

# National Assessment of the Pharmaceutical Management of Tuberculosis in South Africa

**National Strategic Report**

**December 2012**



**USAID**  
FROM THE AMERICAN PEOPLE

**SIAPS**   
Systems for Improved Access  
to Pharmaceuticals and Services



**National Assessment of the Pharmaceutical Management of TB in  
South Africa: National Strategic Report**

---

SIAPS-South Africa

December 2012



This report is made possible by the generous support of the American people through the US Agency for International Development (USAID), under the terms of cooperative agreement number AID-OAA-A-11-00021. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

## **About SIAPS**

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

## **Recommended Citation**

This report may be reproduced if credit is given to SIAPS. Please use the following citation.

SIAPS-South Africa, December 2012. *Pharmaceutical management of TB in South Africa; Rapid Assessment conducted in 7 provinces*. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

## **Key Words**

Pharmaceutical management, Tuberculosis, Supply chain management, Compliance with treatment guidelines, Stock management systems.

Systems for Improved Access to Pharmaceuticals and Services

Center for Pharmaceutical Management

Management Sciences for Health

Ditsela Place, 1204 Park Street

Hatfield, Pretoria, South Africa

Telephone: +27 12 3640400

Web: [www.siapsprogram.org](http://www.siapsprogram.org)

## CONTENTS

Acronyms and Abbreviations .....	vi
Acknowledgments.....	viii
Executive Summary .....	12
Results of the Rapid Assessment; Providing an Uninterrupted Supply of TB medicines ...	12
Results of the Rapid Assessment; Compliance with TB Treatment Protocols .....	15
Recommendations for improvement and way forward.....	16
Purpose of the assessment and process followed.....	20
A. Methodology used.....	20
Challenge of TB in South Africa and the Provinces Assessed .....	24
Overview of Supply Chain Processes for TB .....	28
Selection of TB medicines .....	30
A. Registration of TB medicines and Vaccines.....	32
B. Development of TB treatment guidelines (regimens, drugs and dosages) .....	34
C. Creation of the Essential Drugs List .....	35
D. Role of provinces in creation of the Essential Drugs List and Selection of Medicines for the provinces .....	36
E. Challenges and Best Practices in TB medicine Selection and Recommendations .....	38
Procurement of TB commodities .....	40
A. Quantification of need.....	41
B. Challenges , Best Practices and Recommendations in Quantification .....	42
C. Pre qualifications of suppliers.....	43
D. Bid evaluation and awarding of contracts.....	44
E. General and Special conditions to tender contract.....	47
F. Challenges, Best practices and Recommendations for tender process .....	47
G. Procurement at Provincial Level of TB Medicines.....	49
H. Budgeting for TB Medicines at Provincial Level .....	50
Distribution of TB commodities .....	51
A. Distribution of Provincial Depots for Warehousing of TB Medicines .....	51
B. Regulations governing storage of drugs at depots and pharmacies .....	51
C. Stock holding and infrastructure .....	53
D. Depot management .....	59
E. Ordering processes.....	59
F. Stock management and storage.....	63

G. Challenges, best practices and recommendations for distribution.....	73
Contract management and Payment.....	76
A. Drug monitoring and reporting .....	76
B. Contract management .....	80
C. Expenditure on TB Medicines .....	84
D. Challenges, best practices and Recommendations in Contract Management.....	88
Suppliers Opinions of the TB Pharmaceutical Management Systems within National Department of Health.....	90
A. Drug Registration process.....	90
B. National EDL List.....	90
C. Tendering and contract management .....	91
Use of TB medicines and Facility Management of TB medicines .....	94
A. Storage of TB medicines in health facilities .....	96
B. Availability of medicines .....	96
C. Patient Records Review for TB treatment .....	108
D. GeneXpert machine and testing for resistance.....	114
E. Patient interviews.....	117
F. TB referral system and data integrity.....	120
Challenges in TB pharmaceutical management.....	122
A. Selection.....	122
B. Procurement of TB Medicines .....	123
C. Distribution from provincial depots and sub depots .....	124
D. Distribution to facilities .....	125
Use of products at facility level .....	126
Best Practices .....	128
A. Clinical diagnosis and effective treatment.....	128
B. TB coordinators pull all the strings together.....	129
C. Stock management and ordering at Depot and Facilities.....	129
D. Distribution model to facilities .....	130
E. Stock availability and uninterrupted supply .....	131
F. Governance of the selection of TB medicines and Procurement process.....	131
Solutions .....	133
A. Patient treated holistically and empowered to take TB medication.....	133
B. TB coordinators forming the crucial link between facility TB DOT staff and the community. ....	134
C. District and Sub district TB Stakeholder meetings.....	135

D. Stock management at facility level .....	136
E. Depot stock management and distribution.....	138
F. Budgeting for TB medicines .....	138
G. Contract management .....	139
H. Tendering process .....	139
I. Quantification .....	140
J. Communication and cross directorate working relationships.....	142
K. Distribution enhancement at provincial depot and facility level .....	142
L. Supplier Proposed Solutions .....	143
.....	143

---

## ACRONYMS AND ABBREVIATIONS

APP – annual performance plan  
ARV – antiretrovirals  
BMI - Body Mass Index  
CHC - Community Health Centre  
CHW - Community Health Workers  
CMD – medicines supply depot – Cape Town  
DH = District Hospitals,  
DOT – Directly Observed Treatment  
EDL – essential medicines list  
FEEFO - first earliest expiry first out  
FIFO - first in first out  
GMP - Good Manufacturing Practices  
GPP - Good Pharmacy Practices  
GPP - Good Pharmacy Practices  
GWP - Good Wholesale Practice  
HAST – HIV, AIDS, STI and TB  
HOD - Head of Department  
ICN - Internal Stock Number  
MCC – Medicines Control Council (also refers to medicines regulatory affairs directorate)  
MDR – Multi drug resistant TB  
MSD – medicines supply depot – Auckland Park  
NDOH – National Department of Health  
NSN - National stock numbers  
OMSD – Oudtshoorn sub depot  
PHC - Primary Health Centre  
PICS - Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme  
POD - proof of delivery  
PTB – Pulmonary TB  
PTC - Pharmaceutical and Therapeutics Committee  
RH = regional Hospitals  
SABS - South African Bureau of Standards  
SAPS - South Africa Pharmaceutical Society  
SCMS - Supply Chain Management Systems  
SEP - Single Exit Price  
SM – Smear positive patients with TB

STG's – Standard treatment Guidelines

TB – Tuberculosis

TB = TB hospital

TRP - Tshwane regional pharmacy

## ACKNOWLEDGMENTS

Dr. Kim Faure (Pure Health Consulting), under consultancy agreement with SIAPS South Africa, conducted the assessments and compiled this report. She and her team are acknowledged with sincere thanks.

Many thanks must go to the following people interviewed for this assessment:

- Dr. Lindiwe Mvusi – TB director DOTS
- Dr. Anban Pillay – Deputy Director General Health: Regulation and Compliance
- Mrs. Helecine Zeeman – Director Affordable Medicines
- Mr. Jaco Stokes – National ARV Monitor
- Provincial heads of Pharmacy, TB, HAST Pharmacists, District pharmacists, district TB coordinators, Depot managers and responsible pharmacists of the following provinces:
  - Eastern Cape
  - Free State
  - Gauteng
  - Limpopo
  - Mpumalanga
  - North West
  - Western Cape
- Facility managers and staff at the following facilities in the provinces:

<b>Free State Province, Thabo Mafutsanyane District</b>		
<b>Facility name</b>	<b>Facility type</b>	<b>Town</b>
<b>Mphohadi PHC</b>	Primary health care centre	Bethlehem
<b>Senekal LA</b>	Primary health care centre	Senekal
<b>Mamello CHC</b>	Community health centre	Marquard
<b>Phekolong hospital</b>	District hospital	Bethlehem
<b>Dihlabeng hospital</b>	Regional hospital	Bethlehem
<b>Dr JS Moroka hospital</b>	TB hospital	Thaba Nchu
<b>North West Province, Dr. Kenneth Kaunda district</b>		

*Pharmaceutical management of TB in South Africa*

Facility name	Facility type	Town
<b>Park street town clinic</b>	Primary health care centre	Klerksdorp
<b>Jouberton CHC</b>	Community health centre	Klerksdorp
<b>Tigane CHC</b>	Community health centre	Hartebeesfontein
<b>Ventersdorp hospital</b>	District hospital	Ventersdorp
<b>Tshepong hospital</b>	Regional hospital	Klerksdorp
<b>Tshepong MDR/XDR Unit</b>	TB hospital	Klerksdorp

<b>Eastern Cape Province, Dr Kenneth Kaunda District</b>		
Facility name	Facility type	Town
<b>Buntingville Clinic</b>	Primary health care centre	Nyandeni
<b>Libude Clinic</b>	Primary health care centre	Nyandeni
<b>Ngangelizwe CHC</b>	Community health centre	Nyandeni
<b>St Barnabas hospital</b>	District hospital	Nyandeni
<b>Mthatha hospital</b>	Regional hospital	KSD
<b>Zithulele hospital</b>	Mission hospital	KSD
<b>Gauteng Province, Tshwane District</b>		
Facility name	Facility type	Town
<b>Stanza PHC</b>	Primary health care centre (PHC)	
<b>Holani PHC</b>	Primary health care centre (PHC)	
<b>Laudium CHC</b>	Community health centre (CHC)	
<b>Tshwane DH</b>	District hospital (DH)	
<b>Mamelodi RH</b>	Regional hospital (RH)	
<b>Sizwe TH</b>	Tuberculosis hospital (TH)	

<b>Mpumalanga Province, Gert Sibande District</b>		
<b>Facility name</b>	<b>Facility type</b>	<b>Town</b>
<b>Msimanga</b>	Primary health care centre (PHC)	
<b>Davel Clinic</b>	Primary health care centre (PHC)	
<b>Winnifred Maboja</b>	Community health centre (CHC)	
<b>Standerton DH</b>	District hospital (DH)	Standerton
<b>Ermelo</b>	Regional hospital (RH)	Ermelo
<b>Standerton</b>	Tuberculosis hospital (TH)	Standerton
<b>Western Cape, Eden district</b>		
<b>Facility name</b>	<b>Facility type</b>	<b>Town</b>
<b>Bongolethu</b>	Community health centre (CHC)	Oudtshoorn
<b>Blanco clinic</b>	Primary health care centre (PHC)	George
<b>Bridgeton</b>	Community health centre (CHC)	Oudtshoorn
<b>Oudtshoorn hospital</b>	District hospital (DH)	Oudtshoorn
<b>George hospital</b>	Regional hospital (RH)	George
<b>Harry Comay hospital</b>	Tuberculosis hospital (TH)	George
<b>Limpopo Province, Vhembe district</b>		
<b>Facility name</b>	<b>Facility type</b>	<b>Town</b>
<b>Mbokota</b>	PHC	Vhembe
<b>Bungeni</b>	CHC	Vhembe
<b>Louis Trichard DH</b>	DH	Vhembe



## **EXECUTIVE SUMMARY**

South Africa's challenge of Tuberculosis (TB) is a tremendous one. With the third highest TB prevalence in the world fueled by the HIV epidemic, the challenge is one that deserves a high priority within the strategic decision making and operational implementation systems of the countries Departments of Health. Managing the pharmaceutical selection, procurement, distribution and use of TB medicines forms an integral part in helping the country achieve the Millennium Development Goal target of a reduction in TB cases detected and an increase in those cured under Directly Observed Treatment Strategy (DOTS).

This assessment, conducted in 6 provinces within their National Health Insurance pilot districts, was a rapid assessment of the national strategic supply chain for TB medicines and the operational management of TB drugs from provincial depots to facility and then to the patient. It included elements of compliance with treatment protocols in terms of prescribing and from the patient's point of view of knowledge of treatment requirements. It however does not assess the diagnostic and adherence elements which form part of delivering clinical care and improving the detection of TB cases.

We have therefore hypothesized that in order to improve the countries treatment cure rates and reduce the death rates from TB; South Africa needs to understand its current ability to provide an uninterrupted supply of TB medicines to the patients. Our second hypothesis is that the patients need to have been prescribed the correct treatment for the type of TB, the patient's weight, the phase of treatment and the resistant profile of the TB bacteria.

### **Results of the Rapid Assessment; Providing an Uninterrupted Supply of TB medicines**

The selection of TB medicines for South Africa's Essential Drugs List (EDL) follows a robust governance process with extensive scientific research utilised to determine the correct TB treatments for the countries TB profile and the correct protocols based on the availability of diagnostic investigations. Adherence by the provinces to this EDL for TB is good with only a few provinces deviating from the EDL for non TB medicine procurement.

The tenders for TB medicine were historically performed by National treasury in consultation with the Affordable Medicines Directorate of the National Department of Health (NDOH). This process was changed for the recent TB tender (August 2011) with NDOH taking full control of the process. It did not come without some glitches. The main gaps included the appointment of single suppliers for critical first line TB medicines and a lack of planning to bridge the supply gaps between the old and new contract through bridging stock resulting in shortages in some provinces. Major concern was the shortage of INH in the country for 3 months during the transition period with HIV patients requiring initiation on INH prophylaxis not receiving treatment in some provinces and a shortage of the Fixed Dose Combination for intensive phase (RHZE) for 6 weeks.

Provinces that were unaffected by the drug shortages have robust procurement, warehousing and distribution processes in place with active management thereof. They are distinguished from the other provinces that experienced supply constraints by having sub depots which buffered the health facilities through their effective stock management, planning and prudent distribution policies. In addition effective redistribution processes between facilities within these provinces and a process of rationing the amount of issued out medicines meant patients never experienced a shortage of their essential drugs.

One of the major challenges highlighted by this assessment is the ability of smaller facilities, primary health clinics (PHC's) and community health centres (CHC's), to manage their medicines. The challenges include a lack of suitable infrastructure with storage facilities that are just too small to accommodate the stock being distributed to them sufficiently for them to be able to unpack, store in a manner compliant with good pharmacy practices and control effectively on a regular basis. This is aggravated by inflexible delivery schedules from the provincial depots, with too infrequent deliveries of too large a volume of stock to meet the capacity constraints of the facility. The addition of HIV treatment within these clinics has resulted in a further burden of Anti Retroviral medicines (ARV's) being delivered, overstressing storage capacity due to their high volumes.

Making matters worse is the lack of pharmaceutical professional staff support at these facilities resulting in a reliance on nurses, already stretched with clinical care obligations, to add additional tasks of stock management, ordering and drug availability reporting to their busy days. In provinces with limited pharmaceutical staff innovative rotational systems are being tested, which provide much needed stock management support to clinic staff and have improved instances of oversupply and hoarding of medicines as occurs when staff don't understand the supply chain ordering principles.

The availability of good drug supply information at all levels in the system is severely lacking. Reliance is made on facility staff to report their drug availability on a regular basis as there are no IT systems or stock level reports generated. The definition of availability also vary across provinces and the data is of dubious value as we have witnessed the inability of facility staff to recall drug shortages as no records are kept. Provinces report bimonthly their depot stock levels which are only a snap shot on the day the report is generated. Besides requiring enormous manual effort to supply this information as no IT system reporting capabilities are sufficient to extract this, the data is of limited value as it does not indicate the extent of the problem at facility level.

Our assessment of the average number of days that TB tracer medicines, surgical and ARV's are unavailable ranges between 0.35% and 2.84% of days across the provinces visited. This is minimal compared to the drug availability reports that provinces are generating using their various definitions. The biggest concern is for the availability of TB medicines as ARV's and surgical supplies have much better availability across the provinces. On the day of our assessments (September to November 2011), the same list of tracer medicines was assessed

to determine their availability on the shelf with a range of 68.15 to 100%. Again the availability of TB medicines was on average lower than for ARV's with the biggest stock outs being experienced in the clinics and district hospitals. This shows that the enhanced emphasis on HIV treatment and care through the nationally driven campaigns is improving the management of ARV medicines at facility level. A similar campaign should be encouraged for the TB program.

Poor management of the budgeting processes within most provinces, have resulted in instances of lack of TB vaccines and medicines due to shortage of funds. Budgeting for medicines is performed by the finance department with the previous year's overspend being deducted from the following years budget resulting in a ever decreasing medicine budget year on year. This is out of alignment with the very increasing TB burden experienced through improve surveillance and new diagnostic techniques such as the GeneXpert machine and severely hampers the ability of clinical staff to care for TB patients. This also impacts on payments to suppliers of medicines, resulting in suppliers non delivery or short delivery until payment is effected again impacting supply down the supply chain.

In provinces where financing of TB medicines is not an issue, TB medicines are separated out as a distinct line item within the greater medicine budget which is ring fenced. The budget is managed actively on a monthly basis through variance analysis, through the Pharmaceutical and Therapeutics Committees involvement to improve good prescribing practices and through good governance of purchasing of medicines at all levels. The involvement of finance, pharmacy and TB programmes from sub district up to provincial levels highlights that an integrated approach is taken to the management of this important aspect of drug availability. In these provinces suppliers are paid on time and within 30 days, enhancing the delivery of products to these provinces in preference to others.

Expenditure data per province when proportioned by TB case load shows that in most provinces TB drug spend per patient is much higher than the case load would suggest. This implies that either the provinces are wasting TB medicines (in effective stock management, losses, incorrect prescribing of pack sizes etc) or that the TB case load data from the electronic TB register (eTr) is under describing the true problem and that the case load is in effect much higher. From our investigations at facility level we very rarely found situations of overstocking at facilities for TB medicines although we cannot comment on incorrect dispensing and wastage, therefore we have to assume that the depot expenditures are a more accurate reflection of the true picture of demand imply that the case loads are higher than the eTr stats would suggest.

### **Results of the Rapid Assessment; Compliance with TB Treatment Protocols**

If we assume that the pharmaceutical supply of TB medicines is however not of concern, then we need to investigate the compliance with the TB treatment protocols at facility level. This was assessed through TB blue file audits in all provinces.

Only 68% of all patients received the correct drug at the correct dose for their type of TB and the phase they were in based on the National TB Treatment protocols and guidelines. Treatment of non drug resistant TB was more correct with the intensive phase records being 74% accurate and the continuation phase 69%. MDR treatment protocol compliance was the biggest concern at only 48% compliant, mainly due to very poor documentation of deviations from treatment guidelines which may have been required due to patient clinical factors. There were huge variation between provinces in terms of drugs and dosages prescribed for MDR patients raising a concern around the management of this very difficult type of TB and the implications on future resistance for the country.

We find it inexcusable that clinics and some TB facilities do not have scales to weigh patients in order to ensure accurate dosing. It is also inexcusable that doses are not accurately prescribed based on the patient's weight and adjusted when the weight increases especially given the high rate of co infection of patients with HIV.

Recordkeeping was found to be the major reason for non compliance across most of the facilities assessed and at least a few patients had incomplete records. Surprisingly the compliance of the CHC's and clinics is higher than the district hospitals and TB hospitals who have doctor driven care although the patients admitted are more complicated and require customized care. We however feel that documentation of deviations to standard treatment guidelines is an essential element of the effective care of any patient and using these audit findings we would suggest an extensive review of the prescribing practices for TB in South Africa.

Cost of transport and accessibility of clinics for DOT patients is concerning in some provinces, severely limiting access and compliance with treatment and is perpetuated by the lack of good DOT supporters in the community or use of CHW's.

Poor district and sub district TB co ordinator oversight and follow up of patients results in some provinces where there is no direct communication with patients or between facility based staff and district co ordinators for referrals. Relying on patients to come back to the clinic for their sputum results and initiation of treatment is reactive and with the high incidence of MDR in some provinces this should be urgently looked into. Management of referrals requires a more formal system of communication between sites, both up and down stream, with active tracing of patients and oversight.

Overall patients however were well educated about their TB treatment and understood the implications of not taking their treatment and in most instances the side effects and how to handle them. We were impressed with the nutrition support programs implemented in some districts which created a sense of caring amongst the TB patients. Empowering patients to be in charge of their own treatment through innovative simple solutions was encouraging to see in the absence of good community based supporters. The move to treating patients within the community and not through the primary health system is not something that has occurred in the districts we assessed and would improve the accessibility to care in a number of provinces and therefore also compliance.

### **Recommendations for improvement and way forward**

In providing recommendations we are cognisant of the NDOH's plans to implement a Central Procurement Unit. We have therefore taken the stance of a bottom up approach using the existing resources available based on our assessments. We will focus on driving quality improvement, efficient processes and good management systems to address the shortcomings identified from the ground up to depot level from where the CPU proposal for improved distribution, contract management and integrated of stock management would come in.

The most essential component within the TB management team which requires strengthening is the TB Coordinator who should be forming the crucial link between the facility TB staff and the community. Enhancing her supervising and management responsibilities she should actively performance manage staff on their outcome and process results using the TB stats generated for the eTr. She is the bearer of knowledge and information continually updating the staff with changes to drug availability, suppliers and treatment protocols. Her role as mentor should include regular patient file audits to improve compliance with treatment protocols and provide continuous learning to staff. In her linking role she can make use of the NHLS GeneXpert weekly reports to improve her ability to trace and follow up new patients and resistant patients. Monitoring of the patient referred up and down stream will occur through her active engagement with the facility staff and the community supporters in her region.

Improving the management of drug supply we are proposing that district TB stakeholder meetings are held to which suppliers are invited. These meetings will utilise the TB statistics that the TB Coordinator is gathering from the facilities to improve understanding of the true demand for TB medicines in the region. The involvement of pharmacists, depot managers and finance staff will ensure alignment of drug supply needs with demand and improve the management of shortages and drug supply concerns at the level it impacts the most. These

same TB stakeholder meetings should be repeated at provincial level taking into account the district results and also nationally where only national supply issues need to be addressed.

Improving stock management at facility level we are proposing the move to a “pull” system with ordering based on TB regimen and not individual drugs. We would phase this in over 3 phases. Phase 1 would entail ordering to be performed not against a specific drug but against the number of patients within a specific treatment regimen. This requires nurses at clinic level to think like TB nurses rather than like pharmacists possibly improving their understanding of the drug needs and management process. Regimen based ordering can be tested in clinics first with the direct support of rotating pharmacy staff and TB Coordinators to get the system running effectively before being rolled out.

Phase 2 would introduce the push system once the demand and minimum and maximum order levels are determined accurately for each facility. The push orders would be generated from the depot based on historical demand and forecasting and only requires the facility staff to agree or adjust based on their TB demand which is now being more accurately determined. This push system comes with a performance management systems attached. Facilities repeatedly adjusting push orders and resulting in incorrect drug levels at their facilities are placed back into phase 1 with ongoing mentorship and support from pharmacy staff. This way pharmacy support services which are limited can be stretched across those facilities requiring it more with good performers being assessed on an infrequent basis and mentored by the TB Coordinator.

Phase 3 now links this facility driven system into the Central Procurement Unit utilizing an IT system based stock management system in the larger facilities.

We would propose that small pilot testing project of these quality improvement initiatives should occur for the regimen based ordering and push system and for the TB stakeholder meetings. We would propose the Gauteng Tshwane district, Free State, Mpumalanga Gert Sibande district and Western Cape Eden district as suitable pilot areas. The model to be used would be that of the Institute of Health Improvements Collaborative Learning Series which designs quality improvement initiatives at the ground level and tests changes through small scale pilots with rapid scale up and improvement spread. Monitoring and measurement form an essential component in this methodology. In addition behaviour changing models such as the “Influencer” model will be added to impact on the essential behaviours that require change during this improvement project resulting in a more sustainable solution being tested which can then be rolled out to the country.

In terms of the TB coordinator enhanced role we would propose a clearer understand and investigation first of the human resource and performance requirements of these individuals with a positive deviants assessment of those that are performing in this enhanced role already. This would help paint a picture of what training, mentoring and improvement gaps there are within the current staffing compliment of TB coordinators and inform improvement requirements.

Finally we would propose that the solutions presented here and the findings of this report are made available to the implementation team of the SCMS Central Procurement Unit project so the two may be integrated and linked.



## **PURPOSE OF THE ASSESSMENT AND PROCESS FOLLOWED**

The national assessment for pharmaceutical management for Tuberculosis (TB) in South Africa is aimed at assessing those aspects of the pharmaceutical management system that are critical for ensuring availability of first and second line TB medicines in the public sector.

The Systems for Improved Access to Pharmaceutical Services (SIAPS) program of Management Sciences for Health (MSH), funded by the United States Agency for International Development (USAID), has been providing technical support to the National Department of Health and provinces towards strengthening TB pharmaceutical systems in the country for the past five years.

SIAPS has been requested by USAID to undertake an assessment of the current pharmaceutical management for TB in the country on behalf of the National Department of Health. This assessment was to cover six provinces selected on the basis of the burden of TB: Eastern Cape, Western Cape, Free State, North West, Limpopo and Mpumalanga.

Assessments were conducted within the NHI districts of these provinces covering the following 6 facilities:

- TB hospital
- Regional Hospital
- District hospital
- 2x PHC's
- CHC

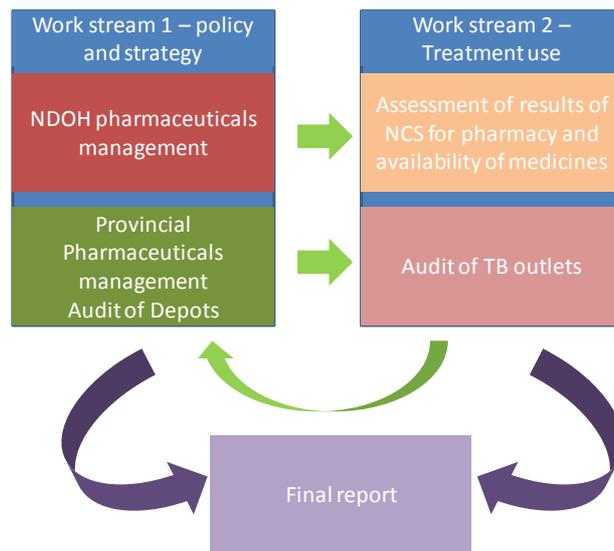
Assessments used indicators to guide data collection developed by USAID and customized by the consultant teams for the South African environment and treatment protocols and aligned with the National Core Standards for Health Establishments.

*Project was conducted by a consulting team from Pure Health Consulting. Contact person Dr Kim Faure, 082 565 1388, [kim.faure@mweb.co.za](mailto:kim.faure@mweb.co.za)*

### **A. Methodology used**

In order to conduct the assessment in a systematic fashion it was divided into two parallel work streams. The work streams worked in parallel to complete the work more efficiently with continuous communication between the two to allow information flow:

**Figure 1 - simplistic view of work streams and interactions**



**I. Pharmaceutical Management from a strategy and policy point of view.** This work stream covered:

- a. In depth assessment of the National Department of Health and Provincial Department of Health in terms of the selection, procurement and distribution of TB pharmaceuticals from a strategic and management point of view;
- b. Evaluation of the selection of medicines for placement onto the National TB Programme guidelines;
- c. Determining the safety and quality of the medicines chosen to be on the Essential Drugs List as determined by the Medicines Control Council and Medicines Regulatory Authority;
- d. Evaluation of medicine procurement from drug request to distribution from a provincial depot or distribution site to the TB outlets and healthcare facility pharmacies;
- e. Benchmarking of outputs against similar information collected by MSH in other countries. (this assumes that this can be made available by MSH)

This stream entailed key informant interviews, process mapping of pharmaceutical management flows and evaluation of the procurement supply chain gaps and challenges. These aspects were assessed at each level of government to enable a complete picture of the supply chain to be formed.

**II. Management of TB pharmaceuticals and use by patients at the TB treatment site level and TB outlet in terms of:**

- a. Availability of the correct medication to the patient,
- b. Healthcare facility management of stock at site level; and

c. Expertise of healthcare providers in following TB protocol.

This field work was conducted through the sampling of facilities and the assessment of onsite patient records, patient interviews, staff interviews and facility pharmacies (TB outlets).

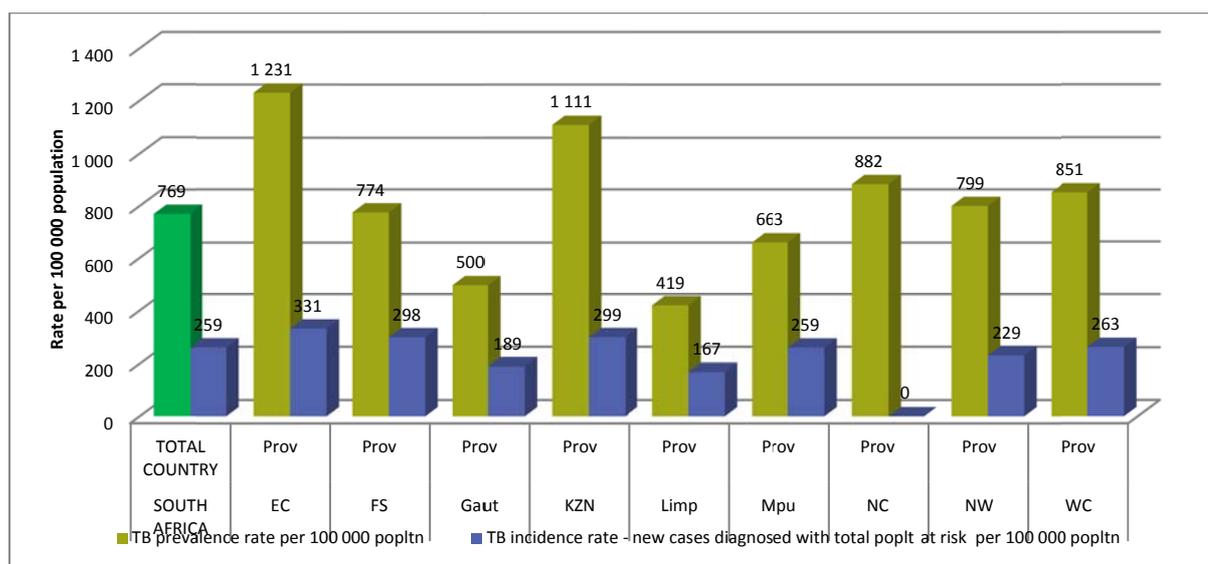


## CHALLENGE OF TB IN SOUTH AFRICA AND THE PROVINCES ASSESSED

South Africa currently has the third highest TB prevalence rate in the world, after India and China. The epidemic is being fuelled by HIV with more than 65% of patients with TB also having HIV.

The Eastern Cape Province has the highest prevalence rate of TB in the country (1,231 per 100 000 population), followed by KZN (1,111 per 100 000 population) and Northern Cape (882 per 100 000 population). Of the provinces which partook in this assessment Limpopo, Gauteng and Mpumalanga had the lowest prevalence rates of the 7 provinces evaluated.

