and Storage of medicines) and the overall total score, the expired medicine and stockout domains reflected deterioration. Thus the programme overall was effective, but outcomes on stockouts and expiries were questionable, and may point to facility-level challenges with stock card data accuracy. A significant correlation was found between the frequency of support visits and change in facility level pharmaceutical performance [r = 0.248, n =110, p =0.009]. Therefore, a relationship between the intensity of support visits and improvement in facility-level pharmaceutical performance was found.

Conclusions

Despite an overall improvement in pharmaceutical performance, absence of a consistent improvement in the stockout and expiry domains points to the complexity of pharmaceutical and health system functioning, and focused interventions at facility level may be too limited when systemic challenges extend beyond the facility. TA interventions added value, however, to be effective, these need to be implemented in a sustained, systematic manner.

Recommendations

Unintended reinforcing of inequity between rural and urban areas is a risk in programme implementation. Therefore, close monitoring, and possible re-direction, of programme support rendered is core to ensuring facilities in urban and rural areas receive equitable support. Since there is a risk of bias or inaccuracy of stockout data obtained from bin card records at facility level, independently obtained stockout data (to triangulate with facility level data) is recommended. Future analysis could explore the association between TA strategy employed and improvement in facility functioning, and an optimal threshold of visit frequency. This would direct optimal use of programme resources.

ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral
CCMDD	Central Chronic Medicines Dispensing and Distribution
CDC	Centres for Disease Control and Prevention
CHC	Community health centre
df	Degrees of freedom
DHIS	District Health Information System
DoH	Department of Health
DSD	Direct service delivery
FEFO	First expired first out
FIFO	First in first out
FMT	Formal Module Training
FTE	Full time equivalent
GPP	Good Pharmacy Practice
HCW	Health care worker
HIV	Human Immunodeficiency Virus
HR	Human resource
ICAP	International Centre for AIDS Care and Treatment Programme
IP	Implementing partner
MSF	Medicines Sans Frontiers
NDoH	National Department of Health
PA	Pharmacist's assistant
PEPFAR	United States Presidents Emergency Fund for AIDS and HIV relief
PHC	Primary health care
RCT	Randomised controlled trial
RHAP	Rural Health Advocacy Project
SAHR	South African Health Review
SEAD	Strategic Evaluation Advisory and Development Consulting
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SIMS	Site Improvement Monitoring System
SOP	Standard operating procedure

SPSS	Statistical Package for Social Science
SVS	Stock Visibility Solution
TA	Technical assistance
TAC	Treatment Action Campaign
TB	Tuberculosis
TROA	Total remaining on ART
UNAIDS	The Joint United Nations Programme on HIV & AIDS
WHO	World Health Organisation
WSR	Wilcoxon signed-rank
X^2	Chi-squared

DECLARATION

I hereby declare that this study **"Assessment of changes in pharmaceutical performance among primary health care health facilities that received technical assistance in a rural district of the Eastern Cape, South Africa"** is my own work and it has not been submitted for any degree or examination to any other university, and that all sources I have used or quoted have been indicated and acknowledged by referencing.

Name: Carmen Jallow

Signature: 

Date: 30 August 2019

ACKNOWLEDGEMENTS

I would like to thank my supervisor and co-supervisor for their responsiveness, insights and support throughout this process.

I would like to thank the Department of Health, implementing partners and the funder for the opportunity to examine the data obtained from this programme, and to reflect on the outcomes.

Particular thanks to Strategic Evaluation Advisory and Development (SEAD) Consulting for enabling me to utilise the data, and for their support, particularly through time and travel, to complete this study.

Thanks to my family for their support.

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DEFINITIONS OF KEY TERMS

Direct service delivery (DSD) – Implementing partner (IP) representative does the job for the facility where there is a lack of capacity for the facility to do the activity themselves (e.g. cycle counts and stock takes done by the implementing partner's staff when facility staff are unavailable to do this).

Expired medicines - At any point in the last 3 months there was evidence (such as recorded on bin cards) the facility had expired medicines of that item.

Facility pharmaceutical functioning – The management of pharmaceuticals and supplies in aspects of supply chain management, monitoring, control, record-keeping, storage, availability and cold chain management as assessed by a total score on data extracted from an IP tool.

Implementing partner (IP)– The organisation given the mandate to implement programmatic activities within the district. The organisation's staff implement support activities at the facilities.

Number of technical assistance (TA) support visits - Number of times a facility was visited in the period of supportive intervention (May 2017 – February 2018) as recorded on an activity tracking electronic application utilised by implementing partner pharmacy advisors (pharmacists).

Stockout – At any point in the last 3 months the facility did not have stock of that item as reflected on bin cards.

Technical assistance (TA) - The support activities deployed by the implementing partner such as training, on-site mentoring, and supportive supervision to bring about transfer of skills and capacity building, with the aim of improving the functioning of the supported entity.

Technical assistance strategy – Type of support activity undertaken during facility visit, such as training (additional Formal Module Training or simple refresher training); informal mentoring; providing job aids; referring matters upstream; and, or direct service delivery (DSD) i.e., doing the job for the facility.

CHAPTER 1: INTRODUCTION

1.1 Background

Worldwide South Africa has the largest human immunodeficiency virus (HIV) burden, with 20% of the global population of people receiving antiretroviral therapy (ART) residing in South Africa (UNAIDS, 2017). With the advent of Universal Test and Treat (NDoH, 2016a), scale up of HIV services is an ongoing priority. This places increased demands on a public health system already beset by human resource (HR) scarcities, budgetary constraints and infrastructural deficits (Jamieson & Kellerman, 2016). Demand within the system is expected to further increase given the estimate that only 56% of an estimated 7.1 million HIV positive people in South Africa are currently on ART (UNAIDS, 2017).

Since 2003 the United States Presidents Emergency Fund for AIDS and HIV relief (PEPFAR) has provided funding for implementing partner (IP) organisations and programmes in South Africa to address the HIV epidemic. Initial funding went towards actual provision of HIV services. More recent efforts, however, focus on supporting in-house (South African government) services (PEPFAR, 2014), in part through technical assistance (TA). TA is defined by PEPFAR as "An established presence and routinised frequent support such as clinical mentoring and supportive supervision of staff, quality improvement support, commodities and consumption forecasting and supply management, to improve the functioning or capacity of that entity" (Gottlieb, 2014: 4). Despite TA being a PEPFAR strategy since 2007, TA interventions have not been rigorously evaluated in settings outside the United States (West, Clapp, Averill & Cates, 2012). With emphasis on implementation science and heightened data utilisation within PEPFAR and its associates, it has become incumbent on partners to demonstrate rigor in the evaluation of their own interventions (Padian *et al.*, 2011).

1.1.1 Primary health care challenges

HR shortages and inequitable distribution across South Africa are well documented (Cook, Couper & Versteeg, 2011). In the Eastern Cape province, public sector pharmacists were 8.8 per 100 000 population, compared with a South Africa average of 11 (South African Health Review (SAHR), 2016). This is against the broader backdrop of health care professional scarcity in South Africa. Pharmacists and registered nurses appear on South Africa's critical skills list ('National List of Occupations in High Demand, 2018'), meaning that these

occupations are experiencing high employment growth in demand and are experiencing shortages in the labour market (Government Gazette, 2018).

In a forecasting analysis of staffing norms, it was calculated that, based on the current South African utilisation rate, and a staffing norm of 0.45 and 0.68 full time equivalent (FTE) pharmacist's assistants (PAs) per 10 000 visits per year at clinics and community health centres (CHCs) respectively; 4 500 post basic pharmacist's assistants were required for South Africa's PHC facilities in 2012 (Daviaud & Subedar, 2012). These numbers are dated, but nevertheless reflect the scale of the staffing gap in terms of pharmaceutical support staff. The post basic pharmacist's assistant cadre is part of the National staffing guidelines (Workload indicator of Staffing Need) adopted by the National Department of Health (NDoH) in 2015, and therefore this staffing cadre should be on-site at primary health care (PHC) facilities (Government Gazette, 2015).

Without pharmaceutical staff based on-site, this leaves facility pharmaceutical duties to nurses, who are typically more focussed on clinical responsibilities, than stock management and dispensing duties (Crowley & Stellenberg, 2015; Bheekie & Bradley, 2016). The absence of dedicated pharmaceutical staff suggests that maintenance and monitoring of pharmaceutical matters may not be prioritised and can be neglected. In the absence of pharmaceutical staff, delegation of these duties to a specified individual (professional nurse) is required (NDoH, 2011). Increasingly, professional nurses are burdened with pharmaceutical-related responsibilities. One example of this is the alternative medicine distribution system (such as Central Chronic Medicines Dispensing and Distribution (CCMDD)), through the use of adherence clubs and other sites acting as medicine pick up points, with the aim of 'decanting' chronic, stable patients from congested facilities. This has benefits to the patient in that it reduces waiting time and frequency to pick up medicines and attend the facility; while decreasing workload for the facility, thereby freeing more time to attend to patients, and decreasing the amount of stock facilities are required to manage on site (NDoH, 2016b). Nevertheless, the CCMDD programme puts a greater degree of responsibility on the facility manager to "supervise implementation and appropriate use of the Adherence Guidelines and relevant tools" and "establish repeat prescription collection strategies" (NDoH, 2016b: 54 & 55).

The above challenges with HR and supply chain are systemic deficiencies that characterise the South African, and other, public health systems. Doumbia, Clark, and Mwansasu (2017)

describe supply chain challenges as common where systems are characterised by limited HR capacity and high turnover, poor leadership, inadequate infrastructure, unreliable supply chain data, and compromised stock storage conditions and practices. Waako *et al.'s* (2009) assessment of the health system in East Africa in terms of the distribution and use of antiretroviral (ARV) medicines, with a particular focus on health care workers (HCWs) involved in supply and management of ARVs, also explored challenges. At facility level it was common that supply management of pharmaceuticals was not managed by pharmacy workers, but by lower to midlevel HCWs (Waako *et al.*, 2009). It was also noted that clinical management of patients was typically the main focus of training, with minimal or no focus on supply management, quantification of needs, inventory control, and storage.

Unsurprisingly these pharmaceutical management aspects were those that HCWs highlighted as key areas where they recognised they required training. Waako *et al.* (2009) identified the limitations affecting facility, and pharmaceutical performance in particular, as HR constraints, including inadequate personnel in the supply chain, limited or no training, inadequate remuneration and associated motivation, and inequitable staffing allocations and distribution. Frequent identified problems were expired medicine and shortages pointing to training needs on quantification and inventory management (Waako *et al.*, 2009). These findings could be extrapolated to the study setting.

1.1.2 Programme

An IP, Strategic Evaluation Advisory and Development Consulting (SEAD), conducted a TA intervention in Amathole District Municipality of the Eastern Cape province from April 2017 to March 2018 with the aim of improving facility level pharmaceutical functioning and reducing stockouts and expired medicines. Baseline assessments were conducted in April 2017, repeat assessments in March 2018, and the TA intervention, comprising site visit support, occurred in the intervening ten months (SEAD, 2018). The TA focus included ensuring and providing availability of and orientation to required policies, guidelines and reference materials; relevant training; and compliance to stock management (ordering, issuing and receiving), stock monitoring (including expiry of medications and stockouts) and storage of medicines (including cold chain maintenance) processes and procedures. Training, mentoring and coaching, and direct service delivery (DSD) i.e. doing the job, were provided. The expected outcome of the intervention was improved facility compliance to the above required procedural processes, with a concomitant effect of reducing expired medicines and stockouts.

1.2 Problem statement

Amathole District Municipality's population falls within the most deprived and lowest socio-economic level ("quintile 1") in South Africa (Massyn *et al.*, 2016: 305). This is reflected in its public health infrastructure, and specific pharmaceutical challenges such as stockouts, limited availability of pharmaceutical staff at PHC facilities, and increased demands on facility nursing staff to support pharmaceutical programme implementation (like CCMDD (NDoH, 2016b). In Amathole in 2016/17 only 70.5% of PHC facilities had 90% of tracer medicines available. This was below the national average of 78.4% facilities, and Amathole ranked as the 14th worst performing district in the country (out of 52 districts) on this indicator (Massyn, Padarath, Peer & Day, 2017). This indicator is based on a status determination of availability of 67 essential medicines for PHC facilities, as extracted from the Essential Medicines List and Primary Health Care Standard Treatment Guidelines, with a 100% score reflecting no stockouts.

Between April 2017 and March 2018, resources were dedicated to TA interventions to improve pharmaceutical management in Amathole, however, a rigorous evaluation of the outcomes of the TA have not been conducted. Whether a significant change between pre and post intervention scores occurred, and whether a dose-response effect exists between number of TA visits and facility pharmaceutical functioning improvements, warrants examination.

1.3 Study setting

1.3.1 Amathole District

This study is based in Amathole District in the Eastern Cape. Amathole, situated centrally, is one of seven districts in the Eastern Cape province. The District has a population of 900 000, and the unemployment rate is 43% (Amathole District Municipality, 2017). Housing infrastructure reflects the rural and underdeveloped nature of this district with only 53% of households living in formal dwellings and 12% of households having piped water in their dwelling (Massyn *et al.*, 2017). Ninety five percent of the population have no medical insurance, thus relying on public health facility services (Massyn *et al.*, 2017). In addition to the district being classified as deprived and at the lowest socio-economic level, health expenditure is also low, reinforcing inequity. Amathole District ranks the second lowest in the country on provincial and local PHC expenditure (Rands 273 per PHC headcount, against the South African average of Rands 389) (Massyn *et al.*, 2017). Moreover, the district trend reflects decreasing expenditure since 2013, in contrast to provincial and national trends of

increasing expenditure (Massyn *et al.*, 2017). Contrasted with this low and decreasing expenditure, demand for public health services is high.

According to the District Health Barometer (Massyn *et al.*, 2017), the Amathole PHC utilisation rate is at 3.5 against an average in the Eastern Cape of 2.7 and in South Africa of 2.3. This high demand is against a backdrop of rurality where typically there are unmet health needs in the population, and challenges such as transport (affected by geographic factors), accessibility of care (due to inequitable distribution of HCWs), acceptability (such as quality and cultural acceptability factors), and financial implications (including cost of care, transport costs and lost work days) may be prohibitive (Rural Health Advocacy Project (RHAP), 2017). These challenges typically limit access to and use of healthcare. Therefore, the seemingly high PHC utilisation rate may not represent the complete need and demand of the community. Specifically, in terms of HIV treatment targets, where across the country an additional two million individuals are to be placed on ART by the end of 2020 (Motsoaledi, 2018), the scale of burden on facilities is increasing. For example, between March 2015 and 2017, the Total Remaining on ART (TROA) in Amathole increased by a third (36%) from 40 281 to 54 608 (Massyn *et al.*, 2017).

Against this backdrop, facility pharmaceutical performance is likely to be compromised. The Eastern Cape, and Amathole District specifically, performs below the national average with regards to pharmaceutical indicators. Examples of this are the percentage of assessed PHC facilities with 90% of tracer medicines available by district. This indicator was 70.5% in Amathole against a South Africa average of 78.4% (Massyn *et al.*, 2017); and conversely, tracer items stockout rate in 2017 was higher in the Eastern Cape than in South Africa as a whole (79.1% vs 74.7% respectively) (SAHR, 2018).

1.3.2 Amathole health sub-districts and facilities

Amathole District comprises four health sub-districts. IPs were mandated to support 107 PHC clinics and five CHCs across the district. Typically, PHC clinics are open 8-hours a day and are managed by a registered nurse. No clinics had pharmacists based at the facility, and at commencement of the intervention only 12 clinics had one or more PAs placed at the facility. Sub-district pharmacists supported facilities' pharmaceutical services; however this support was not standardised and access to facilities was a challenge (unpaved roads and travel costs). Furthermore, at the commencement of this intervention one sub-district (Mbhashe) was

without a sub-district pharmacist (SEAD, 2018). CHCs operate for 24 hours a day and typically (although not all) CHCs had a pharmacist and one or more pharmacist's assistants.

1.4 Purpose

PEPFAR was originally rolled out as an emergency response to the HIV epidemic. With a new phase of PEPFAR emphasising sustainability, there is a need to demonstrate the value of funded activities, particularly in the context of resource constraints and maximising return on investment (Padian *et al.*, 2011). Impact evaluation that allows for causal attribution through comparison with a control (counterfactual) is cited as a conclusive means to establish links between outcomes and the programme implemented (Padian *et al.*, 2011). Nevertheless, Thomas, Curtis and Smith (2011) flag that pure randomised controlled trials (RCTs) are not viable in the programmatic environment as RCTs typically require such factors such as intense intervention, execution of the intervention over a long period (such as a decade), and do not reflect the realities of daily implementation. RCTs are also more suited to biomedical interventions; and behavioural and structural programmes are more challenging to control for, with outcomes not as clear-cut (Thomas *et al.*, 2011). Thomas *et al.* (2011) highlight that PEPFAR interventions involve multiple concurrent and integrated programmes implemented simultaneously, hence it is not possible to clearly separate out the effectiveness of one particular programme without stopping all others. It is within this context this study was conducted. While assessments of the outcomes of programmes implemented in real world settings may not be as clear cut, nevertheless there is a need to examine programmes for their value and outcomes.

The purpose of this study was to assess the outcomes of a pharmaceutical management TA programme as implemented by the IP. This provided insights into how the programme was implemented (in terms of frequency of support visits and TA strategies deployed), as well as the outcomes, in terms of changes in facility pharmaceutical functioning as assessed at baseline and repeat by the IP's tool. It also provided an indication of the effectiveness of the intervention, and variations that occurred in implementation.

1.5 Organisation of chapters

Chapter 2 comprises the literature review. This covers Health System Strengthening, and the use of TA as a Health Systems Strengthening strategy. TA, and supportive supervision as a similar concept, are explored in detail and studies examining the outcomes of TA are described. The specific programme assessed is detailed. The study's methodology, including

the design and analysis methods, are outlined in Chapter 3. In Chapter 4 findings are presented, and a discussion of these is provided in the subsequent Chapter 5. Chapter 6 provides a concluding summary and recommendations.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter begins with a description of Health System Strengthening and, specifically, as related to the pharmaceutical system embedded within the health system. Then, against the backdrop of Health System Strengthening, the definitions and applications of technical assistance (TA) are explored. Of particular focus are conditions for optimal TA, and a critique of TA is provided. Next, studies examining TA, some specifically related to pharmaceutical support, are described and finally, a description of the TA programme assessed in this study is presented.

2.2 Health System Strengthening as the context for technical assistance

The World Health Organisation (WHO) describes the health system as "the collection of organisations and actors whose main intent is to promote, restore and maintain health" (Hafner & Shiffman, 2013: 43). The health system comprises six building blocks (service delivery, health workforce, health information system, medical products and technologies, finance; and governance) (WHO, 2007). In a move away from disease-specific (vertical) programmes, Health System Strengthening gained the attention of WHO in the early 2000s, and has since emerged as one of WHO's main priorities (Hafner & Shiffman, 2013). Health System Strengthening is defined as "Improving the six system building blocks and managing their interactions in ways that achieve more equitable and sustained improvements across health services and health outcomes" (WHO 2007:4).

Primary health care (PHC) has been a central focus for Health System Strengthening (WHO, 2008). Furthermore, PEPFAR has been a leading global funder in promoting and funding Health System Strengthening as part of HIV interventions (Hafner & Shiffman, 2013). This is significant as Health System Strengthening interventions are different to vertical health programmes in that they aim to build up the six building blocks of health systems with the anticipation that this will have positive effects on the entirety of the health system, ultimately impacting patient outcomes. As stated by the WHO (WHO, 2007: iii): "The power of existing health interventions is not matched by the power of health systems to deliver them to those in greatest need, in a comprehensive way, and on an adequate scale". This is evidenced in the era of Universal Test and Treat, where health system bottlenecks curtail the roll out and upscale of health objectives such as initiating all known HIV positive clients on antiretroviral therapy (ART).

These challenges are manifested in the broader health system, with challenges such as supply chain constraints and human resource (HR) scarcities, down to individual health facility units. At facility level health care workers (HCWs) are faced with the competing demands of the immediate need for patient consultation, and the behind the scenes work such as stock and consumables forecasting and ordering, maintaining and applying up to date knowledge of relevant standard operating procedures (SOPs), and other training requirements (Jamieson & Kellerman, 2016; Waako *et al.*, 2009).

2.3 Pharmaceutical Systems Strengthening

The provision of medical products is a core building block of the health system (WHO, 2007) and access to essential medicines a health system priority (Bigdeli *et al*., 2013; Hafner, Walkowiak, Lee, & Aboagye-Nyame, 2017). Essential medicines are those indispensable and necessary to fulfil the priority health needs of the majority of the population, and are required to be available and accessible at all times (WHO, 2002; Wirtz *et al.,* 2016).

Ultimately the availability of essential medicines is an important indicator of a health system's effectiveness and equity (Oliveira, de Naves, & Silver, 2005). The pharmaceutical system's main purpose is to ensure timely and equitable access (through ensuring availability, affordability, accessibility and acceptability of products and services), and positively influencing appropriate use of medicines (Bigdeli *et al.*, 2013; Hafner *et al.*, 2017). The influence of individuals, households and communities on the health system, and specifically in terms of demand for medicines, is also a force acting within the system (Bigdeli *et al.*, 2013).

To ensure access and use of medical products five requirements need to be fulfilled:

1. National policies, standards, guidelines, regulations;

2. Market factors such as pricing information and international trade agreements, negotiation of prices;

3. Manufacturing and product quality control;

4. Effective procurement, supply, storage, distribution processes; and

5. Rational use support through guidelines and training (Hafner *et al.*, 2017).

The pharmaceutical system encompasses all resources involved to achieve these five requirements. As Hafner *et al.* (2017: 572) state, the pharmaceutical system comprises all

"structures, people, resources, processes, and their interactions within the broader health system that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use to improve health outcomes". Strengthening the pharmaceutical health system requires a holistic approach which mirrors the building blocks of the health system and involves addressing HR, governance, information, finances, service delivery and aspects of medical products including accessibility and quality (Systems for Improved Access to Pharmaceuticals and Services (SIAPs), 2018).

As in any system, interactions between the six building blocks define the system better than individual blocks (Hafner *et al.*, 2017). Health and pharmaceutical systems reactions and interactions can make the system resistant to change or cause unintended consequences. The system has to adjust to and learn changed internal and external forces, and change and transform when the existing system is no longer feasible (Hafner *et al.*, 2017).

Resilience in health systems is described as three-fold i.e., absorptive; adaptive and transformative, in that the system has to cope with disturbances or changes (absorb); adapt to changes through adjusting to changing factors; and to reorganise into a new system when previous ways of operating are no longer feasible (transform) (Hafner *et al.*, 2017). It is within this context that any intervention in one part of the health system needs to be understood in terms of how this affects the whole system (Hafner *et al.*, 2017). This understanding can enable interventions to produce sustainable changes. Nevertheless, while sustainability of interventions and solutions is crucial, sustainable solutions may take time (such as required reforms), and interim measures to address immediate gaps may be equally justifiable (Doumbia *et al*., 2017).

Hafner *et al.* (2017) proposed four criteria that can identify system strengthening interventions:

1.There are cross-cutting benefits beyond a single disease;

2.It addresses policy and organisational constraints and strengthens relationships between the building blocks;

3.A permanent systemic impact is produced beyond the term of the project;

4.It is customised to the unique context's constraints and opportunities, with roles and ownership required of the country's institutions.

Thus, while system strengthening is different to support that only addresses current constraints, the two are interlinked – strengthening ensures the system can manage and address future constraints, and system support addresses immediate, current system constraints (Hafner *et al.*, 2017). One way to render both support and strengthening is through TA.

2.4 Technical assistance

2.4.1 Definition

TA has been defined as the "provision of donor funded personnel to supply missing skills and train local people" (Arndt, in Gibson, Hoffman & Jablonski, 2015: 326). This definition relates to the World Bank context where TA is used in developing policy, skills and implementation capacity. Another definition of TA builds on this, stating that TA involves the transfer of skills and knowledge to a client which enables the client to develop or improve services, organisation, programmes or operations (Florin, Mitchell & Stevenson, 1993). Nemec *et al.* (1991) echo this stating that TA is the application of established and tested knowledge and practices to achieve programme objectives, and includes staff training, on site consultation, and the development of resources. In these definitions, TA covers both the filling of short-term gaps and the building of capacity where this is deemed insufficient at local level.