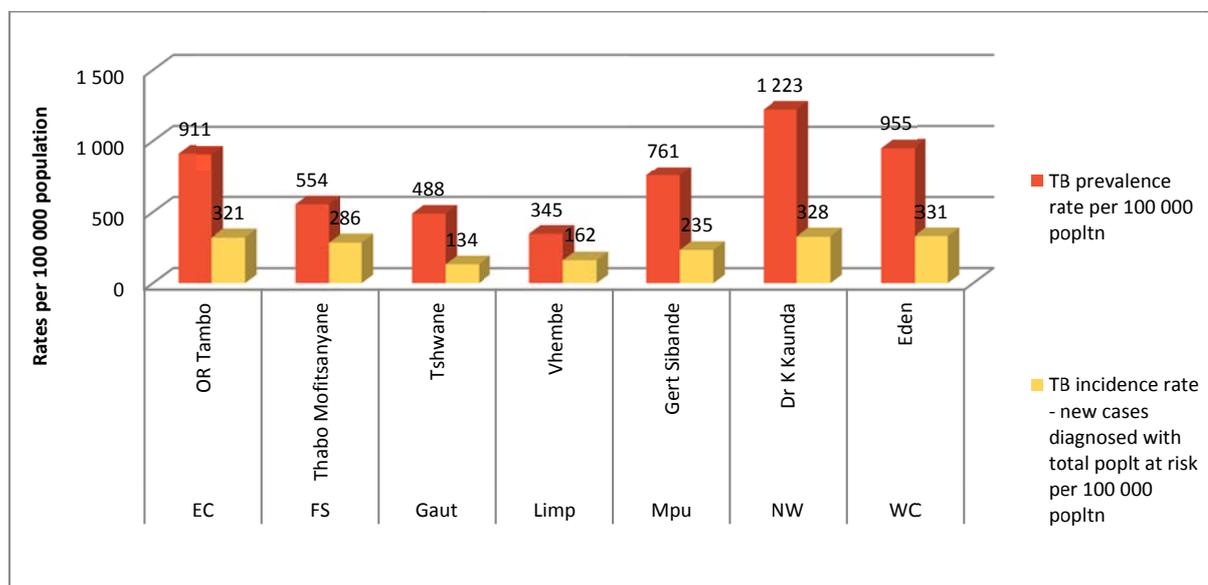
Figure 2 – TB prevalence and Incidence by Province



Source of data: Electronic TB register 2011 statistics, District Health Barometer 2011

Comparison between the NHI districts which form part of this assessment shows that Dr K Kaunda, OR Tambo and Eden districts have the highest prevalence rates. In addition they also have the highest incidence rates showing that new case surveillance is very active in these districts.

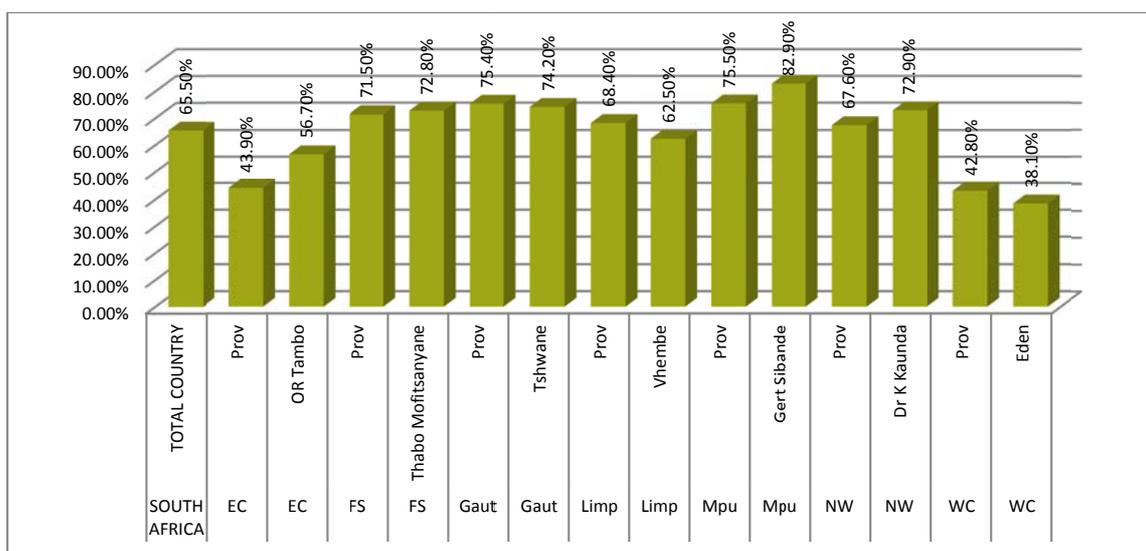
Figure 3 –TB prevalence and Incidence by NHI districts which form part of the PMTB assessment



Source of data: Electronic TB register 2011 statistics, District Health Barometer 2011

In the vast majority of provinces and districts assessed, TB infections were directly linked to HIV with more than 65% of TB patients being HIV positive. Exceptionally high co morbidities exist in the Gert Sibande district (83%). See figure 4 below. The Western Cape, Eastern Cape and Eden districts TB epidemic is however not linked to HIV with very low percentage of TB patients having concomitant HIV (WC – 42.8%, EC – 43.9% and Eden 38.1%).

Figure 4 -Proportion of TB patients who are HIV pos



Source of data: Electronic TB register 2011 statistics, District Health Barometer 2011

TB management in South Africa is not meeting the Millennium Development Goals (Proportion of tuberculosis cases detected and cured under DOTS) target of 85%. However there are some provinces and districts that appear to be making good progress towards meeting these targets or have achieved them already.

The Western Cape and Eden district have achieved high cure and treatment success rates well above 81% and so have OR Thambo district, Gauteng province, Vhembe district, uMzinyati district. See table 1 on next page.

Death rates range from a low of 3.2% (WC and Eden) to a high of 12.7% (Thabo Mofitsanyane district) with the average for the country sitting at 6.5%. Treatment completion rates are lower than the 5% target in most provinces and defaulter rates range between 1.5% to 9.1% of all patients receiving treatment.

The Northern Cape, Western Cape and Eastern Cape have the highest case load of MDR TB in the country (26.58; 21.98; 18.8 per 100 000 population). They also have the highest percentage of MDR patients out of all the TB patients being treated in those provinces. Interestingly KZN has a high incidence per 100 000 population of MDR TB (15.84) but as a proportion of their total TB patient load it is very small (0.01%).

**Figure 5 –MDR incidence and proportion of TB patients**

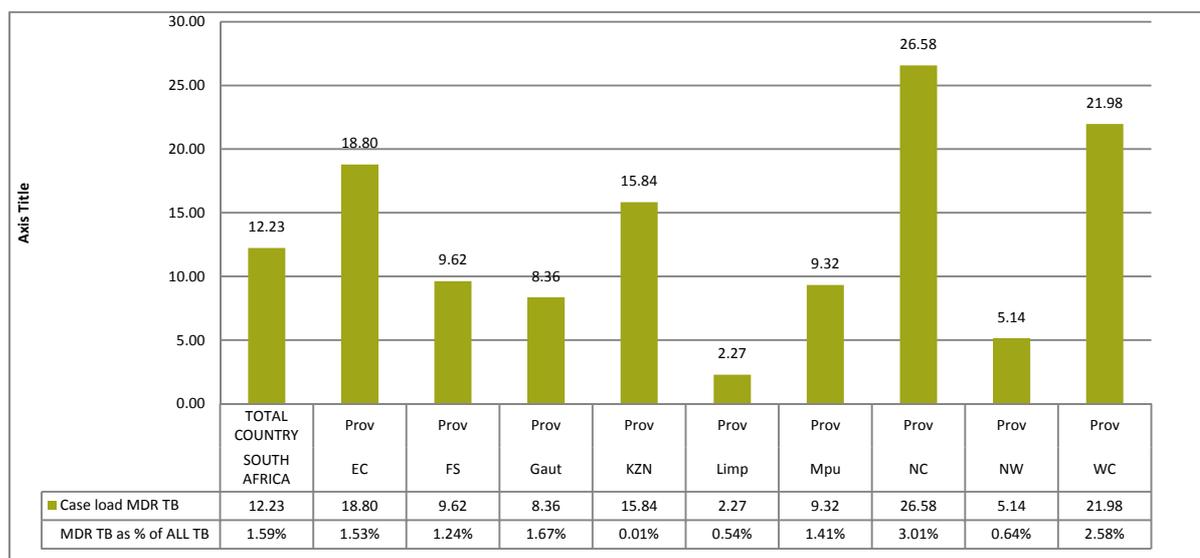


Figure 6 –TB outcome data by province and NHI district 2011\*

	SOUTH AFRICA	EC		FS		Gauteng		KZN			Limpopo		Mpumalanga		NC		NW		WC	
	TOTAL COUNTY	prov	OR Tambo	prov	Thabo Mofitsanyane	prov	Tshwane	prov	uMzinyathi	uMgunglovu	prov	Vhembe	prov	Gert Sibande	prov	pixley ka seme	prov	Dr K Kaunda	prov	Eden
<b>TB cure rate</b>	73.10%	67.10%	70.90%	73.30%	74.90%	78.20%	77.00%	71.30%	84.80%	76.80%	74.70%	79.90%	72.60%	64.00%	70.9	67.7	66.60%	65.80%	81.70%	85.30%
<b>Treatment success rate</b>	78.90%	76.90%	81%	77.80%	77.70%	82.30%	78.70%	77.60%	85.90%	78.10%	77.0	81%	76.40%	72.10%	80.9	77.8	74.80%	79.80%	85%	88.20%
<b>Treatment completion rate</b>	5.90%	9.90%	10.20%	4.70%	2.8%	4.00%	1.70%	6.30%	1.00%	1.40%	2.40%	1.10%	3.8%	8.10%	10.1	10.00%	8.20%	9.40%	3.30%	2.9
<b>TB defaulter rate</b>	6.80%	7.80%	3.50%	4.80%	3.4%	5.50%	8.60%	7.20%	1.50%	6.80%	6%	5.20%	7.50%	9.10%	6.40%	7.30%	8.80%	7.80%	6.80%	5%
<b>Retreatment %</b>	8.08%	9.53%	8.59%	9.16%	6.87%	5.77%	3.06%	4.73%	2.40%	3.32%	5.65%	4.40%	5.98%	3.73%	9.26%	9.73%	7.65%	6.84%	14.49%	18.15%
<b>TB death rate (% of all TB patients)</b>	6.50%	7.40%	8.80%	10.00%	12.70%	5.50%	5.70%	6.20%	8.70%	9.50%	8.50%	4.90%	7.00%	6.80%	5.7	5.60%	7.60%	8.10%	3.20%	3.50%

Definitions of rates \*Comprehensive Standard Operating Procedures for the national TB control Programme 2012, NDOH

**TB Cure rate** = patients who were smear positive at start of treatment that receive a smear/culture negative results in last month of treatment and on at least one previous occasion (at min of 30 days prior). Divided by the total number of new smear positive patients started on treatment in that period

**Treatment completion rate** = patients who were smear positive at start of treatment and have completed treatment but who do not meeting criteria for cured or failed. Divided by the total number of new smear positive patients started on treatment in that period. Target is < 5%

**Treatment Success rate** = number of patients who have successfully completed their treatment schedule (equals cured plus completed treatment).

**Default Rate** = Patients whose treatment was interrupted for more than 2 consecutive months. Divided by the total number of new smear positive patients started on treatment in that period

**Retreatment rate** = patients who required retreatment either post relapse, default or after failure as percentage of all TB patients.

**Death Rate** = patients who demised on during the period of treatment

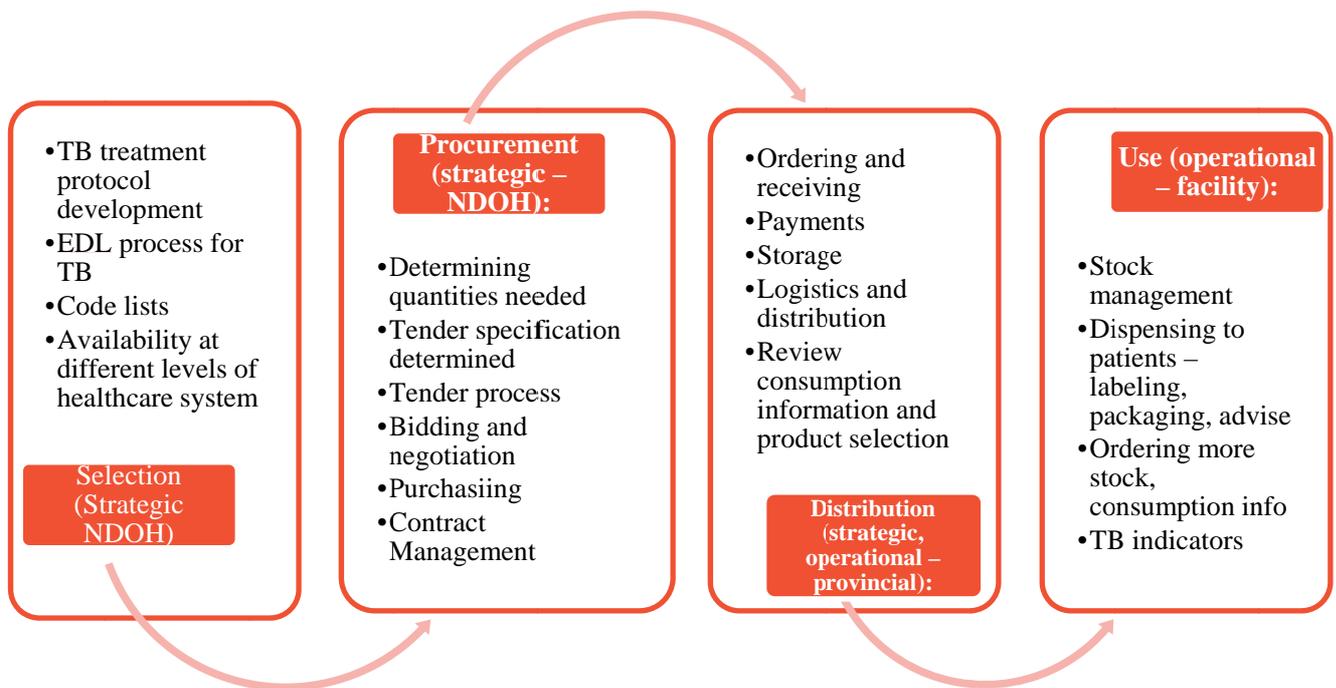
## OVERVIEW OF SUPPLY CHAIN PROCESSES FOR TB

The standard medicine supply management flow contains four vital process steps as illustrated in figure 4 below. These steps have been used to evaluate the 7 provinces in South Africa for effective TB medicine supply. TB medicines are defined for purposes of the report as:

- TB drugs – first and second line agents, paediatrics and those used for HIV/TB concomitant infections
- TB vaccines – such as the BCG vaccine and

TB surgical supplies including items to provide injections and sputum bottles have also been evaluated where possible to complete the picture of the issuing of TB treatment.

Figure 7 - Supply Chain process steps



The Medicine management flow would include:

- **SELECTION** – of the most suitable medicines to treat TB including the registration of these medicines with the Medicines Control Council (MCC) and the compilation of a Standard Treatment Guideline (STG). Selection also involves the mechanisms by which South Africa determines its Essential Drugs List (EDL) for TB medicine and what may be prescribed at which point in the health system. Provinces take this step one further with the compilation of code lists of medicines to be prescribed within a

province and at a specific healthcare level. This influences the ability of the pharmacy and nursing staff to order and dispense;

- **PROCUREMENT** – is the process by which drugs, meeting the criteria of the EDL and TB STG have become part of the stock within a facility. It includes a tendering process with pharmaceutical suppliers through a nationally driven procurement system and the compilation of a National Suppliers Tender Contract from which provinces are able to purchase. However provinces are able to tender outside of these National Tenders for products upon permission from the NDOH and National Treasury which ensures they have the systems in place to monitor the procurement process effectively. Monitoring and evaluating the performance of the suppliers and the facilities in complying with the tender conditions forms part of the procurement process.
- **DISTRIBUTION** –The effective ordering, storage, picking, dispatching and logistic distribution processes ensure that drugs are at the facility for the patients when they are required and includes the infrastructure in terms of depots for warehousing and stock management;
- **USE** – is focused on the facility where drugs are stored, prescribed and issued to the patient. Monitoring of stock levels, consumption information against the disease prevalence provide the bottom up information flow to ensure a safe and effective supply chain. For purposes of our assessment we have included in this section the evaluation of compliance of prescribing with the STG's and whether the patient is educated enough about the medication they are taking and how to take them correctly.

We will follow these process steps in the next few chapters describing at national and provincial levels the findings from our assessment.

## **SELECTION OF TB MEDICINES**

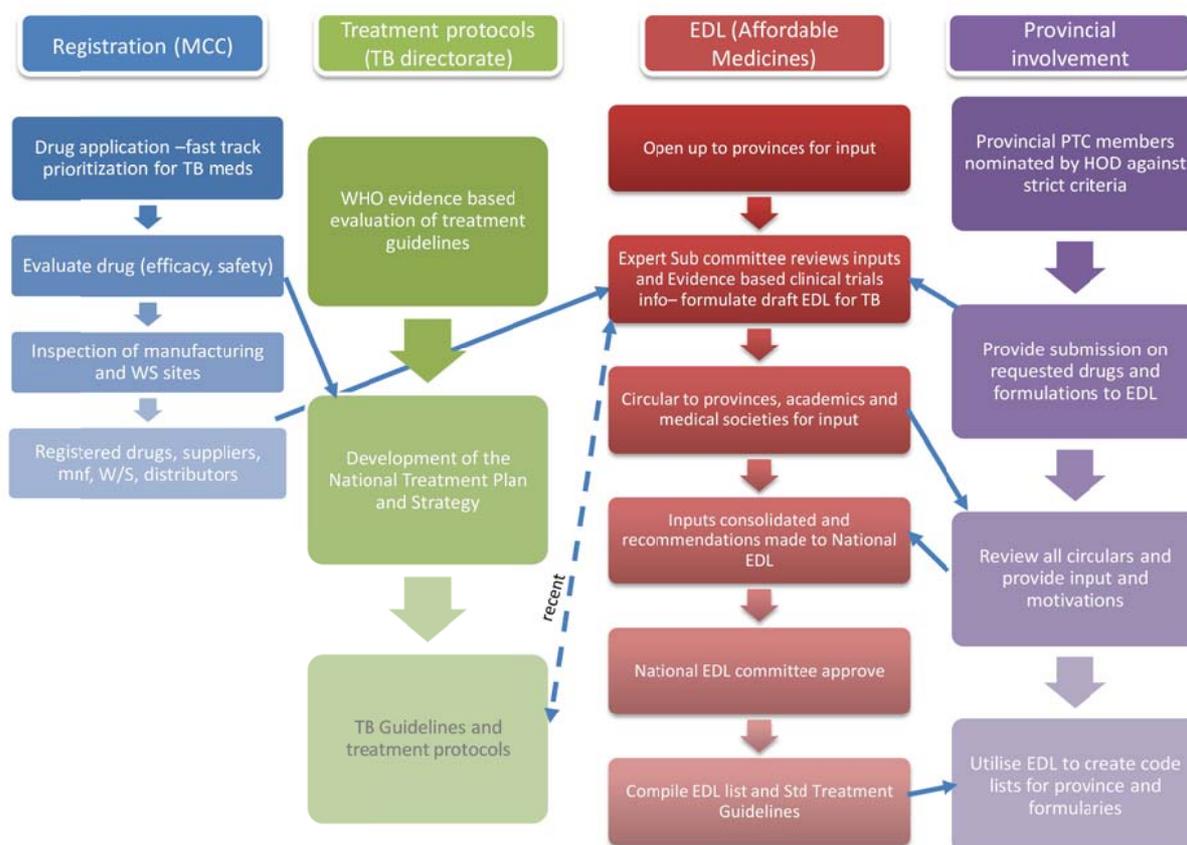
The process of selection of the most suitable medicines to treat TB includes the registration of these medicines with the Medicines Control Council (MCC) and the compilation of a Standard Treatment Guideline (STG) for prescribing against the type of TB. Selection also involves the governance mechanisms by which South Africa determines its Essential Drugs List (EDL) for TB medicine and what may be prescribed at which point in the health system.

Provinces take this step one further with the compilation of code lists of medicines to be prescribed within a province and at a specific healthcare level. This influences the ability of the pharmacy and nursing staff to order and dispense

Selection within South Africa involves 3 separate processes, managed by 4 separate divisions of the NDOH:

- Registration of medicines performed under the governance of the Registrar of Medicines at the Medicines Control Council (MCC);
- Development of suitable TB Standard treatment Guidelines (STG's) based on WHO and other evidence based medicine practices and clinical trials and research. This function is performed by the TB directorate of the NDOH;
- The Governance process around the selection of TB medicines for the Essential Drugs List which constitutes the drugs that may be prescribed in the South African public sector facilities. This is governed by the Affordable Medicines Directorate at the NDOH; and
- Involvement of the provincial Pharmaceutical and Therapeutics Committee (PTC) members in EDL determination and provincial pharmacy staff in the tender process.

**Figure 8 - Simplified processes showing some of the important linkages and handover points within the steps to selecting a drug and interaction of various divisions**



Overall there is good governance of the selection of medicines as the 4 divisions work independently of each other and therefore MCC does not influence which medicines become part of the EDL or STG's and the National EDL Committee does not influence the procurement process within the NDOH. However, these silo's create challenges in communication as the 3 directorates don't necessarily engage actively at any point in the selection flow. This limits for example, the ability of MCC to enhance the STG's and advise to users for the use of medicines based on the extensive information and evidence they have about the drug's safety, efficacy, formulation and shelf life.

The programmes such as TB were recently included in the selection process, a much needed improvement to the determination of EDL's. However their involvement is limited to giving input into specific drugs rather than influencing the quantification and budgeting for TB medicines through the use of surveillance data and actual numbers of TB patients.

Provincial input in the selection process is strong in most provinces through the involvement of the provincial Pharmaceutical and Therapeutics Committee (PTC) members in both the

National EDL Committee and the provincial pharmacists and depot managers in the tender selection and adjudication process. However this input is driven mainly by pharmacy with limited TB programme and health facility staff input with their on the ground experiences in drug use.

The following sections describe the various governance flows in more detail.

## **A. Registration of TB medicines and Vaccines**

### ***Medicine and Vaccine Registration***

TB medicines are an important contributor to reducing the burden of disease in South Africa and as such are classified as “critical” medicines and therefore processed through a “fast track” registration process at Medicines Control Council (MCC).

A governance process informs the decision on which medicines are considered “fast track”. This is determined by the policy unit of Affordable Medicines who review each “fast track” drug registration application to determine whether they meet the criteria. This separation of governance ensures that any evaluation bias by the MCC is removed. However all TB and HIV medicines are recommended for “fast track” so it seems this additional governance step may actually delay the start of the evaluation process, even if it is only by one day.

Fast track applications should be completed within one year from the MCC process point of view. This does not however include the time it takes applicants to respond to any questions or provide additional data as is sometimes required from the MCC evaluators before they are happy to continue processing the application. There have been numerous stability concerns with recent TB medicines and pharmaceutical companies have been required to redo or improve on their stability research data before the drug registrations can be completed. This has delayed the fast track process to between 18 months to 3 years depending on when the products first entered the system.

Fast tracking within the MCC also entails that the TB medicines “jump the queue” at times whether it be at assignment to evaluators or within meeting agendas to discuss their efficacy and safety.

### ***Licensing of Manufacturers and Wholesalers***

All manufacturers and wholesalers are licensed by the Inspectorate and Law Enforcement directorate of the MCC for compliance with international Good Manufacturing Practice (GMP) and Good Wholesale Practice (GWP).

To reduce the delay in reinspecting sites that have other authority’s licenses, there is mutual recognition of other PICS (Pharmaceutical Inspection Convention and Pharmaceutical

Inspection Co-operation Scheme) country inspection reports for drugs to be registered in South Africa. PICS was started to promote uniformity in licensing decisions and to ensure the maintaining of high standards of quality assurance in the development, manufacture and control of medicinal products. There are currently 37 Participating Authorities, however most TB medicines are manufactured in non PICS affiliated countries and therefore the MCC would need to inspect these sites prior to recommending drug registration approval.

The MCC does also recognize the WHO prequalified site reports which are GMP based, so the inspectorate would only redo them if they have expired (greater than 5 years since first WHO report) or if the drug is manufactured in a different part of the plant from which the WHO prequalification was performed i.e. in the tablets section when the capsules were prequalified.

Once a drug is registered and a manufacturer is licensed this information is available to Affordable Medicines as part of the prerequisites for being considered for the national Essential Drugs List and published on the MCC website to the public (which makes it available to the TB directorate).

### ***TB supplies***

There is currently no registration process ensuring the safety and efficacy of medical devices in the MCC or South Africa. This is however planned to become part of the processes of the future MCC when it becomes an independent juristic body.

National Treasury is in charge of the procurement of surgical supplies and requires a sample to be submitted for this process. However there is no quality check of the product before a tender is awarded.

To fill this gap some provinces have taken it upon themselves to evaluate the medical suppliers that are placed on tender. One such process is that of the Western Cape who have very stringent quality and evaluation processes which take place. This includes:

- a physical check on a sample submitted by the interested tenderers which is inspected by clinical nurses to determine if the product complies with the specifications as documented.
- Products which pass this go into the second round which includes South African Bureau of Standards (SABS) testing for quality aspects which cannot be physically observed.
- Then the tender is awarded based on the quality outcomes and points scored.

This is a major gap in the delivery of safe Medicines to TB patients especially when medicines are delivered via injections requiring safe quality needles and syringes.

### ***Communication and linkage between MCC, Affordable Medicines and TB directorate***

Communication between the MCC and other directorates is mainly on a needs basis as the MCC does not take part of any of the committees we describe later on in this report at NDOH level.

The MCC does not play any part in the National Essential Drugs List (EDL) committee when experts evaluate the drugs to be placed on the EDL. They provide input when specifically asked by Affordable Medicines on specific drugs. This means that 2 different sets of individuals are evaluating the drugs to determine if they are suitable for the South African context – firstly for registration as safe and effective and then as suitable for the EDL based on their safety and efficacy.

If there are post marketing surveillance concerns with any drugs the MCC informs Affordable Medicines to review availability of drugs on the shelf or remove items that have had to be deregistered due to safety concerns.

Affordable Medicines does inform the MCC when a drug regimen change is being planned which impacts on a registration of a drug. For example the change from Ofloxacin to Moxifloxacin was communicated to the MCC to monitor the progress more closely of this drug in their registration process as it would become an essential part of the treatment of patients and within the EDL.

MCC is involved in all section 21 applications managed primarily by the Affordable Medicines directorate. Affordable Medicines provides the MCC with a list of potential section 21 drugs and MCC will assist them in their choice by providing information about accredited manufacturing sites based on their inspectorate reports. These are mainly applicants who are in the process of registration or have a recognized authority registration or part of a clinical trial situation. MCC is then required to have reports from the facilities or provinces using these medicines to control the use of section 21 drugs in the country.

### **B. Development of TB treatment guidelines (regimens, drugs and dosages)**

The next step in the selection of TB medicines is the development of the national TB treatment protocol. This process happens from two different perspectives, within two different directorates:

1. The **TB directorate** basis its TB treatment guidelines on those published by the World Health Organisations (WHO). These in turn are mainly determined by the experiences with drug resistance in Africa and in particular in South Africa as it has the highest incidence of TB in Africa and the third highest in the world. The evidence based evaluation is performed by the WHO and not by the TB directorate.
2. The **Affordable Medicines directorate** runs a parallel process through the evaluation of medicines for the National EDL which are then compiled into STG's and published with the EDL for the different levels of care. This review process aligns evidence

based medicines with the treatment guidelines and is a duplication of what the TB directorate also does based on the WHO inputs.

The review of guidelines occurs every 2 -3 years depending on the need

### **C. Creation of the Essential Drugs List**

The Affordable Medicines directorate convenes the National Essential Drugs List (EDL) Committee of experts. They are in charge of the selection of drugs for use within the public sector against the National Drug Policy. This Committee is appointed by the Minister of Health and is made up of clinicians from universities, experts from different clinical disciplines and provincial pharmacy representatives.

They conduct an extensive review of the clinical data of each trial related to drug efficacy and use to determine if a change to the Essential Drugs List is required based on sound clinical evidence. This review is conducted within the expert groups set up as sub committees of the National EDL Committee.

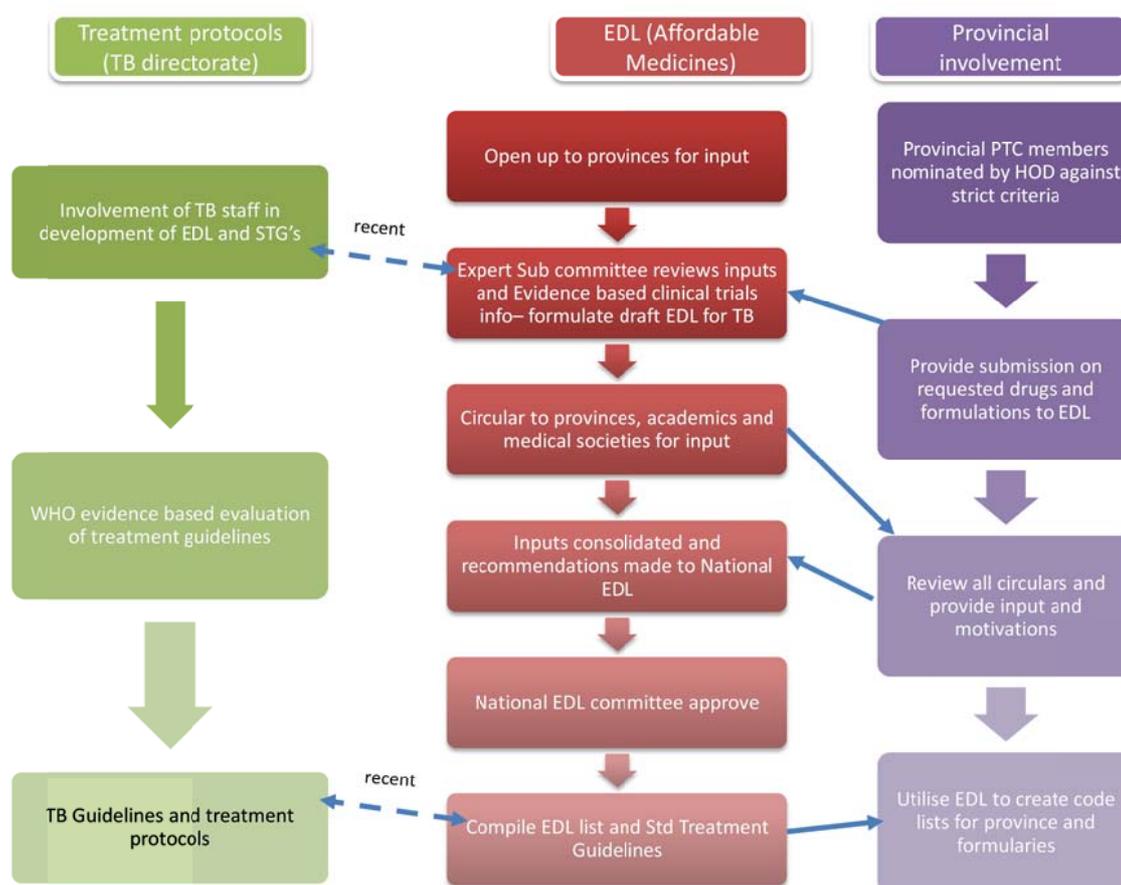
Review of the EDL takes place every 2 years and is split into 3 sections: Primary health, hospital adult and hospital paediatric and tertiary/ quaternary lists.

The National EDL Committee meets monthly on a specific chapter of the EDL, however if critical evidence is published that would change the EDL they will discuss these and publish an amendment to the EDL before it is due for review

The National EDL committee then opens up a specific topic nationally allowing the provincial PTC to submit their requests for new drugs or formulations. These inputs are submitted to the expert sub committees who determine draft the recommendations. These draft recommendations are again sent out via circular to all the academic institutions, medical societies and the provincial PTC's and based on their comments the final recommendation are drafted for approval by the National EDL.

Once approved the National EDL is printed with the STG's and distributed to the provinces and the depots via the pharmacy division.

Figure 9 –Creation of the EDL and Standard Treatment Guidelines and TB protocols



#### D. Role of provinces in creation of the Essential Drugs List and Selection of Medicines for the provinces

Each province has various Pharmaceutical and Therapeutics Committees (PTC's) and provincial Pharmacy heads involved in providing inputs, motivations and time to the development of the EDL. Nominations of provincial representatives to serve on the National EDL or sub committees are made by the HOD of the province against stringent criteria including skill of individual, active involvement in the provincial PTC and capacity to provide monthly inputs at meetings of the national EDL. The heads of pharmacy are also active in the National EDL or sub expert committee providing regional inputs and expertise.

Most provinces have PTC structures active right down to sub district level and most regularly provide input on the efficacy of medicines being used and motivation for new drugs or formulations for the EDL medicines. However the level of engaged involvement and stringent use of evidence based medicines varies across provinces. There is also variation in

the rigorous governance over the influence of suppliers on the EDL process with the Western Cape and Free State standing out as ensuring robust governance systems.

Most PTC's follow strict terms of reference and act as the gatekeeper in terms of ensuring correct usage of medicines in the province. The Provincial PTC consists of persons nominated by the HOD and the chair is elected from this group. The various provinces have different levels of input from academics and specialist doctors or professors in infectious diseases and pharmacology. Most rely on managers from Pharmacy Services and district pharmacists as well as programme staff. Input at District and Hospital based PTC's of doctors is a challenge in most provinces and again they are reliant on the pharmacy staff to continue with some of the work.

The provincial PTC's are generally involved in the development of provincial code lists of drugs that may be used by facility type or level in that province. All provinces appear to have some sort of a code list or formulary in effect. These code lists are used to inform the ordering by facilities within cost effective standards.

The District and sub district PTC's which do exist are more involved in monitoring and evaluation of consumption, usage and prevalence information than decision making on medicines and protocols.

## **E. Challenges and Best Practices in TB medicine Selection and Recommendations**

### *Challenges*

- Prior to 2011 the National EDL Committee did not advise the TB directorate of drug treatment changes based on their extensive research and expertise. So the process of determining the correct drug treatments, formulations and dosages was being duplicated within the TB and Affordable Medicines directorates; this resulted in a delay in the publication of the new TB treatment guidelines which could have been avoided.  
The determination of TB treatment guidelines is now a joint process between the between the TB directorate and the expert National EDL subcommittee reviewing TB drugs effectiveness. Validation is then performed against the WHO treatment guidelines.
- More effective communication and involvement of the 3 directorates in the selection of medicines and determination of guidelines. Two different sets of individuals are evaluating drugs to determine if they are suitable for the South African context – firstly for registration as safe and effective and then as suitable for the EDL based on their safety and efficacy. This delays processes on both sides and could potentially improve resource utilisation if their expertise was combined.

### *Best practices*

Governance of the National EDL Committee process is strict and best in class with the following protocols being observed:

- Expert interrogation of clinical trials data on the active ingredients of drugs and not merely a review of clinical trials articles;
- Extensive input from specialists in the specific discipline i.e. TB are taken into account when reviewing the drugs list and guidelines;
- All members of committees must declare their conflict of interest in terms of clinical trials or specific drugs;
- Meetings are strictly held monthly for each of the EDL lists portfolios (Primary health, hospital adult and hospital paediatric and tertiary/ quaternary lists);
- Active involvement of the relevant directorates within the NDOH in the compilation of the EDL list (this is a recent change to the committees processes)
- Any section 21 drug applications (fast track) are tabled with the National EDL to determine if they are warranted before the Medicines Control Council (MCC) will process them;
- The National EDL committee is not involved in supplier selection, procurement specification design or tendering processes of the NDOH and Treasury

- Committee members include representatives from specialist fields such as health economics, pricing committee, MCC and program directors from NDOH as well as provincial PTC committee member nominated by their provincial Heads of Department (HOD's).
- Extension of these governance principles down to the Provincial PTC in most provinces.

### ***Recommendations***

Roll out of more extensive governance systems and incentivisation of more academics and clinicians to be involved in the PTC structures at all level. This may include that a designated person whose role it is to ensure that PTC meetings occur and that valuable information is collected, analysed and decisions made.

Improved cross directorate communication in terms of ensuring that drugs are used and stored correctly within the facilities and by users through development of appropriate treatment protocols and guidelines such as a paediatric guideline.

## **PROCUREMENT OF TB COMMODITIES**

South Africa runs a mixed model of procurement, with prices tendered and negotiated at national level and actual purchases from approved suppliers occurring at provincial level from budgeted funds.

Procurement is the process by which drugs, meeting the criteria of the EDL and TB STG's, become part of the stock within a facility. It includes a tendering process with pharmaceutical suppliers through a nationally driven procurement system and the compilation of a National Suppliers Tender Contract from which provinces are able to purchase. However provinces are able to tender outside of these National Tenders for products upon permission from the NDOH and National Treasury which ensures they have the necessary systems in place to monitor the procurement process effectively. Monitoring and evaluating the performance of the suppliers and the facilities in complying with the tender conditions forms part of the procurement process.

Prior to 2011, the procurement process for medicines was undertaken by Treasury who were also in charge of contract management. This resulted in long lead times for tenders to be completed due to the large number of individuals required for the process. As of July 2011, the NDOH Affordable Medicines Directorate and provinces are in charge of tendering, procurement and contract management of all drug tenders including TB which was the first tender undertaken in August 2011 and there were a few glitches with the process:

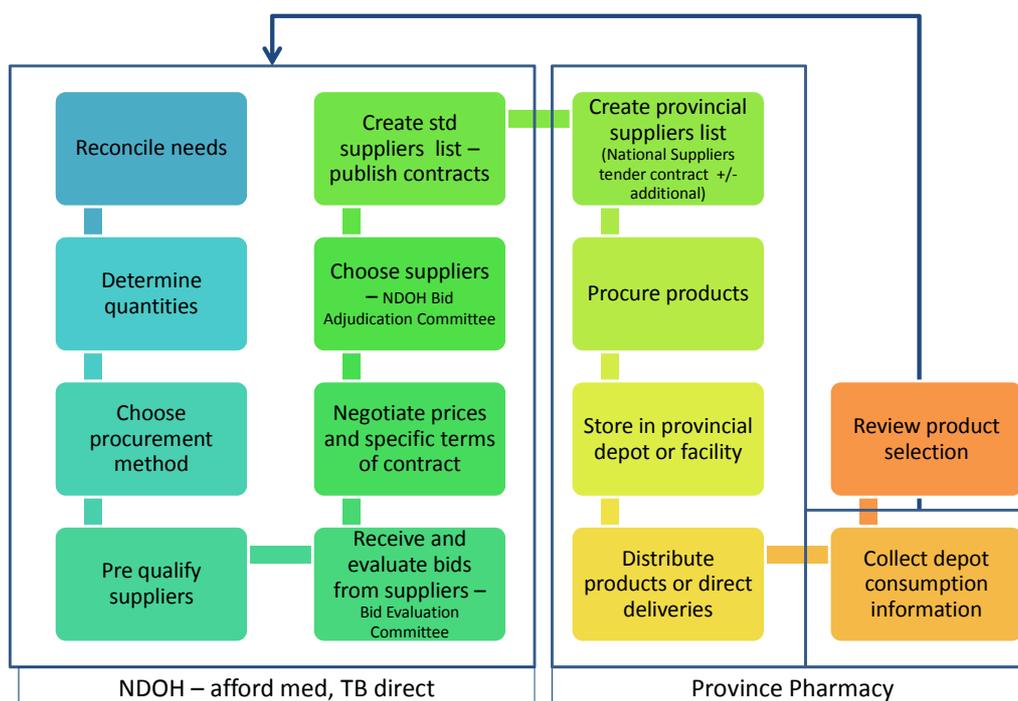
- The tender contracts were awarded 1 week after the contract started meaning some facilities were already running out of stock;
- No communication was sent to the provinces and depots to increase their stock of TB medicines to cover the "set up" period required of the new contracted suppliers. Due to the requirements of new pack sizes and packaging new suppliers need about 3 months from a standing start to get a new product out for delivery. So orders for the new suppliers came in on the 1<sup>st</sup> day of the new contract, with some provinces having far less than their 3 months stock on hand to cover the set up period. This resulted in huge stock shortages in most TB medicines across the country. This has been rectified in the new ARV contract for January 2013;
- Timing of the start of contracts is also important, as starting a new contract on 1<sup>st</sup> January when the factories are closed makes the delivery in the new year a challenge for the manufacturers;

Although there were challenges with this first tender in terms of awarding on time, the NDOH has been able to apply its learnings into a very successful HIV drugs tender recently completed within a 4 months period. Being in control of the process has also allowed NDOH to communicate between transitioning arrangements with the new and old suppliers and the depots ensuring that there is better continuity of drug supply when contracts change.

The procurement process and the creation of the EDL list is separated within the NDOH through the governance processes mentioned in “Selection” although both processes are overseen by the Affordable Medicines Directorate. The National EDL and the MCC do not provide input into the choice of pharmaceutical manufacturers or suppliers for national tenders as the assumption is that once on the EDL and the MCC’s list of licensed suppliers they have been sufficiently quality assured.

However, although a manufacturer is licensed, certain manufacturers are better than others in terms of quality assurance over and above the minimum required for licensing.

Figure 10 – National procurement process flow for South Africa



### A. Quantification of need

Procurement process starts with the determination of the need for medicines for the following 2 years in order to provide these as one of the specifications to the tender bidders.

Consumption data from the provincial depots is used to quantify the medicines needs for the following year. It is mainly a pharmacy driven process; consumption data is gathered by each province from their depot consumption data, adjusted based on their requirements, budget availability and then provided to the Affordable Medicines Directorate as part of the Specifications Meeting.

In some provinces the TB directorates provide break-down of number of patients, XDR/MDR TB and Paediatrics for estimates however because of many variances such as dose per

weight bands, the actual off-take from the depots is easier to use although it does not provide usage data at facility level.

In fact in most provinces the determination of drug quantities and budgeting for drugs for the next financial year are completely separate processes. This results in drug quantities being tendered for for which there is no budget allocated and therefore rationing of medicine quantities occurs in the province.

The Tender Specifications meeting includes the following individuals:

- Each provincial representative
- Health economics directorate
- TB programme directors (not until recently).

These are the same individuals involved in the bid evaluations committee. Needs are adjusted by the Specifications Committee in context of other programmatic improvements being made. For example the introduction of the GeneXpert machine requires reduction in the need for Streptomycin use in retreatment as diagnosis can be made much earlier of resistance and the patient placed on the correct regimen faster. Therefore the needs for Streptomycin were reduced from previous year consumption information.

## **B. Challenges , Best Practices and Recommendations in Quantification**

Best practice in quantification was utilized during the new HIV drugs tender recently completed (October 2012). The HIV programme managers were involved in adjusting the needs for medicines through their knowledge of the number of patients and the treatment guidelines. This was done through the CHAI model developed especially for South Africa by the Clinton Health Access Initiative.

However for TB the prevalence and incidence data is not used to adjust drug needs for tenders. One challenge is that the TB prevalence data available in the eTR (electronic TB register) does not assist in determining the dosage forms given the new weight based treatment guidelines. In addition our examination of cost per TB patient (in section OCntract management and Payment) we discovered that the expenditure data per province when proportioned by TB case load shows that in most provinces the spend is much higher than the case load would suggest.

This implies that either the provinces are wasting TB medicines (in effective stock management, overstocking, losses, incorrect prescribing of pack sizes etc) or that the TB case load data from the eTr is under reporting the true problem and that the case load is in effect much higher. The data collection process would need to be strengthened in order to use TB data for quantification purposes.

The second challenge is that the quantification process is a provincially driven process and when it is tabled at the specifications committee the NDOH directorates (TB, Affordable

Medicines, Health Economics) have very little time to provide inputs and edits before it goes into the tender specifications document.

The third challenge is that the most available data on drug is the consumption data at depot level as no usage data is collected in any of the provinces. There are some district pharmacists who have this sort of usage data for their facilities. They are however not consulted in the process of quantification as the depot is the main responsible point for providing information to NDOH.

The process of quantification should occur in parallel – the TB directorate (using TB data) in conjunction with the statistical services within Health Economics and Affordable Medicines (using consumption data, a CHIA type TB model) should determine the needs for each province. While at the same time the provinces are determining needs based on its knowledge of the consumption (and hopefully accurate use data in the future) and budget constraints. A process of reconciliation of needs should then occur at Specifications Committee level to match requested needs from provinces, with more accurate estimates from NDOH and financial constraints of budgets before a final quantity is determined for tenders.

This would allow accurate estimation of TB treatment needs for South Africa by province, therefore reducing any unnecessary stock outs due to incorrect assumptions. It would also improve the ability of suppliers to meet increased demands as these are more planned up front and not urgent orders towards the end of a contract period. It would also assist the provincial departments in determining their budget needs and estimating their ordering requirements for the TB programme.

*Further recommendations are in the chapter on Solutions.*

### **C. Pre qualifications of suppliers**

Once quantities are determined the tender is then published to the pharmaceutical industry for bids. Importantly there are some preconditions which need to be met prior to a supplier submitting a bid:

- Medicines must be registered with the MCC. This is different for medical supplies as no products are registered with any authority currently;
- Manufacturer must be licensed by the MCC for GMP (Good Manufacturing Practice) and the distributor or wholesaler also (GWP)
- No section 21 drugs will be awarded volumes in the tender contract
- Triple BEE certification is also required
- A sample of the drugs needs to be submitted. In the past these were sent for laboratory testing on quality however this was a duplication of the MCC registration process and has been stopped. Samples are not checked for compliance with pack size, labeling, dosage, a physical quality check and set out criteria of the bid.

- Checks are conducted on the directors of each company to ensure there are no “restricted” directors involved in the supply chain of any of the suppliers

#### **D. Bid evaluation and awarding of contracts**

The Bid Evaluation Committee is comprised of the same members as the Specifications Committee to ensure consistent evaluation of the tender bids. As part of this process, prequalification criteria and scoring are used to determine the preferred supplier list. In the past lab quality reports were requested but this was a duplication of the very extensive quality checks conducted by the MCC on drug registration and have been stopped. A sample is however required to check for compliance with packaging requirements. Poor performance of suppliers on previous contracts can only be used as prequalification criteria if there is sufficient evidence to hold up in court if a supplier is denied an award based on poor performance. Evidence is however lacking as active documentation at contract management level within provinces is not occurring (see section on contract management)

Should there be more than one supplier for high volume products, a split is determined between them based on the points they scored. This is a risk mitigating strategy.

Affordable Medicines then undertakes to negotiate prices with the preferred suppliers short listed. This is based on international benchmark pricing as well as past tender prices. This means that in some instances the suppliers will be awarded tender prices below the prices submitted in their original tender submissions and most definitely below the Single Exit Price published for the private sector (see table of price comparisons in the sectors on next page).

On average the public sector negotiated prices are 35% lower than the private sector single exit price demonstrating the effectiveness of these negotiations. The price negotiations are conducted by the Head of Affordable Medicines herself.

Figure 11 Price comparison of tender prices with private sector and mining

ITEM NO	DESCRIPTION	Quantity Awarded	Unit Pack	Delivered Price	Private Sector	Mining Sector	price differential Public and Private	price differential Public and Mining
1	CAPREOMYCIN 1g injection, 10ml vial	293,100	1g vial	R 82.91	R 122.57		32.4%	
2	ETHAMBUTOL HCl 400mg tablet, 56 tablets as a patient-ready pack. Individually blister packed in strips of 7/14 tablets.	327,600	56 tablets	R 26.92	R 46.09		41.6%	
3	ETHAMBUTOL HCl 400mg tablet, 84 tablets as a patient-ready pack. Individually blister packed in strips of 7/14 tablets.	222,900	84 tablets	R 37.51	R 69.14		45.7%	
4	ETHAMBUTOL HCl 400mg tablet, 100 tablets Individually blister packed in strips of 10 tablets.	315,200	100 tablets	R 45.30	R 83.74	R 83.78	45.9%	45.9%
5	ETHIONAMIDE 250mg tablet, 250 tablets	26,700	250 tablets	R 364.26	R 431.09		15.5%	
6	ISONIAZID 100mg tablet, 84 tablets as a patient-ready pack	70,900	84 tablets	R 15.96	R 12.71		-25.6%	
7	ISONIAZID 100mg tablet, 1000 tablets	23,700	1000 tablets	R 81.47	R 81.30		-0.2%	
8	ISONIAZID 300mg tablet, 28 tablets as a patient-ready pack	2,274,200	28 tablets	R 13.68	R 18.80		27.2%	
9	Kanamycin Sulphate 1g injection, 3ml vial	945,000	3ml	R 11.50	R 17.36		33.8%	
10	PYRAZINAMIDE 500mg tablet, 56 tablets as a patient-ready pack	49,200	56 tablets	R 25.08	R 52.07		51.8%	
11	PYRAZINAMIDE 500mg tablet, 84 tablets as a patient-ready pack	75,200	84 tablets	R 31.35	R 28.59		-9.7%	
12	PYRAZINAMIDE 500mg tablet, 1000 tablets	13,100	1000 tablets	R 287.28	R 929.84		69.1%	
13	RIFAMPICIN 150mg capsule/tablet, 100 capsules/tablets	16,700	100 tablets	R 58.34	R 131.62		55.7%	
14	RIFAMPICIN 450mg capsule/tablet, 100 capsules/tablets	3,700	100 capsules	R 104.80	R 231.53		54.7%	
15	RIFAMPICIN 600mg capsule/tablet, 100 capsules/tablets	6,700	100 capsules	R 84.81	R 431.91		80.4%	
16	RIFAMPICIN 150mg, ETHAMBUTOL HCl 275mg , ISONIAZID	294,700	28 tablets	R 13.63	R 20.39		33.2%	

*Pharmaceutical management of TB in South Africa*

ITEM NO	DESCRIPTION	Quantity Awarded	Unit Pack	Delivered Price	Private Sector	Mining Sector	price differential Public and Private	price differential Public and Mining
	75mg and PYRAZINAMIDE 400mg tablet, 28 tablets as a patient- ready pack.							
17	RIFAMPICIN 150mg, ETHAMBUTOL HCl 275mg , ISONIAZID 75mg and PYRAZINAMIDE 400mg tablet, 56 tablets as a patient- ready pack.	713,600	56 tablets	R 26.94	R 41.36		34.9%	
18	RIFAMPICIN 150mg, ETHAMBUTOL HCl 275mg , ISONIAZID 75mg and PYRAZINAMIDE 400mg tablet, 84 tablets as a patient- ready pack.	869,300	84 tablets	R 39.22	R 61.89	R 80.09	36.6%	51.0%
19	RIFAMPICIN 150mg, ETHAMBUTOL HCl 275mg, ISONIAZID 75mg and PYRAZINAMIDE 400mg tablet, 100 tablets	486,100	100 tablets	R 47.04	R 74.75		37.1%	
20	RIFAMPICIN 150mg, ETHAMBUTOL HCl 275mg , ISONIAZID 75mg and PYRAZINAMIDE 400mg tablet, 112 tablets as a patient-ready pack.	701,000	112 tablets	R 49.99	R 84.15		40.6%	
21	RIFAMPICIN 150mg, and ISONIAZID 75mg coated tablet, 56 tablets as a ready pack.	632,900	56 tablets	R 24.78	R 82.48	R 53.20	70.0%	53.4%
22	STREPTOMYCIN SULPHATE 1g/3ml solution for injection, vial	500,000	3ml	R 5.00	R 4.03		-24.1%	
23	TERIZIDONE 250mg capsule, 100 capsules	136,500	100 capsules	R 641.82	R 1,388.48		53.8%	

Thereafter the preferred suppliers list plus the negotiated prices are tabled at the NDOH's Bid Adjudication Committee. This process used to occur at Treasury and is now fully within the NDOH's control as they become the contracting parties. Should the NDOH's Bid Adjudication Committee approve then the prices and suppliers are compiled into the tender contracts, signed by the Director General of the NDOH (DG), signed by the companies and the published as a circular on the NDOH's website.

All contracts finalized should be sent to the provinces before the start of the contract to enable to them to update their systems and databases with the new supplier codes and product codes. However in some provinces there is a delay in this information being communicated such as the Mthatha depot which still does not have the some of the new drugs and suppliers loaded onto their inventory and ordering system.

TB supplies tenders are managed in a similar fashion except that Treasury is the contracting party and contract manager. In the Western Cape, some Gauteng districts and KZN province, additional tenders for surgical supplies are published and managed at provincial level. The Western Cape manages these tenders very closely under the supply chain division of finance. In addition they have very stringent quality and evaluation criteria which need to be met before any products are placed on the provincial suppliers list (see section under registration of surgical supplies).

#### **E. General and Special conditions to tender contract**

General conditions of the contract are in line with Chapter 16a of the treasury regulations which cover the contractual and payment terms. These are augmented by special conditions which include:

- Lead times stipulated for each supplier and product
- Expiry dates of delivered products
- Labeling and packaging requirements
- Penalties for non delivery, late delivery or incorrect order quantities

#### **F. Challenges, Best practices and Recommendations for tender process**

##### *Challenges*

- The criteria for pre qualification of suppliers are robust. However historical performance of the supplier in delivering product against its contract should be included as criteria. This can be determined through the use of lead time measurements of each supplier against contracted lead times, availability of medicines

of each supplier and volumes supplied versus volumes requested. These indicators should be collected at facility and provincial level and can be used to reduce the points system as part of the scoring system during the tender evaluation process.

- Risk management policy allows for the split of high volume medicines between more than one supplier to limit the risk of stock outs. This is in theory the process for medicines. However the TB contracts awarded since 2011 for 2011 – 2013 don't contain split suppliers for some of the medicines. Situations arise when suppliers just don't put in a bid or the price differential is too great to allow the tender to be split (see reasons below in table 13).

**Figure 12 – Reasons for single suppliers being awarded tenders**

Drug Name and formulation	Reasons for single supplier being awarded tender
<ul style="list-style-type: none"> <li>• Moxifloxacin 400 mg 28 tab ready pack</li> <li>• Pyrazinamide 500 mg tab, 56 or 84 tab as patient ready pack</li> <li>• Rifampicin 600 mg cap, 100 caps</li> </ul>	<p>Volumes relatively small as only limited application (e.g. MDR/XDR) or single agent so splitting does not make economic sense</p>
<ul style="list-style-type: none"> <li>• Rif 150mg, Etham 275mg, INH 75 and Pyrazinamide 400mg , 28 or 56 tabs patient ready pack</li> <li>• Rif 300mg, INH 150mg, 56 patient ready pack</li> </ul>	<p>Too big a price difference between 1<sup>st</sup> &amp; 2<sup>nd</sup> bidders</p>
<ul style="list-style-type: none"> <li>• Rif 60, INH 60mg dispersible tab, 28 or 56's</li> </ul>	<p>Only one registered supplier</p>
<ul style="list-style-type: none"> <li>• Levofloxacin 250 mg tab, 28 tabs patient ready pack</li> </ul>	<p>Volumes relatively small as only limited application (e.g. MDR/XDR) so splitting does not make economic sense</p>

- TB directorate has not been involved in the selection of suppliers for the TB contract. This means that specific program input from on the ground concerns around product packaging or use are not available to the adjudications committee;
- The NDOH does not always inform the provinces and depots in time of the changes to the supplier contracts to allow them to update their supplier and product codes at provincial level and to run down stock of older products in the depot. This results in a delay in moving to the new suppliers once these contracts are awarded in order to complete these processes;

### **Recommendations**

- Some provinces are of the opinion that tender contracts should be split irrespective of the points scored by the company. For the ARV tender in September 2012, the special conditions of the contract which allowed for splits only if a points difference of up to 20% in price occurred was waived. The reasons cited were for critical drugs like the FDC's which improve compliance in patients consideration should be given to ensuring constant supply rather than only on price. In such instances the suppliers have been negotiated with to come to a more acceptable price and ensure split suppliers.
- The tender contracts should be finalized and published 8 weeks before they are due to start to allow for a proper transition between the contracts.
- Potentially the contracts should be staggered I.e. old contract ends in December 2012 but new one starts in October 2012 to allow the new supplier time to get set up while not compromising stock levels.
- The start times can also be staggered between the provinces to allow the new supplier to slowly ramp up their volumes for the new contract i.e. first 4 provinces start in Oct 2012 and then the next lot in Nov 2012 etc.

The critical aim is to prevent a situation whereby there are no contracts in place forcing either extensions or buy outs to occur or emergency stock shortages.

- Contracts should stipulate that suppliers are required to fill orders placed within the contract period even if the volumes are larger than those estimated initially. Without this no supplier is required to honor the end period of the contract compromising the province's ability to secure bridging stock.
- Better quantification of needs is therefore essential to ensure estimates are more accurate and don't impact on suppliers towards the end of the contract period.
- To reduce the set up time suppliers should make plans around a standardized template for the patient ready packs I.e. NDOH could prescribe a patient ready pack template into which the supplier can just add their logo and specifics of the drug. For boxes this may not be possible.

### **G. Procurement at Provincial Level of TB Medicines**

Medicine budgets are decentralised and the provincial governments are therefore in charge of purchasing medicines and supplies. They are able to procure medicines within the tender contract and also outside of it.

All provinces use the National tender suppliers list for purchasing their medicines. Only the Western Cape has additional supplier tenders for medicines that are on their code list which are not part of the EDL and only very rarely will the province perform a supplier agreement for a product that is not on national tender or a limited bid for different medicines.

In the event of a supplier not being able to provide product “buy outs” occur. These buy outs are orders outside of the standard suppliers and products list and are implemented by the depot but only under the authorisation of the provincial HOD. No authorisation of buy-outs is needed from NDOH. Buy outs are difficult to get authorisation for in most provinces except Gauteng where more than 40% of their purchases are buy outs. Some districts within Gauteng are even able to purchase outside of the suppliers tender contract via a 3<sup>rd</sup> party wholesaler.

Most provinces require three quotes of products which are discussed at the quotations meeting for approval. If they are over R500 000 provincial approvals from the HOD is required.

With the recent shortage of ARV medicines in 2012, the Affordable Medicines Directorate was given the authority to order from new suppliers, implement the section 21 buy out and manage the ration of the medicines to the facilities based on the patient numbers and not based on back orders from the depot.

#### **H. Budgeting for TB Medicines at Provincial Level**

Most provinces determine their medicines budget through a finance driven process of prior year’s costs with inflation. There is almost no input from pharmacy or TB program in this process. With the exception of the Western Cape all provinces have a single medicine budget and do not separate out TB or set it aside. ARV’s are set aside as conditional grants in all provinces and therefore separated and ring fenced. As mentioned before there is a clear disjoint between the quantification process managed by the pharmacy division and depot and the budgeting process managed by finance with no input from programmes in either.

Budgeting within the Western Cape could be considered best practice as their budgeting process requires the input of district pharmacists and program managers at sub district and district level through the very active PTC’s and district management committees. PTC’s are involved in consumption monitoring, monthly usage monitoring including costs. The districts meet monthly to discuss variances in medicines budgets. Every quarter the district needs to account at provincial level against their APP (Annual Performance Plan) indicators which include the top 40 usage drivers and their predictions of usage going forward. These forecasts are monitored and compliance with them determines compliance to the APP indicators.

In addition the medicines budget in the Western Cape is ring fenced and cannot be shifted to other budget areas in essence reserving it for the patients. Line items for TB, ARV, family planning, EPI etc exist on this budget. Lab costs (including glucose testing and rapid tests) are separated out as are blood products. The district pharmacists and PTC’s focus on rational prescribing to limit the yearly spend although their budgets in the Eden district have not been cut.

## **DISTRIBUTION OF TB COMMODITIES**

Effective ordering, storage, picking, dispatching and logistic distribution processes ensure that drugs are at the facility for the patients when they are required and includes the infrastructure and distribution of depots for warehousing and stock management.

### **A. Distribution of Provincial Depots for Warehousing of TB Medicines**

Every province has a central provincial depot managing the warehousing of its TB medicines, vaccines and surgical supplies. Exceptions are:

- Gauteng which has six district sub depots,
- Western Cape has a sub depot in Eden District, a chronic dispensing unit and sterile prepacking facility and an ARV central depot in Cape Town;
- Mpumalanga which has an additional sterile prepacking facility in its provincial depot.
- The sterile prepacking facility within the North West has been closed due to non compliance with SAPC requirements.
- The Eastern Cape with 2 main depots and within the Mthatha distribution system are 6 transit areas which function as sub depots.

### **B. Regulations governing storage of drugs at depots and pharmacies**

Regulations governing the functioning and quality control of the depots falls within two different legislations and regulatory bodies:

- The SAPC (South African Pharmacy Council) is more focussed on professional conduct and premises which is governed by the Pharmacy Act, act 53 of 1974. It regulates the pharmacists, pharmacy support personnel and pharmacy premises in South Africa, including the manufacturing, wholesale, community and hospital pharmacies of which the depots form a part. The Council sets and monitors the standards of practice by conducting inspections, approving pharmacy premises for purpose of training interns and pharmacist's assistants, and recommending issuing of pharmacy licenses by the Director General of the NDOH;
- MCC is more focused on the medicines and the control thereof and is governed by the Medicines and Related Substances Act, Act 101 of 1965, as amended. It is a statutory body, appointed by the Minister of Health to register medicines and to ensure that these medicines are of quality, safe and efficacious. Regular inspections are performed at the applicant/manufacturer of such medicines by inspectors to

ensure compliance with quality control and Manufacturing Principles (GMP) as well as compliance with the registration dossier. The GMP inspectors have extensive practical experience in the manufacture and quality assurance of medicines. In addition GWP inspections are performed on all warehouses which include the public sector depots and regional pharmacies for compliance against the warehousing good practices.

Most depots we visited were able to show us their SAPC and NDOH licenses for the facility. In addition they displayed the qualifications of the responsible pharmacists and other professional staff in the facility.

**Figure 13 - SAPC and NDOH licenses at Cape Medical Depot**



We were told that all depots have been licensed by the NDOH however when we performed out mini GPP assessments we found some facilities to be lacking in areas such as security, monitoring of fridge temperatures, compliance with storage standards and rotation of stock (see table ). This we feel needs too looked at in more detail as alignment with the GPP quality standards has been a requirement for the public sector since 2003.