A more recent definition by West *et al.* (2012: 916) states that TA is "a dynamic capacity building process for designing or improving the quality, effectiveness and efficacy of specific programmes, services, or systems". Gottlieb (2014) describes TA more practically, as the provision of frequent, routine support through mentoring and supportive supervision with the aim of improving the functioning of the supported entity. It is notable that the terms TA and capacity building are often used together (Pengelly, 2005). Further to this, Brown (1980) elaborates that capacity building requires a good, ongoing relationship, demands a broad understanding of challenges and context, not just a problem orientation, requires investment in teaching and training, and involves risk in that some of what is done may be 'soft' and does not yield instant 'hard' results. It is notable that capacity building depends on mutual commitment between provider and recipient, and, while TA interventions may be rigorously designed, ultimately provision of TA is not a fixed blueprint, but rather a process (Lethem & Cooper, 1983). Effective TA requires motivation in order for momentum of implementation to be maintained, and through the support and training provided, behavioural change in the recipient (not always easy to assess), is expected (Lethem & Cooper, 1983).

Specifically in the health setting, TA is described as including in-service training, mentoring and coaching, and collaborative work (International Centre for AIDS Care and Treatment Programme (ICAP), 2018; Skosana *et al.*, 2017). Inevitably TA support involves a direct service delivery (DSD) component – where TA practitioners are on site to train or coach they may work alongside site staff to model the correct procedures, and alleviate the facility workload.

TA is a PEPFAR strategy as part of providing Health System Strengthening to inhouse government health care provision. Numerous challenges are experienced by health programmes and clinicians on the ground. Pertinent examples are that the latest research is in scientific journals and not typically accessible or implementable; and even where continuing education is provided, new knowledge does not necessarily change practice and behaviour (Kelly *et al.*, 2000). TA is therefore a means to bridge the gap between latest research and policies, and the practical application thereof.

2.4.2 Background and evolution

TA started post World War Two as a means to promote economic and social stability and development in the undeveloped world (Wilson, 2007). TA initially focussed on exploratory research, training and information dissemination. It was intended as neutral "linear knowledge transfer", not to interfere in the internal political affairs of a country (Wilson, 2007: 186). Early challenges with TA were the risk of taking a short-term gap-filling approach, without a coordinated and coherent long-term plan, and of applying methods incompatible with a different social cultural context (Wilson, 2007).

With the realisation that knowledge and ideas do not effortlessly transfer across cultural and social contexts, research, experimentation and evaluation became an integral part of TA in its variety of settings (Wilson, 2007). With a growing emphasis on participation and understanding of local context, the importance of capacitating local HR to promote full engagement, and ensure clear articulation of local needs and sustainability of TA, emerged (Wilson, 2007). Therefore, TA evolved to have an emphasis on interaction, demonstration and discussion, moving TA from linear knowledge transfer to deeper application and capacity building, with the focus on re-shaping knowledge such that it is applicable to the local context (Wilson, 2007). This evolution of TA occurred in line with changing development paradigms. Gibson *et al.* (2015) describe TA as a mechanism to fill knowledge gaps in

recipient countries and strengthen institutions, but cautioned on the use of TA as a mechanism to monitor and enforce external conditions on people or institutions.

Therefore, over time TA engagements have been re-conceptualised as "learning relationships", to address power imbalances and the one-way traditional TA approach (Wilson, 2007: 195), and emphasise the creation of mutually beneficial relationships. This also resulted in emphasis on the nature of engagement between the two TA stakeholders as crucially important, with TA practitioners required to collaborate and forge dialogue. In fact, Wilson (2007) has proposed that the differences between practitioner and receiver be interpreted as a resource, not a threat, and an opportunity to create knowledge between and with the two parties. This requires the building of trust through repeated engagements, and thereby a shared base from which to work together (Wilson, 2007). This suggests that longer, repeated TA engagements would be more fruitful, with trust and shared understanding built over time.

There has also been a growing impetus for receiving countries to demonstrate ownership and ensure sustainability of programmes through elaborating and shaping programmes according to their requirements and priorities (Wilson, 2007). This ties in with Morgan's (2002: 10) description of the evolution of TA, with the initial focus on accomplishing tasks in the short and long term, thereafter shifting to focussing on building capacity within the recipient country or organisation to have certain capabilities, and lastly assisting recipients to "build the capacity to build capacity".

2.4.3 Technical assistance models and theories

Lethem and Cooper (1983) describe four basic models of TA:

1. Performer or substitute model: TA expert performs the task as specified and required by the recipient;
2. Prescriptive TA: TA provider identifies problem(s) and recommends potential solutions;
3. Counterpart advisor: Recipient works as apprentice to the external expert; and
4. Collaborative: Recipient and provider work together, sharing the responsibility of substantive tasks and results.

As explored in the evolution of TA and as will become apparent in the description of the theories behind TA, the collaborative model is the preferred model purported as the most appropriate and effective; although each approach may have its place.

Where TA is perceived and provided as knowledge transfer from knowledge-rich experts to those in need (Wilson, 2007), this can be problematic as knowledge and skills may not transfer linearly across diverse socio-cultural contexts. Hence the move to describing TA as 'Technical Cooperation'; where an interactive, participatory approach between recipient and the TA provider is emphasised, with a focus on capacity building and innovation – i.e. ways of utilising and applying knowledge in practice interlinkages (Wilson, 2007).

TA can be understood as either being provided on a 'push' or 'pull' basis. This ties in with the question of whether TA should be provided based on an outside assessment, or internal requests for perceived needs (Feinberg, Greenberg & Osgood, 2004). Proactive TA involves bringing specific skills and knowledge to individuals and then assisting recipients to adopt and use the skills and knowledge. A proactive TA approach emphasises the 'push' nature of support, where support is anticipated and provided without waiting for requests for assistance. This is justified by the rationale that those who require assistance most may not perceive or articulate their need (Ray, Wilson, Wandersman, Meyers & Katz, 2012). Push TA is typically based on an external assessment of need, and this is argued as being valuable in determining the degree of need for TA and area of focus of TA, since local informants cannot always specify what TA will address what problem (Feinberg *et al*., 2004). Alternately, pull TA is instigated by the recipient, and characterised by requests regarding perceived needs (Feinberg *et al*., 2004).

A range of theories have been related to the practice of TA, although there is no singular framework for TA. TA borrows from a variety of educational, organisational development, and self-efficacy theories. Three theories that are noted as relevant to TA are Diffusion of Innovation; Social Cognitive Theory and Self-efficacy; and Readiness to Change (West *et al.*, 2012):

Diffusion of Innovation theory explains how a new idea or practice spreads through a social group (Kaminski, 2011). More specifically, in the context of TA, Diffusion of Innovation is about propagating a new practice within a system such that it becomes the norm (Bertrand, 2004). Bertrand (2004) describes how diffusion of an innovation requires communication; innovation-decision process i.e., moving from awareness, to knowledge, persuasion, adoption and finally implementation; and homophily – that those communicating perceive that they are similar to each other and can relate. Furthermore, it is the attributes of the innovation, such as

relative advantage, compatibility, complexity, trialability and observability, that can determine whether an innovation succeeds or not.

- Compatibility is whether the changes required are congruent with current values, experiences and needs. For example, where current values and needs are a focus on immediate patient care ('pushing the que'), and this is what the HCW has experience with and this practice is not challenged, the HCW has little reason to change this focus.
- Complexity i.e., how difficult a skill or change in working or behaving is perceived to be to understand and implement, which particularly impacts on sustainability of interventions.
- Trialability is how easy a skill is to try and experiment; and
- Observability i.e., how evident the change in skill and the effects thereof are to others (Bertrand, 2004).

Bertrand (2004: 118) cites "prestige, convenience or satisfaction" as core factors in whether an innovation is adopted. If changing a practice has initial hurdles and requires efforts greater than the gains of prestige, convenience or satisfaction, adoption of the change may be a non-starter. Thus, for innovation to be adopted into existing practice, the advantage of using it must be clear and easily implemented, and applicable to local context and needs (West *et al.*, 2012).

Adopter categories are also relevant in terms of how quickly individuals and groups adopt innovations, and the influence of opinion leaders (those respected for their knowledge or reputation on the topic) is paramount in promoting the adoption of the innovation (Bertrand, 2004; Ross-Degnan *et al.*, 1997). Ultimately the challenge is to institutionalise change and adapt it to needs and nuances. This requires a process where recipients are mentored through the stages of adoption of an innovation. TA is the tool in such system-change initiatives that facilitates ownership and practical application and integration, and overcomes challenges (O'Donnell *et al.*, 2000).

Social Cognitive Theory and Self-efficacy relates to the requirement for TA practitioners to be confident, experienced and skilled in what they are training others to do (West *et al.*, 2012). This is significant as others learn best from someone who confidently models the skills required (West *et al.*, 2012).

Readiness to Change Theory is relevant as organisations and people are at different stages in being willing to accept or adopt new knowledge and practices (West *et al.*, 2012). Therefore an assessment of readiness to change may assist in prioritising which organisations or individuals are best suited to target TA. In reality, readiness to change goes beyond absence of active resistance, and the best state is for the recipient of TA to have enthusiasm for adopting new practices, even where initial start-up challenges are experienced (Mitchell, Florin & Stevenson, 2002). Thus TA "must be wanted if it is to succeed" and needs to be designed and implemented in a "spirit of partnership" (Lethem & Cooper, 1983: 6).

Kelly *et al.* (2000) cite the following conditions for TA interventions to be effective: HCWs need to be dissatisfied with their current levels of skills, receive intense training and perceive the new method to be better, and receive ongoing follow up and support from someone they perceive as authoritative on the matter. These conditions relate to the theories of Readiness to Change, Diffusion of Innovation, and Social Cognitive theory respectively.

2.4.4 Technical assistance strategies

TA employs various strategies with the aim of increasing knowledge and skills, disseminating best practices, and assisting individuals and systems to adapt and apply updated knowledge and effective practices to enhance outcomes These include training, the development and sharing of educational materials including SOPs, guidelines, and job aids, and mentoring and coaching alongside the recipient.

Education strategies, including dissemination of educational materials and required guidelines and SOPs, and training sessions, are often the default approach taken when sharing updated knowledge and sector-specific developments. However, Low, Tjongarero, Low and Nambundunga (2001) caution that formal training plays only a small role in gaining new workplace skills. Moreover, Ross-Degnan *et al.* (1997) and Rowe, de Savigny, Lanata and Victora (2005) warn that printed and disseminated educational materials, even where they impact on knowledge, do not necessarily influence practice; and the distribution of guidelines alone is ineffective, amounting merely to an administrative exercise. Specifically, job aids in isolation are only effective when the HCW accepts the guideline and doesn't require major behavioural or practice change (Rowe *et al.*, 2005). For Guidelines to be effectively applied, active engagement such as ongoing training, audit, supervision and feedback are required. Thus, literature indicates that training is necessary but not sufficient, and additional support

such as mentoring and coaching is required to supplement and reinforce training (Fixsen, Naoom, Blasé, Friedman & Wallace, 2005; Wandersman, Chien & Katz, 2012).

Therefore, training alone is resource intensive and of limited sustainability unless it is done in conjunction with other interventions. SIAPs flag that training alone does not change behaviours, and refresher training, continuous support, and other factors such as managerial and regulatory interventions, serve to augment training's impact (SIAPs, 2018). Reinforcing strategies such as supportive supervision and guiding documents like SOPs and job aids are noted as necessary to supplement training in capacity building efforts (Doumbia *et al.,* 2017). Training is typically done, not just for knowledge transfer, but to enable trainees to learn and perform new activities. Effective learning and performance are assisted by a number of factors that include having applicable reference and guideline documents in place and available; having skilled people available; opportunities to practice learnings; and adequate resources to do the job required (Kelly *et al.,* 2004).

Ross-Degnan *et al.* (1997) describe how multiple training and support sessions are required to reinforce learning, and a variety of educational strategies such as seminars, workshops, case management examples and practical skill demonstration and practice can have an impact. The outreach visit is a means to enhance the effectiveness of any educational intervention, with Low *et al.* (2001) describing informal learning-by-doing within a supportive environment as far more effective than formal training, and Ross-Degnan *et al.* (1997) citing face to face educational visits as impacting on rational prescribing. Thus, training impact is enhanced by: being delivered on site, utilising multiple modalities (group problem solving, role play, practical skills practice), repeated sessions, and using district level leaders as trainers (Ross-Degnan *et al.*, 1997).

Supervision and performance monitoring utilising indicators, and audit systems where adherence to guidelines and criteria are systematically reviewed and feedback incorporated, have been found to be effective in enhancing HCW performance and programme outcomes (Ross-Degnan *et al.*, 1997; Rowe *et al.,* 2005). This is echoed by Kafuko, Zirabamuzaale and Bagenda's (1997) assertion that TA needs to be multifaceted, comprising regulatory, educational and managerial components. Managerial support can enhance training efforts, but this requires motivated supervisors who assess performance indicators. Although supervision using indicators, audit and feedback can be effective, the sustainability of changes without ongoing supervision is not clear (Ross- Degnan *et al.*, 1997).

Supportive supervision aims to reinforce skills on site. This is pertinent in the health system where activities that build skills on the job – without removing HCWs from facilities – are preferred (Waako *et al.*, 2009). Thus, mentors in the workplace who ensure skills are applied and practiced on the job are a key component of TA, although such support is often lacking after initial training (Low *et al.*, 2001). Mentoring comprises working alongside staff to strengthen staff's skills and troubleshoot arising challenges (O'Donnell *et al.*, 2000). Mentoring, coaching and role modelling are built on personal relationships established between recipient and provider (Lethem & Cooper, 1983). Where relationships and mutual understanding are built, this allows for TA to become collaborative - it is no longer the expert prescribing the solution or the recipient requesting assistance but rather "exchanges in experience" (Wilson, 2007: 192). Moreover, mentoring and coaching as a crucial part of TA, demonstrate that TA is not just about skills transfer but building confidence and creating a supportive environment for learning (Low *et al.*, 2001). Skills and knowledge need to be augmented with support and motivation to implement new learnings in a supportive environment.

DSD is an integral part of TA. Mentoring and coaching may involve a degree of role modelling and job shadowing where the TA provider actually does a job to demonstrate a skill. In some cases, the TA practitioner may conduct DSD to address a time sensitive activity or critical gap others on site have not yet completed, or as a means to assist the workload at an understaffed facility.

In summary, TA covers a spectrum of strategies from training and the dissemination of training or educational materials, to supervision, mentoring and in some cases doing the actual work (DSD). This highlights the significance and complexity of TA as it employs multiple methods and strategies to influence and optimise both knowledge and practical skills application.

2.4.5 Conditions for technical assistance to be effective

There are multiple conditions required for TA to be optimal. These include aspects of the process or manner in which TA is planned and implemented, and characteristics of the TA provider and recipient respectively.

2.4.5.1 Process

Mitchell *et al.* (2002) cite the TA process as requiring the following: the setting of measurable goals, with indicators to assess success, in line with resources; the development

and utilisation of assessment tools to determine what TA is needed; conducting an organisational assessment of readiness to receive the implementation; utilisation of logic models to examine assumptions and the planned, intended effects, and whether these are likely; and due consideration of whether dose strength of initiative is sufficient to bring about change. Ray *et al.* (2012) cite the core aspects of an effective TA process as comprising an accurate assessment of the status quo; development of good relationships with programme staff; knowing the sufficient dose strength to provide; clarity on expectations and priorities; and capacity of the recipient to accept and adopt recommendations.

Initial assessments are recommended as these establish the status quo and allow an understanding of the current context to be built. Nemec *et al.* (1991) state that simply conducting an assessment can mobilise change. Nevertheless, challenges associated with the change process can be significant, and even after the initial assessment, continued engagements between TA practitioner and recipient are of value in the ongoing identification of needs and targeting of TA. In addition, to optimise cost effectiveness and impact, it is recommended to focus TA interventions on priority factors to achieve core outcomes, instead of broad interventions (West *et al.*, 2012).

In summary, a TA project involves analysis of status quo assessment data; identification of strengths and weaknesses; planning together between the TA providers and recipients' goals for TA; identification of strategies to achieve objectives; scheduling of visits; implementation of the plan; and adaptation as necessary (Ray *et al.*, 2012; Nemec *et al.*, 1991).

2.4.5.2 Provider

Ideal TA delivery requires that the providers have in depth knowledge of current and evolving programme needs and challenges, and that emerging trends, evidence, technology and innovations are reviewed on an ongoing basis to see what is feasible and applicable to include in TA programmes (West *et al.*, 2012). In addition, providers require a holistic understanding of the programmes and recipients they serve, including the experience, context, strengths and weaknesses; this enables them to look for solutions that fit local circumstances and needs (West *et al.*, 2012). Therefore effective TA is provided by well-trained and capacitated local providers who understand the context, and who have practical experience, accessibility, cultural competence and good communication skills. Without this competence and confidence, TA providers may default to delivering interventions they are

comfortable with within their own professional remit, but these may not be in line with the needs of the recipient.

Providers' training materials are of relevance too - scientific evidence-based practice, local context, and the knowledge of what applies within the context need to be combined to be fit for purpose (Mitchell *et al.*, 2002; Laing & Ruzardo, 1989). Therefore, trainings and materials must be designed as relevant to stakeholder, and as an example, Laing and Ruzardo (1989) used the target audience in generating their own training material thereby ensuring on the ground experience and knowledge was brought to bear in developing training materials. Without this engagement, the sharing of learning experiences is at risk of being one way, and it is more effective if conducted as joint learning. This demonstrates that core to effective TA interventions is a two-way collaboration between TA provider and recipient, with customisation according to specific needs (West *et al.*, 2012). Effective TA practitioners need to forge and maintain trusting relationships with those they assist.

Practitioner motivation is also a core factor in effective TA (Nemec *et al.*, 1991). Effective support requires the providers themselves to be motivated, capacitated with skills and appropriate tools, alongside having resources such as transport and time, in order to be effective (Rowe *et al.*, 2005). This lifts the supervisory role from just an administrative and auditing function, to a more supportive and effective role and is explored further in Section 2.5 - TA and supportive supervision.

2.4.5.3 Recipient

Recipients of TA vary in willingness to learn and engage, and TA practitioners need to gauge and identify those who are engaged and where inputs will reap outcomes. This relates to the Readiness to Change Theory and the aspects of pull and push in TA implementation. Where TA is 'pushed' there may be resistance from those on the receiving end, who may not see its relevance or view it as a disruptor of established comfortable practices. Conversely, where there is strong pull i.e., appetite, acknowledgement of need, and engagement by recipients; this results in more effective TA. West *et al.* (2012) found that the frequency of requests for TA from recipients for assistance in implementing a programme (pull) was associated with more successful programme. To leverage this, Mitchell *et al.* (2002) describes the potential use of 'seeding' where broad brief training is provided to stimulate interest and determine where uptake would be optimally i.e., where there is pull or appetite to engage with the TA; and then TA is provided to those who indicate interest and receptivity.

Health worker practices, and aspects that influence these, are complex, and HCWs incorporate new guidelines and teachings into existing practices based on professional values, personal goals and motivation (Rowe *et al.*, 2005). This means that new learnings and skills may only be partially incorporated or implemented. Since HCW motivation, performance and engagement are key determinants as to whether TA interventions will gain traction or not, Low *et al.* (2001) advise that tools to support supervision and motivation should be a key part of TA interventions. This is echoed by Rowe *et al.* (2005), who acknowledge that inadequate HCW performance can be a challenge and performance problems cannot be addressed solely by training; therefore supervision and audits are recommended. Supervision is generally accepted as a means to improve recipients' performance, through motivating, increasing job satisfaction, and maintaining contact with central structures (Rowe *et al.*, 2005).

In the health care setting interventions to improve performance are influenced by the recipient's individual factors (including knowledge and motivation); client factors, including severity of illness; work factors (such as availability and complexity of guidelines); and health facility factors (environment, caseload, availability of supplies and supervision) (Rowe *et al.*, 2005). Management, support, motivation, and building the confidence of TA recipients are significant requirements that go beyond training, and a performance management system is a crucial part of supporting staff at facilities (Low *et al.*, 2001)

On a broader 'recipient' level, inhouse country ownership, motivation and engagement with the TA process is viewed as the most important determinant in success of TA interventions (Morgan, 2002). However, assessment and mediation of this factor in TA programmes remains complex.

2.4.6 Critique of technical assistance

While the ideal application of TA has been explored above, TA is not without its limitations and detractors. Morgan (2002) has written a seminal article encapsulating the high-level challenges and negative impact of TA, and a number of pertinent points are explored below.

TA has been critiqued as being bound by who defines the problems and matching solutions (Wilson, 2007). This is particularly significant as TA is typically provided to developing countries, with the bulk of funding coming from the TA provider, not recipient. Therefore power remains in the hands of the supplier. TA then is part of a process of change driven by international development agencies, and this removes ownership and accountability from recipients for the process (Morgan, 2002). This is further exacerbated as development

organisations may be more accountable to their funders than the local authorities whom they assist, and recipient governments may be more responsive and accountable to international donors than local electorates. This undermines ownership and accountability and may result in those who should benefit from programmes not being recognised as pivotal to programme design and implementation (Morgan, 2002).

TA is further critiqued as undermining the autonomy, independence and ownership of in-house staff, creating dependence, and causing national priorities to be set externally by the sheer financial and technological clout of international organisations. This lack of ownership can manifest on the ground as local staff pulling back from fulfilling their duties, as they perceive that there is someone else to do the job (Low *et al.*, 2001). Moreover, there are risks of setting up parallel structures to what exists locally and then undermining the existing local systems through diverting talent into parallel structures. Therefore, TA is critiqued in that it displaces the role of local staff, is resource intensive, doesn't enable skills transfer, and can result in the TA provider actually doing the job, instead of building capacity (Low *et al.*, 2001).

To (artificially) obtain domestic support, development organisations may promise and aim for unrealistic impacts. In addition, TA performance may be difficult to monitor, and fidelity of implementation of projects in alignment with the original planned and designed project may not always be 100%. With pressure to demonstrate impact and with limited buy-in from the recipient, implementing partners (IPs) may end up focussing on task accomplishment rather than more sustainable organisational development and capacity building (Morgan, 2002). Performance is then prioritised over listening, collaboration, experimentation, and nuances of timing (Morgan, 2002). This carries the risk that TA providers focus on clear-cut issues such as project workplans and activities, while the nuances of ownership, culture and context, building relationships, motivation, and legitimacy and credibility of TA providers is overlooked - fundamental aspects that ultimately influence and support change (Morgan, 2002).

Historically TA promoted organisational techniques that were not appropriate in resource constrained environments as they were too complex and costly (Morgan, 2002). This speaks to TA interventions not being sustainable – without in-country ownership and funding, when external support is withdrawn, no legacy remains. Moreover, high costs of TA interventions deny other possible interventions from being funded, thereby limiting intervention

opportunities and types, and it has been argued that TA is driven by self- interest in ensuring TA programme personnel are employed (Morgan, 2002).

TA is critiqued as presenting ideological issues as neutral technical matters. In reality, simple knowledge transfer is not possible, and needs to be applied within the user context to be of any value (Wilson, 2007). Reception of knowledge requires active engagement to receive, assimilate and make useable knowledge that has been received, hence knowledge is shaped by and in the interaction, and perpetuation of the dichotomy of expert-receiver must be avoided (Wilson, 2007). Related to this, TA is at risk of being reduced to the simple transfer of knowledge and application without acknowledging complexities of systems and contexts in which individuals are embedded, therefore the feasibility and absorbability of changes are not considered. TA risks comprising isolated, rational components focussed on activities such as training or policy development, without acknowledging the larger organisational, social, political context (Morgan, 2002). Furthermore, Morgan (2002) warns that most efforts at capacity building fail in both the development and private sector; even where TA is well designed, implemented, and managed, it may be affected by broader financial, political, organisational factors and constraints. These are most obvious where there are social and systemic dysfunctions. Where TA is predicated on the assumption that what is missing is technical knowledge and policies, and that transfer and absorption of technical procedures can be effective, this is designed for failure when situated in a dysfunctional system, where deeper social and organisational issues are at play (Morgan, 2002).

In terms of the implementation of TA interventions, West *et al.* (2012) flag that in practice much TA does not involve systematic assessment of need nor long term planning to impact sustainably, but rather short-term interventions. This ties into the critique that TA is applied in an *ad hoc* manner, when what is really required is an ongoing relationship between the recipient and provider of TA (Low *et al.*, 2001). Thus there is the risk of a simplistic approach to complex problems, and that the capacity required to manage and maintain the systems TA puts in place is not built (Brown, 1980). In addition, TA providers and on the ground staff may operate at odds to each other, as they diverge in terms of priorities: TA providers may focus on ensuring staff adhere to SOPs and formalised requirements, while staff on the ground are more interested in adapting procedures to their practical circumstances (O'Donnell *et al.*, 2000). Furthermore, deeper performance issues may not be adequately addressed nor exposed when building capacity is the focus.

With TA mostly funded by international organisations, TA practitioners may be perceived as fulfilling the more sinister function of monitors and information gatherers (Morgan, 2002). Alternately, this can be interpreted in a positive light as TA is accompanied by an increased amount of donor oversight, and Gibson *et al.* (2015) suggest that this oversight decreases the misuse of resources for patronage and promotes liberalisation.

Ultimately, Morgan (2002) in his critique concludes that TA persists, despite its failures, due to the resource sharing benefits it bestows, and that failures are attributed to the unique contexts, rather than the project ideas, techniques and implementation. Since there is an absence of clear evaluations on cause and effect and outcomes of TA, conclusive decisions on the value add of TA cannot be made either way (Morgan, 2002). Wilson also argues that initial outcomes of TA, such as increased knowledge or changed skills, may be "intangible" (Wilson, 2007: 188). Nevertheless, with limited funding and pressure from funders to provide evidence for return on investment, demonstrating evidence of TA impact in the health sector has become increasingly vital (Jones, 2013; Padian *et al.*, 2011). Despite this, in a review conducted by West *et al.* (2012) on evaluations and assessments of TA interventions, of the 23 published evaluation articles that they found suitable to review, only 2 were non-US based. This reflects the narrow (western) focus of TA evaluations, even though this is a major strategy deployed in Health System Strengthening efforts in the developing world.

2.5 Technical assistance and supportive supervision

Most TA assessment studies have been conducted within the United States, although TA is a strategy that is widely employed by PEPFAR and other development organisations beyond the United States' borders. In order to broaden the review of TA interventions, particularly as related to pharmaceutical support, studies on the effects of supportive supervision are also covered in this section as there are commonalities between TA and supportive supervision.

2.5.1 Technical assistance studies

Florin *et al.* (1993) conducted a study to identify common TA needs of community coalitions (voluntary community programmes) aiming to address alcohol and drug abuse. In the study, TA for organisational structure and operating procedures was provided. It was found that written guidelines and tools, and personal instruction were judged by participants as equally helpful. It was noted that different knowledge area needs can be variously addressed by written materials, skill building through training and practice, and on-site consultation. Therefore, the intervention included training programmes to develop skills, consultation via

phone or face to face; the sharing of publications or other material or guidelines; and creating linkages between similar groups to build a support network (Florin *et al.*, 1993). As a caveat to their study, Florin *et al.* (1993) advised that an outcome evaluation was only appropriate after 3-5 years (the time it takes to attain full programme implementation) of programme implementation, and that therefore they could only conduct a process and implementation evaluation of the programme.

Kelly *et al.* (2000) explored what types of TA approaches were most effective in transferring latest research on HIV prevention to organisations, with a combination of methods implemented in 3 different groups: Group 1. Procedure manuals and instruction guides provided; Group 2. Procedure manuals and instruction guides plus a two-day training workshop on how to implement the intervention; and Group 3: Procedure manuals, workshop and follow up support comprising an initiation assessment including identifying needs, and monthly consultation calls for 6 months follow up and problem-solving support. In this study Kelly *et al.* (2000) found that those who received the 3-fold support (materials, workshop and telephonic consultation support) had the highest levels of adoption and use of the programme on which they had received training.

In a systematic review of prescribing intervention studies by Ross-Degnan *et al.* (1997), different interventions were assessed for impact. Sole dissemination of printed materials consistently had no impact. Training that was multimethod (role play, practical skills), constituted multiple sessions, and included on site sessions had the highest impact. Effective supervision and monitoring, and feedback from audits, was also found to render moderate to high impacts, although the sustainability of the outcomes was not included in the review (Ross-Degnan *et al.*, 1997).

2.5.2 Supervision studies

Supervision is described as including the monitoring of routine activities, reinforcing service norms, providing training, and offering assistance in resolving problems (Foreit & Foreit, 1984). Thus, there are commonalities between TA and supervision, with studies demonstrating that the systematic provision of supervisory support improved the functioning of PHC facilities (Foreit & Foreit, 1984; Loevinsohn, Guerrero, & Gregorio, 1995). A study conducted in PHC facilities in Zimbabwe, demonstrated that supportive supervision and on-site training were effective in improving medicine management (Trap, Todd, Moore, & Laing, 2001). Furthermore, an intervention at facilities in Uganda included additional

strategies such as supply of job aids and guidelines, and repeated re-assessments (Trap *et al.* 2016). This study showed that after a year's support, with an average of 3.4 visits conducted per facility, the median improvement of score between baseline and final assessment was 68.9% (Trap *et al.*, 2018).

Foreit and Foreit's (1984) study in Brazil looked at the impact of the frequency of supervisory support visits. The status quo was routine supervision provided on a monthly basis (visits also included the delivery of medicines). This was thought to motivate workers, although the costs of monthly visits to remote health posts were significant, and time per visit limited. In order to reduce costs and thereby enable additional health posts to be opened, supervision visits were reduced to quarterly, supplemented by additional visits where the need was apparent. A comparison was conducted between the control (status quo) and the experimental (reduced frequency of support) group. During a nine-month period, health posts received average number of visits of 8.5 (control); versus 4.1 (experimental). It was found that quarterly supervision (supplemented by selective support visits where required e.g. to replenish stock) did not reduce programme performance. This was attributed to the type of work the supervisor conducted during supervisory visits. Supervisors mainly attended to the gathering of routine service statistics, with limited engagement between the supervisor and the post's HCW (Foreit & Foreit, 1984). Thus in Foreit and Foreit's (1984) study it was found that reducing the frequency of supervisory visits did not impact on programme performance, and this was attributed to the fact that most supervisory visits did not involve much engagement with the health post's staff, but rather involved gathering of service statistics by the supervisor. On the other hand, a study by Loevinsohn *et al.* (1995) found that frequency of supervisory visits was correlated with improvements in performance of PHC facility indicator score. A dose response effect was found where a group of facilities visited three or more times during a six month intervention period improved their scores significantly more than those visited less than three times in the same period (Loevinsohn *et al.*, 1995). The group that reflected the dose response effect was supported by supervisors using a structured assessment tool; in the control group (no use of structured assessment tool) the number of supervisory visits was not related to changes in performance scores. Therefore, Loevinsohn *et al.*'s (1995) study emphasises that frequency of supervision alone is not enough to improve performance, and rather the use of a standardised tool to assess and provide structured feedback to staff on a regular basis made the supervisory visits effectual. It was concluded that the objectivity of a checklist enabled improved relations with supervisors,

reminded supervisors and HCWs of critical tasks, provided a clear structured way to address key performance areas, and simplified follow up enabling a focus on problem solving. Notably, even though some HCWs felt stock availability was not within their control, availability of medicines and supplies increased markedly in the experimental group, and this was possibly because those responsible began to calculate required stock levels (Loevinsohn *et al.*, 1995). It was also of note that where performance was adequate at baseline, limited improvements between control and experimental groups occurred. Loevinsohn *et al.* (1995) cautioned that this was a 6-month study, therefore the sustainability of effects was not clear, but the crux was that frequency of supervision does matter when done in a structured manner.

2.6 Technical assistance programme

The TA intervention this study assessed is located within the 'Comprehensive Facility-Based TA in the Context of Health System Strengthening in South Africa' PEPFAR Grant. Under the Health System Strengthening objective, a pharmaceutical activity is required to "support South Africa with TA to ensure an effective supply chain for HIV and TB related commodities" (Centre for Disease Control and Prevention (CDC), 2016: 19). The intervention devised and conducted by the IP was formulated in response to this objective (Refer to Appendix A for the TA logic model). This programme was led by a SEAD Senior Pharmacy Advisor with a team of six SEAD District Pharmacy Advisors, all qualified pharmacists. All pharmacy advisors underwent induction and orientation at commencement of the programme in order to be familiar with the objectives of the grant, the facility assessment tool, training materials, and relevant district SOPs. Pharmacy advisors conducted site-visits Monday to Thursday, with Friday as an administration day (SEAD, 2017a).

This programme focussed on a facility-level support mandate, with assessment and support focussed on facility level functioning. The intervention process of the programme was baseline assessment, with findings of the baseline assessments shared at district, sub-district and facility level. After assessment, the support visit phase began with initial Formal Module Training (FMT) (covering all supported facilities), and follow up TA intervention support visits conducted thereafter. A repeat assessment was conducted in March 2018, after the TA intervention phase. Refer to Figure 1 for a representation of the programme phases and timelines.

Initial FMT involved on-site training on four modules covering the topics of Good Pharmacy Practice (GPP), Stock monitoring, Stock ordering and receipt, and Stock storage.

1. GPP, covered an introduction to GPP and including the standards of compliance required with regards to premises, facilities and equipment; services; HR; and pharmacy management.
2. Stock monitoring, included what stock monitoring is and the importance thereof, stock cards, physical counts, expiry date monitoring, discrepancies, and order levels.
3. Stock ordering and receipt, included the importance of stock ordering, the generation and placing of orders, including emergency orders, the receipt of orders, order tracking, and re-order levels.
4. Stock storage: included the importance of, storage processes FEFO (first expired, first out) and FIFO (first in, first out), and requirements for the storage area (SEAD, 2017b).

Follow up support visit TA strategies included:

- Document and refer matter upstream: Where challenges were beyond the Pharmacy Advisor's scope or mandate, the challenge was documented (e.g. on email) and referred or escalated to the relevant person or supervisor to engage further.
- Formal Module Training (FMT) (additional): On-site training of facility staff on the Modules developed as part of this intervention programme (done as an addition to or repeat of the initial FMT)
- Simple refresher training: Referring facility staff to content previously trained on in FMT, referring back to the relevant module and focussing on a particular aspect that required refreshing e.g. calculation of re-order levels, understanding of a particular SOP
- Informal mentoring: Engaging peer to peer with a staff member on an area identified as requiring support, and working alongside the staff member to offer advice and role model how to do things.
- DSD: Actually doing the job at the facility, for the facility; for example, stock counts, updating bin cards.

In the context of Health System Strengthening and Pharmaceutical System Strengthening, SIAPs describes pharmaceutical TA as providing support to address strengthening medicine management practices, building capacity, and ensuring availability of medicines (SIAPs, 2018). This is aligned to the TA intervention programme assessed in this study.

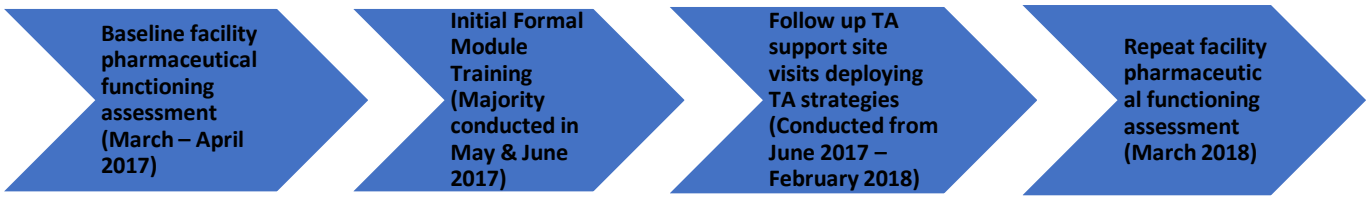


Figure 1 Programme phases with timelines

CHAPTER 3: METHODOLOGY

3.1 Aim and objectives

3.1.1 Aim

To describe and compare changes in facility-level pharmaceutical performance among primary health care (PHC) health facilities that received pharmaceutical management technical assistance (TA) in Amathole District, a rural district of the Eastern Cape, South Africa.

3.1.2 Objectives

1. To categorise and describe PHC facilities according to key facility characteristics.
2. To describe TA interventions conducted at PHC health facilities.
3. To compare differences in facility-level pharmaceutical performance pre- and post-intervention.
4. To explore the possibility of a relationship between intensity of TA visits and improvement in facility-level pharmaceutical performance.

3.2 Study design

A programme assessment, utilising a pre- and post-test study design, was conducted using secondary data. All the units of study i.e. PHC facilities in Amathole District that received the intervention (baseline assessment, support visits including initial Formal Module Training (FMT) and follow up support visits, and repeat assessment) were analysed. The basis of comparison was temporal i.e., before and after (Morroni & Myer, 2014). A pre-test, post-test study design assumes:

1) Level of performance before intervention = X;

2) Treatment or intervention then occurs;

3) Level of performance post intervention = Y;

4) Intervention effect = Y-X (Kothari, 2004).

The intervention effect was determined by the difference in the pre- and post- intervention assessment levels (Kothari, 2004). In contrast to randomised controlled trials (RCT) which aim to establish causal attribution, programme evaluations only allow “plausible connections” to be drawn between the programme and outcomes (Thomas *et al.*, 2011: 20). Hence changes were tentatively attributed to the intervention. Whereas in an RCT, other intervening factors are controlled for by having a control sample that mirrors the intervention

sample, except for the intervention, this was not feasible in this case, given that this was a retrospective assessment of a previously implemented programmatic intervention.

3.3 Study population and sampling

The study comprised secondary data from the total number of the implementing partner (IP) supported facilities. According to the programme mandate, 112 PHC facilities were supported in Amathole District. One hundred and ten PHC facilities were included in the analysis based on the available data. In effect, the study was a census, i.e., all the eligible facilities were included. Limitations of a census are that it may require a large budget and be time consuming where the population is large (Kothari, 2004). However, in this case the IP's mandate was coverage of all the facilities. Advantages of a census are that it accurately reflects the population, and this is particularly of value where the population is heterogenous i.e., varies a lot (Kothari, 2004).

Inclusion Criteria:

1) Amathole District;
2) PEPFAR funded facility;
3) PHC facility (clinic or community health centre (CHC));
4) Supported by the IP during the period April 2017 – March 2018.

Exclusion Criteria:

1) Any eligible PHC facility that did not have pre and or post intervention assessment data and or TA intervention support visit data available.

3.4 Data collection, instrumentation, and processing

This study used secondary data to assess changes in facility level pharmaceutical performance brought about by a TA intervention programme. As cautioned by Tripathy (2013), when undertaking secondary data analysis, the original data should be evaluated in terms of the method of data collection, accuracy, the purpose for which it was collected, and the data content. Hence, the known information on the original data collection method is outlined first and thereafter the secondary data collation process is described.

3.4.1 Original data collection method

Data was collected during the period of programme intervention (April 2017 – March 2018). Data collection procedures involved the administration of a facility functioning tool (Baseline assessment) by a SEAD pharmacy advisor at each facility on commencement of the

programme. The tool was developed by the IP organisation (SEAD) as part of its intervention, and had been used and piloted on another Grant. The tool had face validity and, therefore, was relevant, acceptable and appropriate to the pharmacists conducting the assessments. This was because items included in the tool were based on a number of pharmacy guidelines including: South African Pharmacy Council Requirements; National Core Standards; Ideal Clinic; Department of Health (DoH) Policies; and the Centres for Disease Control and Prevention (CDC) Site Improvement Monitoring System (SIMS) Tool.

The tool was developed as a management tool, not a scale instrument, in order to check the presence or absence, attainment or not, of required pharmaceutical criteria. Findings from the baseline assessment were then analysed on commencement of the programme in order to guide the advisors as to the poorest functioning facilities, and the areas of functioning in the allocated facilities that required the most support or corrective actions.

The IP assessment tool comprised a checklist and for each item on the list the assessor scored the facility either non-compliant, partial, or compliant (Appendix B). There were five sub-sections in the checklist covering Training; Guidelines and reference documents; Stock monitoring (including assessment of a list of 29 items for expiry and stockouts); Stock ordering; and Storage of medicines. Pharmacy advisors were trained on the data collection tool i.e. on the distinction between scoring a compliant or yes, partial, and non-compliant or no answer. Options were clearly stated in dropdown options on the electronic application. Question items were assessed through on-site observation, including document or record reviews, and interviews with facility managers. A hand-held device was utilised for direct data capture on site.

The SEAD Senior Pharmacist conducted supervisory site visits with the pharmacy advisors (pharmacists) to ensure standardisation of the application of the tool and scoring of facilities. Pharmacy advisors had weekly debriefing sessions to facilitate standardisation (SEAD, 2017a). Missing and improbable data was prevented by validation rules i.e. the electronic app did not allow data submission unless all the fields in the questionnaire were complete; and dropdown options delimited assessment findings to pre-determined answers. Appendix B is the original data collection tool (hard copy) that was converted to electronic app format and used in the field by the IP.

3.4.2 Secondary data collation

The secondary data comprised raw data downloaded from four data collection mobile applications ('apps') housed by the IP: Baseline assessments; Initial FMT data; Follow up site visit intervention data; and Repeat assessment data. The data, previously captured by the pharmacy advisors onto a data capturing app utilising an electronic device (tablet), was housed on an Open Data Kit data collection and management platform ('Kobo collect'). Appendix C is the breakdown of the domains and items extracted for the secondary data analysis, and the corresponding response options. A summary of the domains and content follows:

- Policies, guidelines and reference materials (maximum score 10) assessed the availability of up to date policies and guidelines in the facility.
- The Training domain (maximum score 14) covered whether the delegated person managing the store room had attended training on a number of relevant topics, and how recently training had been provided.
- The Stock management domain (maximum score 16) covered aspects of the ordering, receiving and issuing of stock including the use of rosters regarding pharmaceutical duties at the facility, the use of schedules for ordering, and the regular updating of the calculation to determine order quantities.
- Stock monitoring (maximum score 22) assessed the presence and use of stock lists at the facility, whether stock cards were updated and balanced with physical stock, stock take procedures, and the monitoring of expiry dates.
- The Storage (maximum score 30) domain assessed the storage conditions of pharmaceutical products in the facility, including the monitoring of temperature, refrigeration, stock rotation and security.
- The Stockout and expired medicine domains assessed 29 items for evidence of stockout or expiry in the previous three months.

The raw data from the four different apps were downloaded into Excel spreadsheets in August 2018. The 112 facilities were then matched across all the four data sets. Two facilities were found to have repeat assessment data missing, so were excluded from further analysis.

Data fields extracted from the raw data were as per the domains and items listed in Appendix C, and these were scored (where necessary) and consolidated and populated into the data extraction sheet (Appendix D) which served as the final data set.

3.4.2.1 Data extraction tool

The data extraction tool comprised facility characteristics, exposure, and outcome variables.

Facility characteristics: Sub-district; CHC or PHC facility type; PHC headcount (and categorisation thereof); high total remaining on ART (TROA) patient volumes or not; Department of Health (DoH) pharmacy personnel on site (and categorisation thereof).

Exposure variables: Number of TA support visits provided per facility; types of TA strategies utilised at site visits, totalled per facility.

Outcome variables: Seven pharmaceutical functioning domains (Policies and guidelines; Training; Stock management; Stock monitoring; and Storage of medicines; No stockouts; No expired medicines); overall facility pharmaceutical functioning assessment score and percentage.

3.4.2.2 Data extraction process including categorisation

Facility characteristics

PHC headcount volume was categorised into groups reflecting 'small', 'medium' and 'large' volume facilities. The categorisation was based on the NDoH Workload Guidelines (Government Gazette, 2015) classification of facility sizes. Categorisation was done with midpoints between the volumes stated in the Guidelines taken as the lower and upper limits of the 3 volume sizes (small, medium, and large). 'Small' volume PHC headcount facility was any PHC headcount below 16 491 for clinics and below 65 895 for CHCs. For 'medium' and 'large' clinics respectively, the annual PHC headcount fell between 16 491 (lower limit) and 23 086 (upper limit), and 23 087 (lower limit) and 57 905 (actual highest). For CHCs, 'medium' and 'large' categories fell between 65 895 (lower limit) and 85 663 (upper limit), and 85 664 (lower limit) to 92 501 (actual highest) respectively.

Exposure variables

For the initial FMT data, instances of facility visits to provide initial FMT, as evidenced by different dates, were summed together to obtain the total number of visits where initial FMT was provided, per facility. This method, utilising dates as visit instances, was also used to obtain follow up support visit totals per facility. In addition to visit instances, strategies (as selected on the app and indicated by a '1' reflecting an instance of deploying that strategy) were added together. It was possible that at one visit instance the advisor utilised more than one strategy, and utilised one strategy more than once. For example, if the advisor noted that an air conditioner was not operational, and that this would require sub-district intervention

through the sub-district following up with the service provider, this would be logged as a '1' under 'Document and refer matter upstream'. If at the same facility it was also noted that infrastructure, such as shelving or security bars were required for the pharmacy store, this would also be logged as an instance of '1' – 'Document and refer matter'. These matters would then be escalated to the district, district pharmacist and the Prime in order for them to engage with service providers contracted to the DoH and mobilise budgets and planning to install the required infrastructure.

A number (n=10) of facilities had no follow up support visits logged, although they had received initial FMT. Nine of these facilities were in Mbhashe Sub-district. This either reflects the operational challenges experienced by the IP in this sub-district to provide adequate coverage of the allocated facilities, or that data record keeping or capturing and therefore data quality for this sub-district was not well maintained. These facilities were kept in the analysis as they had baseline and repeat assessment data, and had received documented intervention support in the form of initial FMT.

Outcome variables

The extraction process for the baseline and the repeat assessment data was as follows. In the raw data sheets, items comprising each domain (as per Appendix C) were highlighted, and summed together, per domain. Expired medicines and stockouts were removed from the stock monitoring section and separated out in order to make the analysis and findings thereof discrete. In order to standardise scoring of all the domains, all domains were scored such that an increase in score reflected positive improvement. This enabled all domains to be summed together to make an overall performance score. Therefore stockout and expiry data is reflected as 'No stockout' and 'No expired medicine' of the 29 items assessed. The total score of the seven domains was utilised as the proxy score reflecting overall facility pharmaceutical functioning. These totals were then populated per facility into the data extraction sheet.

Data were matched per facility to ensure that all facilities included in the study had: Baseline assessment data; support visit intervention data including initial FMT data and or follow up support visit data from the 'TA intervention app'; and repeat baseline data. The final sample suitable for secondary data analysis comprised 110 facilities.

3.5 Data management, exploration and analysis

Excel and Statistical Package for Social Science (SPSS®) packages were used for secondary data management and analysis. The relevant data from the IP's database were captured into the Excel data extraction sheet. Ten percent (n=9) of facilities were randomly selected and data in the extraction sheet manually compared back with the raw data downloaded from the original database, to verify accuracy of transcription (Houston, Probst & Martin, 2015). As the study utilised secondary data, it was not possible to verify historical data that was based on prior observation by the pharmacy advisors and previously captured at the PHC facilities.

3.5.1 Data exploration

As part of data exploration, histograms and Q-Q plots of the variables were viewed. In addition, the Kolmogorov-Smirnov and Shapiro-Wilk tests were utilised to assess normality. All data elements were found to be non-normally distributed, except for Total Score Baseline, Percentage Score Baseline, and Difference (Repeat-Baseline score). Hence non-parametric versions of all planned statistical tests were utilised.

3.5.2 Analysis

Facility characteristics had descriptive statistics of frequencies and percentages reported. Support visit and pharmaceutical functioning assessment (baseline and repeat) data had medians (with interquartile range) and means reported. Medians are the preferred measure of central tendency for non-normally distributed data as they are affected less by outliers and skewed data (Donges, 2018). Both medians and means were reported for evaluation of the distribution, however statistical analyses were based on medians (Trap *et al.*, 2016). A significance level of $p = 0.05$ was used.

Utilising frequencies, PHC facilities were categorised and described according to key facility characteristics. Frequency analyses were conducted for the study's 110 PHC facilities according to facility characteristic categories i.e. CHC or PHC, PHC headcount volumes, high TROA or not, and whether the facility had DoH pharmaceutical personnel based on site. These characteristics were also disaggregated by sub-district.