Figure 14 – Scores for GPP compliance against indicator

	EC	FS	Gauteng	Mpum	NW	WC
<b>Score for GPP depot</b>	58%	89.5%	89.5% MSD	89.5%	95%	100% MSD
<b>Score for GPP sub depot</b>	68%		84% Tshwane			95% OMSD
<b>Areas of non compliance</b>	Security Storage FIFO Temp monitoring	Security Fridge temp checks	Security Holes Storage FIFO	Temperature checks Cleanliness	Security	Security

As we understand, the MCC is also the only body with enforcement powers. So in the event of a non compliant finding on GWP the MCC issues a warning to the depot manager and if critical it is escalated to Director General of the NDOH to take it up with the necessary HOD of the province. The MCC has the powers to close down a depot or caution the depot manager.

We observed MCC inspectors inspecting the Mpumalanga depot, both the warehouse sections as well as the sterile prepacking facility, so we believe there are overlaps in standards being assessed.

This concurrent jurisdictional overlap between MCC and SAPC may create confusion when for instance the findings of the MCC don't correlate with those of the SAPC. We are not certain a mechanism exists for determining which inspection finding supersedes the others. This is an area which requires some more investigation to ensure that the compliance requirements of facilities are met every time and there is consistency in the way in which the depots are monitored for compliance to quality standards.

### C. Stock holding and infrastructure

Infrastructure varies between provinces with most depots being purpose build and suitable as warehouses. Exceptions are the Gauteng Central Medical Store in Auckland park which is an old abattoir and the Tshwane district sub depot which is an old hospital. The Cape Medical Depot in Cape Town is a 3 storey building with stock receiving and dispatch on the ground floor and with stock being moved to higher levels for holding. The Eastern Cape Mthatha depot is a 2 storey building in need of effective maintenance on this infrastructure to remove holes in floors opening into other levels and compromising the integrity of drugs and security.

The infrastructure of these non purpose built warehouses puts tremendous constraints on stockholding and the ability of staff to monitor and manage stock effectively. They also impact on the ability to secure the warehouse and prevent pilferage especially where small stores are not securable or stock is moved constantly between areas.

Three depots had impressive high security with some even being described as “Fort Knox”. Mpumalanga, Western Cape and North West depots require multiple security checks and entry points, access control and have visible security guards and CCTV monitoring.

We noted that no province is required to monitor pilferage and report on it with any performance management consequences. This is especially a concern in those depots where we noted a security non compliance.

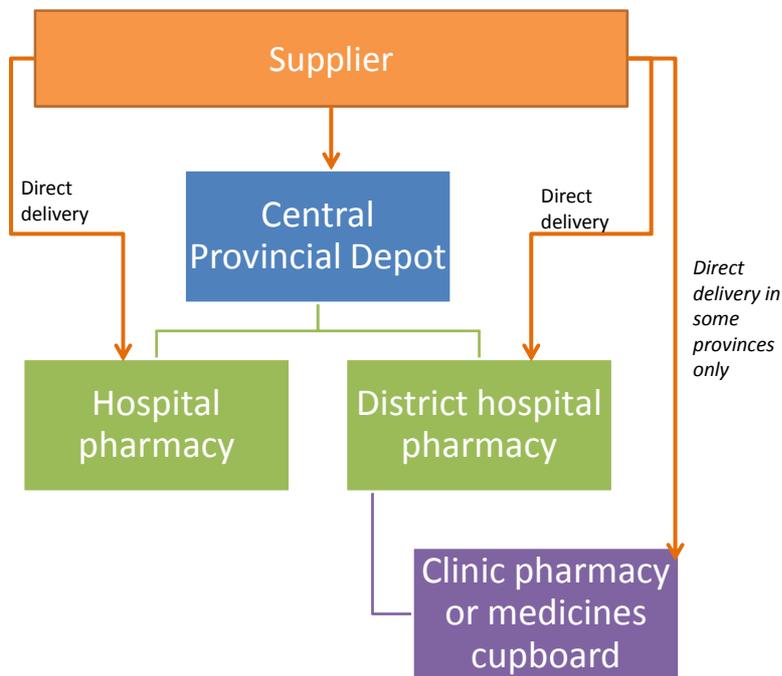
The depots hold stock for the entire province and from there it is distributed down to the hospital pharmacies which are large enough. Clinic pharmacies due to their nature are smaller and unable to hold large volumes, so most provinces deliver stock to the district hospitals or “mother hospital” in a district which fulfills the role of warehouse for the smaller clinics and distributes to them directly.

In Gauteng, Western Cape and Eastern Cape where there are regional sub depots the main depot dispatches the clinics stock in bulk to these sub depots who store it, repackage it and distributed to the clinics or district hospitals. Although this duplicates warehousing resources and may delay product getting to a facility, in Tshwane and Eden Districts the sub depots have been an enormous safety system for buffering the clinics from stock shortages from suppliers. These two districts are the only ones we visited where the facilities serviced did not experience any significant days out of stock when there was a countrywide shortage of INH reinforcing the safety system they afforded these facilities.

This duplicate of storage systems between depot and subdepot does seem unnecessary when a system of transiting of products could rather be used i.e. the sub depot receives stock already packaged by the main depot by facility and only has to hold it until the facility can accept delivery. This was the premise upon which the Eastern Cape transit areas were created however the resource constraints and stock management issues at the Mthatha depot have resulted in bulk stock being supplied to the transit area which requires unpacking, storage and repacking into clinic packages for distribution. In effect the transit area is now functioning as a sub depot. In addition when the Mthatha depot issues out too much stock (to reduce its stock holding value) the sub depot holds onto this and only issues out what the facilities actually need allowing it to stock security and buffer stock to help supply in the event of emergency or disease outbreaks.

In the all provinces, except Gauteng and North West, direct deliveries by the suppliers are encouraged, even if only for bulk items such as intravenous supplies and total parenteral nutrition. Direct delivery orders are placed by the depot with the suppliers on behalf of all the facilities but the deliveries are made direct to the hospital pharmacy or clinic to reduce the volume of stock held at depot level and improve the availability of medicines in the pharmacies. The general process of medicine flow from suppliers is described in the figure 15 below.

Figure 15- Flow of medicines from suppliers to facilities



The value as well as the volume of stock is a function of the direct deliveries policy, the stock holding capacity of the facilities supplied and the frequency of orders (see table 15 below).

The Free State has implemented the direct delivery system well with over 60% of all stock (drugs and consumables and vaccines) being delivered direct to facilities including some of the clinics. This frees up the warehouse to handle the smaller less frequent items and serves as a buffer and reduces its stock holding. Enhancements can be made here through clear definition of minimum order quality and delivery quantity. The Free State has interpreted minimum order and delivery quantities as the same and therefore are limiting which facilities can receive direct deliveries. However the tender contracts don't stipulate the minimum delivery quantity allowing more smaller facilities to piggyback on the larger one ordering power to receive direct deliveries.

The infrastructure constraints of the Gauteng depots are obvious on inspection however they are not making use of direct deliveries to relieve some of this pressure on their stock holding capacity.

Mthatha depot is not effectively using the ability of the transit areas to relieve stockholding pressures.

Mpumalanga has a good direct delivery system mainly for bulk surgical supplies and therefore its high stock holding value reflects the medicines which are stored there.

The Western Cape utilises direct deliveries only for smaller volume items so they are able to control the return of the proof of delivery on the high volume items through their depots. This means that they have large volumes of stock of a high value. They do however have a double buffer system (the Cape Medical Depot holding 3 months and the Oudtshoorn depot holding 2 months) which means in terms of ensuring availability of medicines they very rarely run out of stock such that the facilities experience a shortage.

A similar situation occurs in the Tshwane district where the very efficient sub depot is effectively buffering the facilities from shortages and improving their stock availability.

Challenges with rolling out more extensive direct delivery system include:

- Systems to receive the proof of delivery back from the facilities to effect payment;
- Monitoring capacity at facility level to report delays in delivery. This should be a centralised contract management function of the depot to follow up all orders, however they need the information to be reported in order for this to occur or an IT system which allows the facilities to indicate when they receive an order;
- Access to some of the more remote facilities may require a more customized delivery system in some provinces which is outside of the contractual terms of the tender contracts with suppliers.

Figure 16 Table of stock holding values in each province

	EC	FS	Gauteng	Limpopo	Mpumalanga	NW	WC
<b>Number of facilities served</b>	870	305	417	576	325	365	340
<b>Stock holding value at time of assessment</b>	Mthatha – R35m PE – R70m	R 35 m	CMS – R150 m  Tshwane – R20m	R106m	R 87m	R131m	CMD – R110m ARV – R34m OMSD – R4 – 5m Total = R160m
<b>Volume of stock held</b>	3 months	3 months	CMS – < 8 weeks  Tshwane – 6 weeks only	3 months	3 months	3 months	CMD – 2-3 months OMSD – 2 months
<b>Ordering frequency</b> 1.Hospitals 2.Clinics	Erratic	All - Monthly	All - 2 weekly	1. Weekly 2. Weekly	1. Weekly 2. 2 weekly	Weekly	1. Weekly 2. 2 weekly
<b>% of Direct deliveries</b>	Some DDV's, dependent on capacity of institution	60% high vol bulk items	No DDV's on TB meds	Mainly large items only	Mainly high vol bulk items	No DDV's	21% on small vol and vaccines Central hospitals - 100%
<b>Availability of Medicines on day of assessment.</b>	82.55%	89.42%	94.44%	68.13%	84.57%	97.18%	100%
<b>Historical unavailability as average % days</b>	2.84%	1.12%	0.35%		0.32%	1.49%	0.84%



#### **D. Depot management**

All depots are managed by DOH staff of the pharmacy and finance divisions, except Mpumalanga which is outsourced warehousing with oversight by the DOH in terms of pharmacy depot manager, HAST monitor and HAST pharmacists. Financial processes are provincially driven in all provinces so payments to suppliers are made via the depot finance department upon receipt of funds from the province. Gauteng hospital pays for their own direct deliveries if they are received creating a financial governance concern.

#### **E. Ordering processes**

Ordering from the facilities occurs at various frequencies as shown in table 15 above. This is a function of the provincial ordering policy, the stock holding ability of the facility as well as the logistics and warehousing dispatching procedures. In many provinces the ordering frequency is too infrequent for the storage capacity of the facilities resulting in many emergency orders or stock outs. Many provinces work around this by redistributing amongst the facilities to cover stock shortages before the next order can be placed or received. This may in fact prevent some stock outs from occurring as in the case in the Free State and North West. However this “efficient” back up system is covering a greater issue of lack of frequency orders for the volume of patients seen and the storage capabilities of the facility. In the Eastern Cape ordering is erratic and so is the distribution to the facilities and this is reflected in their very poor availability of medicines on assessment.

Orders from the clinic level are, in all provinces, affected by the manual submission of a stock card or a specific TB order list to the district or mother hospital.

Figure 17 - example of order list from Eden district clinic

*KLIMBEKE*  
**Clinic Sr. Order List** Facility:

	Date								
<b>ART</b>									
1 LACTATE CONTROL SOL 888 MISC ART MISC	1	2	3	4	5	6	7	8	
								1032	ART
2 LACTATE METER 888 METERS ART MISC	1	2	3	4	5	6	7	8	
								1033	ART
3 LACTATE TEST STRIPS 888 STRIP ART MISC	1	2	3	4	5	6	7	8	
								1031	ART
4 ZIDOVUDINE 300MG 60 TAB/CAP ART	1	2	3	4	5	6	7	8	
								1021	ART
<b>TB</b>									
1 AMIKACIN SULPH INJ 500MG 2 ML INJ/IV	1	2	3	4	5	6	7	8	
								3201643	TB
2 CAPREOMYCIN 1G INJ 10 ML INJ/IV	1	2	3	4	5	6	7	8	
								3208745	TB

The district hospital pharmacists checks these orders against various criteria such as the minimum and maximum levels of that facility which are drawn from past consumption information (although not updated regularly enough), compliance with the code list for that facility type and order frequency. The pharmacist then captures this order on the pharmacy system. Most provinces have a financial vetting process at this point which serves as a governance step. Orders (manual print outs off the pharmacy inventory system) are first submitted to the district pharmacists and district manager who authorises the order against budget for that district or facility. This is in general a long process requiring the occurrence of a meeting - “district financial evaluation committee” - for the process to be completed and the print out to be signed by the relevant authorised person.

There are no provinces in which the ordering process from facility to depot is completely electronic although the Free State and Western Cape central hospitals system comes the closest with an integrated system. Approved orders in the Free State are submitted electronically from the district hospital to the depot via their IT system along with the faxed copy of the authorised order. The electronic order is only logged into the depot system once the authorised manual copy is received. Herein lies additional delays with faxes going missing delaying the logging of this order on the depot system.

In the Western Cape orders are placed through the JAC system by the central hospital directly onto the depot system through an interface. As there is no financial vetting taking place no manual order authorisations are needed and orders are placed immediately.

In all other provinces, the manual order plus the manual approval are faxed, posted or driver delivered to the depot again with huge delays due to orders going missing.

All depots recapture orders from facilities onto their electronic system. In Limpopo their client services department tracks all manual orders received to ensure every facility has

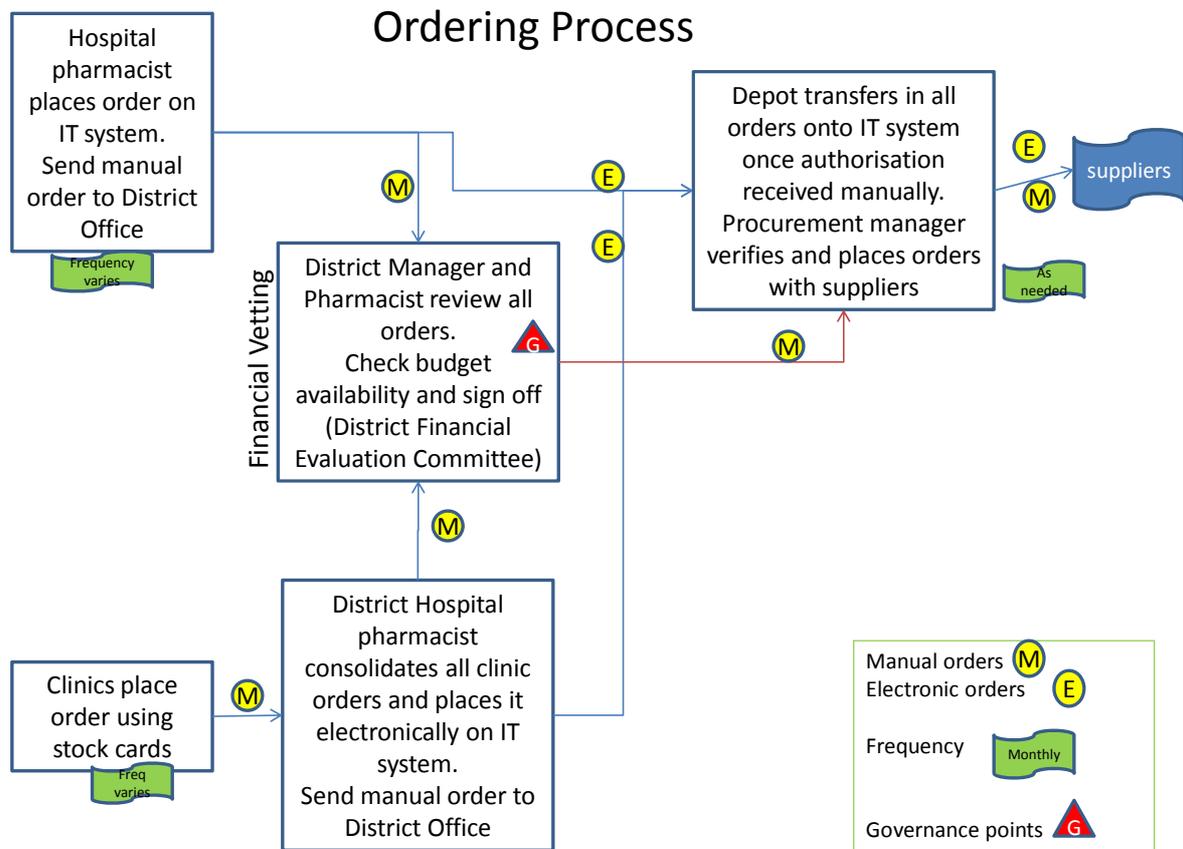
ordered. They also proactively contact those for whom they have not received an order to ensure that the manual authorisation has not gotten lost.

Most provinces have a two level quality and vetting process for orders:

- First level occurs at the district hospital or pharmacist who checks compliance with code lists, order quantities and financial availability through the district manager or financial committee;
- Second level is at the depot when the procurement manager checks the code list compliance, order quantities;
- And within the North West additional 2 levels of vetting have been introduced after these which include:
  - The TB director of the province checking all TB orders against compliance and budget; and
  - The facility checking their own budgets against spend.
- The Western Cape does not have a financial vetting process for orders but does perform monthly variance analysis at sub district and district level. Managers are performance managed against their forecasts and their compliance against these forecasts and budgets.

Most depot ordering systems allow them to determine a suitable order amount per drug and formulation. This “provisioning advise” takes into account available stock levels in the depot, the required minimum and safety stock levels in depot and also quantities demanded. It is vetted by the depot manager and procurement staff with manual adjustments in most circumstances. Some are able to place these orders electronically with the suppliers while others fax or post their orders in.

Figure 18 Standard Order Process Flow



## **F. Stock management and storage**

### *IT systems for warehousing and ordering*

Most provinces run a combination electronic ordering and manual authorisation systems.

The MEDSAS system is utilised by 9 of the 12 depots in the country and is a good stock management and ordering system. It contains additional functionality such as traceability which has never been ‘switched on’ by the developers as there is no maintenance of the system. This system is however not integrated with remote modules used by some of the facilities to place their orders on and in some provinces the reporting capabilities and inventory management functions do not support the ability of staff to monitor stock levels and reorder quantities. This results in lots of manual interventions into a system to generate order. It also requires that, for example in 2 provinces (EC and Gauteng) they close down their depots for 3 weeks in order to perform biannual stock takes as the system is unable to provide them with an accurate stock level at any point in time.

These same system reports are utilised by the depots when reporting bimonthly to NDOH on their drug levels. If they are able to generate them, the provinces requires enormous manual adjustments to convert this information to the format required by the NDOH for reporting. This is a labour intensive, non value adding process as the stock levels are only a snap shot in time and do not reflect the trends in availability of days out of stock.

Oracle DSMS is used in the NW, was installed in Gauteng but never switched on and is being looked at by the Mpumalanga depot. It is a far better system for warehousing and stock management and reporting although even in the NW manual orders are required by the facilities. It has enhanced traceability of batches dispatched however in order to enable this function any redistribution of stock at facility level needs to come back via the depot in order to trace it to its new facility. The system allows for bar coded scanning of products into and within and out of the depot improving the efficiency of the warehousing and storage process.

### *Receiving and storage*

Almost all depots follow a similar receiving process in which a number of checks are performed at various points:

- Receiving clerk receives products from delivery van. The clerk checks the following:
  - Delivery note against original order printed off the IT system against the physical delivery amounts (triple check);
  - The expiry dates (there is variation in what is accepted across provinces ranging from 12 - 18 months being accepted);
  - The batch numbers; and

- Any damaged products or problems with cold storage items – these are immediately given back to the supplier if the delivery van is still there and the supplier is notified of any issues. The responsible pharmacist is also notified.
- In the Free State, Western Cape, North West and Gauteng, a Pharmacy Assistant or pharmacist performs a fine check and opens 10% of the cartons to verify expiry and batch numbers and product integrity. In Mpumalanga this fine check does not include product integrity or a sample as there are no pharmacy staff in the warehouse;

**Figure 19 – Pharmacists performing quality control of sample of each batch of medicines– Cape Medical Depot**



- The Gauteng Medical Stores Department also send samples of each batch to their lab for testing of active ingredients. This process we are told takes 24 hours to complete but is a duplicate of the national regulatory processes within the MCC and that of the EDL committee;
- The warehouse staff checks all products again before it is taken into the stores

Only the Mpumalanga warehouse uses palletted storage systems with forklift trucks moving the stock from receiving into the stores and onto the shelves. Most other depots have a mixture of pallettes and boxed storage systems which are manually moved. All products are stored on shelves off the ground. TB and ARV medicines are additionally stored in a separate lockable cage in the Mpumalanga and Mthatha depot providing additional security and control.

Classification systems for storage on shelves varies across the provinces and can range from using the system allocated provincial supplier codes (ICN) number to place the stock on a particular area on a shelf as indicated by the IT system (Mpumalanga, NW, FS, WC, Limpopo) or a more simple system of splitting medicines by type into a store room and then placing them in any order within the store (Tshwane sub depot).

In the Free State medicines with the same ingredients but different formulations and dosage forms are placed into separate stores in order to reduce errors in picking. Other depots use a system of separating the same ingredients in the same store but in different shelf places.

The way in which stock is stored on the shelf to facilitate good picking and rotation also varied and was dependent on the warehousing infrastructure and shelving available (see pictures below):

- Stock was placed on the shelf in either pallets or boxes within a specific holding spot assigned by the system – so pickers need the IT system to indicate from which place and batch to pick;
- Stock is placed in a vertical order with the last to expire on top and the first at the bottom to facilitate easy picking;
- Stock is placed horizontally with first to expire on the right with picking to start from here
- Stock was placed in high piles in random places on the floor on pallets requiring the staff to figure out which was FIFO.

**Figure 20 - Various storage systems**

Systems assigned placement on shelf – Mpumalanga depot



Vertical placement – Cape Medical Depot



Random placement – Ekurhuleni sub depot, Gauteng



Random placement – Mthatha Depot, EC



Horizontal placement on shelf – Oudshoorn Sub Depot



### ***Stock counts and management***

Most warehousing staff confirmed they follow the FIFO (first in first out) and FEEFO (first earliest expiry first out) systems of storage and rotation and we didn't discover any expired stock on the shelf. However the efficient nature of being able to rotate stock depended on the storage system used as described above.

Most depots performed cyclical counts on their stock on a daily basis, usually only of a very small sample of products. This meant that the time to cyclically count every item in the depot varied between 1 week to 6 months. The methods of counts also varied and were determined by the stock management system or lack thereof:

- **Manual bin card system** - Each product on the shelf has a bin card which monitors the amount of stock added or taken off the shelf and to which “demander” it is sent. The warehouse staffs verify stock levels with bin card levels indicated.
- **Manual bin cards plus electronic system** –stock on shelves is checked against the system recorded amount. Discrepancies are reported to the pharmacists who recons all orders received, and dispatched. Adjustment are made on the bin cards and system only once the stock verifications officer has checked and then the operations manager and procurement pharmacists approved the adjustments.
- **Electronic only system** - Counts are performed manually first before they are correlated with the system. Any discrepancies are notified to the warehouse manager who signs off the adjustment on the system in conjunction with the stock control manager and depot manager.

- **No system at all** - in these facilities staff do not perform any checks.

Challenges identified with cyclical counts include that in the manual bin card system there is no process which requires the bin cards and system stock levels to be correlated on a regular basis. So although the bin cards are checked against the stock levels, they are not checked against the system. In addition, most bin cards viewed did not have an indication of the minimum stock levels or safety or reorder levels which are required to allow proactive monitoring of the stock on the shelves by the warehouse staff. This meant that unless the warehousing system generated a provisioning advise there was no push system from the stores to alert to low levels or trigger an order.

In some facilities it was almost impossible to perform a stock correlation counts (see results in table below). as the IT system was so dynamic it was unable to provide the staff with a true reflection of the actual stock that should be on hand. And in Mpumalanga there were multiple opened batches with half picked boxes of stock, unequal numbers of boxes on shelves so counting just one item would have entailed extensive time.

**Figure 21 – Print out of inventory system for Gauteng with no ability to determine stock on hand**

Ledger Transaction Report from 2012/10/22 to 2012/11/22 Page : 4  
 Depot Code: 70702289 Date : 2012/11/22  
 Depot Name - MEDICAL SUPPLIES DEPOT ARV STOCK DEPOT  
 ICN : 181783672 Open Balance 14387 Time :12:56:27PM  
 Description: EFAVIRENZ TABLET 600MG,30'S

Number	Date	Demander Code	Demander Name	Dem / Ord No	Dem / Ord Qty	IV / RV Qty	Running Total	Status
IV 100160	2012/10/26	701529	THUTHUKANICCMT	ARV40/12	3000	1500	134885	DES
IV 100159	2012/10/26	701529	THUTHUKANICCMT	ARV/10/1	2000	500	136385	DES
IV 100115	2012/10/26	701401	MULDERSDRIFT CLINIC	MUL103	2900	2000	136885	DES
IV 100177	2012/10/26	701400	NOKUTHELA NGWENYA COMMUNITY H	PHC099	3000	500	138885	DES
IV 100123	2012/10/26	701399	EKANGALA DARK CITY CHC	10:12P	800	800	139385	DES
IV 100185	2012/10/26	701379	JABULANI DUMANE CHC	JDC15/12	2000	1000	140185	DES
IV 100184	2012/10/26	701379	JABULANI DUMANE CHC	JDC14/12	3000	500	141185	DES
IV 100128	2012/10/26	701351	DIEPSLOOT CLINIC	ARV09/12	1500	1500	141685	DES
IV 100127	2012/10/26	701351	DIEPSLOOT CLINIC	ARV08/12	1500	500	143185	DES
IV 100101	2012/10/26	7012612	HEIDELBERG HOSPITAL	W00007	3000	1000	143685	DES
IV 100100	2012/10/26	7012612	HEIDELBERG HOSPITAL	W00006	3000	1000	144685	DES
IV 100292	2012/10/26	70123451	WEST RAND REGIONAL PHARMACY	WRR1277	10000	10000	145685	DES
IV 100170	2012/10/26	701231	STANZA BOPAPE CLINIC	SBCD101	9000	2000	155685	DES
IV 100200	2012/10/26	7011844	SOUTH RAND HOSPITAL	SR36/12	2800	1500	157685	DES
IV 100199	2012/10/26	7011844	SOUTH RAND HOSPITAL	SR23/12	500	500	159185	DES
IV 100390	2012/10/26	7011658	NATALSPRUIT HOSPITAL	W88/12P	2600	600	159685	DES
IV 10039	2012/10/26	7011658	NATALSPRUIT HOSPITAL	W79/12P	1200	1200	160285	DES
IV 100227	2012/10/26	7011624	TEMBISA HOSPITAL	AC009	2800	1800	161485	DES

Figure 22 – Tenofivir counting system at ARV depot

The ARV depot in Cape Town has severe space constraints and no shelving for stock so they create palletted piles. However they have a system of consistent number of boxes in depth and height which allowed them to count a mountain of stock of Tenofivir in under 5 minutes, a feat that in some other depots may have taken 1 hour.

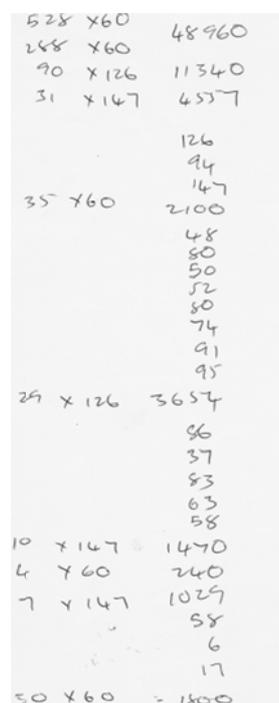


Figure 23 – Correlation of physical count of sample of products and stock on bin card or system

	EC	FS	Gauteng	Mpum	NW	WC
<b>K1 - average % time out of stock (in days)</b>	Unable to determine	13.35%	Unable to determine	13.5%	Unable to determine	Unable to determine
<b>K2 Availability on day</b>	Mthatha - 71% KSD - 100%	100%	87.5% - MSD 100% - Tshwane	100%	100%	100% both at ARV depot
<b>C7 - corresponding stock levels and physical count</b>	Mthatha - 29% KSD - 0%	Not performed	25% - MSD 100% Tshwane	Impossible to perform	100%	100% MSD 80% OMSD 100% ARV
<ul style="list-style-type: none"> <li>• K1 indicator: Average percentage of time <b>out of stock</b> for a set of TB tracer commodities in TB facilities:</li> </ul>						

- K2 indicators: - Average Percentage of a set of Tracer TB and ARV Commodities **available** in TB Facilities and Medical Stores. An item is considered to be available if even one unexpired item is in stock.
- C7 indicator: - percentage of physical count corresponding with the either the electronic or the stock card record system.

It is important to note here that the reporting of stock availability and the performance of the K1 indicator for average percentage of time out of stock for a set of tracer drugs was not an easy task to perform in most depots because they don't keep such records. This surprised us as we understood they had to report to NDOH bimonthly as such.

We then discovered that there are various levels in the health system reporting stock availability and with different definitions (this is discussed in more detail in the section on reporting):

1. Level one is from the health facilities on a weekly or monthly basis to the district pharmacists to reports this provincially.
  - a. The definition of unavailability varies with some provinces taking it to mean zero stock on shelf and others less than minimum.
  - b. The list of drugs that are reported on also varies with some provinces only using the National Core Standards tracer list and others 220 items considered critical
  - c. Drug availability is calculated not by the number of days the drugs are out of stock on the shelf but by the number of products for which there has been stock outs in the last week i.e. if there are stock outs of 2 out of the 10 drugs at the facility then a 20% stock unavailability score is reported. However those 2 drugs could have been out of stock for only 1 day each which means the true unavailability would be 2.86% ( $2 \text{ days O/S} / (10 \text{ drugs} \times 7 \text{ days}) = 2.86\%$ ). This is a far more accurate score for true unavailability.
  - d. The recollection of drugs being unavailable is usually from the memory of the staff or the pharmacy and not a recorded statistic in any facility. We did find 2 facilities (Holani clinic, Tshwane and Winnifred Maboia, Mpumalanga) who collected this information accurately.
2. Level two is the reporting from the depots to the facilities about stock availability:
  - a. Some provinces do this through the PTC committees, via email and communiqués sent to pharmacists and notices to facilities.
  - b. The definition of stock outs at depot level also varies with Gauteng defining it as no product of any pack size being available. This is not communicated to the facilities as such creating situations where stock is not delivered to the facility because they order the incorrect pack size (one that is out of stock).
3. Level three is reporting of depot stock levels to NDOH on a bimonthly basis. This takes a snapshot view of the depot at the time the report is generated. It contains the stock on hand, dues out and orders placed. As this is a dynamic report the true value of it in determining stock availability is not certain. It only gives an impression of the

volume of products in the system and not the true extent of days that products have been unavailable for.

### ***Fulfillment of orders***

In most depots the system generates a picking list for each facility when those orders are ready to be dispatched. This picking list indicates to the picker where, in which store, on which shelf and in which spot on the shelf, to find the stock. The Mpumalanga and NW systems generate picking lists with specific batches to pick and the placement on the shelf. In other depots staff are only directed to the designated medicine shelf and once there need to determine which is the first to expire stock. Many of these depot's storage systems already indicate to them where to start picking from i.e. vertical with first to expire at the bottom or horizontal with first to expire on the right. In some the stores were so disorganized with no system to ensure FIFO picking occurred.

One concern with the system generated picking of batches is that unless controlled it may result in multiple boxes being opened of different batches at once (see picture). This occurs as the system picks the first to expire and then new stock arrives with an earlier expiry date which becomes the first to pick. Older expiry batches are half picked leaving open boxes. It also makes stock counting an impossible job with hundreds of loose items than need to be reconciled at every count meaning cyclical counts are tedious processes.

Picking in some depots is supervised by pharmacy staff that quality check all orders picked prior to them being sealed and sent to dispatch. In the Free State and Western Cape and Limpopo there is a double checking system by pharmacists, firstly of items picked from the store, then the products consolidated for each hospital order.

In some provinces there are no pharmacists involved in quality control at any point in the stock picking process. In some provinces, such as the North West this does not cause issues with incorrect stock or orders being delivered as quality controls are in place. However in the Eastern Cape and Mpumalanga there are

**Figure 24 – Open batches with loose items in Mpumalanga store for TB medicines**



numerous reports of incorrect orders being received by facilities demonstrating that the quality checks performed by general assistants is not sufficient.

**Figure 25 Pharmacy assistant picking stock off shelf using trolley for easy handling**



Turnaround time from order being received at depot and confirmed on system to dispatch to facility varies widely amongst the provinces from a low of 3 -4 days to a high of 3 - 4 weeks. This is a function of the delays in the additional financial vetting process, the manual submission of authorizations, the order frequency policy and the stock holding capacity of the facilities.

However in those provinces with the fastest turnaround time there is also the least stock outs experienced in the sites as more frequent deliveries improve the stock management by the nurses in clinics. The ARV depot in Cape Town works on a flexible ordering and delivery policy ensuring the good supply of drugs in the province.

One exception is for the Free State which has the longest turnaround time but has one of the least stock outs assessed at facility level. Their efficient redistribution process allows for stock to be moved effortlessly between facilities, in effect buffering the reduced order frequency and limited stock outs to the patient. This may however be masking a larger problem with order frequency which should be investigated.

### ***Logistics and delivery to the facility***

Most provinces have an outsourced logistics provider, normally a courier type company with formal tracking of boxes. UTI in the Western Cape has installed their tracking system at the depots and sub depot to allow the creating of proof of deliveries and the scanning in of boxes on receipt to ensure the consignment is complete.

The vast majority of provinces have a scheduled delivery route and days so facilities are aware of when to expect their stock. However in the Eastern Cape the ordering system is erratic and so too is the delivery schedule. It is unplanned, unscheduled and irregular. In most instances the clinics have to collect their own orders from the transit area or depot as there are no delivery vehicles. Alternatively they have to rely on personnel visiting the facility to deliver their stock.

## **G. Challenges, best practices and recommendations for distribution**

### *Challenges*

- Concurrent jurisdiction of SAPC and MCC for compliance of GWP and GPP for depots and regional pharmacies. This needs to be harmonised and investigated further to ensure correct governance of the depots standards of quality
- Warehousing infrastructure that meet standards as well as capacity requirements of provinces medicine and surgical needs. These impact severely on the ability of staff to manage stock, rotation of stock, availability of medicines and ensure good quality storage standards are maintained. Fit for purpose built facilities should be investigated for all depots where there is an infrastructure concern.
- Ineffective use of direct deliveries from suppliers to reduce stock holding in warehouses including the misunderstanding of the difference between minimum order quantity and the fact that the contract does not stipulate a minimum delivery quality.
- IT systems not integrating between facilities and depot preventing electronic processing of orders. The additional administrative and governance process of financial vetting which delays orders being placed and then requires additional manual ordering paperwork which gets lost in the system.
- Poor quality control systems in warehousing both at receiving, in storage and picking. The use of general assistants in warehouses seems to result in inadequate quality control of stock and complaints of incorrect deliveries from facilities.
- Inability of perform accurate and frequent stock counts due to poor systems of stock management is unacceptable. If the IT system is unreliable then manual stock cards can be used and counts performed. We don't feel that the IT system constraints should prefer good stock management
- Reporting of drug availability at the various levels within the health system is inconsistent and does not enhance the management of suppliers.

### *Solution*

- The SAPC and MCC inspections for depots and regional pharmacies should be harmonized to ensure consistent application of good quality standards with enforcement actions being taken on non compliances. These inspections could fall part of the new Office of Standards Compliance remit in a mutual recognition agreement with the SAPC and MCC and should be discussed further.
- Fit for purpose built facilities should be investigated for all depots where there is an infrastructure concern.

- Relieving some of the pressure on depots through good use of the direct deliveries system from suppliers in relation to the position of facilities and risks involved.
- The IT systems to support real time ordering at all levels on the same platform will reduce some of the additional administrative time required to completed these tasks. In addition, an effective IT system will enhance visibility at the depot and district hospital level of facility stock levels, usage data and ensure a more inactive approach to ordering and supply management. Traceability of batches can then also be improved upon.



## **CONTRACT MANAGEMENT AND PAYMENT**

Monitoring and evaluating the performance of the suppliers and the facilities in complying with the tender conditions forms part of the contract management. It requires the collection and reporting of drug availability information as well as supplier compliance with terms of contracts. In addition the processes by which suppliers are paid is governed by strict procedures and compliance with contractual terms such as lead time and order fulfillment.

Contract management was previously the role of National Treasury (ended June 2011) and now sits with the NDOH's Affordable Medicines directorate who are in the process of putting staff and systems in place to manage the contracts.

The final contracted supplier lists and tender contracts are communicated to the depots as a circular at least 1 month prior to the start to facilitate a smooth transition. This did not happen with the August 2011 TB contract which was only received by the depots a week after the start of the contract meaning some facilities were already running out of stock.

The depots/ facilities cannot place an order on a new contract before the contract starts, and once the contract is in place there is still a lead time to delivery. The NDOH contract manager will also advise the depots and facilities to place post dated orders in the event of a suspected shortfall with the original suppliers to ensure availability. As long as orders are received prior to the contract ending, even if the delivery date is after the contract has ended, the order should be honoured.

However, no communication was sent to the provinces and depots to increase their stock of TB medicines to cover the "set up" period required of the new contracted suppliers for the August 2011 tender. This resulted in huge stock shortages in most TB medicines across the country. This has been rectified in the new ARV contract for January 2013.

### **A. Drug monitoring and reporting**

#### ***National Department of Health Reporting***

Provinces are to report drug availability and any contractual issues to Affordable Medicines to take up with the suppliers. A codification process has been designed by the military to enhance the collection of consumption and use data at the depot's and assist in tracking orders and products delivered to the facilities. As part of the tender contract, each supplier is provided with a supplier number and a national stock number (NSN) for the product. National stock numbers are linked to specific products. The depots have the NSN, and also have an internal code (ICN) which links to the NSN on their systems so they are able to store and find the products in the depot. In addition the codes should assist the Affordable Medicines Directorate to monitor and evaluate the supplier's compliance towards the contract conditions as part of the contract management process.

Currently, the depots in the provinces report bi-monthly the following information:

- Stock on hand for ARV's, TB and a basket of tracer and chronic medicines, vaccines and anti-malarials
- Quantity on order
- Previous 2 weeks issues (should be however the IT system reports can only generate what is currently on issue)
- Dues out – stock that has been demanded by the facilities

These reports are compiled in excel by each province and consolidated at NDOH and are used to predict demand and determine whether the country or a specific province is in danger of running out of stock. Numerous challenges occur with this process as not all the stock systems within depots are able to provide this information without manual intervention. To support this, Affordable Meds is in the process of implementing Infomaker that takes the reporting information directly from the depot IT system and drops it into the report format alleviating time consuming report compilations. The value of the data is also questionable when you understand the source and we feel that a more important indicator would be the number of days stock is unavailable.

### ***Supplier reporting***

In addition, the suppliers are required to submit monthly reports to NDOH on:

- Orders processed
- Deliveries made
- Note - there is no reporting on lead times met required.

Challenges are experienced here as not all suppliers are reporting regularly the information required enabling correlation of reports from provinces on stock availability.

### ***Provincial reporting and monitoring***

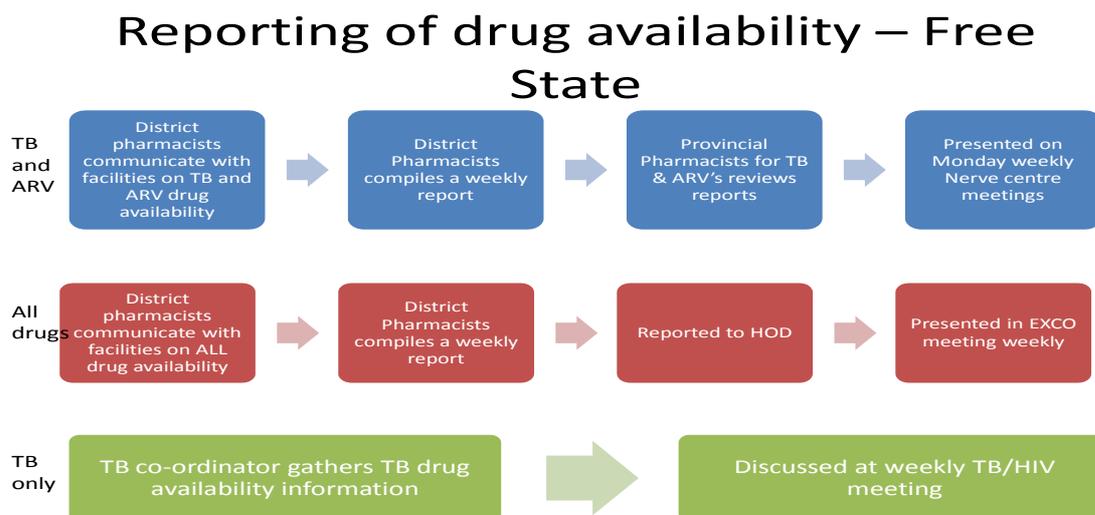
Provinces submit a bimonthly report on excel to the NDOH which details as above the drug availability at depot level only. This report is compiled at the depot based on the previous 2 weeks stock situations.

However all provinces have some sort of drug availability reports collected from facilities weekly to monthly in addition to the national report. These reports are never presented to NDOH. This very proactive stock level monitoring system helps determine potential future stock issues before they should occur. This allows the provinces to make provisions with the

suppliers for additional medicines or to redistribute between facilities to ensure stock outs do not occur. Differences between the provinces in this reporting include:

- Definition of stock unavailability varies with some provinces interpreting it as zero stock on shelf and others less than minimum levels;
- Percentage drug availability is calculated not by the number of days the drugs are out of stock on the shelf but by the number of products for which there has been stock out in the last week. So if 5 of the 10 drugs had a situation of even one day stock out then the drug availability is 50%;
- Sample of drugs varies from just the National Core Standards tracer drugs and supplies to 220 items. In some provinces TB and ARV medicines are separately reported;
- Reports are generated via different sources. In most provinces the facility manager (clinic) or pharmacist (hospitals) reports against the sample of drugs the drug availability. Some provinces have additional reports coming in from TB co-ordinators on TB medicines;
- Levels of reporting information also vary. Some such as the Free State have a 3 pronged reporting line of upstream communication to executive management at provincial level(see figure x):
  - TB and ARV drugs are reported to the district pharmacists who communicate this to provincial pharmacists in charge of TB and ARV's.
  - All drug availability is reported similarly by the district pharmacists to the HOD and then presented at the Executive management meeting weekly
  - The TB co-ordinator receives the TB drug information from the district TB co-ordinators and presents this to the weekly TB/HIV meeting;

Figure 26 – Example of reporting of drug availability – Free State



Mpumalanga also reports upstream to various levels within the provincial department:

Figure 27 – Reporting levels for Mpumalanga

Reporting point	Frequency
<b>A. Provincially to the TB directorate, Primary health directorate and Chief Director of Hospitals</b>	weekly
<b>B. Chief director of Primary Health in the district</b>	weekly
<b>C. District management meetings – submissions of 4 weeks averages</b>	monthly
<b>D. ARV monitor at Depot who collates this and submits it to the province and also to the NDOH</b>	Bi monthly
<b>E. Facilities</b>	Bi monthly

- Other provinces have active downstream reporting of “dues out” (dues out = no stock on hand in depot and they owe facilities or little stock but not sufficient to fulfill the demand). In the Western Cape, weekly “dues out” meetings are held at the central medical depot (CMD) based on the consumption data from the depot and its required 3 months stock holding levels. This is communicated to all pharmacists and facility

managers and proactive rectification plans are implemented as determined through the PTC's.

- Very few provinces are collected or reporting usage data at facility.

In Gauteng one of the district pharmacists was collecting usage data on a weekly basis from the clinics in the metro area. This was however never presented to depot or provincial managers for management of stock availability of for the determination of stock reorder levels.

In the Western Cape, district's account quarterly at provincial level against their Annual Performance Plan (APP) indicators which include the top 40 **usage** drivers and their predictions of their usage going forward. These forecasts are monitored and compliance with them determines compliance to the APP indicators for individual manager performance. The usage data does not form part of any pharmaceutical service discussion at provincial levels. This information could be quite valuable to the province as it completes a picture that the depot does not have which is accurate usage information and would be valuable to understand facilities needs, projections for future, determining quantification for contracts etc.

## **B. Contract management**

In most provinces it is the responsibility of the depot procurement manager and the designated TB, HIV & ARV provincial pharmacists who are primarily responsible for liaising with the suppliers over critical stock items to ensure constant supply and form the main point of contract management.

In the Free State, due to the high levels of direct deliveries the hospital pharmacists have become contract managers in their own right ensuring their delivery times are met. This has however led to chaos with every pharmacist phoning the same supplier directly about a similar drug supply issue. The depot only gets involved in direct delivery contract management when issues arise and are escalated to them.

In the North West the contract management is the responsibility of the TB Directorate and the depot manager. The TB Directorate, along with the depot manager, produce a monthly report detailing stock on hand and actively manage potential stock outs and over stocking within the province and with the suppliers.

The provinces are supposed to report suppliers for:

- Delayed deliveries in terms of lead time,
- Non deliveries
- Or short deliveries

Very few actually do this as only the Western Cape, Eastern Cape and Free State actively monitor this information at present. Mpumalanga has the ability to monitor this however they are not actively reporting this until they have sorted out their payment processes.

The system is reactive so the depot staff are only aware of delayed deliveries when they are not received at the depot in the expected time, preventing them from putting in place contingencies earlier. Part of the issue is that suppliers do not inform the depot of their lead time delays and are sometimes hard to get hold of when deliveries are not on time for corrective actions to be instituted sooner. In situations of direct deliveries, very few pharmacists report delays in deliveries to the depot to allow them to take up these repetitive problems with the suppliers or report it to the central contract management unit at NDOH Affordable Medicines.

In the Western Cape they have appointed a provincial contract manager responsible for contractual compliances by the suppliers. All contract breaches are reported to her and she takes this up with the suppliers. Contract management is effected from the finance department at the depot. this entails penalties for lead times exceeding contractual arrangements. These penalties are taken off the supplier's next invoice and have caused major upsets in the industry.

If the situation becomes dire and provincial stock levels are being impacted, the Western Cape and Free State provinces issue warning letters requesting the suppliers to provide reasons within 1 week or face a buyout situation. Only Western Cape has recovered buy outs against suppliers to date.

As of November 2012 Mpumalanga and Free State they will start implementing the provisions of the "special conditions" of the contract themselves through penalties on invoices to late delivery suppliers. They will then also be able to implement buys outs against suppliers. To enable this they are in the process of sorting out their late payments to suppliers and ensure that suppliers are paid on time going forward.

According to the contractual terms the NDOH should be managing these penalties on behalf of the provinces. When contract management was run by National Treasury, the provinces informed us that their reported issues of non compliance did not lead to any penalties or recoveries being instituted. They have therefore taken the option of putting systems in place provincially to deal with these issues. We understand that Affordable Medicines is gearing up to provide these services in the future. This includes each province having an assigned Affordable Medicines contact person allocated to follow up with suppliers on behalf of the province.

Quarterly quantification meetings are supposed happen between the NDOH and the suppliers in which quantities are matched to contractual volumes and issues with stock availability and supply constraints discussed. These are however not happening - for the TB contract the first meeting was held in September 2011 and has only just happened for the second time since

then. Or the meetings are run in such a fashion that limits the input from suppliers and creates an environment where suppliers are unable to voice their concerns with contract supply without divulging sensitive competitive information to the other suppliers.

### ***Governance of contracts***

Most provinces have a very strict policy in terms of buyouts or buying outside of contracts (which is not allowed in all provinces except Gauteng).

In all provinces standard procedures are followed in legal compliance letters to suppliers who are unable to supply before a buyout process is followed. This includes the sourcing of 3 other quotes and HOD approvals before another supplier for services can be used.

Provinces are however not required to report to Affordable Medicines on their buy outs or off contract purchases leaving the system open to abuse as is evident in the Gauteng province.

In Gauteng, although the province utilises the National Suppliers database facilities are able to order outside of the national tender contracts and these processes are managed by the depot. A study conducted by SCMS in May 2012 revealed that 70% of stock was non EDL which places additional pressure on the depot to manage, order and process non contract drugs.

Section 21 purchases are also strictly controlled. Although in some provinces Affordable Medicines still has to monitor that all drugs ordered are taken up by the provinces to limit the amount of “unregistered” product floating around the depots.

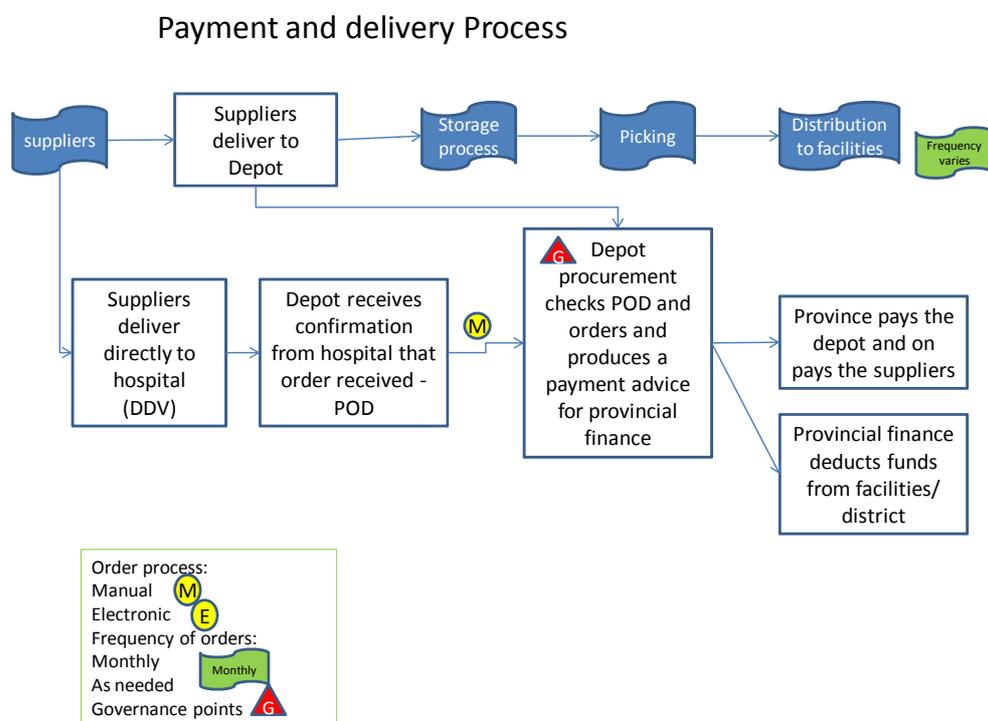
### ***Provincial Payment***

Most provinces process payments to suppliers from the depots finance department. They require the proof of delivery (POD) slips for this to occur. Herein lie challenges in getting the POD's back from facilities. All proof of delivery notices are required to be sent back to the depot from the clinics and hospitals. Finance staff performs checks on these POD's against the orders before submitting them for payment.

In the North West, all invoices are checked against the contract at the depot level by the depot manager and then submitted to the TB Directorate for verification before being submitted to treasury for payment.

Finance then submits their required payments to the provincial finance departments who authorise and pay the depots. The depots then on pay the suppliers.

Figure 28 – Standard Payment process



Lead times to payment vary across the provinces:

- Mpumalanga prepares a goods received voucher by the 25-26<sup>th</sup> of each month for all deliveries received at depot and facilities. This is submitted to the provincial finance department. Within one week the province pays the depot contractor who on pays the suppliers. This means that suppliers receive their payments 30 – 60 days after delivery.
- Western Cape pays suppliers weekly so payment is generally made in 30 days
- The Free State depot is able to pay suppliers more frequently if it has a surplus in its trading account otherwise most payments are over 30 days.

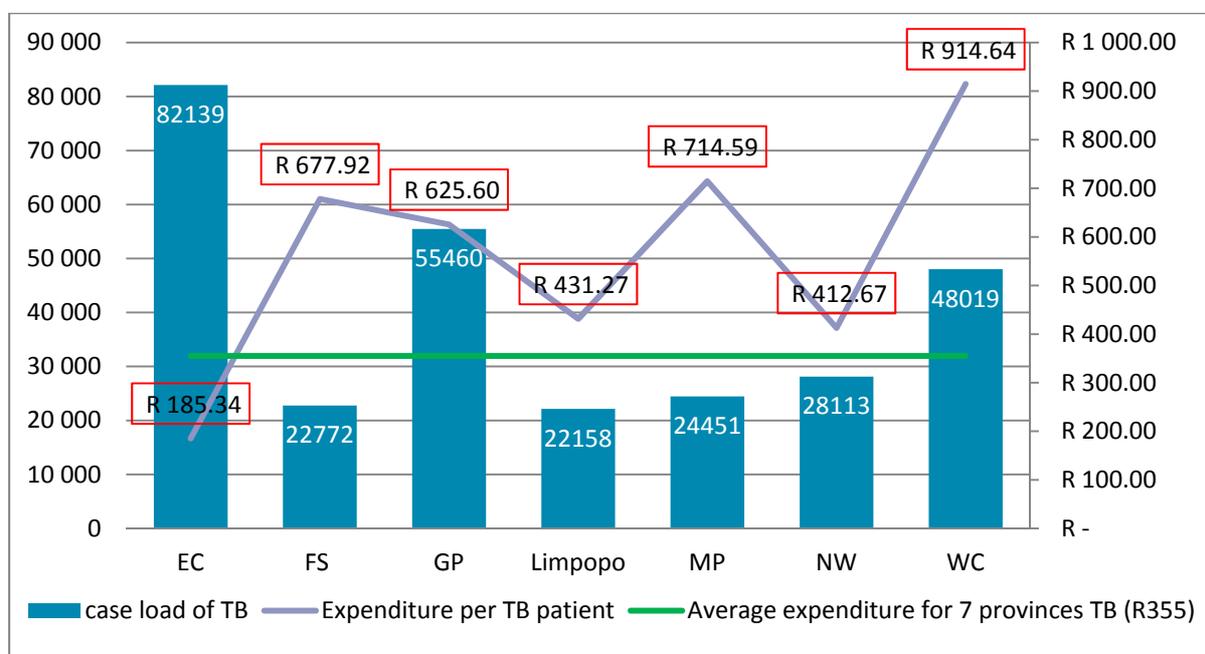
Suppliers are well aware of the provincial payment processes and will favour a province for supply of short stock items if it pays faster than others.

### C. Expenditure on TB Medicines

Total expenditure for TB medicines over the last financial year are detailed in the table below. These figures are exported from the depot financial system and in most cases are for the period 01/04/2011 till 31/03/2012. However in some provinces we were unable to get recent figures for expenditure and have included their 2009/2010 figures instead. The expenditure is mainly from depot receipts of orders they have placed however in the WC this is for issues to demanders. Mpumalanga mentioned that their issues expenditure is far higher anyway.

Expenditure data per province when proportioned by TB case load shows that in most provinces the spend per patient is much higher than the case load would suggest.

Figure 29 – Spend per patient for non resistant TB



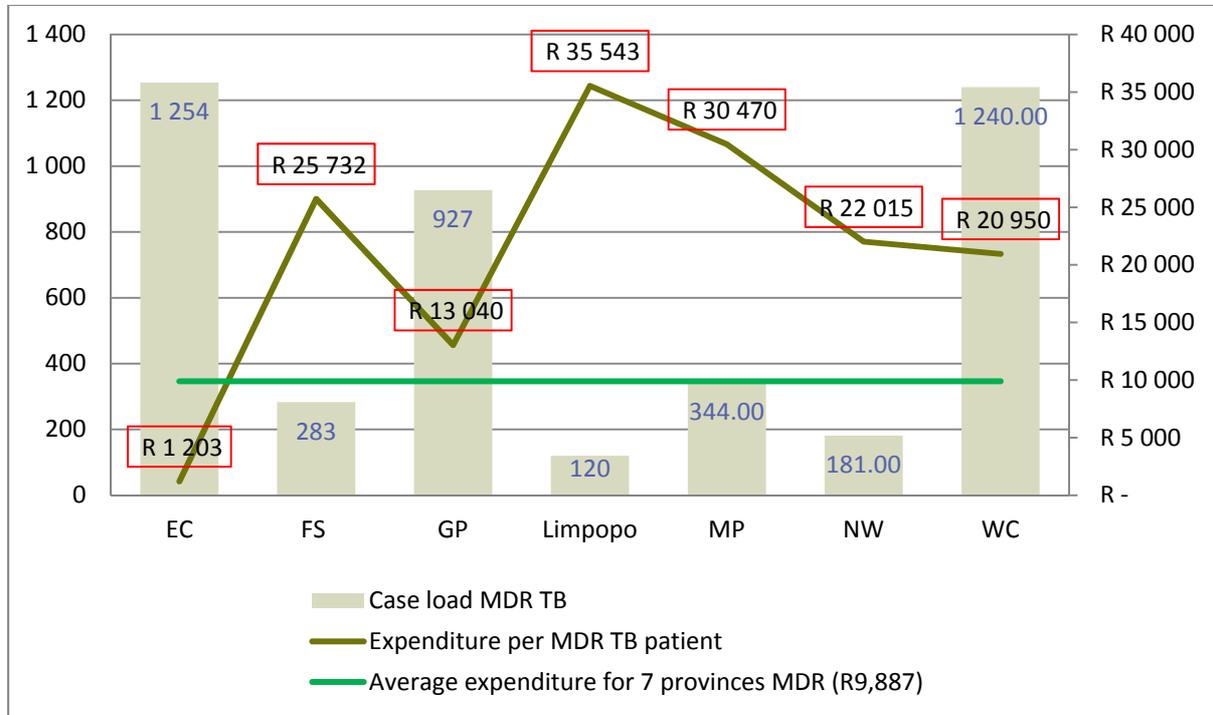
EC and Limpopo = 2009/2010 figures

This implies that either the provinces are wasting TB medicines (in effective stock management, overstocking, losses, incorrect prescribing of pack sizes etc) or that the TB case load data from the eTr is under reporting the true problem and that the case load is in effect much higher. From our investigations at facility level we very rarely found situations of overstocking at facilities for TB medicines, therefore we have to assume that the depot expenditures are a more accurate reflection of the true picture of demand imply that the case loads are higher than the eTr stats would suggest.

For MDR TB the data is similar, except in the WC and EC where the high case load substantiates the high spend by patient. All other provinces have higher spends than the WC and EC and yet their case loads are very small in relation. As mentioned in the “Use in

facilities” section, the roll out of the GeneXpert machine is improving the case finding of MDR cases meaning we should see and increase in these MDR stats going forward because the spend is already there.

Figure 30 – Spend per patient for MDR TB



EC and Limpopo = 2009/2010 figures

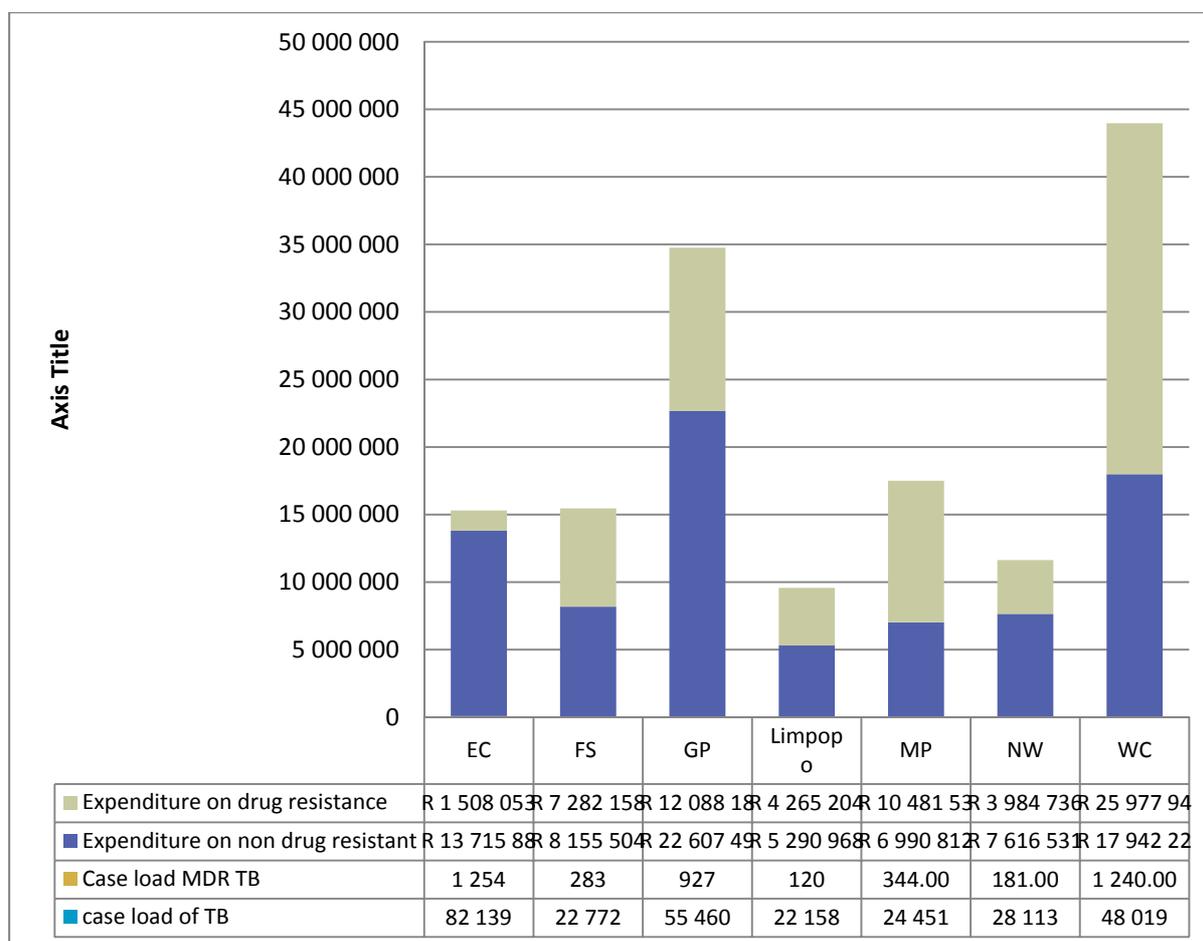
*Pharmaceutical management of TB in South Africa*

**Figure 31 – Provincial Expenditure on TB medicines**

	<b>EC</b>	<b>FS</b>	<b>Gauteng</b>	<b>Limpopo</b>	<b>Mpum</b>	<b>NW</b>	<b>WC</b>
Population	6,671,958	2,941,281	11,091,032	5,282,554	3,689,832	3,519,144	5,641,903
Case load of TB	82,139	22,772	55,460	22,158	24,451	28,113	48,019
TB prevalence per 100 000 population	1,231	774	500	419	663.00	799.00	851.00
Case load MDR TB	1,254	283	927	120	344.00	181.00	1,240.00
MDR prevalence per 100 000 population	18.80	9.62	8.36	2.27	9.32	5.14	21.98
<b>Total Expenditure</b>	<b>R 15,223,939.11</b>	<b>R 15,437,663.05</b>	<b>R 34,695,676.30</b>	<b>R 9,556,172.00</b>	<b>R 17,472,348.25</b>	<b>R 11,601,267.00</b>	<b>R 39,111,610.00</b>
Expenditure on first line drugs	<b>R 13,715,885.85</b>	<b>R 8,155,504.83</b>	<b>R 22,607,495.10</b>	<b>R 5,290,968.00</b>	<b>R 6,990,812.10</b>	<b>R 7,616,531.00</b>	<b>R 19,737,597.00</b>
Expenditure on drug resistance	<b>R 1,508,053.26</b>	<b>R 7,282,158.22</b>	<b>R 12,088,181.20</b>	<b>R 4,265,204.00</b>	<b>R 10,481,536.15</b>	<b>R 3,984,736.00</b>	<b>R 19,374,013.00</b>
Cost per TB patient	R 185.34	R 677.92	R 625.60	R 431.27	R 714.59	R 412.67	R 814.50
Cost per MDR TB patient	R 1,203	R 25,732	R 13,040	R 35,543	R 30,470	R 22,015	R 15,624
<i>Period of report</i>	2009/2010	01/04/2011 till 31/03/2012	01/04/2011 till 31/03/2012	01/04/2011 till 31/03/2012	01/04/2011 till 31/03/2012	2009/2010	2009/2010

Figure 31 compares expenditure from the depot for TB medicines split by type of TB i.e. non drug resistant and drug resistant. Provinces, such as FS, MP, NW with similar case loads of non drug resistant TB (180 – 340) are spending about R7 – 8 million per annum on these patients. The WC, Gauteng and EC have the highest case loads of non resistant TB however their spend is vastly different; WC spends less than Gauteng but has a higher case load. Gauteng spends more than EC although it has a lower case load. We feel this needs to be investigated more as mentioned above, these provinces are either wasting TB medicines or the TB stats are under reported.