To describe TA support visit interventions conducted at PHC health facilities, frequencies and measures of central tendency and dispersion (medians with interquartile range, and means) were analysed for the TA intervention support visit data (i.e. number of visits and strategies utilised), per facility characteristic category. Chi-square tests were conducted within the different facility characteristic groups. The chi-square test provides the statistical

significance of observed differences, and is used for nominal (categorical) data, and where data are not normally distributed (McHugh, 2015). The use thereof enables conclusions to be drawn about whether exposure variables (support visits and strategies) differed significantly across various facility characteristic categories.

To compare differences in facility-level pharmaceutical performance pre- and post-intervention, measures of central tendency and dispersion (medians with interquartile range, and means) were analysed per facility characteristic for baseline and repeat scores across the seven pharmaceutical domains, the total facility-level pharmaceutical performance score, and the total percentage.

To determine whether scores differed significantly between baseline and repeat assessments, the related samples Wilcoxon signed-rank (WSR) test was conducted on the nine outcome variables. The WSR is the nonparametric version of the T test, which determines whether the mean difference between two scores over two points in time is statistically different from zero (Tredoux & Durrheim, 2002). Use thereof enables a claim to be made whether a significant change occurred between the two time points, and the change tentatively attributed to the intervention.

To determine whether there was a relationship between number of TA visits and improvement in facility-level pharmaceutical performance, correlation between number of TA support visits and percentage change in overall facility-level pharmaceutical performance scores between baseline and repeat assessments was conducted utilising Spearman's correlation coefficient. The non-parametric correlation calculation was utilised due to the non-normal distribution of the support visit data. Correlation enables the strength in relationship between two continuous variables to be established (Tredoux & Durrheim, 2002). Cause and effect cannot be concluded from the statistical findings, with conclusions based on the analyst's judgement (Tredoux & Durrheim, 2002).

3.6 Validity and reliability

Selection bias of facilities was not a risk as this was a census of the facilities included in the original programme implementation. Observer bias was a risk in the original programme implementation, particularly for the post-intervention assessment, as pharmacy advisors re-assessed the facilities they had supported during the TA intervention. Steps by the IP to eliminate bias in the baseline and repeat assessments were:

- Supervision visits with the pharmacy advisors by the Senior Pharmacist to verify scoring of facilities was accurate and standardised across all pharmacy advisors.

- Weekly debriefs to discuss scenarios and scoring implications of scenarios (to obtain shared clarity on 'partial' scoring).
- Weekly data reviews where pharmacy advisors re-looked at their data ('eye balled' raw data) to identify any errors prior to final submission. There was limited need for this as there were fixed options on the electronic app dropdown options which didn't allow for nonsensical data to be captured. The app also required all fields to be completed, therefore preventing missing data (SEAD, 2017a).

3.7 Ethics statement

Approval of the study for degree purposes was obtained from the University of the Western Cape Senate Higher Degrees committee and ethical approval was obtained from the Biomedical Research Ethics Committee (Ethics Reference Number: BM18/9/15) (Appendix E). Consent to utilise the data was received from the IP and the IP's Prime (Appendix F). As requested by the Grant's Prime (TB HIV Care Association, which sub-awarded the pharmaceutical component to SEAD), engagement occurred with the CDC, the programme funder, to establish permission to conduct the programmatic assessment. Feedback from the CDC was that such permission was not required as the study involved use of historical programmatic data collected in the course of programme implementation.

Approval from the DoH, Eastern Cape Province, Eastern Cape Health Research Committee (EC_201901_006) was obtained once ethical approval was secured, through registering the study on the National Health Research Database (Appendix G). An email informing the DoH Amathole District Manager of the study was submitted.

No patient-related data was utilised in this research. Facility level data on facility pharmaceutical functioning were utilised, and aggregated findings (at a sub-district level) described. Therefore, no facility was named or pinpointed as poorly performing with regards to pharmaceutical services. All data are kept by the primary researcher on a password protected device, in a password protected folder, backed up on Dropbox. In addition to the thesis, a presentation on findings will be prepared and shared with interested parties (the IP and DoH).

CHAPTER 4: RESULTS

4.1 Introduction

This chapter reports the findings of the study which described and compared changes in facility-level pharmaceutical performance among primary health care (PHC) facilities that received pharmaceutical management technical assistance (TA) by an implementing partner (IP) in Amathole District, a rural district of the Eastern Cape, South Africa between April 2017 and March 2018. One hundred and ten (n=110) PHC facilities had a baseline assessment ('pre-test' April 2017), received TA intervention in the form of one or more support visits, and had a repeat assessment ('post-test' March 2018), and were included in the study.

The following findings are described: PHC facilities according to key facility characteristics; interventions conducted at PHC facilities, including frequency of support visits and strategies utilised; comparison of differences in facility-level pharmaceutical performance pre- and post- intervention; and the relationship between intensity of TA support visits and change in facility-level pharmaceutical performance.

4.2 Primary health care facility characteristics

The PHC facilities were characterised according to sub-district, facility type, headcount volume, whether the facility was classified as high total remaining on ART (TROA), and whether Department of Health (DoH) pharmaceutical staff were on site (Table 1). The 110 facilities included in the analysis were spread across four sub-districts, with Amahlathi Sub-district having the most facilities at 30% (n=33), and Nkonkobe the fewest at 20% (n=22). The majority (95.5%) of facilities were clinics (n=105), with five facilities community health centres (CHCs) (4.5% of the sample). Mbhashe had three CHCs, Mnquma and Nkonkobe had one CHC each, and Amahlathi had no CHCs.

Overall, 53% (n=58) of facilities were classified as being large volume facilities based on annual PHC headcount, 27% (n=30) were medium volume facilities, and a fifth (n=20) were small volume. Amahlathi Sub-district had almost double the number of large volume facilities compared to the other three sub-districts.

Eighty six percent (n=95) of facilities were classified as non-high TROA, with 14% (n=15) high TROA. High TROA facilities were classified by the programme implementers as those facilities with a high volume of total clients remaining on ART. High TROA facilities were distributed unevenly across the sub-districts, with Mnquma and Mbhashe having seven and

five high TROA facilities respectively, and Nkonkobe and Amahlathi having two and one high TROA facilities respectively.

Fifteen percent (n=17) of facilities had DoH pharmaceutical staff on site at the baseline assessment, with 84.5% (n=93) of facilities with no on-site pharmaceutical staff. Nkonkobe had half the number of facilities with pharmaceutical staff on-site compared to the other sub-districts (1.8% of Nkonkobe facilities had pharmaceutical staff on-site, compared to other sub-districts where 3.6-5.5% of the sub-districts' facilities had pharmaceutical staff on site). Baseline assessments reflected that there were no pharmacists at clinic level. Three CHCs had pharmacists, one CHC had two pharmacists, and two CHCs had one pharmacist each. In terms of pharmacist's assistants (PAs), 93 facilities (84.5%) had no PA at the time of baseline assessment, eleven facilities had one PA, four facilities had two PAs and one facility each had three and four PAs.

Table 1 Characteristics of PHC facilities at baseline assessment by sub-district

	Amahlathi		Mbhashe		Mnquma		Nkonkobe		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%
Total	33	30	30	27.3	25	22.7	22	20	110	100
Facility type										
PHC	33	30	27	24.5	24	21.8	21	19.1	105	95.5
CHC	0	0	3	2.7	1	0.9	1	0.9	5	4.5
Headcount volume										
High	21	19	12	10.9	12	10.9	13	11.8	58	52.7
Medium	6	5.5	11	10	6	5.5	7	6.4	30	27.3
Low	6	5.5	7	6.4	7	6.4	2	1.8	22	20
High TROA										
Yes	1	0.9	5	4.5	7	6.3	2	1.8	15	13.6
No	32	29.1	25	22.7	18	16.4	20	18.2	95	86.4
Pharmaceutical staff on site										
Yes	4	3.6	6	5.5	5	4.5	2	1.8	17	15.5
No	29	26.4	24	21.8	20	18.2	20	18.2	93	84.5

4. 3 Technical assistance support visit interventions

TA interventions were conducted after the baseline assessment. TA was provided during site visits and comprised initial Formal Module Training (FMT), and thereafter follow up support visits continued to support the facilities and reinforced the practice and application of initial FMT. At follow up visits, advisors categorised the support they provided into six intervention

strategy categories i.e. Document and refer matter 'upstream'; Informal mentoring and advice; Formal Module Training (additional); Simple refresher training; Provide job aids; and Direct service delivery (DSD).

TA intervention data presented is two-fold – the frequency of visits for initial and follow up support; and the type of strategy employed at the follow up support visit. Support visit data from May 2017 to February 2018 are reported overall and per facility characteristic in Table 2. Note that the visits where the baseline and repeat assessments were conducted are excluded from this data.

The totals reflected in Table 2 indicate that follow up visit instances were almost double the initial FMT visits, and that the strategies used most frequently at follow up support visits were Informal mentoring or advice, DSD, and Document and refer matter upstream. More detailed analysis of support visit data follows in Section 4.3.1.

4.3.1 Analysis of PHC facilities' support visit frequencies

Support visit frequencies, disaggregated per facility characteristic, are presented in Table 3. Overall, the median number of visits per facility to provide initial FMT was 2 (1-2), with a mean of 1.8 visits per facility. Follow up support visits were provided with a median of 3 (1-5), and an average of 3.3. This meant in total the number of visits provided per facility occurred with a median of 4 (3-7), and a mean of 5.

Table 2 PHC facilities – total support visits and intervention strategies

	Support Visits			Follow Up Visit Intervention Strategies						
	Initial FMT	Follow up visits	Total visits	Total strategies	Document and refer matter 'upstream'	Informal mentoring/ Advice	Formal module training	Simple refresher training	Provide job aids	DSD
Overall	195	358	553	1654	400	538	34	206	56	420
Sub-district										
Amahlathi	77	152	229	560	62	231	3	108	12	144
Mbhashe	47	31	78	241	59	32	0	61	32	57
Mnquma	46	69	115	361	36	246	1	12	3	63
Nkonkobe	25	106	131	492	243	29	30	25	9	156
Facility type										
PHC	188	340	528	1548	342	525	34	201	56	390
CHC	7	18	25	106	58	13	0	5	0	30
Headcount volume										
Large	41	70	111	271	43	125	2	37	2	62
Medium	53	79	132	404	88	125	20	53	19	99
Small	101	209	310	979	269	288	12	116	35	259
High TROA										
Yes	23	52	75	255	96	83	0	8	0	68
No	172	306	478	1399	304	455	34	198	56	352
Pharmaceutical staff on site										
Yes	28	54	82	313	91	87	2	53	12	68
No	167	304	471	1341	309	451	32	153	44	352

The number of visits to conduct initial FMT differed significantly between sub-districts, with Amahlathi Sub-district facilities receiving almost twice as many visits for initial FMT as Nkonkobe Sub-district. Differences carried through to number of follow up support visits, with Amahlathi facilities receiving a median of five follow up visits, whilst Mbhashe Sub-district received a median of one follow up support visit per facility. Nkonkobe Sub-district received an increased number of follow up support visits, compared to initial FMT. Findings were, for initial FMT X^2 (15, n=110) =41.4, p<0.001, for follow up support visits X^2 (33, n=110) =98.3, p<0.001, and for total visits X^2 (39, n=110) =98.5, p<0.001. All these differences were statistically significant, and reflect that the programme was not uniformly implemented in all sub-districts. Total visits per facility therefore differed significantly across the sub-districts, with Mbhashe only receiving a third of the total number of support visits Amahlathi facilities received.

Table 3 Support visits per facility characteristic

Characteristics	Facilities	Total visits			Initial Formal Module Training Visits			Follow up support visits		
	%	Median (IQR); Mean	chi-square test (X^2, df)	chi-square test (p value)	Median (IQR); Mean	chi-square test (X^2, df)	chi-square test (p value)	Median (IQR); Mean	chi-square test (X^2, df)	chi-square test (p value)
Overall		4 (3-7); 5			2 (1-2); 1.8			3 (1-5); 3.3		
Sub-district										
Amahlathi	30	7 (6-8); 6.9	98.5; 39	**<0.001**	2 (1-3); 2.3	41.4; 15	**<0.001**	5 (3-6); 4.6	98.3; 33	**<0.001**
Mbhashe	27.3	2 (2-4); 2.6			1 (1-2); 1.6			1 (0-1.3); 1.03		
Mnquma	22.7	4 (2.5-6); 4.6			2 (1-2); 1.8			2 (1-4); 2.8		
Nkonkobe	20	4 (3-9.3); 6			1 (1-1); 1.1			3 (2-7.3); 4.8		
Facility type										
PHC	95.5	4 (3-7); 5	26.3; 13	**0.015**	2 (1-2); 1.8	1.3; 5	0.934	3 (1-5); 3.2	25.6; 11	**0.007**
CHC	4.5	3 (1.5-9.5); 5			1 (1-2); 1.4			1 (0.5-8); 3.6		
Headcount volume										
Large	52.7	4.5 (2-6.8); 5.1	38.4; 26	0.056	2 (1-2); 1.9	12.8; 10	0.238	3 (0-5.3); 3.2	29.8; 22	0.125
Medium	27.3	4 (2-5); 4.4			1.5 (1-2.3); 1.8			2 (1-4); 2.6		
Small	20	4.5 (3-7); 5.3			1 (1-2); 1.77			3 (2-5); 3.6		
High TROA										
Yes	13.6	4 (2-6); 5	15.6; 13	0.270	2 (1-2); 1.5	6.0; 5	0.305	2 (1-5); 3.5	13.7; 11	0.249
No	86.4	4 (3-7); 5			2 (1-2); 1.8			3 (1-5); 3.2		
Pharmaceutical staff on site										
Yes	15.5	4 (2.5-6.5); 4.8	13.6; 13	0.401	2 (1-2); 1.7	2.0; 5	0.844	2 (1-5); 3.2	10.3; 11	0.501
No	84.5	4 (3-7); 5.1			2 (1-2); 1.8			3 (1-4.5); 3.3		

Note: Statistically significant p values are in bold

Between clinic and CHC facility types, clinics received a median of 2 visits for initial FMT, whilst CHCs received one visit, but this was not significantly different. However, there was a significant difference between follow up support visits provided to clinics, with a median of three visits, whilst CHCs received a median of one visit. This difference made the overall visit difference between facility types statistically significant.

Visit frequencies per facility headcount volume category did not differ significantly and for initial FMT the median was 2, 1.5, and 1 for large, medium, and small facility sizes respectively, with total visits 4.5 (large and small) and 4 (medium).

The number of visits between high TROA and non-high TROA categorised facilities were similar and not significantly different. The median number of visits for initial FMT across both TROA categories was two, with the total number of support visits being a median of four for both high TROA and non-high TROA classified facilities.

Number of visits provided for initial FMT, and total visits where facilities had or did not have DoH pharmaceutical staff on site both had a median of 2 and 4 respectively. Therefore the intensity of support in the form of frequency of visits did not differ significantly between facilities that had pharmaceutical staff on site, or not.

4.3.2 Analysis of support visit strategies

Strategies utilised at follow up support visits, disaggregated per facility characteristic, are presented in Table 4. Informal mentoring and advice (2 (0-7); 4.9) was most commonly utilised, followed by DSD (2 (1-5), 3.8) and Document and refer (1 (0-4); 3.6). Support visit strategies were used variably across sub-districts, with 'Informal mentoring and advice' utilised most in Amahlathi and Mnquma Sub-districts, and 'Document and refer matters upstream' used mostly in Nkonkobe. Mbhashe facilities received a mix of strategies, with no one strategy clearly utilised most (Document and refer; Simple refresher training; and DSD, were all utilised to similar degrees). Additional FMT, and Provision of job aids were the least utilised follow up support strategies, and this can be explained as initial FMT had preceded the follow up support visits, hence repetition thereof would not be required unless there were new staff members. Job aids would also be a once off intervention, and may have been supplied as part of initial contact (initial FMT) sessions at facilities.

Across sub-districts there were significant differences in number of support visits and in the use of the strategies of 'Informal mentoring and advice' and 'Formal Module Training (FMT)'. Amahlathi and Mnquma facilities received Informal mentoring and advice more than

the other sub-districts, while Nkonkobe facilities received additional FMT far more as a follow up support strategy than other sub-districts. Intervention strategies chosen between clinics and CHCs were not significantly different, except for DSD. DSD as a strategy was utilised statistically significantly more often at clinics compared to CHCs.

The only significant difference between strategies deployed at high TROA and non-high TROA facilities was the use of the strategy of 'Document and refer', which was higher in high TROA facilities. There were no significant differences in intervention strategies utilised across the different headcount volume categories of facility.

Between sites that had pharmaceutical staff on site and those without, there was no significant difference between strategies utilised, except for the provision of job aids.

Table 4 Follow up support visit strategies per facility characteristic

Characteristics	Facilities	Document and refer matter 'upstream'		Informal mentoring/advice		Additional Formal Module Training		Simple refresher training		Provide job aids		Direct service delivery	
	%	Median (IQR); Mean	chi-square test (X^2, df; p value)	Median (IQR); Mean	chi-square test (X^2, df; p value)	Median (IQR); Mean	chi-square test (X^2, df; p value)	Median (IQR); Mean	chi-square test (X^2, df; p value)	Median (IQR); Mean	chi-square test (X^2, df; p value)	Median (IQR); Mean	chi-square test (X^2, df; p value)
Overall		1 (0-4); 3.6		2 (0-7); 4.9		0 (0-0); 0.3		1 (0-3); 1.9		0 (0-1); 0.5		2 (1-5); 3.8	
Sub-district													
Amahlathi	30	1 (0-1.5); 1.9	**73.7, 54; 0.039**	5 (3-9); 7	**119.1, 15; <0.001**	0 (0-0); 0.1	**33.8, 15; 0.004**	2 (0-5); 3.3	26.0, 33; 0.761	0 (0-0.5); 0.4	26.4, 18; 0.091	4 (2-6); 4.4	**72.6, 51; 0.025**
Mbhashe	27.3	1 (0-3.3); 2		0 (0-1.3); 1.1		0 (0-0); 0		1 (0-4); 2		0 (0-2); 1.1		1.5 (0-3.3); 1.9	
Mnquma	22.7	1 (0-3); 1.4		7 (3.5-14.5); 9.8		0 (0-0); 0		0 (0-1); 0.5		0 (0-0); 0.1		1 (1-3.5); 2.5	
Nkonkobe	20	7.5 (2-13); 11.1		0.5 (0-1); 1.3		0 (0-1.5); 1.4		1 (0-2); 1.1		0 (0-1); 0.4		3 (0.8-10.8); 7	
Facility type													
PHC	95.5	1 (0-4); 3.3	24.4, 18; 0.141	3 (0-7); 5	9.8, 21; 0.981	0 (0-0); 0.32	0.6, 5; 0.986	1 (0-3); 1.91	5.4, 11; 0.910	0 (0-1); 0.5	2.0, 6; 0.923	2 (1-5); 3.7	**29.4, 17; 0.031**
CHC	4.5	1 (0-28.5); 11.6		1 (0.5-5.5); 2.6		0 (0-0); 0		1 (0-2); 1		0 (0-0); 0		0 (0-15); 6	
Headcount volume													
Large	52.7	0 (0-1.3); 2	45.8, 36; 0.126	3.5 (0-9.5); 5.7	31.3, 42; 0.886	0 (0-0); 0.1	9.4, 10; 0.495	0 (0-1); 1.7	25.1, 22; 0.291	0 (0-0); 0.1	13.5, 12; 0.335	2 (0-4); 2.8	41.2, 34; 0.184
Medium	27.3	1 (0-3); 2.9		2 (0-6.3); 4.2		0 (0-0); 0.7		1.5 (0-3); 1.8		0 (0-1); 0.6		2 (0-5); 3.3	
Small	20	2 (0-4.5); 4.6		2 (1-7.3); 5		0 (0-0); 0.2		1 (0-3); 2		0 (0-1); 0.6		3 (1-6); 4.5	
High TROA													
Yes	13.6	1 (0-5); 6.4	**31, 18; 0.029**	3 (1-9); 5.5	28.1, 21; 0.411	0 (0-0); 0	2.1, 5; 0.831	0 (0-1); 0.5	6.0, 11; 0.873	0 (0-0); 0	6.5, 6; 0.368	2 (0-5); 4.5	**28.3, 17; 0.042**
No	86.4	1 (0-4); 3.2		2 (0-7); 4.8		0 (0-0); 0.4		1 (0-3); 2.1		0 (0-1); 0.6		2 (1-5); 3.7	
Pharmaceutical staff on site													
Yes	15.5	1 (0-3); 5.4	17.9, 18; 0.463	2 (0-9); 5.1	22.5, 21; 0.370	0 (0-0); 0.1	2.6, 5; 0.766	0 (0-3.5); 3.1	17.4, 6; 0.097	0 (0-0); 0.7	**16.7, 6; 0.010**	3 (0-5); 4	16.4, 17; 0.498
No	84.5	1 (0-4); 3.3		2 (0-7); 4.9		0 (0-0); 0.3		1 (0-3); 1.7		0 (0-1); 0.5		2 (1-5); 3.8	

4.4 Pharmaceutical functioning of PHC facilities

This section presents findings of facility level pharmaceutical performance at baseline and repeat assessment across the seven pharmaceutical functioning domains, and the overall total score and percentage. Overall means per domain are reflected in Figure 2. Comparative findings (baseline and repeat) for five domains i.e., Guidelines and reference materials availability; Training; Stock management; Stock monitoring; Storage of medicines are presented in Table 5. Comparative findings for 'No expired medicines'; 'No stockouts'; overall raw score; and overall percentage are presented in Table 6.

4.4.1 Baseline findings

Overall, the worst performing domains at baseline were Training (45%), Stock management (55%), and Stock monitoring (63%). Refer to Figure 2. The low training domain score reflects a paucity of regular pharmaceutical-specific training. The stock management domain score suggests the lack of routinised procedures to ensure ordering occurred systematically. The low score for stock monitoring indicates that required procedures (such as stock card maintenance and stock take procedures) were not adhered to, with the risk that stock levels and expiry dates were not monitored and managed accordingly. Guidelines and reference materials (73%), and Storage (74%) domains both scored fairly in the baseline assessment. This reflects that up to date reference and policy materials were available and storage conditions reasonably complied with requirements. No specific sub-district consistently performed the worst across all domains, although Mbhashe Sub-district had the lowest median overall percentage (71.3%), with Mnquma the second poorest performing overall (74%) at baseline. On the whole, CHCs scored higher on overall performance (83.5%) than PHCs (75%), and large volume, high TROA, and facilities with pharmaceutical staff on site scored higher than their corresponding categories. Baseline performance of Stock management, Stock monitoring and Storage were all higher at CHCs than PHCs. Refer to Tables 5 and 6.

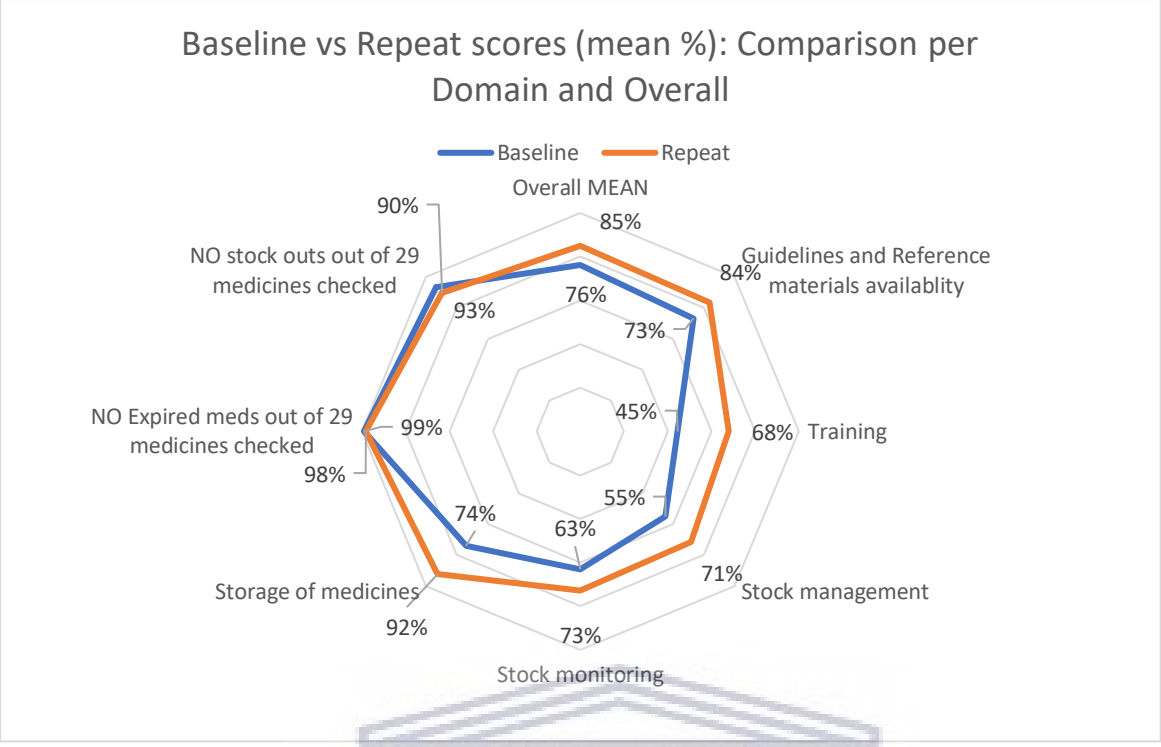


Figure 2 Means (in percentage) across seven domains and overall: Baseline and repeat scores

4.4.2 Repeat assessment findings

On repeat assessment, the lowest scoring domains remained Training (68%), Stock management (71%), and Stock monitoring (73%), although these all showed improvement. Refer to Figure 2. The sub-district profile remained the same with Mbhashe (81%) and Mnquma (83.7%) Sub-districts remaining the worst performing overall, although the margin between the other two sub-districts had closed. Refer to Table 6. Interestingly, the picture of better performing facilities by characteristic changed, with medium and small volume facilities, non-high TROA, and facilities with no DoH pharmaceutical staff on site, performing better than category counterparts. This was in contrast to baseline findings, although the margins were small.