**Figure 32 –Split of expenditure between non drug resistant and drug resistant TB medicines by province**



Data for Limpopo is incorrect

The case for Multidrug resistant TB is more interesting in that the WC with one of the highest case loads of MDR TB patients is spending almost double the Gauteng’s spend and 16 times the EC spend for a similar load of patients. We also feel this needs investigation as we are unable to determine if this spend is cost effective or not.

## **D. Challenges, best practices and Recommendations in Contract Management**

### ***Challenges***

- In the past National Treasury did not implement contract management principles effectively with the resultant behaviour of lack of reporting of breaches by suppliers within the provinces. This can be remedied once the Affordable Medicines has the capacity to contract management nationally. Alternatively, the responsibility for some of the contract management functions can reside in provinces where they have capacity.
- NDOH is provided with limited information about stock availability at depot level. It is unable to monitor effectively the consumption within the facilities due to poor visibility of the facility stock levels, aggravated by poor IT systems. Reporting of stock availability at facility level is also not consistent across the provinces limiting the use of this information nationally.
- Quarterly quantification meetings nationally need to occur more regularly and in such as fashion that partnerships are created with the suppliers who will be willing to engage with the department on issues of mutual concern such as drug supply and fluctuating demands.

### ***Best Practices***

- The Western Cape and in future the Free State and Mpumalanga are taking on the responsibility for contract management in an active way. They are reporting regularly from facilities to within the various levels within the provincial department, they are liaising with suppliers and actively improving and controlling the level of stock within their depots and facilities.
- Western Cape, Eastern Cape are monitoring contract lead times and other breaches and putting in place penalties for non compliance which have resulted in improved service delivery in the province.

### ***Recommendations***

- NDOH should be monitoring the level and value of buy outs in the provinces both to control excessive spending and to influence future tender quantifications processes.
- Future tender contracts should, have a clause that states when buy outs are made the money will be deducted from the supplier's next invoice instead of
- All reporting of stock availability by provinces should be augmented by quarterly quantification meetings with suppliers in which the drug supply, demand, forecasting and compliance with contractual terms are supposed to be discussed. Pharmaceutical companies should also present their ordering data to see if this matches consumption data and together the parties can determine demand for the next 3 months period. Provinces are also able to provide insights into whether any screening campaigns are

being planned which may impact on the demand for drugs so suppliers can factor this into their manufacturing processes

- District level quantification meetings can be held. This will link the programme staff that are monitoring prevalence, implementing initiatives for screening and treatment and the pharmacists in a more collaborative fashion. This way the clinical services are able to link with the suppliers of the products to meet the demands and so facilitate better functioning of the TB programmes on the ground.

## **SUPPLIERS OPINIONS OF THE TB PHARMACEUTICAL MANAGEMENT SYSTEMS WITHIN NATIONAL DEPARTMENT OF HEALTH**

A number of the pharmaceutical companies currently awarded tender contracts for the supply of TB medicines were contacted to provide their insights into the pharmaceutical management of TB in South Africa.

### **A. Drug Registration process**

TB is classified as an essential priority medicine and as such should undergo a 1 year registration process.

Their latest formulations have taken around 3 years to undergo registration. This was because one of the companies who had been awarded the tender discovered that they had deterioration of their formula when it was on the shelf so the MCC insisted that all products awaiting registration required upgraded bioavailability and stability data in addition to the normal requirements to be submitted. This resulted in a delay in registration.

An area of concern raised by the pharmaceutical companies is that the MCC does not take into account the reciprocal relationship with PICS accredited authorities who have conducted inspections of manufacturing sites previously. The MCC redo these inspections, causing delays in the registration process as most sites are overseas and require high level NDOH approve before site visits can be conducted. Should the MCC take into account the reciprocal agreements on inspections with PICS and WHO then registration of TB priority medicines could be fast tracked easier.

A larger consideration should also be given to drugs already registered fully with the FDA or with WHO in the registration process in South Africa. Granting them provisional registration would allow new formulations such as TB drugs in sachets soluble in water and xxx to be introduced into the market place sooner benefiting patients and improving compliance.

Another concern is with the number of staff available at the MCC to perform evaluations, the skill of the evaluators and their lack of focus on specific therapeutic lines to improve the evaluations performed.

Most pharmaceutical companies acknowledged that there are companies that submit substandard dossiers for drug registration. However there should be a process in which companies with reputable high quality dossiers can benefit from the efforts put in with reduced turnaround times for registration.

### **B. National EDL List**

For 54 years there has not been a change in drug for TB only minor changes in formulations and dosage so there has not been a major need for getting drugs onto the national EDL.

Pharmaceutical companies agreed that in general it is very difficult to get a new drug formulation onto the national EDL list. They require a large number of key local opinion leaders with a unique reason to support the motivation of a new formulation that could eventually make it onto the EDL. Most of these key opinion leaders are academics or sit on the Pharmaceutical and Therapeutics Committees of each province or hospital.

Other avenues for creating interest in a drug formulation for the national EDL is to conduct pilot studies in South Africa using the key opinion leaders to run these trials. The trials should cover a cross section of provinces to gather sufficient local data if that has not already been done during the phase 3 trials as part of drug testing.

As TB is not traditionally a profit making product very little research is being done into new drugs and formulations. TB Alliance, a not for profit company, is campaigning to change this and encourage companies to invest in research.

### **C. Tendering and contract management**

The TB tender issued in August 2011 was the first tender that NDOH took over from National Treasury and there were a few glitches with the process:

- The tender contracts were awarded 1 week after the contract started;
- No communication was sent to the provinces and depots to increase their stock of TB medicines to cover the “set up” period required of the new contracted suppliers. Due to the requirements of new pack sizes and packaging new suppliers need about 3 months from a standing start to get a new product out for delivery. So orders for the new suppliers came in on the 1<sup>st</sup> day of the new contract, with some provinces having far less than their 3 months stock on hand to cover the set up period. This resulted in huge stock shortages in most TB medicines across the country. This has been rectified in the new ARV contract for January 2013;
- Timing of the start of contracts is also important, as starting a new contract on 1<sup>st</sup> January when the factories are closed makes the delivery in the new year a challenge for the manufacturers;

Quantification of drug needs for the tenders could be split out by province or depot. This would allow the pharmaceutical companies better ability to plan, while taking into account logistical arrangements for improved lead time.

Communication to the pharmaceutical companies prior to the tender is also important. This should include changes to pack sizes or packaging requirements as well as changes to quantities from previous years.

Communication to the pharmaceutical companies as well as the depots around how much stock to maintain during transitions between contracts is fundamental to prevent stock shortages from new suppliers in the future.

In terms of the contract management processes these could be improved upon to ensure that the erratic off take that the pharmaceutical suppliers experience is improved to allow them to better meet the demands of the facilities. Some suggestions they made are:

- Quarterly quantification meetings on ARV and TB medicines should be pre scheduled so they occur regularly;
- At the quantification meetings each provinces should present their previous 3 months consumption data for each product plus provide an estimate on the demand from orders and prevalence data. Provinces are also able to provide insights into whether any screening campaigns are being planned which may impact on the demand for drugs so suppliers can factor this into their manufacturing processes;
- Pharmaceutical companies should also present their ordering data to see if this matches consumption data and together the parties can determine demand for the next 3 months period.

Suggestions have been made to place Monitors in each district that monitor the off take from each facility and feed this into a CHAI like model which determine orders needed based on current stock holding.

It is also critical to link the programme staff that are monitoring prevalence, implementing initiatives for screening and treatment and the pharmacists in a more collaborative fashion. This way the clinical services are able to link with the suppliers of the products to meet the demands and so facilitate better functioning TB programmes on the ground.

#### **a. Supplier Customer Service**

Some of the suppliers have customer service call centres dedicated to ensuring that orders are tracked and out of stocks are managed. They supply bimonthly reports to the depot managers with all out of stock orders and correlate orders requests from the depot with their orders logged to ensure no orders have gone missing.

These bimonthly reports should also contain an indication of the expected best date for delivery which is not always accurate as they are impacted by the manufacturing site and logistics.



## USE OF TB MEDICINES AND FACILITY MANAGEMENT OF TB MEDICINES

The following facilities were visited in 7 provinces during the assessment. During the course of the assessment it became apparent that Limpopo was recently included in a similar assessment and thus we included Gauteng Tshwane district. However, some information was sourced from the Limpopo assessment and will be provided in the relevant section.

<b>Free State Province, Thabo Mafutsanyane District</b>		
<b>Facility name</b>	<b>Facility type</b>	<b>Town</b>
<b>Mphohadi PHC</b>	Primary health care centre	Bethelehem
<b>Senekal LA</b>	Primary health care centre	Senekal
<b>Mamello CHC</b>	Community health centre	Marquard
<b>Phekolong hospital</b>	District hospital	Bethlehem
<b>Dihlabeng hospital</b>	Regional hospital	Bethlehem
<b>Dr JS Moroka hospital</b>	TB hospital	Thaba Nchu
<b>North West Province, Dr. Kenneth Kaunda district</b>		
<b>Facility name</b>	<b>Facility type</b>	<b>Town</b>
<b>Park street town clinic</b>	Primary health care centre	Klerksdorp
<b>Jouberton CHC</b>	Community health centre	Klerksdorp
<b>Tigane CHC</b>	Community health centre	Hartebeesfontein
<b>Ventersdorp hospital</b>	District hospital	Ventersdorp
<b>Tshepong hospital</b>	Regional hospital	Klerksdorp
<b>Tshepong MDR/XDR Unit</b>	TB hospital	Klerksdorp
<b>Eastern Cape Province, Dr Kenneth Kaunda District</b>		
<b>Facility name</b>	<b>Facility type</b>	<b>Town</b>
<b>Buntingville Clinic</b>	Primary health care centre	Nyandeni
<b>Libude Clinic</b>	Primary health care centre	Nyandeni
<b>Ngangelizwe CHC</b>	Community health centre	Nyandeni
<b>St Barnabas hospital</b>	District hospital	Nyandeni
<b>Mthatha hospital</b>	Regional hospital	KSD

Zithulele hospital	Mission hospital	KSD
<b>Gauteng Province, Tshwane District</b>		
<b>Facility name</b>	<b>Facility type</b>	<b>Town</b>
Stanza PHC	Primary health care centre (PHC)	
Holani PHC	Primary health care centre (PHC)	
Laudium CHC	Community health centre (CHC)	
Tshwane DH	District hospital (DH)	
Mamelodi RH	Regional hospital (RH)	
Sizwe TH	Tuberculosis hospital (TH)	
<b>Mpumalanga Province, Gert Sibande District</b>		
<b>Facility name</b>	<b>Facility type</b>	<b>Town</b>
Msimanga	Primary health care centre (PHC)	
Davel Clinic	Primary health care centre (PHC)	
Winnifred Maboa	Community health centre (CHC)	
Standerton DH	District hospital (DH)	Standerton
Ermelo	Regional hospital (RH)	Ermelo
Standerton	Tuberculosis hospital (TH)	Standerton
<b>Western Cape, Eden district</b>		
<b>Facility name</b>	<b>Facility type</b>	<b>Town</b>
Bongolethu	Community health centre (CHC)	Oudtshoorn
Blanco clinic	Primary health care centre (PHC)	George
Bridgeton	Community health centre (CHC)	Oudtshoorn
Oudtshoorn hospital	District hospital (DH)	Oudtshoorn
George hospital	Regional hospital (RH)	George
Harry Comay hospital	Tuberculosis hospital (TH)	George
<b>Limpopo Province, Vhembe district</b>		
<b>Facility name</b>	<b>Facility type</b>	<b>Town</b>
Mbokota	PHC	Vhembe
Bungeni	CHC	Vhembe

Louis Trichard DH	DH	Vhembe
-------------------	----	--------

### A. Storage of TB medicines in health facilities

- The majority of hospitals have suitable pharmacy stores for their medicines which are well air-conditioned and with good security. Medicines were stored neatly on shelves and off the floor, with compliance to the rotation standard of First In First Out (FIFO) and First Expiry First Out (FEFO) being maintained. Surgical supplies are generally kept in bulk stores and in most instances these areas were disorganised and unstructured making assessments here difficult.
- Clinics however have the challenge of lack of suitable infrastructure with storage facilities that are just too small to accommodate the stock being distributed to them sufficiently for them to be able to unpack, store in a manner compliant with good pharmacy practices and control effectively on a regular basis.
- This is aggravated by inflexible delivery schedules from the provincial depots, with too infrequent deliveries of too large a volume of stock to meet the capacity constraints of the facility. Incorrect deliveries of excessive quantities which sometimes occur in poorly managed depots, pushes the system over the edge with excess stock sitting outside the pharmacies exposed to the elements.
- The impression we have is that the addition of HIV treatment within these clinics has resulted in a further burden on these stores, overstressing storage capacity due to their high volumes.
- However there are clinics that do seem to put in place effective stock management systems despite the constraints on space and resources demonstrating that with some good management skills and some process and systems thinking some of the constraints can be overcome.
- Time and training issues of staff should be addressed through mentorship by pharmacy professionals and the TB Coordinator. Mentorship is preferred to training as it is onsite and requires staff to experience within their own environment how things can be made better.

### B. Availability of medicines

Availability of the correct medication stored in a secure and well managed environment is a prerequisite for a successful TB program and successful outcomes for patients.

#### *Ordering of medicines*

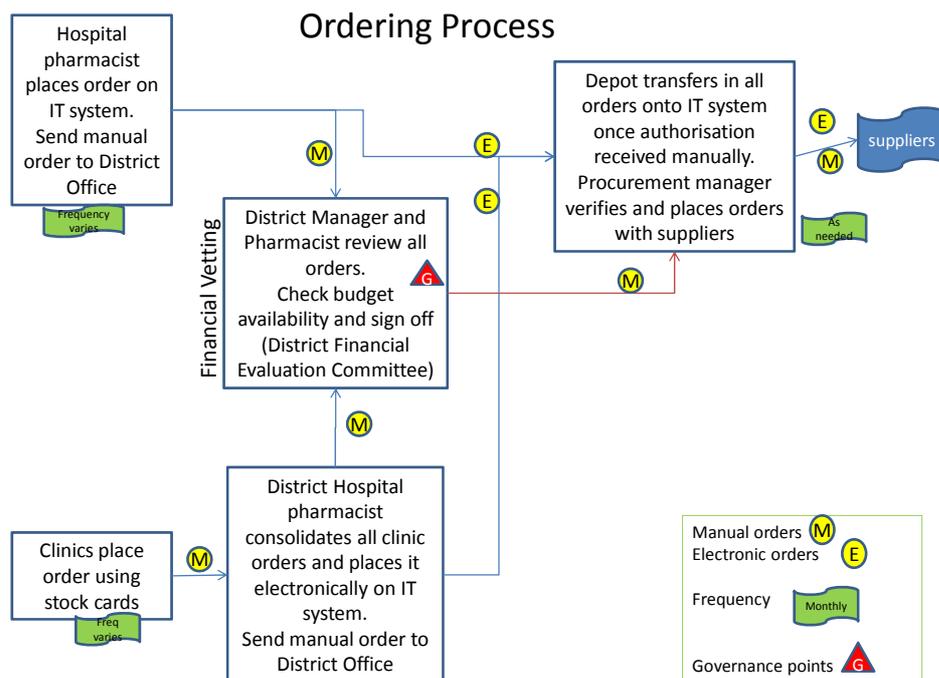
The availability starts with the correct orders being placed for the demand. Ordering at clinic level is performed by nurses and seems to be performed in most cases without a clear system for determining quantities. Lack of good stock cards or stock management control with accurate minimum and maximum levels combined with poor staff understanding of ordering processes hampers good correct quantities being ordered.

Even at hospital level case loads are not taken into account when quantifying although the ordering practices are more systematic with electronic inventory systems helping to generate reorder quantities.

Ordering is a manual process from clinic to the “mother hospitals” or district pharmacy where quality and financial vetting processes occur (see figure 33 below). The orders are checked for compliance to code lists for the type of facility as are provincially determined. The order quantity is compared to historical order levels although these are only for short periods of time and don’t take into account the seasonality of demand. Minimum and maximum levels are also checked with facilities not being able to order above their maximum without motivation. Most provinces also have a financial authorisation process here whereby the budget of the district or facility is checked for available funds before being signed off by the district manager or hospital manager.

These manual orders and their signed authorisations are sent by fax or post or delivery to the depot where the orders are effected onto the depot system.

Figure 33 - standard ordering process



### Measuring availability of medicines

Stock control and recordkeeping thereof was a clear constraint in smaller facilities with on average better recordkeeping in the hospitals.

Stock cards and their use were not consistently found in all facilities. There was even a facility that did not attempt any recordkeeping with the explanation that the stationary needed could not be obtained. Hospitals mainly used electronic inventory systems to control their stock with some form of bin card system for manual reconciliation purposes.

This led to difficulty obtaining accurate information for determining availability and at times verbal reporting and recounts from staff had to be accepted. However, it is believed that despite these constraints in data validity valuable information providing a peek into the management and availability of medicine and other commodities could be obtained.

**The assessment included the number of days that a tracer TB medicines, surgical and ARV's (as per list in table 1 below) was out of stock in a particular month and a review of whether there was stock available at that moment in time on the shelf. An item is considered to be available if even one unexpired item is in stock.**

**Table 1 – Tracer TB medicines, surgical supplies and ARV's evaluated for stock outs**

<b>TB medicines</b>	<b>Drug resistant TB medicines</b>
1. Rifampicin 150 mg/isoniazid 75 mg tablet (RH)	1. Kanamycin 1g/3ml vial injection ( <b>K</b> )
2. Rifampicin 300 mg/isoniazid 150 mg tablet (RH)	2. Moxifloxacin 400mg ( <b>M</b> )
3. Rifampicin 150 mg/isoniazid 75 mg/pyrazinamide 400 mg/ethambutol 275 mg tablet (RHZE)	3. Ethionamide 250mg tablets ( <b>Em</b> )
4. Rifampicin 60 mg/isoniazid 30 mg/pyrazinamide 150 mg dispersible tablets	4. Terizidone 250mg tablets ( <b>T</b> )
5. Rifampicin 150 mg tablet (R)	5. Pyrazinamide 500 mg tablets ( <b>P</b> )
6. Ethambutol 400 mg tablet (E)	6. PAS
7. Isoniazid 100 mg tablets (I)	7. Clofazamine
8. Isoniazid 300 mg tablets (I)	
9. Streptomycin 1 g/3 ml vial (S) injection	
10. Streptomycin 5 g/15 ml vial (S) injection	
<b>Surgical Supplies</b>	<b>ARV's</b>
11. Water for injection	1. Abacavir 20mg/ml solution
12. Syringes 5ml	2. Lamivudine 10mg/ml solution
13. Unsterile gloves - Medium	3. Lopinavir/Ritonavir 80/20mg/ml solution
14. Surgical Masks	4. Nevirapine 10mg/ml solution
15. TB masks - N95	5. Efavirenz 50mg capsules
16. Needles - 21 GX 1/2 (Green)	6. Efavirenz 600mg tablets
17. Alcohol swabs	7. Lamivudine 150mg or 300mg capsules/tablets
18. GeneXpert cartridges	8. Lamivudine 150mg/Zidovudine 300mg tablets/capsules (PEP)
19. Sputum bottles	9. Lopinavir/Ritonavir 200/50mg tablets
	10. Nevirapine 200mg tablets
<b>Vaccines</b>	11. Stavudine 30mg capsules
1. BCG vaccination	12. Tenofovir 300mg tablets
2. Latex BCG Syringe with needle	13. Zidovudine 300mg tablets

### **Results and interpretation of pharmacy assessment**

Table 2 below provides the stock out and stock availability indicators of the 6 provinces that were assessed. The indicators called K1 and K2 are provided for all the TB, ARV and surgical supply tracer commodities that were assessed as well as the K1 and K2 indicators for the TB and ARV commodities separately. The definitions of the indicators are provided at the bottom of the table.

*Note that for the Eastern Cape the period assessed was different. Mthatha depot was on strike from September to October 2012 and due to poor stock cards it necessitated verbal recollection for days out of stock which hampers the accuracy of this indicator as discussed above.*

*Pharmaceutical management of TB in South Africa*

**Table 2 –Results of pharmacy assessment for stock availability**

Facility name	District	K1 % days stock unavailable Total %	K1 TB medicines %	K1 ARV's %`	K1 Surgical supplies %	K2 % of stock available on day of assessment total %	K2 TB medicines %	K2 ARV's %	K2 surgical supplies %
Eastern Cape	OR Tambo	2.84	8.02	1.55	0.00	82.55	63.41	85.25	95.74
Free State	Thaba Mofutsanyane	1.12 %	1.46	0.48	1.59	89.42	78.33	98.61	89.47
Gauteng	Tshwane	0.35	0.22	0.29	0.00	94.44	96.05	93.18	93.9
Limpopo	Vhembe	-	-	-	-	68.13	73.08	80.56	48.28
Mpumalanga	Gert Sibande	0.32	0.54	0.18	0.29	84.57	91.49	68.75	98.04
North West	Dr Kenneth Kaunda	1.49	2.27	0.00	2.01	97.18	97.92	95.56	98.04
Western Cape	Eden	0.84	1.91	0.17	0.10	100.00	100.00	100.00	100.00

\* Inventory system: 1=Computer, 2=Manual ledger, 3=Bin card;\*\* includes TB, ARV and surgical item tracer products K1 % of time out of stock, K2 % available in store on shelf

K1 indicator: Average percentage of time out of stock for a set of TB tracer commodities in TB facilities:

K2 indicators: Average Percentage of a set of Tracer TB and ARV Commodities available in TB Facilities and Medical Stores. An item is considered to be available if even one unexpired item is in stock.

**Average percentage of time out of stock**

On average, the percentage of time out of stock over the historical period September 2011 to August 2012 was not a significant in the provinces assessed. The province with the most **stock outs** was Eastern Cape at 2.84% of the time and the province with the lowest average stock out was Mpumalanga with 0.32%. As noted before the Mthatha depot strike occurred over the assessment period and has negatively impacted the Eastern Cape scores, however if we exclude the days that the depot was unable to deliver for we still see a stock unavailability of 2.18%. This means that there was poor availability at the facilities prior to the supply running out from the depot. Contextualizing the extent of the problem is the last page of the dues out report sent to Zithulele Hospitals in the OR Tambo district of the Eastern Cape shoing that 164 items with total dues out of over 271 000 units outstanding (figure 34 below).

**Figure 34 - Zithulele hospitals eastern Cape Dues out report from Mthatha Depot**

900500 ZITHULELE HOSPITAL		DATE	SID	OPEN BALANCE	RECEIPTS IN TRANSIT	RECEIPTS IN SUSPENCE	DUES IN TOTAL	DUES OUT TOTAL		
N	DESCRIPTION									
9714836	SELENIUM SULPHIDE SHAMPOO APPLICATION 2.5%; 50ML	22/11/2012	1.00 EA	0	0	0	300	36		
9714845	CHLORHEXIDINE GLUCONATE 0.5% IN ALCOHOL 70%; HAND DISINFECTANT; 5L	16/08/2012	5.00 LR	12	0	0	1100	11		
9714845	CHLORHEXIDINE GLUCONATE 0.5% IN ALCOHOL 70%; HAND DISINFECTANT; 5L	09/11/2012	5.00 LR	12	0	0	1100	16		
9714965	AMOXICYLLIN AND CLAVULANIC ACID TABLETS 250MG AND 125MG; 15'S	22/11/2012	15.00 TT	0	0	0	2000	400		
9715110	AQUEOUS CREAM BP,WIDE MOUTH; 500G	22/11/2012	500.00 GM	0	4004	0	5304	220		
9715489	SALBUTAMOL INHALANT SOLUTION; 5MG/ML; 20ML	22/11/2012	20.00 ML	1	1800	0	2800	40		
9716026	APRON;PLASTIC;SMOOTH;FULL BODIED;SINGLE USE;WHITE;1100MM	22/11/2012	1.00 EA	0	0	0	220000	2000		
9717360	BLADE,SCALPEL,SURGICAL,STERILE; SIZE 24; 100'S	22/11/2012	100.00 EA	0	0	0	550	16		
9750564	METOCLOPRAMIDE HYDROCHLORIDE TABLETS 10MG;500'S	22/11/2012	500.00 TT	0	0	0	1000	10		
9752693	METHOTREXATE TABLETS2,5MG;100'S	09/11/2012	100.00 TT	0	0	0	100	8		
9753433	PARACETAMOL TABLETS 500MG; 500'S	02/08/2012	500.00 TT	0	0	0	5000	40		
9753433	PARACETAMOL TABLETS 500MG; 500'S	09/11/2012	500.00 TT	0	0	0	5000	40		
9753533	FERROUS SULPHATE COMPOUND TABLETS SUGAR COATED;1000'S	19/07/2012	1000.00 TT	0	0	0	1681	3		
9753533	FERROUS SULPHATE COMPOUND TABLETS SUGAR COATED;1000'S	09/11/2012	1000.00 TT	0	0	0	1681	8		
9754592	BOTTLE, SCREW CAP CLEAR PVC;ROUND;500ML	22/11/2012	1.00	0	0	0	0	100		
<b>GRAND TOTAL</b>							<b>214573</b>	<b>41715</b>	<b>2713206</b>	<b>40676</b>

oms with Dues Out : 164

The stock unavailability days also shows that on average the stock out in TB medicine was higher than for ARV medicine across all provinces except Gauteng. This shows that the enhanced emphasis on HIV treatment and care through nationally driven campaigns is improving the management of ARV medicines at facility level. This should be highlighted and encouraged for more programs to follow suit.

The impact of the INH countrywide suppliers shortage can be seen in figure xx below when the days out of stock of the TB medicines is performed with the INH excluded. Although staff report the INH shortage as impacting on patient care it only contiributed a small percentage to the total TB medicine unavailability. On average the percentage of time stock unavailability of TB medicines increases from 2.2% to 2.3% when INH is excluded which implies that other TB medicines were contributing more to the overall TB medicine unavailability figures. The greatest impact was experienced in the district hospitals where the percentage of days stock unavailable worsens from 3% to 3.7% when INH is excluded.

The TB medicines that contribute to this worsening of stock availability days are (in order of most days out of stock in table 3):

Table 3 – TB medicines contributing to the most days out of stock

TB medicines contributing the most to days out of stock	Total number of days out of stock (across all facilities assessed)	Where was stock out mostly experienced
RHZ	540	PHC
PZA 500mg	430	
Rifampicin	293	
Ethambutol	268	DH
Streptomycin 1 mg	254	PHC

In terms of where these TB medicines were out of stock, the PHC's followed by the district hospitals and CHC's have the highest frequency of stock outs.

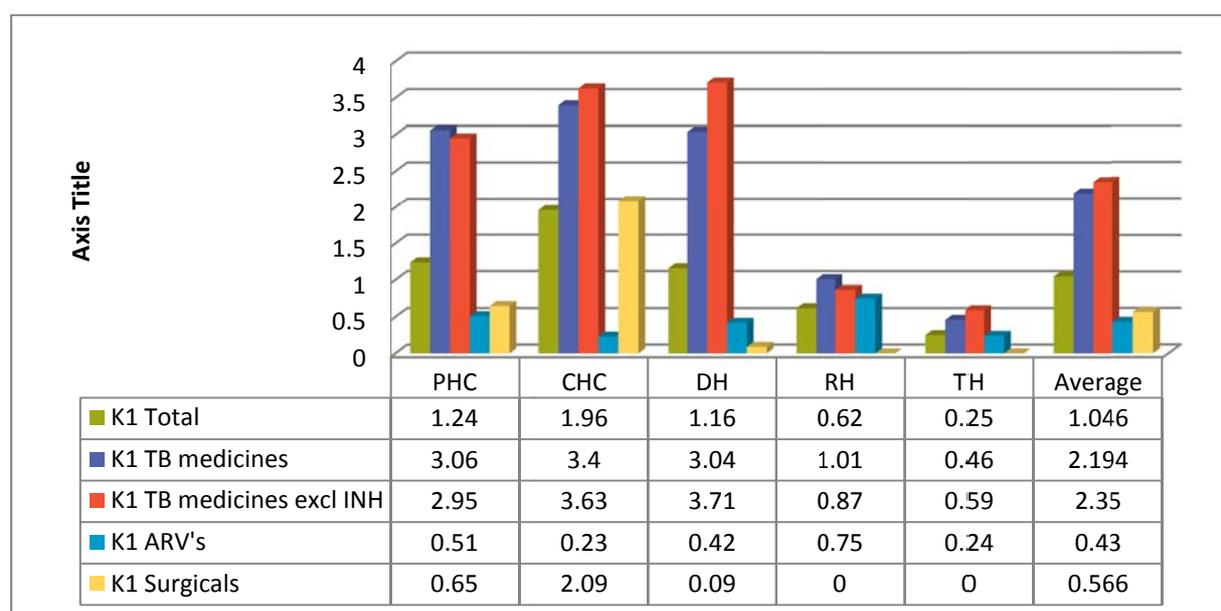
For ARV;s the drugs contributing to the most number of days out of stock were Efavirenz 600mg, Tenofovir And Stavudine.