Table 5 Baseline and repeat facility performance scores of five pharmaceutical functioning domains

	Guidelines and reference materials (max. score 10)			Training (max. score 14)			Stock management (max. score 16)			Stock monitoring (max. score 22)			Storage of medicines (max. score 30)		
	Baseline	Repeat		Baseline	Repeat		Baseline	Repeat		Baseline	Repeat		Baseline	Repeat	
	Median (IQR); Mean	Median (IQR); Mean	WSR (Z, p value)	Median (IQR); Mean	Median (IQR); Mean	WSR (Z, p value)	Median (IQR); Mean	Median (IQR); Mean	WSR (Z, p value)	Median (IQR); Mean	Median (IQR); Mean	WSR (Z, p value)	Median (IQR); Mean	Median (IQR); Mean	WSR (Z, p value)
Overall	*7 (6-10); 7.3*	*8 (8-10); 8.4*	***Z=4.6; p<0.001***	*6 (4-8); 6.2*	*10 (7-12); 9.5*	***Z=-7.1; p<0.001***	*9 (6-11); 8.8*	*11 (9-13); 11.4*	***Z=-6.4; p<0.001***	*13 (11-16); 13.89*	*16 (14-18); 16*	***Z=-4.8; p<0.001***	*23.3 (19.5-26); 22.2*	*28 (26.5-29); 27.7*	***Z=-9.0; <0.001***
Sub-district															
Amahlathi	7 (6-9); 7.2	8 (8-10); 8.4		7 (4-8.5); 6.6	9 (8-10); 8.8		7 (5-10); 7.8	10 (9-11.5); 10.1		13 (12-14.5); 13.5	15 (14-17.5); 15.6		24 (21.5-26); 23.2	27 (26-27); 26.7	
Mbhashe	6 (4.8-6); 6	8 (6-8); 7.4		4 (3.8-7); 5	6 (5-7.3); 6.6		9 (7-11); 8.8	11 (9.8-13); 11.2		12.5 (10-14.3); 12.5	16 (13-17); 15.3		22 (17.8-24); 21.1	28 (26.9-29); 27.7	
Mnquma	8 (7-10); 8.2	10 (10-10); 9.6		7 (5.5-8); 7.3	11 (10-11.5); 10.8		8 (5-11); 8.1	11 (10-13); 11.2		13 (10.5-15); 12.28	16 (12-17.5); 15.2		20.5 (18-23.3); 20.1	29 (26.3-29); 27.9	
Nkonkobe	10 (7-10); 8.5	8 (8-8); 8.2		6.5 (5-7.3); 6.1	13 (13-13); 13		11.5 (9.8-13); 11.2	15 (14.5-15); 14.1		19 (14.8-21); 18.2	20 (18-20); 18.6		26 (25.1-28); 24.9	29.3 (29-29.6); 29.1	
Facility type															
PHC	7 (6-9.5); 7.3	8 (8-10); 8.4		6 (4-8); 6.3	10 (7-12); 9.4		9 (6-11); 8.7	11 (9-13); 11.4		13 (11-16); 13.81	16 (13.5-18); 15.9		23 (19.5-26); 22.14	28 (26.5-29); 27.7	
CHC	7 (4.5-10); 7.2	10 (6.5-10); 8.6		4 (4-6); 4.8	11 (9.5-14); 11.6		12 (7-15); 11.2	13 (10-13.5); 12		17 (9-21.5); 15.6	18 (16.5-19); 17.8		28 (17.5-28.5); 24	29 (28.5-29.5); 29	
Headcount volume															
Large	7.5 (6-9.3); 7.7	9.5 (7.8-10); 8.6		7 (4-8); 6.1	10 (7.8-12); 9.9		8.5 (5.8-11); 8.5	11.5 (9.8-13.3); 11.6		13.5 (11.8-15.3); 13.9	15.5 (12.8-18.3); 15.9		23.5 (21.6-25.3); 22.9	28.3 (26.4-29); 27.6	
Medium	7 (5-9.3); 7.2	8 (8-10); 8.2		5.5 (4-7.3); 6	10 (5-11.5); 9.1		9 (5.8-11); 8.8	11 (9-13), 11.2		13 (11.8-16); 13.5	16 (13-17.3); 15.8		21.25 (18-25.6); 21.2	28 (26.4-29); 27.7	
Small	7 (6-10); 7.3	8 (8-10); 8.4		7 (4-8); 6.5	10 (7-12); 9.6		9 (7-12); 9	11 (9-14); 11.5		14 (11.8-17); 14.1	16 (14-18); 16.2		23.8 (19.9-26); 22.5	28 (27-29); 27.8	
High TROA															
Yes	7 (6-10); 7.3	8 (6-10); 8.2		6 (4-7); 5.6	12 (10-13); 11.33		11 (5-12); 9.3	13 (10-14); 12.4		15 (10-17); 13.8	18 (16-20); 17.7		23.5 (19-28); 22.8	29 (28.5-29.5); 28.7	
No	7 (6-10); 7.3	8 (8-10); 8.4		6 (4-8); 6.3	10 (7-11); 9.2		9 (6-11); 8.7	11 (9-13); 11.3		13 (12-16); 13.9	16 (13-18); 15.8		22.5 (19.5-26); 22.1	28 (26.5-29); 27.6	
Pharmaceutical staff on site															
Yes	7 (4.5-9.5); 6.94	8 (8-10); 8.8		4 (3.5-7.5); 5.4	11 (7-12); 10.1		11 (6.5-12.5); 10	13 (9.5-14); 12		14 (12-16.5); 14.1	16 (13-18); 16		22 (21.3-26.8); 22.2	29 (26.8-29); 28	
No	7 (6-10); 7.4	8 (8-10); 8.3		7 (4-8); 6.4	10 (7-12); 9.4		9 (6-11); 8.6	11 (9-13); 11.3		13 (11-16); 13.9	16 (14-18); 16		23.5 (19.5-26); 22.2	28 (26.5-29); 27.7	

Table 6 Baseline and repeat facility performance scores on two pharmaceutical functioning domains and overall scores

	No expired meds (max. score 29)			No stockouts (max. score 29)			Total performance score (raw) (max. score 150)			Total performance score (percentage)		
	Baseline	Repeat		Baseline	Repeat		Baseline	Repeat		Baseline	Repeat	
	Median (IQR); Mean	Median (IQR); Mean	WSR (Z, p value)	Median (IQR); Mean	Median (IQR); Mean	WSR (Z, p value)	Median (IQR); Mean	Median (IQR); Mean	WSR (Z, p value)	Median (IQR); Mean	Median (IQR); Mean	WSR (Z, p value)
Overall	*29 (29-29); 28.7*	*29 (28-29); 28.5*	***Z=-2.8; 0.005***	*28 (26-29); 27.1*	*28 (24-29); 26*	***Z=-2.2: 0.028***	*113 (104-125.3); 114.3*	*126.75 (121-134); 127.5*	***Z=-8.0; <0.001***	*75.3 (69.3-83.5); 76.2*	*84.5 (80.7-89.3); 85*	***Z=-8.0; <0.001***
Sub-district												
Amahlathi	29 (28-29); 28.6	29 (28-29); 28.4		28 (26-29); 27.4	28 (26-29); 26.9		115 (103.5-121.5); 114.2	126 (121.3-129.3); 124.9		76.7 (69-81); 76.1	84 (80.8-86.2); 83.3	
Mbhashe	29 (29-29); 28.8	29 (28-29); 28.7		27 (24-28.3); 25.9	25 (22-28); 24.2		107 (99.4-114.1); 108.5	121.5 (116.5-126.3); 121.1		71.3 (66.3-76.1); 72	81 (77.7-84.2); 80.7	
Mnquma	29 (28-29); 28.6	28 (27-29); 28.1		27 (26-28); 26.9	24 (22-27.5); 24.2		111 (101.3-121); 111.4	125.5 (122.5-132); 127		74 (67.5-80.7); 74.3	83.7 (81.7-88); 84.7	
Nkonkobe	29 (29-29); 29	29 (29-29); 28.8		29 (29-29); 28.6	29 (29-29); 28.9		132.5 (121.8-133.3); 126.4	143 (138.9-143.6); 140.6		88.3 (81.2-88.8); 84.3	95.3 (92.6-95.8); 93.7	
Facility type												
PHC	29 (29-29); 28.7	29 (28-29); 28.5		28 (26-29); 27.1	28 (24-29); 26.2		112.5 (104-125); 114	126.75 (121.3-133.5); 127.5		75 (69.3-83.3); 75.97	84.5 (80.8-89); 85	
CHC	29 (28.5-29); 28.8	29 (28.5-29); 28.8		28 (27-29); 28	21 (15-27.5); 21.2		125.25 (102.5-134.5); 120.8	128.5 (118-138.8); 128.42		83.5 (68.3-89.7); 80.5	85.7 (78.7-92.5); 85.6	
Headcount volume												
Large	29 (29-29); 28.8	29 (28-29); 28.5		28 (26.8-29); 27.5	22 (18.5-28); 22.4		116 (106.4-123.6); 115.3	124.3 (118.9-129.5); 124.2		77.33 (70.9-82.4); 76.9	82.8 (79.3-86.3); 82.8	
Medium	29 (28-29); 28.7	29 (28-29); 28.5		28 (25.8-29); 26.8	28 (24-29); 26.7		111.25 (99.4-122); 112.1	126.75 (121-134); 127.3		74.17 (66.3-81.3); 74.7	84.5 (80.7-89.3); 84.9	
Small	29 (29-29); 28.7	29 (128-29); 28.5		28 (25-29); 27.1	28 (424.8-29); 27		115.5 (104-127.5); 115.1	127 (123.8-136.1); 128.8		77 (69.3-85); 76.8	84.7 (82.5-90.8); 85.9	
High TROA												
Yes	29 (28-29); 28.73	28 (28-29); 28.3		28 (27-29); 27.73	21 (14-26); 19.9		118 (106-126.5); 115.3	125.5 (119.5-135); 126.5		78.67 (70.7-84.3); 76.9	83.7 (79.7-90); 84.3	
No	29 (29-29); 28.73	29 (28-29); 28.5		28 (25-29); 27	28 (24-29); 26.9		113 (103-125); 114.2	127 (121.5-134); 127.7		75.33 (68.7-83.3); 76.1	84.7 (81-89.3); 85.1	
Pharmaceutical staff on site												
Yes	29 (29-29); 28.8	29 (28-29); 28.5		28 (26-29); 26.8	23 (20.5-29); 23.6		117.5 (99.3-125.3); 114.1	125.5 (121.3-131.3); 127		78.3 (66.2-83.5); 76.1	83.7 (80.8-87.5); 84.7	
No	29 (29-29); 28.7	29 (28-29); 28.5		28 (26-29; 27.2	28 (24-29); 26.4		112 (104-125.5); 114.4	127 (121-135); 127.6		74.7 (69.3-83.7); 76.2	84.7 (80.7-90); 85.1	

4.4.3 Comparison of baseline and repeat assessment findings

All five domains of: Guidelines and reference materials availability; Training; Stock management; Stock monitoring; and Storage of medicines showed improvements between baseline and repeat scores. This was also true for the overall pharmaceutical functioning score. All these findings were significant with $p<0.001$. Refer to Figure 2 and Tables 5 and 6. The poorest performing domain at baseline was Training (mean of 45%). Whilst performance of this domain increased by the greatest degree (23%) to 68%, it remained the lowest scoring domain. Storage of medicines improved by 18%, from an average of 74% to 92%. Out of the five domains that showed improvements, the domain that showed the least improvement was Stock monitoring, increasing by 10% from an average of 63% to 73%. The overall mean score improved 9%, from 76% to 85%.

Domain improvements were consistent across all the category types (sub-district, facility type, headcount volume, high or non TROA, and pharmaceutical staff on site or not) between baseline and repeat, with one exception. The exception was Nkonkobe Sub-district which reflected a drop in Guidelines and reference materials availability in the repeat assessment.

Although significant improvements occurred in the five aforementioned domains and the total score, the expired medicine and stockout domains reflected deterioration. This was statistically significant, with the 'No expired medicines', $p = 0.005$, and for the 'No stockouts' indicator, $p = 0.028$.

Therefore the picture for expired medicines and stockout data did not show consistent improvement. It is notable, however, that the baseline scores reflected good pre-intervention performance, so there was a limited margin for improvement. Nevertheless, all sub-districts reflected a decrease in 'No expired medicines', meaning at repeat assessments there were increased items of expired stock identified. For stockout data, Nkonkobe was the only sub-district to show an increase in 'No stockouts' (i.e. an improvement in medicine availability), whereas all other sub-districts reflected a decrease in 'No stockouts' at repeat per the 29 items re-assessed. The stockout data appears to have particularly deteriorated in the following categories of facilities: CHCs, large PHC headcount volume, high TROA, and facilities with pharmaceutical staff on site. It is notable that there is a lot of overlap between these facility characteristics.

As the expired medicine and stockout findings were unexpected, a sub-analysis was conducted to explore the raw data further. In both the baseline and repeat assessment source data, 'not applicable (N/A): item not kept in stock' had been recorded by the assessing pharmacy advisors at varying facilities for various medicine stock items. This meant that assessors found that, out of the 29 items they were required to assess for stockouts and expiries, one or more items were items not kept in stock at that facility. The facilities with 'N/A' items were not consistent between baseline and repeat

assessments. As the data was secondary, and assessors could not be contacted for further verification, this data was taken at face value. Therefore, 'items not kept in stock' were not counted as stockouts or expiries. This data quality concern, however, was noted and may have impacted on the stockout and expired medication scores. The possible reasons for the lack of improvement in the No stockouts and No expired medicines domains are explored in the discussion.

4.5 Relationship between frequency of visits and change in facility pharmaceutical performance

A significant correlation was found between the two variables, frequency of support visits and change in facility level pharmaceutical performance [r = 0.248, n =110, p =0.009]. This demonstrates a relationship between the intensity of support visits and improvement in facility-level pharmaceutical performance. In the scatterplot below (Figure 3) each dot represents a facility. The plot shows where the facility is placed in terms of the percentage difference between baseline and repeat overall performance scores, and the frequency of support visits. The trendline reflects an upward trend, suggesting the more frequent the visits, the greater the improvement in pharmaceutical performance. This trend was significant at the p=0.05 level.

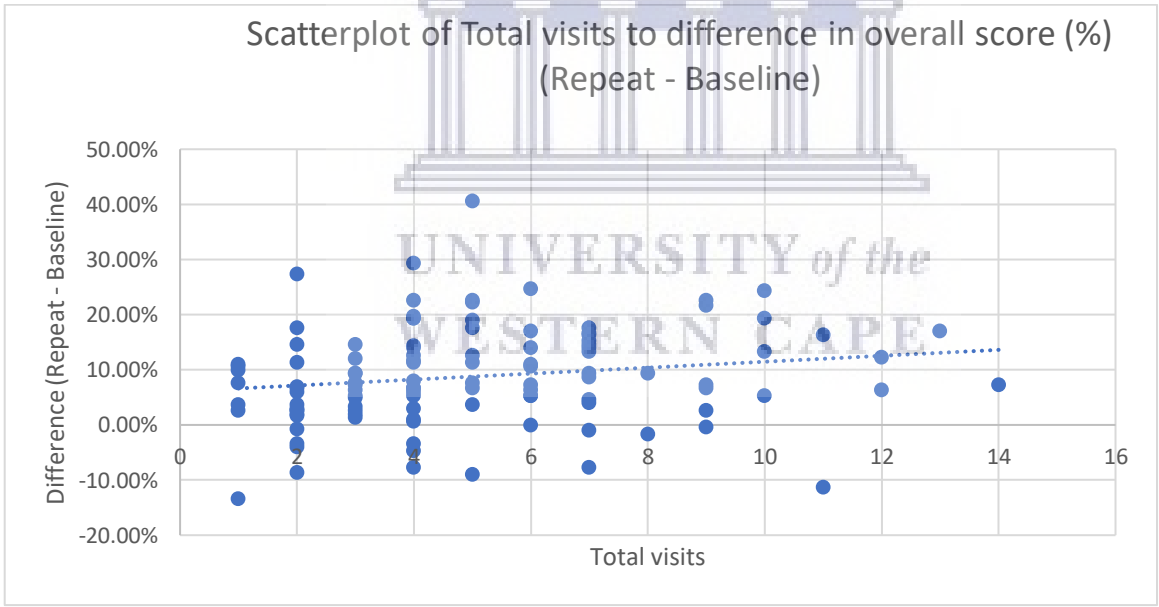


Figure 3 Number of support visits and percentage difference in performance scores (repeat-baseline) scatterplot

CHAPTER 5: DISCUSSION

5.1 Introduction

This study described and compared changes in the pharmaceutical performance in 110 primary health care (PHC) facilities in the Amathole District, Eastern Cape, South Africa, that received a pharmaceutical management technical assistance (TA) intervention by an implementing partner (IP). Findings of particular note were that facility visit frequencies differed significantly between the four sub-districts, performance across pharmaceutical domains and overall pharmaceutical performance scores improved significantly, except for stockout and expired medicine data, and frequency of visit was positively correlated to difference in score between baseline and repeat assessment. These findings are the focus of this discussion chapter.

5.2 PHC facilities support visits

5.2.1 Frequency of PHC facility support visits

The mean support visit frequency of 5, with a median of 4, compares with Trap *et al.*'s (2018) study, where facilities received an average of 3.4 medicine management support visits in the first year of the supervision programme. Closer examination of the visit data, however, reflects that programme implementation did not occur uniformly across the four sub-districts. This is reflected in the significant difference in number of support visits that were rendered between the sub-districts, with Mbhashe Sub-district receiving significantly fewer visits than other sub-districts. A closer examination of the sub-districts, in particular of their rurality profile, may serve to offer further insight to this difference.

Rurality scores, devised by RHAP (2018), place facilities on a scale where 0 represents an equal balance between rural and urban, negative scores indicate urban, and positive scores rural. The further away from 0, the greater the degree of urban (-) or rural (+). Scores for PHC facilities are not available, but district hospital rurality scores can be taken as a proxy for surrounding clinics' likely rurality scores. Amahlathi's five hospitals have an average rural index of 0.85, and Mbhashe's one district hospital has a score of 1.25. Nkonkobe and Mnquma score 0.94 and 1.53 respectively (RHAP, 2018).

In this study the rurality of Mbhashe Sub-district seemed to contribute to operational challenges experienced by the IP in Mbhashe Sub-district. Challenges included transport difficulties (rural terrain and distances between facilities meaning prolonged travelling time to facilities) and programme staffing (challenges to recruit programme staff to support this sub-district) (SEAD, 2017a). This impacted on the frequency of visits which could be rendered to the more rural sub-districts' facilities. Ultimately more frequent visits were provided to the urban sub- districts, in

comparison to rural sub-districts' facilities. Therefore, it appears that this partner support programme, with the unintended variation in implementation, may have reinforced existing urban-rural imbalances.

Rural facilities are typically challenged with limited DoH support in terms of supervisory visits and supply chain (RHAP, 2017). Diseconomies of scale exist due to additional distance and time taken to service rural facilities (RHAP, 2017). This translates to rural facilities typically having limited supervision and support of health care workers (HCWs), and this can impact negatively on staff performance and retention (Cook *et al.*, 2011). Maldistribution of HCWs between rural and urban facilities is also common, as HCWs are less likely to work in rural areas (Cooke *et al.*, 2011). Community service as a means to direct HCWs to rural and underserved areas has been implemented, but this enforced system is experiencing challenges in funding and accommodating posts for newly qualified HCWs, and does not solve long term retention in rural areas (Reid, 2018). These challenges were evidenced as, on commencement of the programme, Mbhashe Sub-district was the only sub-district without a DoH sub-district pharmacist in post (SEAD, 2018).

5.2.2 Intervention strategies used during PHC support visits

Overall 'Informal mentoring and advice' was the most common TA strategy. This is congruent with the programme logic model, where training (initial FMT) was provided as a common foundation of required pharmaceutical knowledge. It was then incumbent on the pharmacy advisors to support the facilities in implementing practices according to the training. On-site modelling and mentoring of correct practices and procedures, to reinforce training, is a documented approach in TA and supportive supervision studies, and has been shown to be more effective than training alone (Rowe *et al.*, 2005; Trap *et al.*, 2018; Ross-Degnan *et al.*, 1997).

DSD was also a common strategy and, given the district profile where 85% of facilities had no pharmaceutical staff on site, advisors undertook specifically pharmaceutical tasks where it was evident facility staff did not have the capacity to do so. 'Document and refer' reflects the context and constraints within which the programme operated. Some facility challenges identified by IP pharmacy advisors required DoH district support and intervention. Examples of this were requirements for infrastructure, which the programme brief and budget did not cover; requirements to engage with service providers (such as maintenance contracts between the DoH and service providers of air conditioners); and DoH staff performance.

It is interesting to note that different intervention strategies were deployed in the various sub-districts. The variation in choice of TA strategies may reflect that different sub-districts, according

to advisors' professional judgement, had differing challenges that required correspondingly different interventions.

'Informal mentoring and advice', offering peer to peer support, was the preferred strategy in Amahlathi and Mnquma, and suggests that the challenges encountered at these sub-districts' facilities were deemed by advisors to be resolvable within the facility, by capacitating staff in the facility. In Nkonkobe, the predominance of the strategy 'Document and refer' suggests more entrenched and intractable challenges that required referral to higher authorities. This may have been due to infrastructure limitations, and possibly HR shortages and challenges that could not be addressed at facility level. Mbhashe, the poorest performing sub-district, and also the sub-district that received the least visits, had a mix of strategies deployed (mainly DSD, Simple refresher training, and Document and refer), with no one strategy taking predominance. This may reflect the complexity of challenges experienced and that advisors' professional judgement deemed a range of strategies were called for in attempting to resolve challenges.

The main difference in intervention data between clinics and CHCs was that clinics received statistically significantly more frequent visits than CHCs, and that DSD was utilised as a support strategy more in PHCs than CHCs. This can be attributed to the fact that CHCs typically had pharmaceutical staff on site, hence did not require such frequent support visits. Likewise, that DSD was more commonly rendered at clinics than CHCs can also be explained by the presence of DoH pharmaceutical staff at CHC level who would conduct required pharmaceutical activities at CHC level.

'Document and refer' was utilised statistically significantly more at high TROA facilities. This may reflect the pressure on pharmacy advisors to drive progress in the high TROA facilities, since the programme had highlighted these facilities as priority facilities. This could also reflect common infrastructural challenges in high TROA facilities (storage space, shelving, functional air conditioners) due to the high number of ART patients (Crowley & Stellenberg, 2015). These challenges require infrastructural upgrades and interventions. Such interventions pharmacy advisors could not affect independently, but required escalation to the Prime and district as this had planning and budgetary implications. DSD was also significantly higher at high TROA facilities and again, may reflect programmatic pressures on high TROA facilities requiring DSD interventions such as stock counts, receiving and packing of stock, and updating of bin cards including calculation of minimum/maximum levels to relieve facility staff of these duties.

5.3 Changes in pharmaceutical performance at PHC facilities

Improvements in pharmaceutical performance were found in five domains (Guidelines and reference materials, Training, Stock management, Stock monitoring, and Storage), and overall. However, two domains of No Stockouts and No Expired medicines did not reflect improvement.

Consistent improvements across the domains of Guidelines and reference materials, Training, Stock management, Stock monitoring, and Storage were noted. The first two domains are supportive in ensuring staff have the foundations for on-the job skills (Rowe *et al.*, 2005; Ross-Degnan *et al.*, 1997; Low *et al.*, 2001). As such these domains could be described as necessary but not sufficient - Training is shown to increase knowledge however, TA is shown to be most effective as it reinforces training with mentoring and on-the-job- application (Rowe *et al.*, 2005; Ross-Degnan *et al.*, 1997; Low *et al.*, 2005).

Improvements in Stock management, Monitoring, and Storage occurred and are notable as these impact on the quality of pharmaceutical services and products, such as maintaining the availability and integrity of products, and ultimately clinical care (NDoH, 2011). Average scores for these domains improved from 55, 63 and 74 per cent at baseline respectively, to 71, 73 and 92 per cent at repeat assessment respectively. While these areas showed improvement, an adequate score (defined as 75% of the maximum score by Trap *et al.*, 2018) was only attained in the domain of Stock storage.

The Stock management domain includes aspects such as the ordering of stock, the delegation of a responsible person, the maintenance of records on ordered, received and issued stock, and a schedule of stock ordering, with a known method used and calculation regularly updated to determine quantities. This domain scored the second lowest at baseline and at repeat assessment, with an improvement of 16%. In Trap *et al.*'s (2018) study, stock ordering and reporting was found to be the domain most resistant to improvement. This was attributed to lack of familiarity with ordering schedules that had changed, and absence of accountability and feedback on maintaining accurate ordering and reporting systems (Trap *et al.*, 2018). The IP's regular support visits aimed to build familiarity of non-pharmaceutical staff with ordering schedules and procedures, and through the year-long relationship and ongoing feedback, foster accountability. The improvement in score suggests this was achieved.

The Stock monitoring domain included assessment of the regular updating of stock cards (for receipts, issues, orders), regular stock takes conducted, expiry date monitoring when stock is received, stored and issued, disposal of expired medicines as per requirements, and balancing of Schedule 5 and 6 registers. This domain included the completion of bin cards, a key aspect in

quantification and ensuring availability of stock. Studies have found that facility staff find maintaining stock records a challenge (Trap *et al.*, 2016). This may explain why this domain showed the least degree of improvement between baseline and repeat assessment (10%). This is of note as Amathole District operates on an order-based system, which requires accurate records of medicines use in order to forecast and order correctly (SEAD, 2017a). Improvement in the Stock management and Monitoring domains would be expected to have an impact on reducing expired medicines and stockouts.

Stock storage covered the conditions of storage including access and temperature control, infrastructure (including boxes off the floor) adequate lighting, protection from direct sunlight, and pest control (SEAD, 2017b). On the whole, CHCs scored higher overall storage performance than clinics, and large volume, high TROA, and facilities with pharmaceutical staff on site scored higher than their corresponding categories. Storage conditions, including space, have been noted to be a challenge in PHC facilities. Crowley and Stellenberg (2015) found that only half of the clinics they assessed had sufficient storage space at current stock volumes. This typically leads to storage of stock on the floor, and the storage of cleaning materials with pharmaceutical supplies. This is of relevance in the scale up of the ART programme, and highlights the urgency with which utilisation of external Pick up Points are necessary in order to decongest patients from facilities, and ease infrastructural pressures on facilities (NDoH, 2016b).

Overall, Mbhashe Sub-district had the lowest total score, with Mnquma the second lowest performance. It is of note that these two sub-districts are the more rural (RHAP, 2018), and the implications of this have been discussed earlier. At baseline, CHCs scored higher on overall performance than PHCs, and large volume, high TROA, and facilities with pharmaceutical staff on site scored higher than their corresponding categories. Interestingly, on repeat assessment the picture of better performing facilities by characteristic changed, with medium and small volume facilities, non-high TROA and facilities with no DoH pharmaceutical staff on site performing better than category counterparts at the end of the intervention. This is in contrast to baseline rankings, although the margins were small. This may suggest that the impact of support was disproportionately effectual at facilities that typically have less support (i.e. no DoH pharmacy staff on-site), suggesting increasing margins of return when un-supported facilities are supported, rather than when (internally) supported facilities have support augmented. This finding is echoed in Trap *et al.*'s (2018) Ugandan medicines management support programme, where PHC facilities' overall medicines management score increased significantly higher than higher level health facilities in response to the support intervention.

Baseline performance of stock management, monitoring and storage were all higher at CHCs than PHCs and this is to be expected as CHCs typically have better infrastructure and staffing (including DoH pharmaceutical staff), which PHCs may lack. Similar findings (between government vs private facilities) were found in Uganda, where better storage conditions were found in donor funded facilities, versus government (Trap *et al.*, 2016). These differences reflect that there are better resourced sectors and levels of care, and these differences manifest in tangible 'on the ground' realities, and may serve to reinforce pre-existing inequities.

Expired medicines and stockouts showed a significant difference between baseline and repeat assessments, however this was a negative change, with an increase in expired medicines and stockouts at repeat. This is of note as the main aims of the IP programme were to decrease expired medicines, and the associated wastage, and improve the availability of medicines (CDC, 2016). The stockout data appears to have particularly deteriorated in the following categories of facilities: CHCs, large PHC headcount volume, high TROA, and facilities with DoH pharmaceutical staff on site. It is notable that there is a lot of overlap between these facility characteristics.

It is possible that bin cards, the source document the assessing pharmacy advisors used to determine stockouts or expiries in the past three months, may not have been well maintained prior to the support, and therefore dependence on this source for information provided inaccurate data, particularly at baseline assessment. Increased support through the programme may also have increased diligence and accuracy of use of bin cards, which may have increased the accuracy with which stock expiries and stockouts could be determined at the repeat assessment. It is also possible that this finding was a function of the pharmacy advisors' familiarity with the assessment tool and with the facilities. On initial assessment, expired medicines, which may have been neglected or packed away for disposal later, may not have been unearthed by the pharmacy advisors, but, with familiarity with the facilities, the advisors could track down expired stock. Throughout the programme's year-long support, programme staff acted to address identified stockouts by placing emergency orders, borrowing stock from nearby facilities, and substituting with suitable alternatives (SEAD, 2018). Therefore, during the course of the programme, all stockouts that were identified and reported were addressed through DSD interventions to immediately address the gap and ensure patients received required medications or substitutes where appropriate (SEAD, 2018).

The two poorest performing sub-districts on stockouts were Mbhashe and Mnquma. These two sub-districts showed a greater deterioration in medicine availability between baseline and repeat assessment, whereas Amahlathi showed a minimal decrease and Nkonkobe showed an improvement. Mbhashe and Mnquma Sub-districts are supported by Mthatha Depot, whereas

Amahlathi and Nkonkobe are supported by Port Elizabeth Depot. Challenges with the management and logistics at Mthatha Depot are on record and may have been a large factor in the medicine availability challenges in Mbhashe and Mnquma Sub-districts. In 2012, Medicines Sans Frontiers (MSF) and other Civil Society organisations provided an intervention at Mthatha Depot when a crisis, precipitated by flooding and a labour dispute, caused essential medicine supply interruptions from September – December 2012 (MSF, RHAP, Section27 & TAC, 2013). Although this crisis was short-lived, the report's authors indicated it pointed to the deep-rooted challenges of limited human resource capacity, poor management (including governance and adhering to required protocols), corruption, and inadequate oversight by Provincial and National authorities (MSF *et al.*, 2013).

Whilst a "catastrophic situation" exists at the depot, and supply chain in the province is in a "state of chaos" (Section27 & TAC, 2013: 3), it is acknowledged that there are other factors at play. Downstream, the MSF *et al.* report (2013) established that many facilities do not keep accurate records; therefore, stock balances and consumption levels are unknown, resulting in overordering and overstocks at facilities. In addition, overordering by facilities is done as a way to pre-empt depot delivery interruptions, reflecting a failure of facilities' trust in the depot to fulfil orders. This results in overstocks and imbalances in medicine availability between facilities, with the associated risk of medicine expiry and stockouts. To address this, the report recommended the deployment of additional pharmacy personnel to PHC facilities in order to train and capacitate facilities in the monitoring of stock levels and consumption volumes (MSF *et al.*, 2013). In effect, the programmatic intervention by the IP implemented this recommendation. Upstream, the depot has been negatively affected by suppliers not providing according to targets, and inaccurate projections by provincial authorities (Section27 & TAC, 2013). This brings to light the complex interrelated nature of the health and pharmaceutical system, and highlights that the facility is a node within that system with aspects within its control, and other aspects subject to greater forces.

5.4 Frequency of facility support visits associated with degree of improvement

Frequency of visits was positively associated with differences in pharmaceutical performance score between baseline and repeat assessment. This aligns with previous studies where frequency of visits has been shown to impact on performance outcomes (Loevinsohn *et al*, 1995; Trap *et al.*, 2018). Trap *et al.* (2018) found that the maximal improvement occurred at the second visit (after the initial support visit). Thereafter, gains in performance still occurred, but with decreasing margins. Furthermore, the number of visits was a significant factor in whether the facility achieved adequate performance in the first year of support (Trap *et al.*, 2018). This is supported in this study, as it was shown that the more frequent the visits, the greater the improvement in score from baseline to repeat

assessment. It is noted, however, that there are potential confounders to this finding, in that frequency of visits may have been provided to more accessible and urban facilities, and that these facilities, with better support and infrastructure from the DoH, were therefore able to make greater improvements. Other studies have shown that it is not necessarily the frequency of visit, but the quality of support when it is provided – Foreit and Foreit (1984) found that reducing support from monthly to quarterly visits did not impact on facility performance as supervisory activities focussed mainly on administrative functions such as the collection of health post statistics. Where supervisors provide standardised support according to a checklist of key indicators, frequency of support did impact on improvement in performance (Loevinsohn *et al.*, 1995). The regular visits of the IP pharmacy advisors to specifically support staff with regards to pharmaceutical functions is in line with the recommendation that where pharmaceutical services fall to non-pharmacy facility staff, oversight by a pharmacist is still required (Cook *et al.*, 2011).

5.5 Summary

At baseline, pharmaceutical performance in the 110 PHC facilities assessed in Amathole District was moderate and, after the intervention, an average overall performance score improvement of 9% was found. Five domains showed improvement whilst two domains, stockout and expired medicines, did not show consistent improvement. Support visit frequencies were found to differ significantly between the four sub-districts. An association between frequency of visits and degree of improvement was found, suggesting that more frequent visits resulted in a greater improvement. This suggests that the intervention was effective, although limitations are noted.

5.6 Limitations

Data quality queries in the original datasets could not be clarified or corrected. This is a challenge with utilising secondary data as the accuracy and quality of secondary data cannot be verified, and data may also be outdated, reflecting a picture that has since changed (Tripathy, 2013). Data quality of stock card documentation may have compromised the accuracy of stockout and expired medicine assessments at baseline and repeat assessments. Triangulation of stockout data with facility level District Health Information System (DHIS) or Stock Visibility Solution (SVS) data may have assisted in establishing the accuracy of the stockout picture at facilities, however this was not conducted in this study.

A pre-post-test design is liable to maturation, regression to the mean, and test effects (staff may be more diligent with procedures once they know they are being assessed) (Kothari, 2004). Additionally, other intervening factors during the study may have impacted on changes in pharmaceutical functioning. Ideally a control group of facilities would have enabled control for

unmeasured and varying factors that impacted facility pharmaceutical performance throughout the district. However, this was not required as part of programme implementation, and this study is a secondary analysis of the programme implementation data.

It is not possible to discount individual variations in the way support was provided, particularly with regards to the interventions, where 'soft skills' are pre-eminent in enabling efficacy of support. Quality of rapport between TA provider and recipient (West *et al.*, 2012) and competency of the individual provider in supportive supervision (Henry, Nantongo, Wagner, Embrey & Trap, 2017) are key components of TA effectiveness, yet were not measured in this study. Likewise, the quality of intervention, and the duration of site visits, were not measured nor monitored, and these factors are potentially additional conditions impacting on outcomes. Facility receptiveness and staffing levels may also have had an impact on the effect of the intervention, and these variables were not explored.

The assessment was multidimensional, covering a range of pharmaceutical domains that constitute facility pharmaceutical performance. However, the facility is but one 'node' within the greater pharmaceutical and health system. Analysing facility performance, without concurrently noting and tracking other system aspects, such as depot performance and national stockouts, may provide an inaccurate picture. The facility node within the health system can be subject to the ebbs and flows, fortunes and misfortunes, of entities beyond itself. While this study focussed on facility level performance, the programme also endeavoured in engaging at sub-district, district and provincial levels, including raising matters regarding Mthatha Depot functioning (SEAD, 2018). These engagements were not included in this facility-level study.

CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

This study set out to describe and compare changes in facility-level pharmaceutical performance at 110 primary health care (PHC) health facilities that received pharmaceutical management technical assistance (TA) in Amathole District in the Eastern Cape, South Africa. Secondary, historical data, from an implementing partner's (IP) pharmaceutical TA programme, was utilised. The analysis included a pre-test post-test comparison of facility pharmaceutical functioning performance, and correlation to determine the relationship between number of TA support visits and changes in facility pharmaceutical functioning. Notable findings were that facility visit frequencies differed significantly between sub-districts, suggesting that the IP experienced challenges in standardising implementation across sub-districts that varied in terms of rurality. This may have, unintentionally, reinforced inequities between the urban and rural sub-districts. Overall pharmaceutical performance improvement was 9%. Performance across pharmaceutical domains and overall scores improved significantly, except for stockout and expired medicine data. This indicates that the intervention was effective, however there were concerns regarding the data quality of the stockout and expiry assessments. The absence of a consistent improvement in these domains also points to the complexity of pharmaceutical and health system functioning, and the TA intervention, focussed at facility level, may have been too limited to effect systemic improvements when challenges extend beyond the facility. Frequency of support visit was positively correlated to difference in score between repeat and baseline scores. This indicates that ongoing TA interventions added value, however, to be effective, these need to be implemented in a sustained, systematic manner.

6.2 Recommendations

IP programmes need to pay close attention to the fidelity of programme implementation to ensure that facilities in urban and rural areas receive equitable support. This is because rural areas are typically already disadvantaged and require maximal effort and resources (arguably additional) in order to render levels of support that equate to those rendered to urban areas. In practice this suggests rural sub-districts should receive heightened support, albeit at the expense of urban areas.

Facility level TA support does not occur in a health system vacuum, and other levels and structures of the health system must be concurrently engaged to maximise impact and ensure synergy of efforts.

As interpersonal 'soft skills' are a core aspect of TA, and competencies vary between TA providers, this aspect of TA delivery requires closer monitoring and further research. Structured, documented

supervisory support of TA providers to assess consistency of skill and delivery, and to capacitate competency of TA providers, is recommended.

Furthermore, beyond the quantitative aspects of TA (such as visit duration), further research is recommended on the quality of TA provision. This would offer insights into the variations in quality of TA provision, and would also clarify how to better support TA providers, who typically work remotely.

Future analysis could explore the association between TA strategy employed and improvement in facility functioning. This would further elucidate, beyond the frequency of support visits, which TA support strategies deployed at visits are most impactful i.e., associated with greater improvements. An optimal threshold for number of support visits that impact facility performance could also be modelled, to ensure effective and efficient use of programme resources.

While this IP programme, and the subsequent secondary data analysis, utilised stockout data obtained at facility level, it is noteworthy that independent sources of stockout data are available such as DHIS and SVS data. Use of these independent sources of data would assist in verification and triangulation of stock out findings. This externally sourced data, blind to the intervention, would not be at a risk of observer bias.

Although this study was located in a specific district and province in South Africa, similar studies of programmes currently implemented could be conducted in different regions, covering a variety of technical speciality-focussed TA, for example the technical areas of laboratory services and monitoring and evaluation.

REFERENCES

Amathole District Municipality (2017). *Amathole profile.* [Online]. Available: http://www.amathole.gov.za/index.php/general-info/about-us [Downloaded 28.08.2018 06:00 AM]

Bertrand, J. (2004). Diffusion of Innovations and HIV/AIDS. *Journal of Health Communication, 9*(S1): 113-121.

Bheekie, A. & Bradley, H. (2016). Re-engineering of South Africa's primary health care system: where is the pharmacist? *South African Family Practice, 58*(6): 242-248.

Bigdeli, M., Jacobs, B., Tomson, G., Laing, R., Ghaffar, A., Dujardin, B. & Van Damme, W. (2013). Access to medicines from a health system perspective. *Health Policy and Planning, 28*: 692-704.

Brown, A. (1980). Technical assistance to rural communities: stopgap or capacity building? *Public Administration Review, 40* (1): 18-23.

CDC (2016). *Programmatic implementation and technical assistance (TA) for HIV/AIDS and tuberculosis (TB) prevention, care, and treatment services throughout the health system in South Africa under the President's Emergency Plan for AIDS Relief (PEPFAR). CDC-RFA-GH16-1643.* [Online]. Available: www.grants.gov [Downloaded: 24.06.2016 08:30 AM]

Cooke, R., Couper, I. & Versteeg, M. (2011). Chapter 10: HR for rural health. *South African Health Review 2011*: 107–118.

Crowley, T. & Stellenberg, E. (2015). An evaluation of the adequacy of pharmaceutical services for the provision of antiretroviral treatment in primary health care clinics. *Health South Africa, 20:* 83-90.

Daviaud, E., & Subedar, H. (2012). *Staffing norms for primary health care in the context of PHC Re-engineering.* Report to the National Department of Health. Medical Research Council Cape Town South Africa. October 2012. [Online]. Available: www.mrc.ac.za/sites/default/files/files/2016-07-14/StaffingNorms.pdf [Downloaded: 29.04.2019 08:15 AM]

Donges, N. (2018). *Introduction to descriptive statistics.* Towards data science. [Online]. Available: https://towardsdatascience.com/intro-to-descriptive-statistics-252e9c464ac9

[Downloaded: 10.05.2019 20:15 PM]

Doumbia, S., Clark, A., & Mwansasu, A. (2017). *Defeating malaria through pharmaceutical systems strengthening: results from the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Programme.* MSH/SIAPS. [Online]. Available: https://www.msh.org/blog/2017/08/09/defeating-malaria-through-pharmaceutical-systems-strengthening-1 [Downloaded: 29.04.2019 08:05 AM]

Feinberg, M., Greenberg, M., & Osgood, W. (2004). Technical assistance in prevention programmes: correlates of perceived need in communities that care. *Evaluation and Programme Planning, 27*: 263–274.

Fixsen, D., Naoom, K., Blase´, S., Friedman, R., & Wallace. F. (2005). *Implementation research: A synthesis of the literature*. Tampa, FL: University of South Florida, Louis de la Parte Florida Mental Health Institute, National Implementation Research Network; Florida Mental Health Institute publication 231. [Online]. Available: https://nirn.fpg.unc.edu/sites/nirn.../files/resources/NIRN-MonographFull-01-2005.pdf [Downloaded: 29.04.2019 08:15 PM]

Florin, P., Mitchell, R., & Stevenson, J. (1993). Identifying training and technical assistance needs in community coalitions: A developmental approach. *Health Education Research, 8*(3): 417-432.

Foreit, J. R., & Foreit, K. G. (1984). Quarterly versus monthly supervision of CBD family planning programmes: an experimental study in northeast Brazil. *Studies in Family Planning, 15*(3): 112–120. [Online]. Available: https://doi.org/10.2307/1965461 [Downloaded: 29.04.2019 08:15 AM]

Gibson, C., Hoffman, B., & Jablonski, R. (2015). Did aid promote democracy in Africa? The role of technical assistance in Africa's transitions. *World Development, 68*: 323–335.

Gottlieb, A. (2014). *Review rationale & context for MER: programmatic shifts.* OVC M&E Meeting. February 19 – 20, 2014. [Online]. Available: https://slideplayer.com/slide/8106255/ [Downloaded: 15.09.2018 19:15 PM]

Government Gazette (2015). *Implementation guideline of health workforce normative guides and standards for fixed primary health care facilities*. 2 October 2015, Number: 39244: 4 -46. [Online]. Available: https://kipdf.com/implementation-guideline_5ac5a6f31723dd082ffd4be3.html [Downloaded: 15.09.2018 19:25 PM]

Government Gazette (2018). *National list of occupations in high demand: 2018.* 22 June 2018, Number: 41728: 4-18. [Online]. Available: www.dhet.gov.za/Information%20Systems%20Coordination/GAZETTE.pdf [Downloaded: 15.09.2018 19:30 PM]

Hafner, T. & Shiffman, J. (2013). The emergence of global attention to health systems strengthening. *Health Policy and Planning, 28*: 41-50.

Hafner, T., Walkowiak, H., Lee, D., & Aboagye-Nyame, F. (2017). Defining pharmaceutical systems strengthening: concepts to enable measurement. *Health Policy and Planning, 32*: 572–584.

Henry, R., Nantongo, L., Wagner, A., Embrey, M. & Trap, B. (2017). Competency in supportive supervision: a study of public sector medicines management supervisors in Uganda. *Journal of Pharmaceutical Policy and Practice,* 10(33).

Houston, L., Probst, Y., & Martin, A. (2015). Measuring data quality through a source data verification audit in a clinical research setting. *Studies in Health Technology and Informatics, 214*: 107-113.

ICAP (2018). *HIV technical assistance.* [Online]. Available: http://icap.columbia.edu/global-initiatives/global-technical-assistance/ [Downloaded: 10.05.2018 19:55 PM]

Jamieson, D. & Kellerman, S. (2016). The 90 90 90 strategy to end the HIV pandemic by 2030: can the supply chain handle it? *Journal of the International AIDS Society, 19* (1).

Jones, H. (2013). Technical assistance: how to get value for money. *The Guardian,* 29 January, 2013. [Online]. Available: https://www.theguardian.com/global-development-professionals-network/2013/jan/29/development-technical-assistance-value [Downloaded: 10.06.2018 19:55 PM]

Kafuko, J., Zirabamuzaale, C., & Bagenda, D. (1997). *Rational drug use in rural health units of Uganda: effect of national standard treatment guidelines on rational drug use.* World Health Organisation, International Conferences on Improving use of Medicines. [Online]. Available: http://archives.who.int/icium/icium1997/posters/2f3_text.html [Downloaded: 10.05.2018 19:55 PM]

Kaminski, J. (2011). Diffusion of Innovation theory. *Canadian Journal of Nursing Informatics, 6*(2). [Online]. Available: http://cjni.net/journal/?p=1444 [Downloaded: 10.04.2019 06:55 AM]

Kelly, J, Somlai, A, Benotsch, E., Mcauliffe, T., Amirkhanian, Y., Brown, K., Stevenson, L., Fernandez, M., Sitzler, C., Gore-Felton, C., Pinkerton, S., Weinhardt, L., & Opgenorth, K. (2004). Distance communication transfer of HIV prevention interventions to service providers. *Science, 305*(5692) :1953-1955.

Kelly, J., Somlai, A., DiFranceisco, W., Otto-Salaj, L., McAuliffe, T., Hackl, K., Heckman, T., Holtgrave, D., & Rompa, D. (2000). Bridging the gap between the science and service of HIV prevention: transferring effective research-based HIV prevention interventions to community AIDS service providers. *American Journal of Public Health, 90*(7): 1082-1088.

Kothari, C. (2004). *Research methodology: methods and techniques.* New Delhi: New Age International.

Laing, R. & Ruzardo, R. (1989). The essential drug programme in Zimbabwe: new approaches to training. *Health Policy and Planning 4*(3): 229-234.

Lethem, F. & Cooper, L. (1983). *Managing project-related technical assistance: the lessons of success.* World Bank Staff Working Papers -Number 586; Management and Development Series-Number 13. Washington DC: The World Bank.