Please refer to the provincial reports for detailed which are discussed.

The average time out of stock was also assessed by facility type across provinces (figure 35). This highlights two important issues:

- Days out of stock is on average a larger problem in facilities part of district health system i.e. clinics, CHC's and district hospitals.
- Stock out in TB medicine is on average more than for ARV medicine and surgical supplies

Figure 35: Average time out of stock for TB and ARV tracer list by facility type for period September 2011 to August 2012



***Assessment of availability on day of assessment***

Assessing the availability of commodities on the day of assessment using the same list of tracer items we see availability ranged from 48% in Limpopo province to 100% in Western Cape. An item is considered available if one unexpired item is in stock. Surgical supplies surprisingly were found not to be a problem except in Limpopo province where the availability of surgical supplies is very poor. And as with the availability days TB medicine on average are less available than ARV medicine.

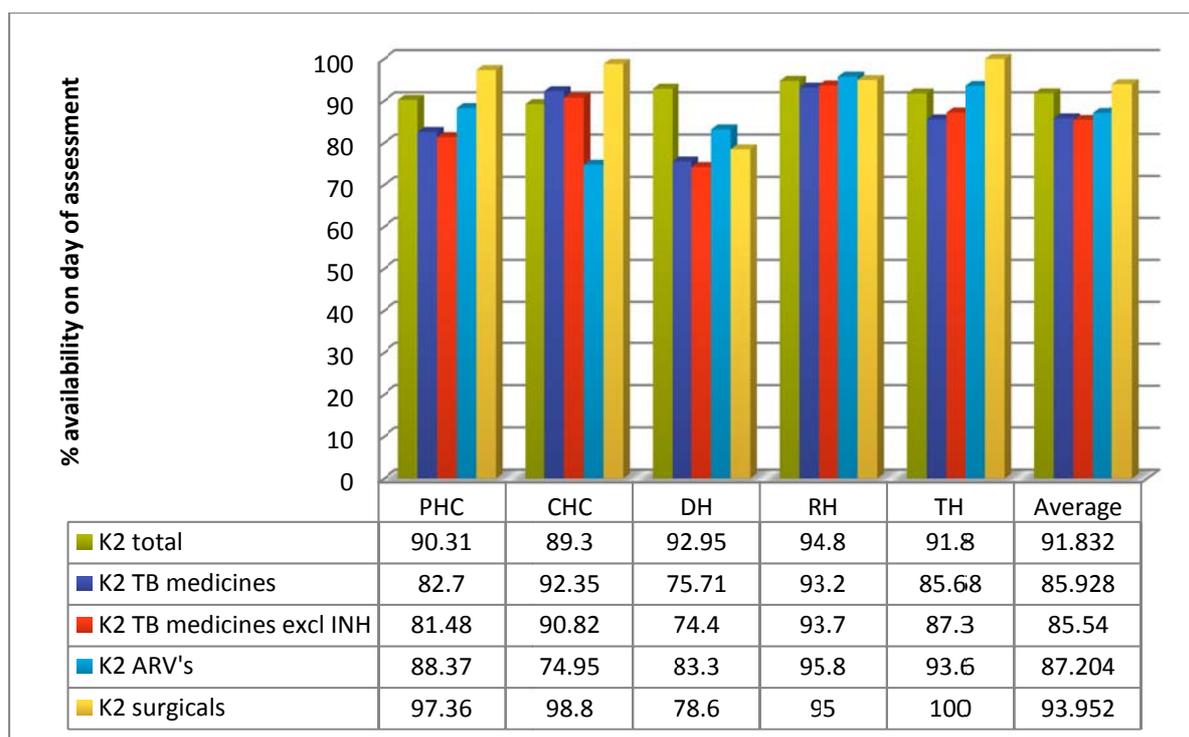
Figure 36 below highlights that consistent with the stock outs the most problems with availability seem to be experienced in clinics and district hospitals who have the lowest availability scores. Availability was on average lower for TB medicine than for ARV's although there appear to be lower availability of ARV's in CHC's.

The TB drugs that were mostly unavailable were:

- RH 150/75mg
- RH 300/15mg
- RHZE
- RHZ
- Rifampicin
- Ethambutol
- INH 100 and 300 mg

This would impact severely on the ability of staff to provide the correct treatment for both the intensive and continuation phases.

**Figure 36: Average availability of Commodities in tracer list on day of assessment by type of facility**



### Stock and physical count correspondence

To estimate this a physical count was done of a few selected TB and ARV tracer drugs and then compared to the adjusted record count as indicated either in the electronic or the stock card record system. Table 4 below indicates the total number of units of medication that did not correspond when a physical count was conducted as well as the average percentage of stock items that did not correspond to record count during stock take.

Table 4 –Sample of TB medicines and ARV's on which stock counts were performed

TB medicines	ARV's
Rifampicin 150 mg/isoniazid 75 mg/pyrazinamide 400 mg/ethambutol 275 mg tablet (RHZE)	Efavirenz 600mg tablets
Ethambutol 400 mg tablet (E)	Lamivudine 150mg or 300mg capsules/tablets
Streptomycin 1 g/3 ml vial (S) injection	Tenofovir 300mg tablets
Streptomycin 5 g/15 ml vial (S) injection	
<b>Drug resistant TB medicines</b>	
Kanamycin 1g/3ml vial injection (K)	
Moxifloxacin 400mg (M)	

Stock control activities is lacking in most provinces (Table 5). The province with most records corresponding with physical counts was Eastern Cape with 76%. It must however be noted that only 5 facilities were included here due to the fact that no recordkeeping at all was done in one facility and was thus possible to assess. It is suggested that the 76% correspondence found is not an accurate reflection of practices in Eastern Cape. The province with the most units unaccounted for was Gauteng with 3133 medicine units being unaccounted for mainly too much stock.

**Table 5 – Average % of stock records that correspond with physical count (C7) and absolute discrepancies by specific drugs and facilities**

Province	District	C7 indicator (%)*	Total units not corresponding
Free State	Thaba Mofutsanyane	68.42	1413
Gauteng	Tshwane	70.59	3133
Eastern Cape	OR Tambo	76.67	1065*
Mpumalanga	Gert Sibande	71.43	999
North West	Dr Kenneth Kaunda	46.88	577
Western Cape	Eden	72.73	107

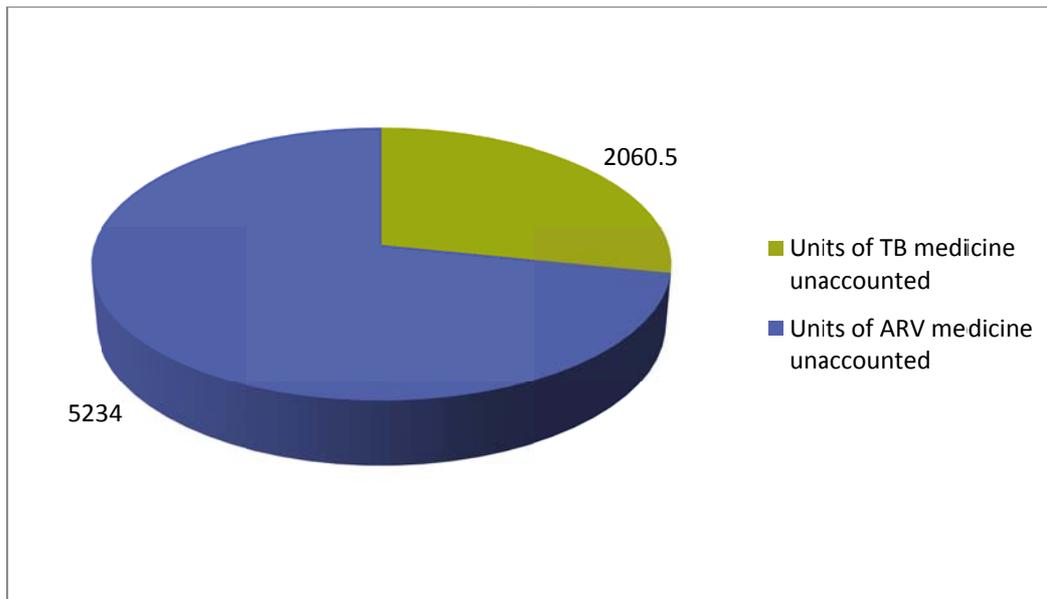
\*only 5 facilities

\*C7: Average percentage of stock records that correspond with physical counts for selected medicines storage facilities  
 Differences:  
 - Negative value indicates missing units  
 - Positive value indicates more units on shelves than in record

It was clear during the assessment that stock control of ARV medicine are worse than for TB medicine with more than double the units unaccounted for as highlighted in the figure below. (See table above for the medicine that was assessed.) It must be noted that larger quantities of ARV medicine than TB medicine must be managed in most facilities possibly contributing to this observation.

In the majority of facilities the stock record over reported the amount of ARV stock implying there were too few units based on the records. It could be that either the stock has been lost or pilfered or that inaccurate record keeping and the high volume movement of these drugs means that staff are unable to keep records up to date. This does need to be investigated further as we know that there is a big black market for ARV's.

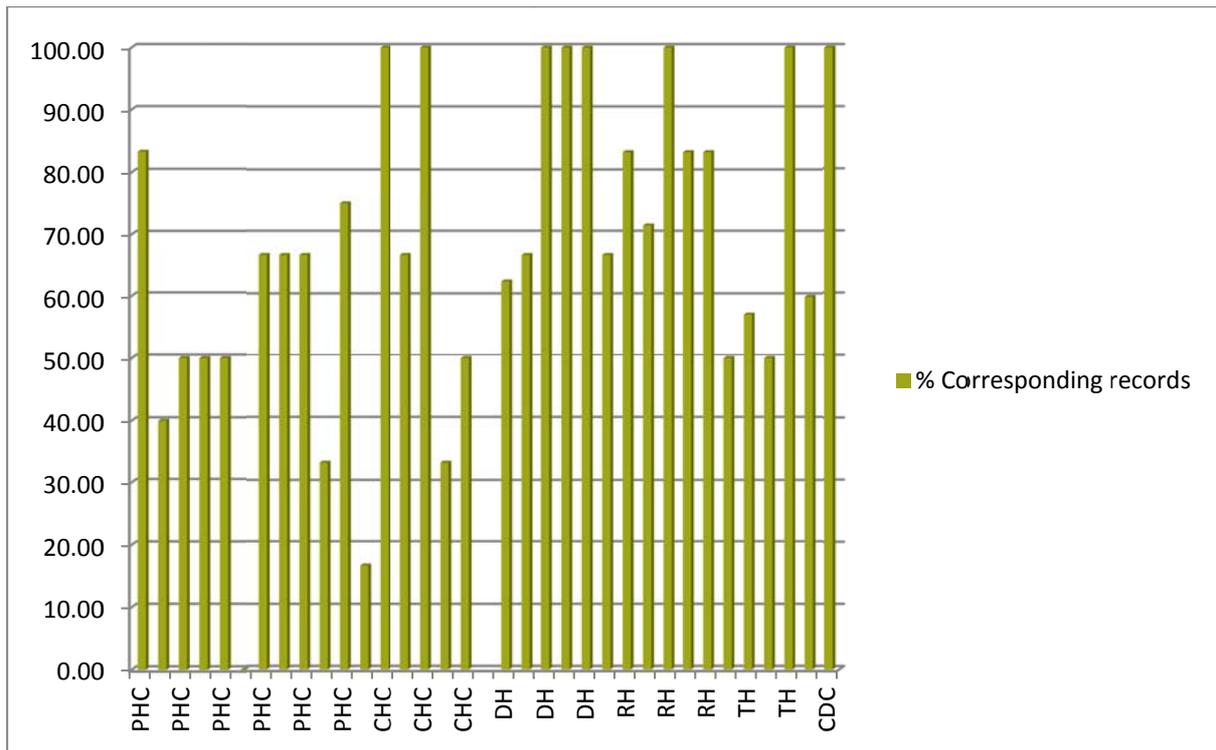
**Figure 37: Units of medicine unaccounted for TB medicine and ARV medicine**



Stock control at smaller facilities such as PHC's and CHC's is not performed as well as that are the larger facilities (see figure 38 below). This is due to the lack of pharmaceutical professional staff support at these facilities resulting in a reliance on nurses, already stretched with clinical care obligations, to add additional tasks of stock management, ordering and drug availability reporting to their busy days. The hospitals are better resourced and the pharmacies run by qualified pharmacists skilled and competent mostly in performing this task.

In provinces with limited pharmaceutical staff innovative rotational systems are being tested, which provide much needed stock management support to clinic staff and have improved instances of oversupply and hoarding of medicines as occurs when staff don't understand the supply chain ordering principles.

Figure 38: Percentage correspondence of records by facility type



### **C. Patient Records Review for TB treatment**

Patient TB files were randomly selected to assess for the estimation of the K3 indicators measuring compliance with the National Treatment Guidelines (NTG's). Fifteen files per facility were assessed with a few extra files in the smaller facilities with the higher load of TB to accommodate the lack of patients in the district and regional hospital.

**Correctness was assessed for both type of drugs used as prescribed in the national guidelines and the strength of the drugs prescribed according to weight and as per the national guidelines.**

#### *Compliance with Standard Treatment Guidelines and TB protocols*

Recent changes to TB treatment protocol as described in the EDL book (yellow for hospitals) for 2012 have not reached the facilities yet so most staff are using the older EDL version. In addition the National TB Treatment Guidelines appear to be filed away and no reference materials is available at the desk where prescribing is occurring to ensure compliance with the protocols. Some of the changes were as follows:

- Regimens 1 and 2 or Pulmonary TB (PTB) and retreatment PTB are based on the patient's weight. Drug dosages are adjusted for increasing weight;
- The same applies to the paediatric guidelines which are in the process of being updated again due to the lack of a suitable paediatric drug formulation in the country.
- Drug resistance TB has new second line agents available in the country for treatment
- Regimen 2 is being phased out with the roll out of GeneXpert machines

**Summary of TB treatment guidelines used to determine compliance are provided for in Annexure B.**

#### *Results of record review.*

The table 5 below highlights the results found during the record review in the 6 provinces.

- A total of 768 patient TB files were reviewed.
- On average only 67.97% of records were deemed correct according to the National treatment guidelines.
- The intensive phase records were on average more correct than the continuation phase records with 74% and 69% respectively.
- Compliance therefore decreases from intensive to continuation phase with seemingly very poor compliance for MDR patients (figure 39).

Figure 39: Compliance with NTG's in districts assessed by regimen and phase of treatment

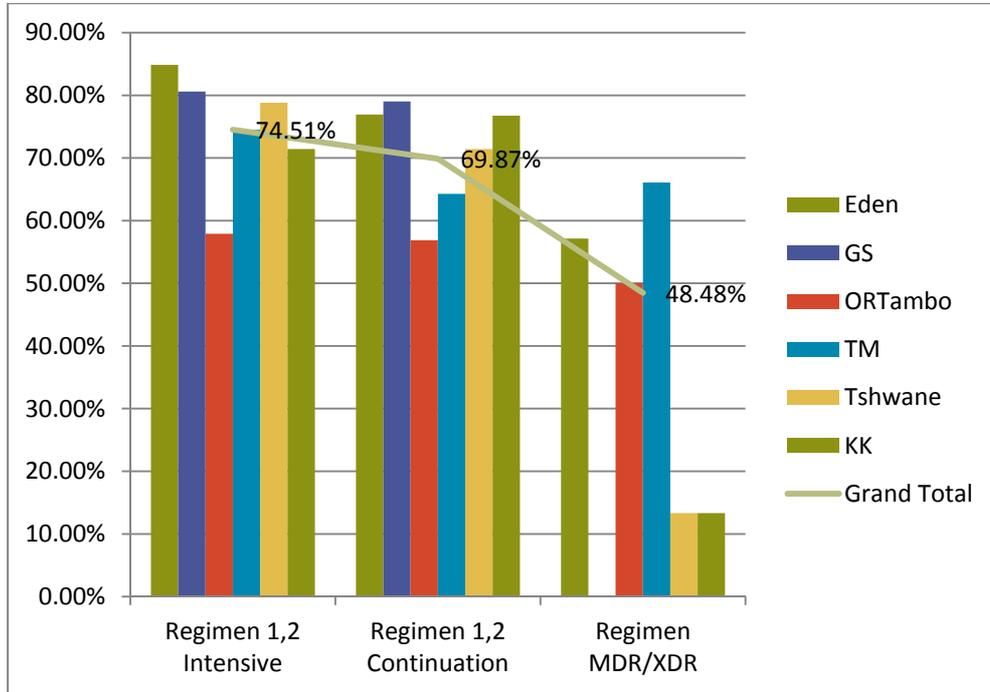


Table 5 - Patient record review results in 6 provinces

	% SM+ prescribed correct medicines			% SM+ prescribed correct medicines - initiation phase			% SM+ prescribed correct medicines - continuation			% SM+ prescribed correct medicines - DR TB		
	Nr of records total	Nr of all records correct	K3 (%)	Nr records int* phase	Nr correct int* phase	K3 A (%)	Nr records cont** phase	Nr correct cont** phase	K3 B (%)	Nr records DR# TB	Nr correct DR# TB	K3 C (%)
Free State	168	113	67.26	51	38	74.51	56	36	64.29	56	37	66.07
Gauteng	114	79	69.30	85	67	78.82	14	10	71.43	15	2	13.33
Eastern Cape	140	76	54.29	76	44	57.89	51	29	56.86	6	3	50.00
Mpumalanga	137	104	75.91	67	54	80.60	62	49	79.03	-	-	
North West	122	80	65.57	63	45	73.43	43	33	76.74	15	2	13.33
Western Cape	87	70	80.46	66	56	84.85	13	10	76.92	7	4	57.14
<b>National</b>	<b>768</b>	<b>522</b>	<b>67.97</b>	<b>408</b>	<b>304</b>	<b>74.51</b>	<b>167</b>	<b>239</b>	<b>69.87</b>	<b>99</b>	<b>48</b>	<b>48.48</b>

\*Intensive phase, \*\*Continuation phase, #Drug resistant pulmonary TB

Table 6 – Indicators description for patient records review

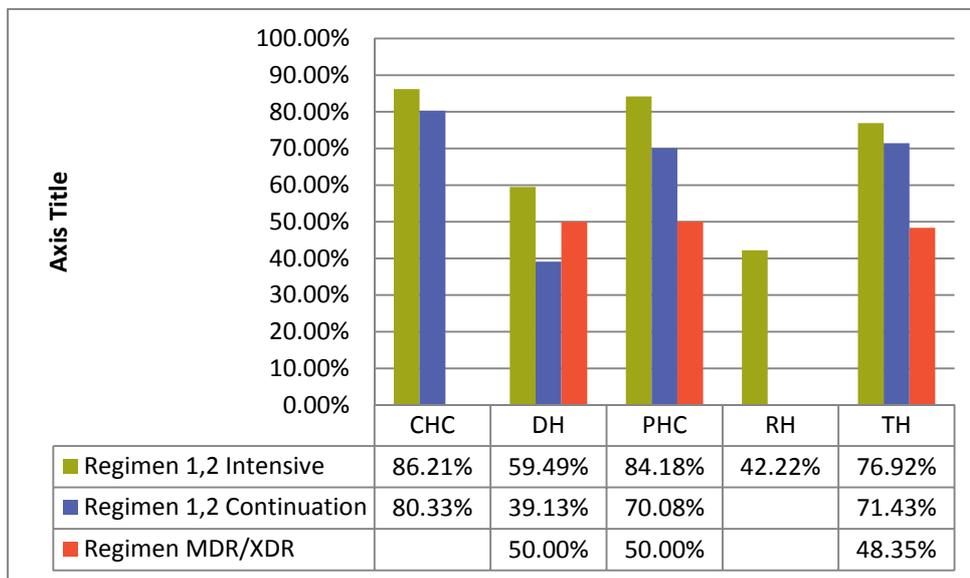
K3 A indicator: Percentage of smear-positive patients with **pulmonary TB** who were prescribed correct medicine in conformity with the South African National Department of Health standard treatment guidelines for the **intensive phase**.

K3B indicator: : Percentage of smear-positive patients with **pulmonary TB** who were prescribed correct medicine in conformity with the South African National Department of Health standard treatment guidelines for the **continuation phase**.

K3C indicator: Percentage of **drug resistant smear-positive patients** who were prescribed correct medicine in conformity with the South African National Department of Health standard treatment guidelines for **MDR and XDR TB** during the **intensive/injectable phase** and the **continuation phase**.

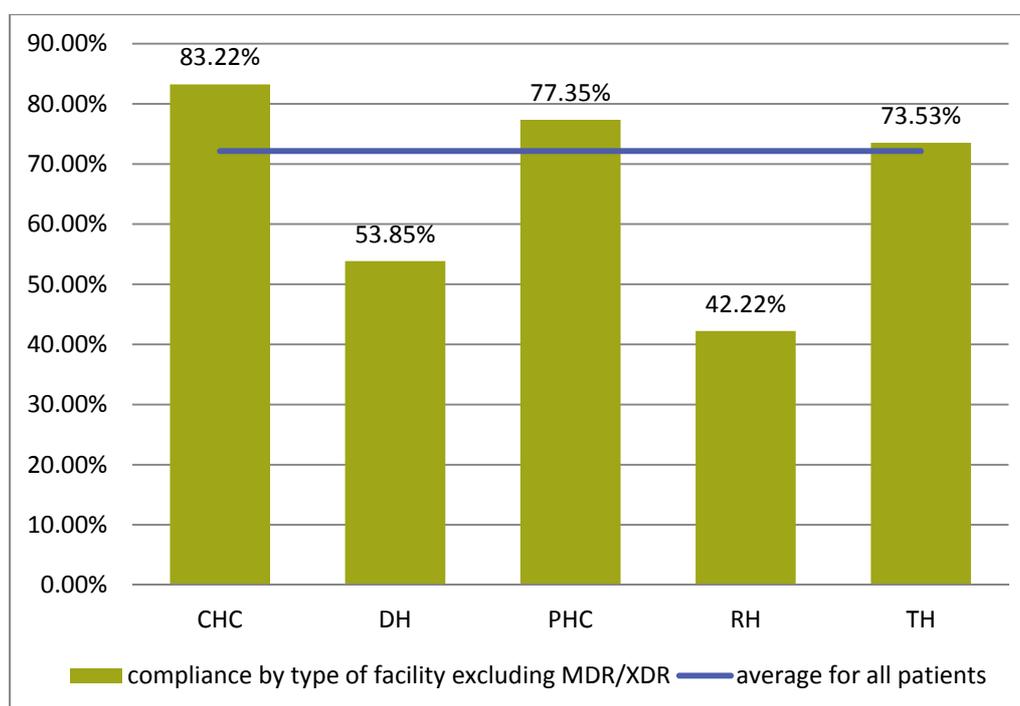
- The most common reason found was that weights and other important information to classify the patient and determine the correct regime were not recorded. The second most common reason were dose error, either to low or too high for weight of patients.
- Recordkeeping was found to be a concern across most of the facilities assessed and at least a few patients had incomplete records to some extent.
- Comparison of compliance in different phases of treatment and regimes by type of facility (figure 40) shows that PHC facilities as well as CHC's do relatively well with around 85% compliance for the intensive phase of treatment. The continuation phase shows poorer compliance across all facilities and is especially poor within the district hospitals

Figure 40: Compliance to NTG's for different regimes and phases of treatment by type of facility



- When non drug resistant TB patients are assessed it transpires that CHC's are most compliant with NTG's followed by PHC's (see figure 41). The hospital's fare rather poorly considering that treatment is doctor prescribed and driven. It must be acknowledged that patients admitted in hospital are more complicated and need more individualized care. However the reasons for deviating from guidelines in terms of drugs or dose could not be ascertained from the records. Extreme deviations like double dose of Moxifloxacin (800mg) prescribed were found with no explanations.
- Recordkeeping was also found to be a concern in the hospitals as in the PHC's and CHC's with a number of records not containing weights and other information.

Figure 41: Compliance by type of facilities for regimen 1 and 2 patients, excluding MDR/XDR patients



- The MDR records were the least accurate when compared to the National treatment guidelines for MDR and XDR with only 48% of records considered correct. Recordkeeping was also a problem in these records with weights not recorded. There were huge variation between provinces in terms of drugs and dosages prescribed. Examples of specific case studies are provided in the provincial reports. See table 7 below for description of some of the regimes found to be prescribed in the provinces. The regime that was most different from the National guidelines was in North West province where a number of patients classified as having MDRTB were prescribed RHZE, Moxifloxacin, Kanamycin and Ethionamide. The reason why a patient classified as resistant against rifampicin and INH would be described these drugs could not be ascertained from the records.

Table 7: MDR regimes prescribed for some patients in the provinces assessed

Province	MDR regimen prescribed
Free State	STG with substitutions: <ul style="list-style-type: none"> <li>• Kanamycin or Amikacin</li> <li>• Moxifloxacin or Ofloxacin</li> </ul>
Western Cape	<ul style="list-style-type: none"> <li>• Kanamycin/Capreomycin,</li> <li>• Ethionamide</li> <li>• Ethambutol/Terizidone</li> </ul>

<b>Province</b>	<b>MDR regimen prescribed</b>
	<ul style="list-style-type: none"><li>• MoxifloxacinT</li><li>• PZA</li></ul>
<b>Eastern Cape</b>	STG
<b>North West</b>	<ul style="list-style-type: none"><li>• RHZE</li><li>• Moxifloxacin</li><li>• Kanamycin</li><li>• Ethionamide</li></ul>
<b>Gauteng</b>	STG

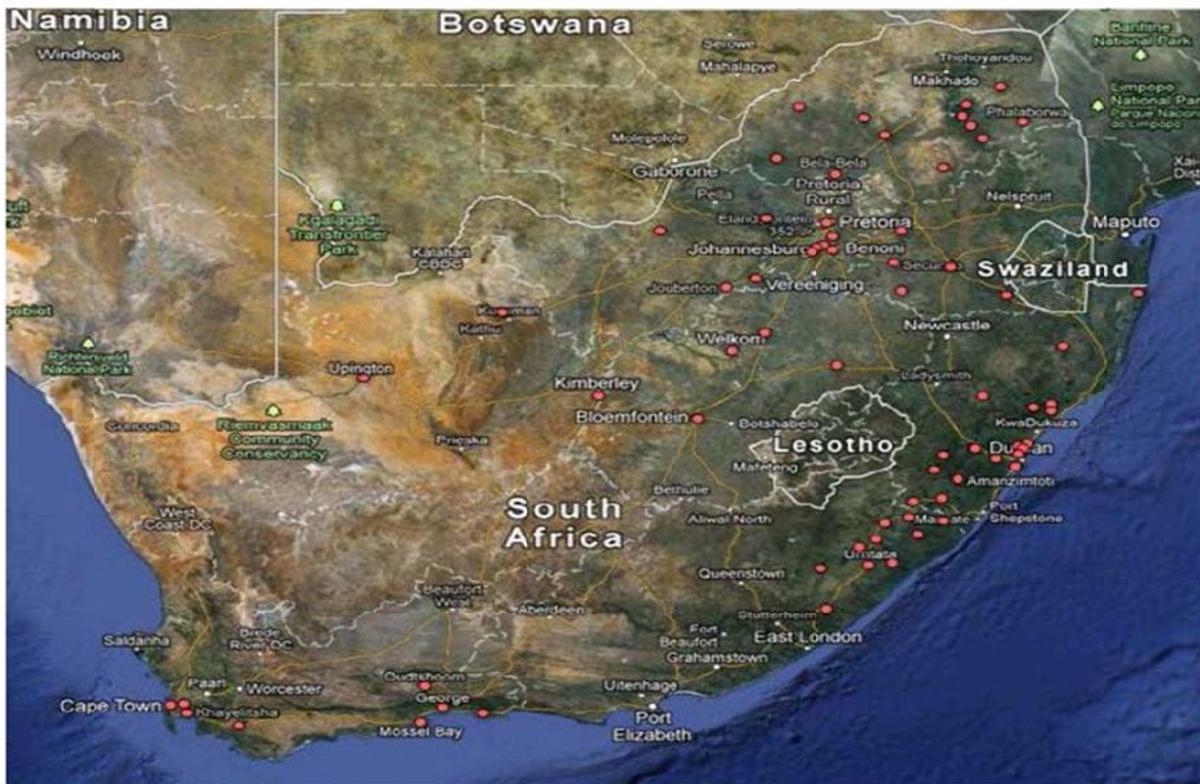
In summary: Compliance with NTG's is surprisingly poor considering the simplicity of the regimes. Many patients were found not being weighed or with the weights not recorded. Doses according to weight bands were often incorrect. Recordkeeping was not found to the standard to be expected. The need for proper recordkeeping and careful prescribing must be reinforced. The deviations from MDR guidelines warrant further investigation as a risk exists that we are perpetuating more drug resistance in the future through non compliance with guidelines.

#### D. GeneXpert machine and testing for resistance

The GeneXpert machines will dramatically change the way patients with retreatment TB are medicated. The GenXpert allows the diagnosis of resistant TB to be made within 2 hours within the laboratory and 24- 48 hours later the results are made available to the facility. National Health Laboratory Services (NHLS) is in charge of the procurement and roll out of the machines to 143 laboratories in the country to date. These machines vary in size and capacity to test samples with the larger labs getting machines with a capacity for 192 test per 8 hour day.

**Figure 42 – GeneXpert machine placements across SA**

**Figure 1: Current GeneXpert Placement (72 testing centers, 104 analysers, Gx4: 49; Gx16: 54; GX48:1) \*20 clinic placements**



The plan is not to make the machines available at point of care, as many TB staff and pharmacists believe in the provinces, but to make it available in the most cost effective manner. This includes taking into account the existing infrastructure of laboratories and staff who have been trained to use the equipment.

Utilising the existing laboratory infrastructure also allows the NHLS to link each GeneXpert machine to their Laboratory Information System (LIS) which links to a centralised datawarehouse repository of all lab results. Functionality within the data warehouse allows for reports to be generated of the number of sputums tested, the positive results and the resistance proportions by district, sub district, lab and facility.