Loevinsohn, B. P., Guerrero, E. T., & Gregorio, S. P. (1995). Improving primary health care through systematic supervision: a controlled field trial. *Health Policy and Planning, 10*(2), 144–153. [Online]. Available: https://doi.org/10.1093/heapol/10.2.144. [Downloaded: 10.04.2019 06:45 AM]

Low, A., Tjongarero, A., Low, A., & Nambundunga, B. (2001). Donor support to human resource capacity building in Namibia: experience of resident TA support for workplace learning and assessment of alternative options. *Journal of International Development, 13*: 269-285.

Massyn, N., Peer, N., English, R., Padarath, A., Barron, P. & Day, C. (2016). *District Health Barometer: 2015/16.* Durban: Health Systems Trust. [Online]. Available: http://www.hst.org.za/publications/district-health-barometer-201516-0 [Downloaded: 05.05.2018 19:30 PM]

Massyn, N., Padarath, A., Peer, N. & Day, C. (2017). *District Health Barometer: 2016/17.* Durban: Health Systems Trust. [Online]. Available: https://www.hst.org.za/publications/Pages/District-Health-Barometer-201617.aspx [Downloaded: 05.05.2019 19:30 PM]

McHugh, M. (2015). The chi-square test of independence. *Biochemia Medica, 23*(2):143–149.

Mitchell, R., Florin, P., & Stevenson, J. (2002). Supporting community-based prevention

and health promotion initiatives: developing effective technical assistance systems.

Health Education & Behavior, 10: 620-639.

Morgan, P. (2002). Technical assistance: correcting the precedents. *Development Policy Journal UN Development Programme, 2*: 1-22.

Morroni, C., & Myer, L. (2014). Chapter 7: Study design. In R. Ehrlich & G. Joubert (eds). *Epidemiology: A research manual for South Africa*, 3rd Edition. Cape Town: Oxford University Press: 78-96.

Motsoaledi, A. (2018). *Investment in ARVs proven correct.* The Sunday Independent. Dispatch. 22 July 2018. [Online]. Available: https://www.iol.co.za/sundayindependent/dispatch/investment-in-arvs-proven-correct-16176556 [Downloaded: 06.05.2019 19:30 PM]

MSF, RHAP, Section27 & TAC (2013). *Emergency intervention at Mthatha Depot: the cost of inaction.* Mthatha, Eastern Cape, Republic of South Africa, January 2013 [Online]. Available: https://www.msf.org.za/sites/default/files/.../emergency-intervention-Mthatha-depot.pd [Downloaded: 06.05.2019 19:30 PM]

NDoH (2011). *National Core Standards for health establishments in South Africa.* [Online]. Available: http://www.rhap.org.za/wp-content/uploads/2014/05/National-Core-Standards-2011-1.pdf [Downloaded: 06.05.19 19:40 PM]

NDoH (2016a). *Circular: implementation of the Universal Test and Treat strategy for HIV positive patients and Differentiated Care for stable patients.* August, 2016.

NDoH (2016b). *Adherence Guidelines for HIV, TB and NCDs.* February 2016.

Nemec, B., Forbess, R., Cohen, M., Farkass, M, Rogers, E., Anthony, W. (1991). Effectiveness of TA in the development of psychiatric rehabilitation programmes. *Journal of Mental Health Administration 18(*1): 1-11.

O'Donnell, L., Scattergood, P., Adler, M., Doval A., Barker, M., Kelly, J., Kegeles, S., Rebchook, G., Adams, J., Terry, M., & Neumann, M. (2000). The role of technical assistance in the replication of effective HIV interventions. *AIDS Education and Prevention, 12*: 99-111.

Oliveira, J., de Naves, S., & Silver, L. (2005). Evaluation of pharmaceutical assistance in public primary care in Brasília, Brazil. *Rev Saude Publica, 39*(2): 223-230.

Padian, N., Holmes, C., McCoy, S., Lyerla, R., Bouey, P., & Goosby, E. (2011). Implementation science for the US President's Emergency Plan for AIDS Relief (PEPFAR). *Journal of Acquired Immune Deficiency Syndrome,* 56(3): 199-203.

Pengelly, T. (2005). *Technical assistance for the formulation and implementation of intellectual property policy in developing countries and transition economies.* Issue paper number 11, International Centre for Trade and Sustainable Development (ICTSD). [Online]. Available: https://www.ictsd.org/sites/default/files/downloads/2008/12/pengelly_ta_final.pdf [Downloaded: 10.05.2019 19:00 PM]

PEPFAR (2014). *PEPFAR 3.0: Controlling the epidemic: delivering on the promise of an AIDS-free generation.* Office of the U.S. Global AIDS Coordinator.

Ray, M., Wilson, M., Wandersman, A., Meyers, D. & Katz, J. (2012). Using a training-of-trainers approach and proactive technical assistance to bring evidence-based programmes to scale: an operationalization of the interactive systems framework's support system. *American Journal of Community Psychology, 50*:415–427.

Reid, S. (2018). Chapter 5: 20 Years of community service in South Africa: what have we learnt? *South African Health Review 2018*: 41-50.

RHAP (2017). *Rural health resource mapping guide: underserved rural communities - who cares?* The Rural-Proofing Policy and Budgeting Programme: Rural Health Advocacy Project. [Online]. Available: http://rhap.org.za/rural-health-resource-mapping-guide-cares/ [Downloaded: 10.05.2019 19:35 PM]

RHAP (2018). *RHAP rurality index: facility index 2018.* [Online]. Available: http://rhap.org.za/our-projects/defining-rural/facility-index-2018/ [Downloaded: 10.05.2019 19:30 PM]

Ross-Degnan, D., Laing, R., Santoso, B., Ofori-Adjei, D., Lamoureaux, S., Hozergeil, H. (1997). *Improving pharmaceutical use in primary care in developing countries. a critical review of experience and lack of experience.* Presented at the International Conference on Improving use of Medicines, Chiang Mai, Thailand, April 1997. [Online]. Available:

http://archives.who.int/prduc2004/Resource_Mats/RossDegnanReviewV4.doc. [Downloaded: 06.05.2019 19:50 PM]

Rowe, A., de Savigny, D., Lanata, C. & Victora, C. (2005). How can we achieve and maintain high-quality performance of health workers in low-resource settings? *Lancet, 366:* 1026–35.

SAHR (2018). *South African Health Review.* Durban: Health Systems Trust. [Online]. Available: http://www.hst.org.za/publications/South%20African%20Health%20Reviews/SAHR%202018.pdf [Downloaded: 10.05.2018 19:15 PM]

SEAD (2017a). *Interim Progress Report (01 October 2016 – 31 March 2017): Programmatic Implementation and Technical Assistance (TA) FOR HIV/AIDS and Tuberculosis (TB) Prevention, Care and Treatment Services throughout the Health System in South Africa - TB HIV Care Consortium, Amathole District.* SEAD, 2017.

SEAD (2017b). *Pharmacy Training Modules: Good Pharmacy Practice; Stock monitoring; Stock ordering and receiving; Stock storage*. SEAD, 2017.

SEAD (2018). *Interim Progress Report (01 October 2017 – 31 March 2018): Programmatic Implementation and Technical Assistance (TA) FOR HIV/AIDS and Tuberculosis (TB) Prevention, Care and Treatment Services throughout the Health System in South Africa - TB HIV Care Consortium, Amathole District.* SEAD, 2018.

Section27 & TAC (2013). *Death and dying in the Eastern Cape: an investigation into the collapse of the health system.* [Online]. Available: https://www.spotlightnsp.co.za/wp-content/uploads/2019/03/Death-Dying.pdf [Downloaded: 06.05.2019 19:50 PM]

SIAPS (2018). *Toward building resilient pharmaceutical systems: SIAPS final report.* Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Programme. Arlington, VA: Management Sciences for Health. [Online]. Available: http://apps.who.int/medicinedocs/en/d/Js23408en/ [Downloaded: 10.05.2018 19:55 PM]

Skosana, C., Lunika, L. Martin, C., Molele, A., Qolesa, S., James, S., Delany- Moretlwe, S. & NW & GP Departments of Health (2017). *A technical assistance approach to implementing adolescent and youth friendly services (AYFS) in primary health care facilities in two subdistricts*. 8th South African AIDS Conference, ICC Durban. [Online]. Available: www.saaids.co.za/Presentations%20AIDS%202017/...%2015%20June%202017/Hall% [Downloaded: 10.05.2018 19:55 PM]

Thomas, J., Curtis, S., & Smith, J (2011). Letters to the editor: the broader context of implementation science. *Journal of Acquired Immune Deficiency Syndrome, 58*(1):19-21.

Trap, B., Todd, C., Moore, M., & Laing, R. (2001). The impact of supervision on stock management and adherence to treatment guidelines: a randomised controlled trial. *Health Policy and Planning, 16*(3): 273-280.

Trap, B., Ladwar, D., Oteba, M., Embrey, M., Khalid, M. & Wagner, A. (2016). Article 1: Supervision, Performance Assessment, and Recognition Strategy (SPARS) – a multipronged

intervention strategy for strengthening medicines management in Uganda: method presentation and facility performance at baseline. *Journal of Pharmaceutical Policy and Practice,* 9(21).

Trap, B., Musoke, R., Kirunda, A., Oteba, M., Embrey, M. and Ross-Degnan, D. (2018). Article 2: Longitudinal study assessing the one-year effects on supervision performance assessment and recognition strategy (SPARS) to improve medicines management in Uganda health facilities. *Journal of Pharmaceutical Policy and Practice,* 11(15).

Tredoux, C. & Durrheim, K. (2002). *Numbers, hypotheses and statistics: a course in statistics for the social sciences*. Cape Town: UCT Press.

Tripathy, J. (2013). Secondary data analysis: Ethical issues and challenges. *Iranian Journal of Public Health*, *42*(12): 1478-1479.

UNAIDS (2017). *Country overview: South Africa.* [Online]. Available: http://www.unaids.org/en/regionscountries/countries/southafrica [Downloaded: 21.10.2017 19:55 PM]

Waako, P., Odoi-Adome, R., Obua, C., Owino, E., Tumwikirize, W., Ogwal-Okeng, J., Anokbonggo, W., Matowe, L. & Aupont, O. (2009). Existing capacity to manage pharmaceuticals and related commodities in East Africa: an assessment with specific reference to antiretroviral therapy. *Human Resources for Health, 7*:21.

Wandersman, A., Chien, V., & Katz, J. (2012). Toward an evidence-based system for innovation support for implementing innovations with quality: tools, training, technical assistance, and quality assurance/quality improvement. *American Journal of Community Psychology, 50*(3-4). [Online]. Available: https://www.researchgate.net/publication/224854772_Toward_an_Evidence-Based_System_for_Innovation_Support_for_Implementing_Innovations_with_Quality_Tools_Training_Technical_Assistance_and_Quality_AssuranceQuality_Improvement [Downloaded: 10.05.2018 19:55 PM]

West, G., Clapp, S., Averill, E. & Cates, W. (2012). Defining and assessing evidence for the effectiveness of technical assistance in furthering global health. *Global Public Health,* 7(9): 915-930.

WHO (2002). *WHO policy perspectives on medicines — the selection of essential medicines.* Geneva: WHO. [Online]. Available: https://apps.who.int/medicinedocs/pdf/s2296e/s2296e.pdf [Downloaded: 10.05.2019 19:40 PM]

WHO (2007). *Everybody's business: strengthening health systems to improve health outcomes*. Geneva: WHO. [Online]. Available: https://www.who.int/healthsystems/strategy/everybodys_business.pdf [Downloaded: 10.05.2019 19:40 PM]

WHO (2008). *The world health report – primary care now more than ever.* Geneva: WHO.

[Online]. Available: https://www.who.int/whr/2008/en/ [Downloaded: 10.05.2019 19:40 PM]

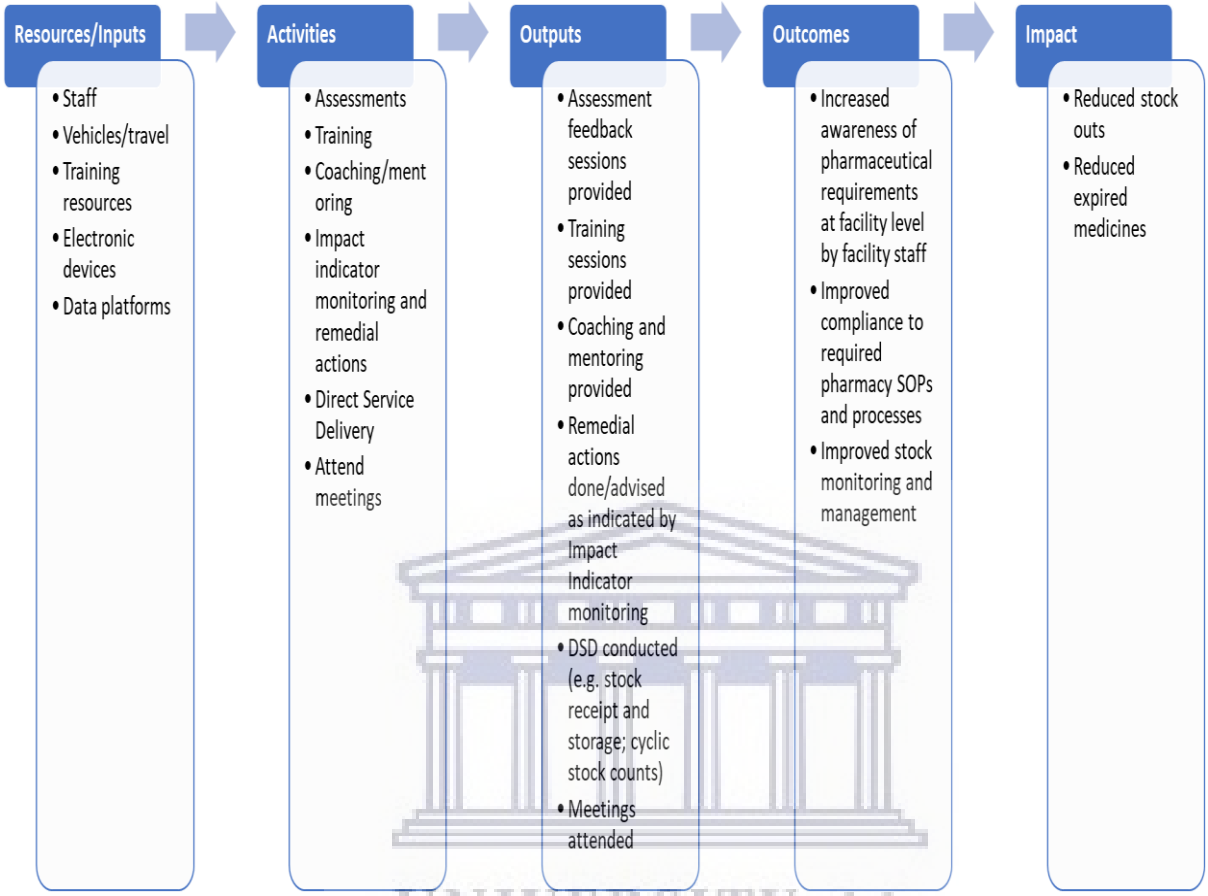
Wilson, G. (2007). Knowledge, innovation and re-inventing technical assistance for development. *Progress in Development Studies, 7* (3) :183–99.

Wirtz, V., Hogerzeil, H., Gray, A., Bigdeli, M., de Joncheere, C., Ewen, M., & Reich, R. (2016). Essential medicines for universal health coverage. *The Lancet.* [Online]. Available:

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31599-9/fulltext [Downloaded: 10.05.2018 19:40 PM]

APPENDICES

Appendix A: TA programme logic model



Appendix B: Implementing partner (SEAD) facility pharmacy assessment tool

SEAD

Pharmaceutical Services Baseline and Continuous Assessment Tool

PURPOSE:

1. To ensure optimal management of pharmaceuticals and supplies in aspects of supply chain management, monitoring, control, record-keeping, storage, use and cold chain management.

OBJECTIVES - To assess the following with regards to Management of Pharmaceuticals and Supplies.

A. South African Pharmacy Council Requirements
B. National Core Standards
C. Ideal Clinic
D. DoH Policies
E. Adherence Guidelines
F. CDC Site Improvement Monitoring System (SIMS) Tool

SEAD Pharmacy Services Facility Assessment Tool

Demographic Data:

1 Facility Name

2 Interviewee Name and Designation (dropdown box)

3 Interviewer Name/s and Designation (dropdown box)

4 Date of Visit Time:

5 Location & Province (dropdown box)

6 Number of fulltime staff

Doctors		Pharmacists		Lay Counsellors	
Professional Nurses		Registered Pharmacist Assistants		CHW's	
Enrolled Nurses		Other Clinical staff		Administrative staff	
Enrolled Nursing Assistant				Support staff	

7 Types of Services provided at Facility: *(Tick all applicable)*

General Outpatient		HTS		Cervical Screening	
Chronic Disease		ART		STI's	
TB		PMTCT		Immunisations	

8 Operating Hours of Facility: *(Tick where applicable)*

24 hours / day		12 hours / day		8 hours / day	
Full week		Weekdays only		Part week	

9 Pharmaceutical services: *(Yes / No)*

Pharmacy		Bulk Store		Consulting Room	

10) Medicine Supply source

Depot (Port Elizabeth or Umtata)		Direct Delivery (DDV)		Hospital	

11) Has the facility attained an Ideal Clinic status: (YES/NO)

12) Are Pharmaceutical services licenced by the SAPC? (Yes/ No)

13) Does the facility receive pharmaceutical services support?

Options: 1. District Pharmacist
2. Sub-district Pharmacist
3. Sub-district PHC Manager
4. Cluster Manager/ Clinic Supervisor
5. Other

Head Count:

14) Average Patient Volumes per month:

15) Computer/ Data Systems used

Tier.net

Etr.net

DHIS

Rx Solution

Remote Demander Module (RDM)

Other

Systems of Communication: *(Yes / No)*

16 Functional telephone

17 Functional Fax facility

18 Cellular phone Reception

19 Functional Internet

20 Functional Email

SEAD Assessment Tool: **A. South African Pharmacy Council Requirements & Training**

Information Source:	**Who:**	Operations Manager; Pharmacy Manager; Nurse in charge; Pharmacist Assistant; Clinic Supervisor; Sub-district Pharmacist; Other
	What:	Documented Policies, SOP's or Guidelines

A1. Policies, Guidelines and Reference Materials **Score**

ASSESSOR QUESTION: *[Assessor to ask and observe the evidence]*

DOES THIS FACILITY HAVE THE FOLLOWING REFERENCE DOCUMENTS?

A 1.1 Good Pharmacy Practice (GPP) Manual

A 1.2 Compendium of Acts and Laws for Pharmacy

A 1.3 Daily Drug Use OR other interaction reference source

A 1.4 MIMS Desk Reference (MDR) / South African Medicines Formulary (SAMF)

A 1.5 Essential Medicines List (EML)

A 1.6 NDOH Standard Treatment Guidelines

A 1.6.1 PHC (2014)

A 1.6.2 Adult (not applicable at PHC level)

A 1.6.3 Paediatric (2014)

OPTIONS:

1. No: Staff are not aware of need
2. No: misplaced
3. Yes: manual/ electronic copy available and up to date
4. Yes: manual/ electronic copy available and not up to date
5. No: not available

Comments:

SEAD Facility Assessment Tool:

A. South African Pharmacy Council Requirements & Training

Information Source:	**Who:**	Designated person managing the store room
	What:	Documented Training Log or Register, Personnel Files

A2. Training

Score

ASSESSOR QUESTION: *[Assessor to ask and observe the evidence]*

HAVE YOU ATTENDED ANY PHARMACY RELATED TRAINING?

A2.1 Drug Supply Management - Supply / Order / Inventory Management (medicines)	
A2.2 Stock Visibility Solution (SVS)	
A2.3 Pharmacovigilance course	
A2.4 National Adherence Guidelines	
A2.5 CCMDD	
A2.6 OTHER	

Options:

1. Yes: in last 3-6 months
2. Yes: more than 6 months ago
3. No training attended

A2.7 Do you have a record(s) of the training/s (Yes/ No)

Comments:

SEAD Facility Assessment Tool: **B. Supply Chain Management**

Information Source:	**Who:**	Manager or Supervisor or Stock Controller
	What:	Supply Chain / Stock Management SOP; Stock Cards, Stock Books; Consumable Requisition forms (NHLS + Provincial); Consumable Delivery Receipts (NHLS + Provincial)

B1. SUPPLY CHAIN MANAGEMENT AND FORECASTING **Score**

[Assessor to ask and observe the evidence]

STOCK MANAGEMENT (ORDERING, RECEIVING and ISSUING):

B1.1 Does facility have a SOP/guideline/policy on how to order stock?

Options:

1. Facility has a SOP which is used regularly and up to date
2. Facility has a SOP which is used regularly but not up to date
3. Facility has a SOP but is not used regularly and not up to date
4. Facility does not have a SOP

B1.2 Is there a dedicated person to place orders and manage stock?

Options:

1. Yes: Pharmacist
2. Yes: Pharmacist Assistant
3. Yes: Delegated facility staff
4. Yes: Other
5. No

B1.3 Does the pharmacy have a duty roster? (Yes/No)

B1.4 What record-keeping system is used for stock management (for stock ordered, received and issued)?

Options:

1. Manual (Stock cards)
2. electronic management system
3. Combination of 1 and 2
4. Other
5. None

B1.5 Is there a schedule for ordering/ receiving of stock?

Options:

1. Facility has a schedule and it is adhered to
2. Facility has a schedule but it is not adhered to
3. Facility does not have a schedule.

B1.6 Does the facility have a schedule for internal orders? (Yes/No)

B1.7 What method is used by facility to determining order quantities? (forecasting)

Options:

1. Re-Order Level
2. Minimum and Maximum levels
3. Other
4. None

B1.8 Is the calculation used to determine order quantities updated regularly? (Yes/ No)

1. Yes: updated every year
2. Yes: updated every 6 months
3. No not updated

B1.9 Does the facility monitor or track medicine deliveries by the medical depot?

Options; 1. Facility uses Dues Outs List to track orders

2. Facility uses Back-order List to track orders
3. Facility uses other mechanism to track orders
4. Facility does not track orders

B1.10 Did facility receive full order for ARVs in the last 3 months. (Yes/ No)

B1.11 Did facility receive full order for other medication in the last 3 months? (Yes/ No)

SEAD Facility Assessment Tool: **B. Supply Chain Management**

Information Source:	**Who:**	Pharmacist, Manager or Supervisor or Stock Controller
	What:	Stock Cards, Stock Books, Spot-checks of listed stock

B2. STOCK MONITORING

B2.1 Does facility have a SOP/guideline/policy on how to monitor stock?

Options:

1. Facility has a SOP which is used regularly and up to date
2. Facility has a SOP which is used regularly but not up to date
3. Facility has a SOP but is not used regularly and not up to date
4. Facility does not have a SOP

B2.2 Does the pharmacy have a facility stock list? (Yes/ No)

B2.3 Does the facility have a Depot catalogue? (Yes/ No)

B2.4 Do consulting rooms have stock lists? (Yes/ No)

B2.5 Does the emergency trolley have a stock list? (Yes/ No)

B2.6 Are stock cards regularly updated (for receipts, issues, orders)?

Options:

1. Yes: updated and balances with physical stock
2. Yes: updated but does not balance with physical stock
3. No: not updated

B2.7 Stock take done every 6 months (stock-take report) (SOP+ evidence)

Options: Yes: done every 6 months

Yes: done every 12 months

No: not done in the last 12 months

B2.8 Is actual stock levels checked against what is recorded (Stock/ cyclic counts)

1. Stock/ Cyclic counts are done at least monthly and recorded
2. Stock/ Cyclic counts are done but not regularly
3. Stock/ Cyclic counts are not done

B2.9 Does the facility monitor expiry dates when stock is received, stored and issued?

1. Yes: short-dated stock list is available
2. Yes: short-dated stock list is available but not up to date
3. No short-dated list available

B2.10 Did the pharmacy have any expired medicines in the last 3 months? (Yes/ No)

B2.11 Are expired medicines are disposed of according to prescribed procedures? (Yes/ No)

B2.12 Did the facility always have stock for all ARVs in the past 3 months? (Yes/ No)

B2.13 Did the facility always have stock for all other medication in the past 3 months? (Yes/ No)

B2.14 Are S5 and S6 registers checked and balanced regularly? (Yes/ No)

IN THE PAST THREE MONTHS ASSESS THE FOLLOWING MEDICINES:

ARVs **Stock items**	Does facility regularly maintain the stock system i.e. when stock is received and issued?	Does facility monitor expiry dates (i.e. when received, stored and issued)?	Did facility have any expired stock in the last 3 months?	Is actual stock levels checked against what is recorded?	Is the calculation used to order, updated regularly?	Did facility always have stock for all ARVs in the past 3 months?	Did facility receive full order for ARVs in the last 3 months?
Abacavir 20mg/ml 240ml or 60mg dispersible							
Abacavir 300mg tabs 56's							
Abacavir/ Lamivudine 300mg/ 150mg 56's							
Efavirenz 200mg tab 28's/56's/90/84's							
Efavirenz 600mg tab 28's							
Lamivudine oral sol 10mg/ml							
Lamivudine 150mg tabs 56's							
Lopinavir 80mg & Ritonavir 20mg/ml							
Nevirapine 50mg/5ml suspension							
Tenofovir 300mg, Emtricitabine 200mg & Efavirenz 600mg tab 28's							

Other **Stock items**	Does facility regularly maintain the stock system i.e. when stock is received and issued?	Does facility monitor expiry dates (i.e. when received, stored and issued)?	Did facility have any expired stock in the last 3 months?	Is actual stock levels checked against what is recorded?	Is the calculation used to order, updated regularly?	Did facility always have stock for all other medication in the past 3 months?	Did facility receive full order for other medication in the last 3 months?
Phenytoin 100mg tabs 84's							
Isoniazid tab 300mg tabs 28's							
Rifampicin 60mg & Isoniazid (INH) 60mg 56's							
Rifampicin 300mg & Isoniazid (INH) 150mg tablets 56's							
Rifampicin 150, Ethambutol 275mg, Isoniazid (INH) 75mg Pyrazinamide (PZA) 400mg tabs 56's/84's/112's							
Co-Trimoxazole suspension 50ml or 100ml							
Co-Trimoxazole 480mg tabs 56's							
Adrenaline 1:1000 injection							
Diazepam 10mg / 2ml injection							
Promethazine 25mg/ml IM							
Hydrochlorothiazide 12.5 or 25mg tabs 28's							
Metformin 500mg or 850mg tabs 28, 56's and 84's							
Vaccine Pentavalent (Pentaxim) / Hexavalent (Hexaxim)							

	Spot check medicines	Does facility regularly maintain the stock system i.e. when stock is received and issued?	Does facility monitor expiry dates (i.e. when received, stored and issued)?	Did facility have any expired stock in the last 3 months?	Is actual stock levels checked against what is recorded?	Is the calculation used to order, updated regularly?	Did facility always have stock for all ARVs in the past 3 months?	Did facility receive full order for ARVs in the last 3 months?	Is stock stored correctly?
Acute	Paracetamol 500mg tablets								
Acute	Amoxicillin 125mg/5ml suspension								
Chronic	Metformin 500mg or 850mg tablets								
Chronic	Hydrochlorothiazide 12.5 or 25mg tablets								
ART	TEE (FDC)								
ART	Lopinovar/Ritonavir solution								
TB	Rif. 150/INH 75/PZA 400/EMB 275 mg								
TB	Rifinah 300/150								
Vaccines	Hexavalent								
Vaccines	Polio (bOPV)								
Other	Co-trimoxazole suspension								
Other	INH 300 mg tablets								
Conceptio	Ovral								
Conceptio	Depo Provera								
Surgical su	Gloves exam n/sterile medium /box								
Surgical su	Insulin syringe with needle /box								

SEAD Facility Assessment Tool: **B. Supply Chain Management**

Information Source:	**Who:**	Pharmacist, Manager or Supervisor or Stock Controller
	What:	Stock Cards, Stock Books, Spot-checks of listed stock

B3. STORAGE OF MEDICINES **Score**

ASSESSOR QUESTION: *[Assessor to ask and observe the evidence]*

B3.1 Is there a SOP for storage of medicines?

Options:

1. Facility has a SOP which is used regularly and up to date
2. Facility has a SOP which is used regularly but not up to date
3. Facility has a SOP but is not used regularly and not up to date
4. Facility does not have a SOP

B3.2 HOW ARE MEDICINES STORED IN THIS FACILITY:

B3.2.1 Medicines and supplies are stored in secure, locked area - Bulk store or Medicine Room / Dispensary (Yes/ No)	
B3.2.2 Only authorised personnel have access to Bulk store / Medicine room/ Dispensary (Signage and evidence) (Yes/ No)	
B3.2.3 Medicines and supplies are stored neatly according to a classification system (e.g. dosage forms or alphabetically) (Yes/ No)	
B3.2.4 Medicines and supplies are stored off the floor (Yes/ No)	
B3.2.5 Is stock rotation practised (FIFO/ FEFO)?	
B3.2.6 Bulk store / Medicine room/ Dispensary - adequate infrastructure (space, humidity, light) (Yes/ No)	
B3.2.7 Bulk store / Medicine room/ Dispensary - maintained, clean and tidy, infestation/ pest free	
B3.2.8 Bulk store/Medicine room/ Dispensary - temperature controlled (Options: 1. air-con, 2. thermometer, 3. both, 4. none)	
B3.2.9 Temperature monitoring is done twice daily and is within safety range (less than 25 degrees Celsius)	

3 **2** **1**

Comments:

SEAD Facility Assessment Tool: **B. Supply Chain Management**

Information Source:	**Who:**	Pharmacist, Manager or Supervisor or Stock Controller
	What:	Refrigerator, Temperature Logs, Cold-chain maintenance logs, Spot-checks

B4. STORAGE: COLD CHAIN MAINTENANCE **Score**

ASSESSOR QUESTION: *[Assessor to ask and observe the evidence]*

B4.1 Is there a SOP for maintenance of cold chain?

Options:

1. Facility has a SOP which is used regularly and up to date
2. Facility has a SOP which is used regularly but not up to date
3. Facility has a SOP but is not used regularly and not up to date
4. Facility does not have a SOP

B4.2 HOW IS COLD CHAIN MAINTAINED IN THIS FACILITY:

B4.2.1 Is there a dedicated and functional refrigerator? (Yes/ No)

B4.2.2 Does the Refrigerator(s) have working thermometer(s)? (Yes/ No)

B4.2.3 Is Record-keeping of refrigerator temperatures done twice daily?

Options:

1. Yes: Facility has an up to date temperature chart
2. Yes: Facility has a temperature chart but it's not up to date
3. No: Facility has no temperature chart

B4.2.4 Is storage in refrigerator appropriate? - only medicines/ vaccines, not in door (Yes/ No)

B4.2.5 Access to emergency power / generator in the event of power failure (Yes/ No)

B4.2.6 Is there a contingency plan in case of power failure? (Yes/ No) (SOP and/ or presence of cooler boxes and ice packs)

B4.2.7 Is there a Scheduled for defrosting and cleaning of refrigerator?

Options:

1. Yes: Schedule is available and adhered to
2. Yes: Schedule is available but not adhered to
3. No schedule available

Comments:

C. Department of Health Priority Programmes:

Question 1. Does the facility use CCMDD programme?

	Yes	No	No. of Patients	Comment
CCMDD				

Question 2. Does the facility use other decanting strategies?

	Yes	No	No. of Patients	Comment
Adherence /Chronic Clubs				
Fastlane				
Spaced booking				
Pick up Point (PuP)				
Other				

Question 3. Does the facility use Stock Visibility Solutions (SVS) for reporting on stock availability?

Yes, reports submitted regularly	Yes, but reports not submitted regularly	No	Comment

Question 4. Does the facility have a system in place to manage and report adverse drug reactions?

Options:

1. Yes: system in place and reports have been submitted
2. Yes: system in place but no reports have been submitted
3. No system in place

Appendix C: Items extracted in secondary analysis

Domain	Item	Response options	Score per option	Total question items per domain	Maximum score per domain
Policies, guidelines and reference documents	Good Pharmacy Practice (GPP) Manual	Per each item listed: Does the facility have the document:		**5**	**10**
	Essential Medicines List (EML)	No: Staff are not aware of need	0		
	NDOH standard treatment guidelines: Adult	No: misplaced	0		
	NDOH standard treatment guidelines: PHC	Yes: manual/ electronic copy available and up to date	2		
	NDOH standard treatment guidelines: Paediatric 2014	Yes: manual/ electronic copy available and not up to date	1		
		No: not available	0		
Training	Drug supply management - Supply/order/inventory management (medicines)	Per each subject listed: Has the designated person managing the store room attended training?		**7**	**14**
	Stock visibility solutions (SVS)	Yes: in last 3-6 months	2		
	Pharmacovigilance course	Yes: more than 6 months ago	1		
	National adherence guidelines	No training attended	0		
	CCMDD				
	Other				
	Are adequate training records in place?	Yes	2		
		No	0		
Stock management (Ordering, Receiving &	SOP/guideline/policy on how to order stock?	Facility has a SOP which is used regularly and up to date	2	**8**	**16**
		Facility has a SOP which is used regularly but not up to date	1		

Issuing)		Facility has a SOP but is not used regularly and not up to date	0		
		Facility does not have a SOP	0		
	Dedicated person to order and manage stock?	Yes: Pharmacist	2		
		Yes: Pharmacist Assistant	2		
		Yes: Delegated facility staff	1		
		Yes: Other	1		
		No	0		
	Duty roster in place?	Yes	2		
		No	0		
	Is there a schedule for ordering/receiving stock?	Facility has a schedule and it is adhered to	2		
		Facility has a schedule but it is not adhered to	1		
		Facility does not have a schedule	0		
	Schedule for internal orders?	Yes	2		
		No	0		
	Method to determine order quantities?	Re-Order Level	2		
		Minimum and Maximum levels	2		
		Other	1		
		None	0		
	Calculation used to determine order quantities updated regularly?	Yes: updated every year	1		
		Yes: updated every 6 months	2		
		No not updated	0		
	Monitor or track medicine deliveries by the medical depot?	Facility uses Dues Outs List to track orders	2		
		Facility uses Back-order List to track orders	2		
		Facility uses other mechanism to track orders	1		
		Facility does not track orders	0		

Stock monitoring	SOP/guideline/policy on how to monitor stock?	Facility has a SOP which is used regularly and up to date	2	**11**	**22**
		Facility has a SOP which is used regularly but not up to date	1		
		Facility has a SOP but is not used regularly and not up to date	0		
		Facility does not have a SOP	0		
	Facility stock list present?	Yes	2		
		No	0		
	Depot catalogue present?	Yes	2		
		No	0		
	Stock lists in consulting rooms or wards?	Yes	2		
		No	0		
	Stock list in emergency trolley?	Yes	2		
		No	0		
	Are stock cards regularly updated (for receipts, issues, orders)?	Yes: updated and balances with physical stock	2		
		Yes: updated but does not balance with physical stock	1		
		No: not updated	0		
	Stock take done every 6 months (stock-take report) (SOP+ evidence)?	Yes: done every 6 months	2		
		Yes: done every 12 months	1		
		No: not done in the last 12 months	0		
	Stock levels checked against what is recorded (Stock/ cyclic counts)?	Stock/ Cyclic counts are done at least monthly and recorded	2		
		Stock/ Cyclic counts are done but not regularly	1		
		Stock/ Cyclic counts are not done	0		
	Monitor expiry dates when stock is received, stored and issued?	Yes: short-dated stock list is available	2		
		Yes: short-dated stock list is available but not up to date	1		

		No short-dated list available	0		
	Expired medicines disposed according to prescribed procedures	Yes	2		
		No	0		
	S5 and S6 registers checked and balanced regularly?	Yes	2		
		No	0		
Stock storage	Is there an SOP for storage of medicines?	Facility has a SOP which is used regularly and up to date	2	**15**	**30**
		Facility has a SOP which is used regularly but not up to date	1		
		Facility has a SOP but is not used regularly and not up to date	0		
		Facility does not have a SOP	0		
	Storage in secure, locked area - Bulk store or Medicine Room / Dispensary	Yes	2		
		No	0		
	Only authorised personnel have access to Bulk store / Medicine room/Dispensary (Signage and evidence)	Yes	2		
		No	0		
	Stored neatly according to a classification system (e.g. dosage forms or alphabetically)	Yes	2		
		No	0		
	Products stored off the floor	Yes	2		
		No	0		
	Bulk store / Medicine room/ Dispensary - has adequate infrastructure (space, humidity, light)	Yes	2		
		No	0		
	Bulk store / Medicine room/ Dispensary - is maintained, clean and tidy, infestation/ pest free	Yes	2		
		No	0		
	Temperature monitoring is done twice daily and is within safety range (less than 25 degrees Celsius)	Yes	2		
		No	0		
	Is stock rotation practiced (FEFO/FIFO)	Yes	2		

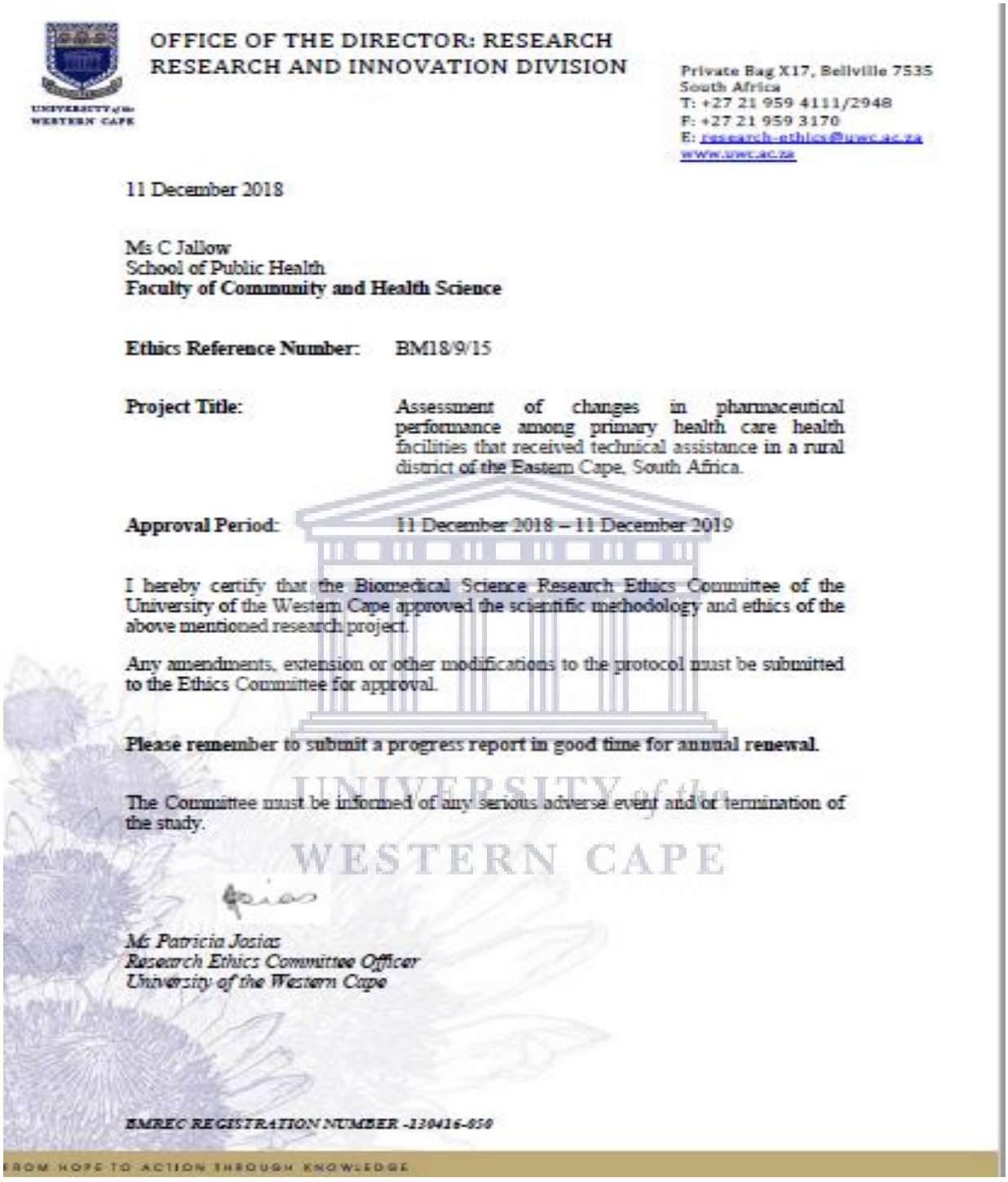
		No	0		
	Bulk store/Medicine room/ Dispensary - is the area temperature controlled?	Air conditioner	1.5		
		Thermometer	1.5		
		Both	2		
		None	0		
	Is there an SOP for maintenance of cold chain?	Facility has a SOP which is used regularly and up to date	2		
		Facility has a SOP which is used regularly but not up to date	1		
		Facility has a SOP but is not used regularly and not up to date	0		
		Facility does not have a SOP	0		
	Is there a dedicated, functional refrigerator	Yes	2		
		No	0		
	Is there a working thermometer in refrigerator	Yes	2		
		No	0		
	Is there access to emergency power / generator in the event of power failure	Yes	2		
		No	0		
	Is there a contingency plan in case of power failure (SOP and presence of coolers/ice packs etc.)	Yes	2		
		No	0		
Expiry and stockout	Abacavir 20mg/ml 240ml or 60mg dispersible tablet	No Stock out in past 3 months	1	**29**	**29**
	Abacavir Lamivudine 300mg 150mg combination tablet 56 s (FDC)	No Expiry in past 3 months	1	**29**	**29**
	Efavirenz 200mg tab 28 s 56 s 84 s	There was stockout in past 3 months	0		
	Efavirenz 600mg tab 28 s	There was expiry in last 3 months	0		
	Lamivudine oral sol 10mg per ml				
	Lamivudine 150mg tabs 56 s				
	Lopinavir 80mg Ritonavir 20mg ml				
	Nevirapine 50mg per 5ml suspension				

	Tenofovir 300mg Emtricitabine 200mg Efavirenz 600mg tab 28 s (FDC) Phenytoin 100mg tabs 84s Isoniazid tab 300mg tabs 28 s Rifampicin 60mg INH 60mg 56 s Rifampicin 300mg INH 150mg tablets 56 s Rif/INH/PZA/ETH tabs 56 s 84 s 112 s Co Trimoxazole suspension 50ml or 100ml Co Trimoxazole 480mg tabs 56 s Adrenaline (1:1000) injection Diazepam 10mg/2ml injection Promethazine 25mg/ml IM Hydrochlorothiazide 12.5 or 25mg tabs 28 s Metformin 500mg or 850mg tablets 28s, 56 s and 84 s Vaccine Pentavalent/Hexavalent Paracetamol 500mg tablets Amoxicillin 125mg/5ml suspension Polio bOPV Ethinyl estradiol and norgestrel tablets 28's (Ovral) Depo Provera Gloves exam non sterile medium Insulin syringe with needle				
	Total			**104**	**150**

Appendix D: Data extraction tool

		Facility characteristics at baseline						Coded Baseline Facility Characteristics		Assessment findings - Baseline								Assessment findings - Repeat								Difference (Repeat - Baseline)	# of VISITS			TA Strategies utilised					
Subdistrict	Facility Name	PHC/CHC	PHC headcount	High TROA/not	# Professional nurses	# Pharmacists	# Pharmacist Assistants	Headcount volume (small/med/large)	DoH Pharm Staff onsite (Yes/No)	Guidelines and Reference materials availability	Training	Stock management (ordering, receiving, issuing)	Stock monitoring	Storage of medicines	NO Expired meds out of 29 medicines checked	No stock outs out of 29 medicines checked	TOTAL Score	TOTAL Percentage	Guidelines and Reference materials availability	Training	Stock management (ordering, receiving, issuing)	Stock monitoring	Storage of medicines	NO Expired meds out of 29 medicines checked	No stock outs out of 29 medicines checked	TOTAL Score	TOTAL Percentage		Initial FMT	TA	TOTAL VISITS (excluding assessment visits)	Document and refer matter 'upstream'	Informal mentoring/advice	Formal module training	Simple refresher training	Provide job aids	Direct service delivery (Help do the job)

Appendix E: UWC ethics approval



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11 December 2018

Ms C Jallow
School of Public Health
Faculty of Community and Health Science

Ethics Reference Number: BM18/9/15

Project Title: Assessment of changes in pharmaceutical performance among primary health care health facilities that received technical assistance in a rural district of the Eastern Cape, South Africa.

Approval Period: 11 December 2018 – 11 December 2019

I hereby certify that the Biomedical Science Research Ethics Committee of the University of the Western Cape approved the scientific methodology and ethics of the above mentioned research project.

Any amendments, extension or other modifications to the protocol must be submitted to the Ethics Committee for approval.

Please remember to submit a progress report in good time for annual renewal.

The Committee must be informed of any serious adverse event and/or termination of the study.

Ms Patricia Josias
Research Ethics Committee Officer
University of the Western Cape

BMREC REGISTRATION NUMBER -130416-050

FROM HOPE TO ACTION THROUGH KNOWLEDGE

Appendix F: Consent from implementing partner to utilise in-house data

From: Harry Hausler [mailto:Hhausler@tbhivcare.org]
Sent: 06 August 2018 11:19 AM
To: Peter Manyike <Peter.Manyike@sead.co.za>
Cc: Tim Tucker <Tim.Tucker@sead.co.za>; Gareth Lowndes <Gareth@tbhivcare.org>; Katherine Young <Katherine@tbhivcare.org>; Sarah Mullin <Sarah@tbhivcare.org>
Subject: Re: Request for use of SEAD in-house data for an MPH mini thesis by one of our staff members - Mrs Carmen Jallow

Dear Peter,

This is to confirm that Carmen Jallow may use data generated from SEAD's programmatic pharmaceutical support to Amathole district during the period March 2017 to March 2018 under the following conditions:

Permission is requested and granted from CDC – please proceed to contact Marelize van Wyk

Ethical approval for the protocol is granted by UWC.

Kind Regards,

Harry

Harry Hausler
Chief Executive Officer

www.tbhivcare.org • Hhausler@tbhivcare.org

T: 021 425 0050 • **C:** 082 779 0045 • **F:** 021 421 9439
HO: 7th Floor • 11 Adderley Street • Cape Town • 8001 • South Africa
PO Box 2589 • Cape Town • 8001

TBHIVCARE

From: Peter Manyike <Peter.Manyike@sead.co.za>
Date: Monday, 23 July 2018 at 14:00
To: Harry Hausler <Hhausler@tbhivcare.org>
Cc: Tim Tucker <Tim.Tucker@sead.co.za>
Subject: Request for use of SEAD in-house data for an MPH mini thesis by one of our staff members - Mrs Carmen Jallow

Dear Prof. Hausler

See the attached letter from one of our staff members, Mrs Carmen Jallow, who is our Compliance and Integration Manager.

At SEAD we encourage our employees to constantly improve themselves through studying for higher degrees, which will hopefully be of benefit to SEAD, primes, consortium partners and the communities we serve.

We are therefore supportive of Carmen's request to use our programmatic pharmacy data for her MPH degree at the University of the Western Cape's School of Public Health.

We kindly request your kind review of Carmen's request with and possible approval, and further guidance on how to take this process forward in terms of whether the funders' approval, I.e., CDC, is also required.

In addition, we kindly request your kind permission to contact Ms Marelise Van Wyk at CDC for advice, as we would like this to be deemed programme evaluation and not research.

We look forward to your favourable consideration of this request.

Kind regards

Peter

SEAD

DR. PETER MANYIKE
DEPUTY CEO

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1ST FLOOR, PECANWOOD
26 CHARLES DE GAULLE
CENTURION 0046

Appendix G: Eastern Cape Department of Health study approval

Province of the
EASTERN CAPE
HEALTH

Enquiries: Zonwabele Merile Tel no: 083 378 1202

Email: zonwabele.merile@echealth.gov.za Fax no: 043 642 1409

Date: 30 January 2019

RE: Assessment of changes in pharmaceutical performance among primary health care health facilities that received technical assistance in a rural district of the Eastern Cape, South Africa. (EC_201901_006)

Dear Carmen Jallow

The department would like to inform you that your application for the abovementioned research topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health in writing.

2. You are advised to ensure, observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and shall remove or not collect any information which can be used to link the participants.

3. The Department of Health expects you to provide a progress update on your study every 3 months (from date you received this letter) in writing.

4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Eastern Cape Health Research Committee secretariat. You may also be invited to the department to come and present your research findings with your implementable recommendations.

5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

SECRETARIAT: EASTERN CAPE HEALTH RESEARCH COMMITTEE