Challenges with the use of the machine expressed by the NHLS staff are:

- The courier system to collect sputums from clinics. These collect in the morning and deliver to the lab by afternoon resulting in specimens only being tested from the next day resulting in more than 48 hours delay in results;
- SMS printers are available in 1900 sites to which the results are sent back. However, as clinic patients don't have a clinic number or unique identifier the results need to be linked to a lab number generated by the NHLS lab and the staff then need to link this back to a patient. Patients names are printed on the results assisting with this process, however we are concerned about incorrect linkage to patient is more than one patients with the same name attends that clinic;

Challenges expressed during our visits by the facility staff includes:

- Unavailability of cartridges during August and October 2012 resulting in a backlog of results;
- Loss of critical staff in some labs who know how to operate the machines. Left over staff unable to perform the tests due to lack of training;
- Administrative backlogs with samples sitting in fridges for days until the only lab technician has time to log them into the system and then process;
- Poor communication of the new protocol for retreatment testing with GeneXpert in the Eastern Cape mainly.

The North West province TB manager indicated that she would like to use the results of the GeneXpert for quantification for the next tender. When we discuss this with NHLS they indicated that correctly the information was really valuable for quantification however with some constraints as the unique number of tests was difficult to assess (i.e. some patients can be tested more than once reflected increased volume).

The NHLS currently reports quarterly to the national TB, HIV meeting where TB and HIV managers from provinces are represented. These reports are available on their website.

Figure 43 GeneXpert results June July 2012 – Source NHLS website



Table 1: GeneXpert MTB Results by province

Province	MTB Detected	MTB Not Detected	Test Unsuccessful	Grand Total	% MTB Detected
Eastern Cape	9,334	47,579	1,985	58,898	15.85
Free State	8,035	47,870	158	56,063	14.33
Gauteng	6,857	46,326	1,049	54,232	12.64
Kwa-Zulu Natal	24,287	103,732	3,937	131,956	18.41
Limpopo	3,430	28,955	398	32,783	10.46
Mpumalanga	4,340	22,252	1,659	28,251	15.36
North West	4,525	23,726	1,427	29,678	15.25
Northern Cape	4,906	25,709	833	31,448	15.60
Western Cape	8,246	41,037	142	49,425	16.68
<b>Grand Total</b>	<b>73,960</b>	<b>387,186</b>	<b>11,588</b>	<b>472,734</b>	<b>15.65</b>

Table 2: Provincial GeneXpert RIF Results in MTB detected cases

Province	Inconclusive	Resistant	Sensitive	No Result	Grand Total	% RIF Resistant
Eastern Cape	122	687	8,409	116	9,334	7.36
Free State	105	452	7,453	25	8,035	5.63
Gauteng	70	457	6,320	10	6,857	6.66
Kwa-Zulu Natal	354	1,914	21,632	387	24,287	7.88
Limpopo	54	254	3,093	29	3,430	7.41
Mpumalanga	64	363	3,835	78	4,340	8.36
North West	62	375	4,079	9	4,525	8.29
Northern Cape	60	304	4,514	28	4,906	6.20
Western Cape	90	387	7,765	4	8,246	4.69
<b>Grand Total</b>	<b>981</b>	<b>5,193</b>	<b>67,100</b>	<b>686</b>	<b>73,960</b>	<b>7.02</b>

These reports are also available on a weekly basis for the TB coordinators if they require them. We have however not encountered one TB coordinator who is making use of these very valuable reports to help contact trace, follow up and monitor progress of patients.

NHLS also indicated that by next year they will be able to generate reports by facility with the individual test results on them to improve monitoring and follow up at clinic level.

### **E. Patient interviews**

Patient compliance and adherence to prescribed treatment are an essential component for successful patient outcomes. An indicator to assess patient education with relation to the treatment that they are taking for TB has thus been included. Patients that can correctly describe the following are considered to be well educated:

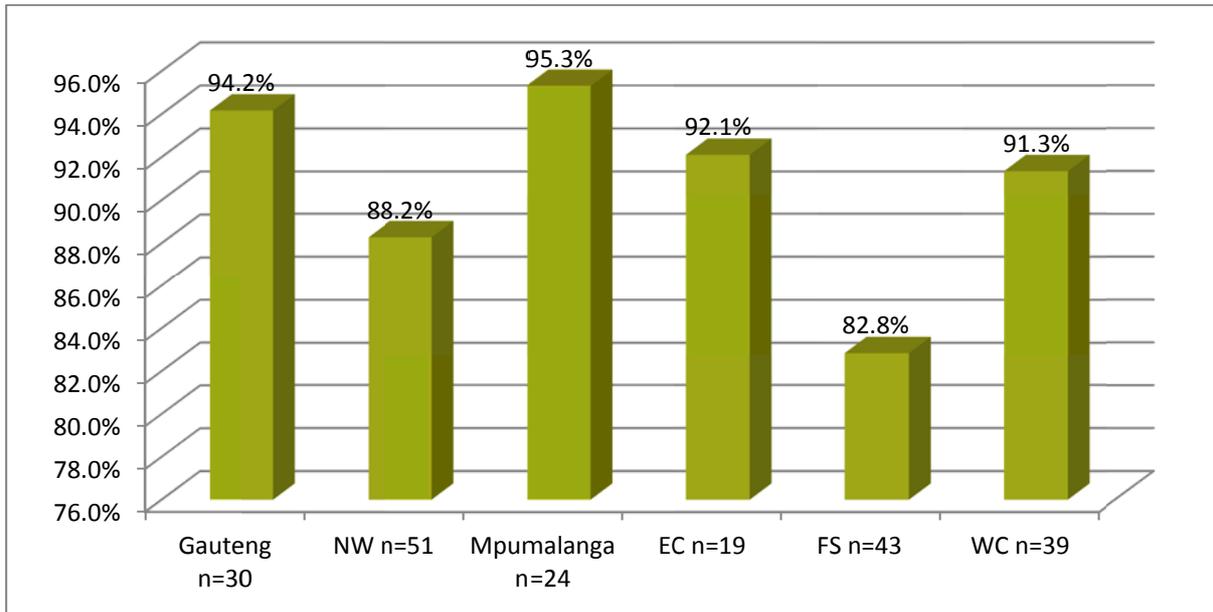
- What medicine to take (name, color, or other marker of a pharmaceutical product)
- How many tablets of each to take
- How many times a day/week to take them
- Total length of treatment
- Potential sign of adverse reactions such as unusual skin rash and what to do about them
- Consequences of not taking the prescribed medicine

#### ***Results of patient interviews***

It was attempted to interview 15 patients per facility. However this was not attained in most provinces. Patients seem to attend the clinics only in the mornings and in limited numbers. Access to clinics due to transport cost is a possible explanation as well as community DOT. It must be noted though that most facilities indicated limited access to TB tracers and community health workers to render the appropriate community support leading to the assumption that many patients have to accept responsibility for their own treatment with seemingly little support from the health care sector.

- Only 206 patients were interviewed as opposed to the 768 records reviewed.
- Either nine percent (89%) of patients were able to answer all questions as described above.
- Figure 44 below provides the percentage of patients who could correctly describe how prescribed medication should be used per province. Patients in Gauteng, Mpumalanga, Eastern Cape and Western Cape were seemingly the best educated with over 91% able to answer all the questions regarding treatment regime. Eastern cape data is only for 19 patients and must be taken with some caution.

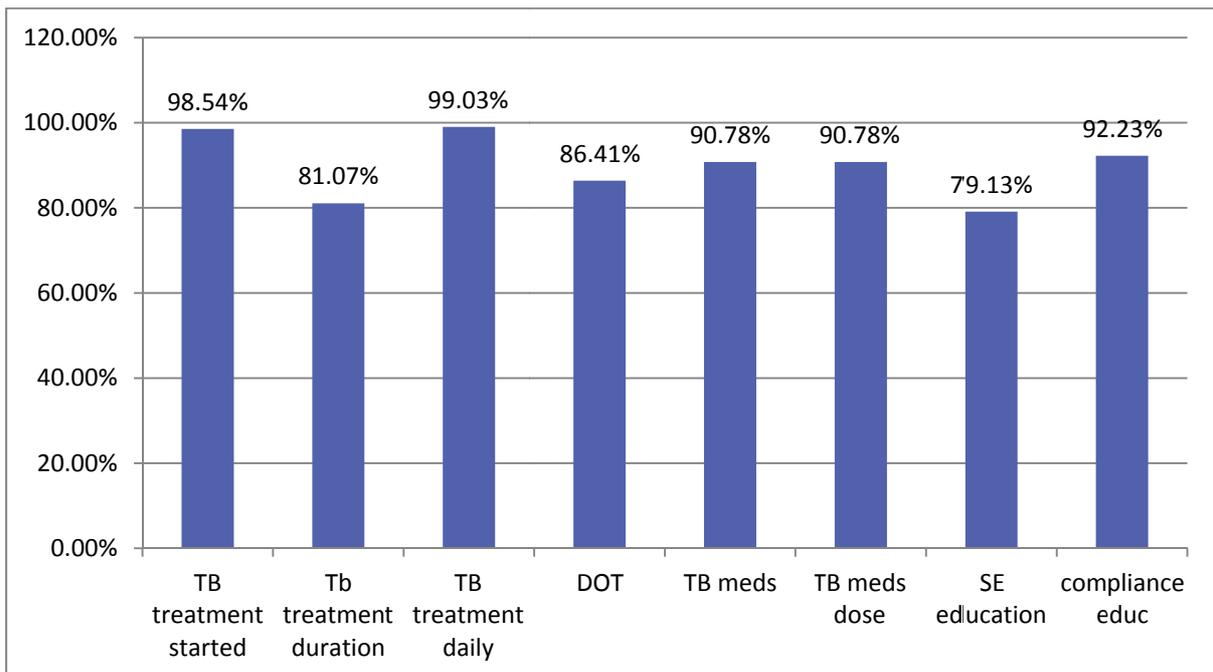
Figure 44 - Percentage of TB patients who could correctly describe how the prescribed medication should be used



C5: Percentage of TB patients who could correctly describe how the prescribed medication should be used

Figure 45 below highlights the percentage of patients that correctly answered specific questions. The question least patients could answer was regarding side effects and the management thereof with only 79% correctly answering.

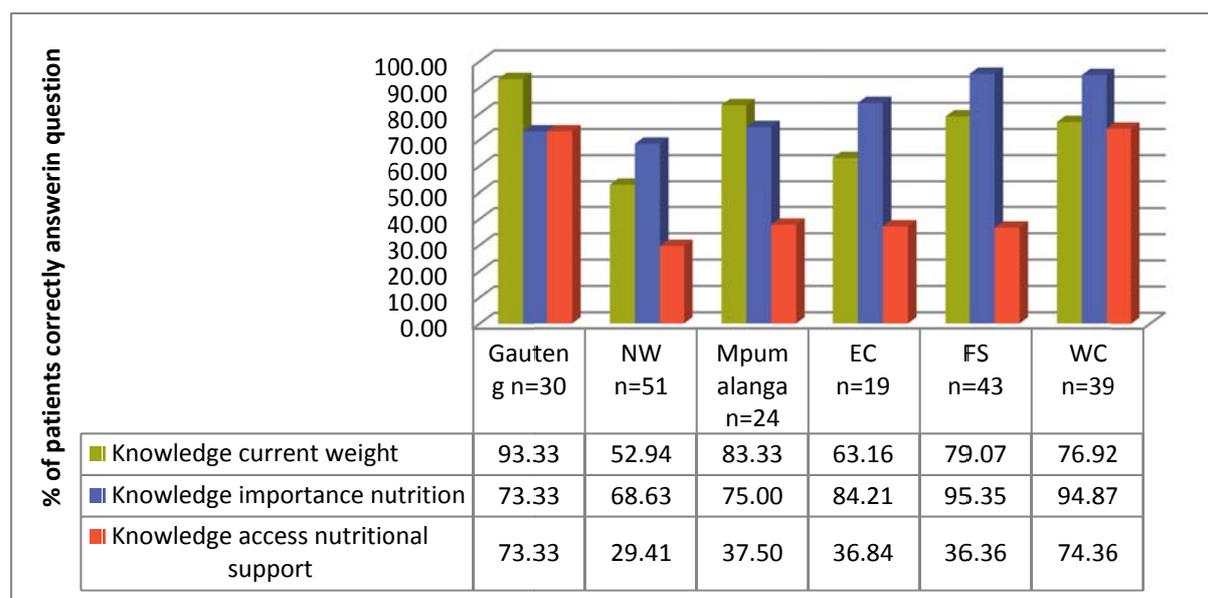
Figure 45: Percentage patients that correctly answered questions



### Nutrition education

Additional questions regarding nutrition of patients were asked namely if they know what their current weight is, that nutrition is important and how to access the nutrition support program. Figure 46 highlights the answers by province. Knowledge of weight in North West and Eastern Cape provinces are poor with only 52% and 63% of patients being able to answer respectively. This corresponds with the findings during record review. Very few patients with the exception of Gauteng and Western Cape knew where to access nutritional supplements.

Figure 46 – Nutrition education results



### Patients payment for TB services

Patients were also asked if they have to pay for their TB treatment. No patient indicated that they have to pay except one patient in the North West hospitalized with MDR indicating that an invoice was sent to his medical aid.

### Access of care

Most patients access care by walking to facilities. In some rural areas patients have to pay up to R50 to travel to the clinic. Taxi costs of R6 to R20 were mentioned regularly. It becomes very difficult for low income patients to access care and daily DOT at the clinic is not feasible. Community DOT in line with the re-engineering of PHC needs to be strengthened. Unfortunately many facilities indicated a disconnect with the community health worker program. One comment was made that staff cannot follow up patients because the re-engineering of PHC took all their CHW's away.

#### **F. TB referral system and data integrity**

A few important issues were identified during the interviews with staff in terms of continuity of care and data integrity.

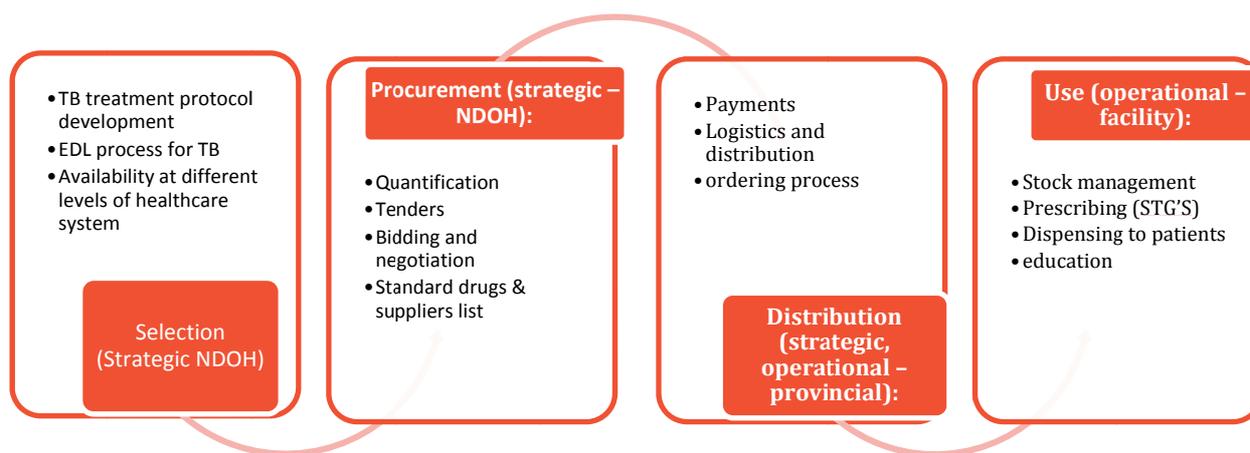
- Continuity of care in most provinces needs urgent attention. Referral policies do not include the follow up of patients after referral or discharge. Facilities depend on patients presenting themselves at the relevant facility with the documentation. Better communication between facilities and between facilities and communities are needed. The sub-district HAST coordinators are ideally suited to fill this gap. Review of the current role of these coordinators is needed.
- Information generated at facilities is not used after feedback in the form of indicators to improve care. Very few facilities indicated that this is done. Feedback is also not provided consistently to facilities. Performance management using the indicators of facilities would assist in improving services and patient outcomes.



## CHALLENGES IN TB PHARMACEUTICAL MANAGEMENT

There are substantial challenges to delivering good quality services within the pharmaceutical management of TB which do need to be highlighted. The framework we will use is the supply chain process from selection, procurement and distribution to use at facility (figure 32).

**Figure 47 - Supply Chain process steps**



### A. Selection

There are numerous delays in the registration process for TB medicines in the past although there is a “fast track” process designed to speed this up. Some challenges are due to resource constraints on the part of the MCC, however poor quality documentation and data from suppliers also results in unnecessary delays in registration.

Good governance processes are followed for inspection of manufacturing sites which can also delay the registration although we felt they are necessary. We understand there is a process to improve the efficiency of the MCC and implement a new regulatory body which we believe is important however interactions with the suppliers in this regard should also be considered when designing processes to improve registration speed for critical drugs.

Provincial involvement in the selection of the National EDL is not consistent across all provinces with some providing minimal input or none at all. This stems from poorly functioning PTC's in these provinces and the lack of involvement from the provincial pharmacy and TB programme staff. Sometime just the wrong staff are sent to participate.

Closer working relationships are needed between the programme directorate (TB and HIV/TB), Affordable Medicines and MCC in development of new treatment guidelines for TB based on the research and clinical effectiveness information collected through the National EDL and registrations of drugs processes. This would improve the development of practical clinical guidelines for TB medicine administration especially for difficult protocols

such as the paediatric one. Having the insights of the MCC on bioavailability and quality of product for protocol formulation and their knowledge of the suppliers manufacturing and capacity constraints may improve the ability to provide access to the best quality medicines in the country through enhanced prequalification criteria for tender suppliers.

## **B. Procurement of TB Medicines**

Quantification of need remains a challenge in every province, with depot consumption data being the main indicator of demand. Ideally we feel that the TB statistics of demand and type of TB should be used more actively in determining the quantities for tenders. However as have seen from the comparison of financial spend for TB and MDR by case loads there appears to be huge concerns with the accuracy of the TB data and also with the ineffective treatment costs for patients making both sets of data challenging to base assumptions on.

The second challenge is that the quantification process is a provincially driven process and when it is tabled at the specifications committee the NDOH directorates (TB, Affordable Medicines, Health Economics) have very little time to provide inputs and edits before it goes into the tender specifications document. This process should run in parallel

The third challenge is that the provinces rely on consumption data at depot level for estimates. There are some district pharmacists who collect usage data for their facilities. They are however not consulted in the process of quantification as the depot is the main responsible point for providing information to NDOH.

The TB tender had a number of flaws in it however these have been rectified to some extent in the last ARV tender. These challenges included:

- The lack of good monitoring data on the performance of suppliers against their past contract obligations prevent the NDOH from excluding poor suppliers from tendering processes. Without robust monitoring information on lead times, order fulfillments and buy out situations, inefficient suppliers continue to provide poor services to the country without penalty removing any incentives for improvement. This is both a contract management issue as well as a good governance issue for tenders.
- Risk management policies were not followed in awarding split tenders for the critical TB medicines in the August 2011 tender resulting in the main drugs used for the initiation and continuation phases of non resistant TB being awarded to a single supplier. Although this has as yet not provided any supply concerns it is a risk that should have been avoided through the split of suppliers without price being the only concern.
- Provincial procurement has limited governance of procurement policies in a handful of provinces, with facilities being able to procure outside of tender contracts and performing buy outs and section 21 orders without national or provincial control. This results in poor warehousing management and therefore supply issues in those

provinces where depot staff are focusing on off contract procurement processes and not management of the facility and the drug supply chain.

### **C. Distribution from provincial depots and sub depots**

#### ***Warehousing***

Infrastructure of the warehouses does not meet the needs of good medicine management, both in terms of size and purpose built, in a handful of the provinces. This puts tremendous constraints on stockholding and the ability of staff to monitor and manage stock effectively creating challenges with the storage of drugs, the correct rotation to ensure FEFO principles are applied, expired stock being removed and the correct picking from the correct batches. It also results in discrepancies when cyclical counts or biannual stock counts are performed. We noted that no province is required to monitor pilferage and report on it with any performance management consequences.

Most warehouses make use of the MEDSAS system for both order capturing and stock management, with system generated provisioning advises based on demand information, stock on hand etc. However the functionality of the system is different in the provinces including the ability of the system to generate the reports needed to accurately reflect stock available, dues out and orders placed for bimonthly reporting to NDOH. Manual intervention is required both for order generation with suppliers and for reporting of drug availability, increasing the likelihood of errors. Poor management of back orders and order quantities from facilities negatively impacts on these systems ability to determine stock needs for supplier orders.

Most warehouses have pharmacy staff in charge of quality control, storage, counting, picking and checking. Most indicated they have too few staff to adequately quality control. Others make use of general assistants only and have problems with incorrect deliveries occurring to facilities due to lack of professional staff quality control systems.

#### ***Ordering***

There is no true electronic ordering system in any of the provinces. Those that have the capability from the facility pharmacy system to the depot, still require a manually faxed financial authorisation to accompany the order before they can be placed. This unnecessarily delays orders being placed or when manual authorisations get lost prevents them from occurring all together. Although the financial vetting process is important for governance reasons, making it more efficient or rather monitoring spend monthly may improve the system functioning and limit the admin burden on staff involved.

Ordering from the facilities relies on the nurses in charge of the clinics to have good systems of stock counting and management which is lacking especially in the smaller centres. Limited pharmacy support either within the facility or from the “mother” hospital is hampering the efficient management of drugs at clinic level although the staff do seem to be trying their best.

Ordering frequency does not take into account the capacity of certain clinics to hold the stock resulting in clinic pharmacies or storerooms brimming with disorganized items and unopened boxes cluttering the corridors. Stock rotation and management become impossible in such circumstances adding to the already high burden of administration for the clinic staff.

Some depots are incorrectly delivering products to facilities – either too much or stock ordered in incorrect pack sizes or stock with short expiration dates. And the returns process requires authorizations first so stock remains in facilities, exposed to the elements waiting for collection.

#### **D. Distribution to facilities**

Use of direct deliveries to facilities by suppliers of the bulk stock seems to relieve pressure on the warehouses however not enough provinces make use of this services. Their impression is that, in order to receive stock on direct delivery the facility needs to order the minimum quantity. This only applies to the depot orders and facilities can receive any quantity on direct delivery. Using these principles some of the smaller facilities may be able to relieve their storeroom capacity constraints better with improved frequency of smaller orders.

Challenges with rolling out more extensive direct delivery system include:

- Systems to receive the proof of delivery back from the facilities to effect payment needs implementation;
- Monitoring capacity at facility level to report delays in delivery needs to be put in place. This should be a centralised contract management function of the depot to follow up all orders, however they need the information to be reported in order for this to occur or an IT system which allows the facilities to indicate when they receive an order;
- Access to some of the more remote facilities may require a more customized delivery system in some provinces which is outside of the contractual terms of the tender contracts with suppliers.

#### ***Ensuring uninterrupted supply***

Almost all the facilities and provinces we visited had supply issues with INH towards the end of 2011 beginning of 2012. This was as a result of poor planning through contract management and tender processes nationally, supplier issues, increased unplanned demand as well as poor buffering on the depot side. Provinces that did not feel the supply issues are distinguished by having regional sub depots which added an additional buffer layer, good stock holding compliances within the depots and good redistribution policies between facilities.

#### ***IT systems***

The MEDSAS system is utilised by 9 of the 12 depots in the country and is a good stock management and ordering system. It contains additional functionality such as traceability which has never been ‘switched on’ by the developers as there is no maintenance of the system.

This system is however not integrated with remote modules used by some of the facilities to place their orders and in some provinces the reporting capabilities and inventory management functions do not support the ability of staff to monitor stock levels and reorder quantities. This results in lots of manual interventions into a system generated order. It also requires that 2 provinces (EC and Gauteng) close down their depots for 3 weeks in order to perform biannual stock takes as the system is unable to provide them with an accurate stock level at any point in time.

These same system reports are utilised by the depots when reporting bimonthly to NDOH on their drug levels. If they are able to generate them, the provinces require enormous manual adjustments to convert this information to the format required by the NDOH for reporting. This is a labour intensive, non value adding process as the stock levels are only a snap shot in time and do not reflect the trends in availability of days out of stock.

### ***Reporting of stock availability***

As mentioned before the stock availability reporting is at different levels within the health system; from facilities to depot, from depot to facilities and from the depot to NDOH. The definitions of stock availability and the reporting mechanisms and samples are not providing an accurate view of the true stock situation on the ground. When we assessed historical stock availability on our tracer samples we found limited issues on the ground except in some provinces such as the Eastern Cape. The problems are mainly at clinic level.

In addition the bimonthly status report sent by depots to NDOH takes a snap shot view of the depot at the time the report is generated. As this is a dynamic report the true value of it in determining stock availability is not certain. It only gives an impression of the volume of products in the system and not the true extent of days that products have been unavailable for.

Collection of similar indicators at all levels in the health system should be encouraged to determine accurate stock availability and identify stock concerns before they become such.

### **Use of products at facility level**

The review of the use of TB medicines, ARV’s and TB surgical supplies revealed some major challenge in compliance with the Standard Treatment Guidelines by type of TB. Only 68% of all patients received the correct drug at the correct dose for their type of TB and the phase they were in. MDR treatment protocol compliance was the biggest concern, mainly due to very poor documentation of deviations from STG’s which may have been required due to patient clinical factors.

It is inexcusable that clinics and some TB facilities do not have scales to weigh patients in order to ensure accurate dosing. It is also inexcusable that doses are not accurately prescribed

based on the patient's weight and adjusted when the weight increases especially given the high rate of co infection of patients with HIV.

Treating patients in silos within the primary health settings adds to this concern with poor collaboration between TB and HAART nurses in combined treatment and initiation of care. Patients return for multiple visits or stand in multiple queues to get treatment if they have more than one condition.

Cost of transport and accessibility of clinics for DOT patients is concerning in some provinces, severely limiting access and compliance with treatment and is perpetuated by the lack of good DOT supporters in the community or use of CHW's.

Poor district and sub district TB co ordinator oversight and follow up of patients results in some provinces where there is no direct communication with patients or between facility based staff and district co ordinators. Relying on patients to come back to the clinic for their sputum results and initiation of treatment is reactive and with the high incidence of MDR in some provinces this should be urgently looked into. Nurses not having access to a phone to contact patients for follow up is not sufficient excuse for not performing good follow up.

Management of referrals requires a more formal system of communication between sites, both up and down stream, with active tracing of patients and oversight.

Efficient use of TB staff time should be investigated through a time and motion study. We are under the impression that the TB staff are only working in the mornings as we never encountered patients coming for DOT in the afternoon. Utilising their "spare" capacity to assist with TB medicine management, ordering and stock control would vastly improve the management at least on this level. Follow up and contact tracing including education of CHW's is another good use of spare time.

## **BEST PRACTICES**

Best practices and good processes and methodologies were collected throughout the provinces. In presenting these back we decided to view them from the point of a patient – what supports the patient to remain compliant on treatment, complete a course without interruption and make sure he/she has access to safe drugs every time. We have tried wherever possible to indicate in which province/s the best practices occurred.

### **A. Clinical diagnosis and effective treatment**

- Active awareness campaigns with public media displays encouraging early diagnosis and treatment of TB patients (NW)
- All provinces still run a mostly clinic based service for TB, however pockets exist where community based treatment is becoming more acceptable (WC – Eden, FS);
- Patients attend clinic within walking distance of work or home (WC - Eden, Gauteng - Tshwane). This means that there is no additional costs incurred for transport which can be quite expensive in some provinces.
- Staff at the clinic are actively involved in screening patients, following them up with sputum results and making use of the GeneXpert machine to distinguish resistant TB early and define a correct treatment regimen (all except Eastern Cape)
- Some clinics visited have the SMS printer which provides them with the results of the GenXpert sputums specimens with 24 – 48 hours. This information they can then use to inform the patients and contact them to start their treatment or refer them to the nearest TB hospital if they are MDR (all except Eastern Cape)
- Education is provided to TB patients which improved compliance through an understanding of the impact of treatment on their outcomes, impact of compliance to treatment and possible side effects to watch out for (FS – Thabo, Mpu – GS, WC – Eden)
- Education campaigns are boosted by patient empowerment in DOT treatment. Patients have pigeon holes in DOT room where their medication is stored. They retrieve, choose and take the correct medication on their own (although they are supervised they hardly know it) (WC – Eden);
- Staff diligently monitor patient weights at least monthly and Body Mass Index (BMI) (Mpu – GS) in order to place the patient onto their nutritional program and provide nutritional support;
- Weight based treatment regimens are followed with at least 80 % adherence on assessment. ( EC- Eden) Weights are rechecked at continuation phase and dose adjusted accordingly ( no provinces yet);
- Pharmacists check prescription of TB DOT staff for compliance to treatment guidelines (Mpu – GS). This serves as a quality check in the system;

- TB hospitals actively encourage self sufficiency in TB Patients from an early stage to make the transition back to normal life easier (WC – Eden, Gauteng - Tshwane);
- Once patients move onto continuation phase, DOTS supporters in the community are engaged and trained to continue treatment outside of the clinic (WC – Eden).
- Compliance with TB treatment guidelines are good with weight based dosages being initiated and revised if the weight changes bands. Correct drugs are prescribed and the correct duration of treatment is completed. Documentation is available if there are changes to the standards guidelines due to compliance issues or side effects experienced by the patients –isolated hospitals.

#### **B. TB coordinators pull all the strings together**

- The district and sub district TB coordinators actively involved in managing TB patients in their area. They follow up new patients, do contact tracing by linking with the Community Health Workers (CHW), monitor patient referred up and down stream to ensure they are not lost. They do this in partnership with the facility TB staff (WC-Eden, Mpu, FS);
- Ensuring communication reaches the facility staff through training and updating staff on guideline changes, treatment and supplier changes and issues with stock availability falls jointly with the TB coordinators and the District pharmacy staff (FS – Thabom, WC – Eden);
- Staff are supervised on the clinical side and performance managed against treatment outcomes, screening and compliance with completion rates (WC – Eden);
- TB coordinators are involved within their respective district management meetings and PTC's in monitoring stock availability and consumption (FS – Thabom, WC – Eden);

#### **C. Stock management and ordering at Depot and Facilities**

- Stock availability and management is the joint responsibility of the TB DOTS staff and the facility manager (FS – Thabom, Mpu – GS, FS). They work closely together to order the correct TB medicines for the clinic;
- Where clinics do not have pharmacy support, rotating pharmacy assistants bring weekly support within a sub district (FS, WC – Eden). This support includes monitoring of min/max levels and adjustments as needed, stock counting and ordering.
- Frequency of ordering is consistent with the infrastructure in terms of space at facilities to keep the stock. So smaller facilities receive orders more frequently (FS, WC – Eden, Mpu);
- Manual authorizations are reconciled to ensure that all facilities have placed their orders. This is performed by a client services department who track and proactively contact those for whom they have not received an order. This improves medicine availability in the province (Limpopo)

- All clinic orders are vetted by the district pharmacists and district hospital pharmacy for consistency, compliance with provincial code lists, compliance within min/max levels. This process is efficient and does not delay the ordering of medicines (FS – Thabom, WC – Eden, xxx, )
- Vetting of budget for orders is not undertaken as this results in delays in ordering. However financial management systems are closely monitored on a monthly basis by finance, pharmacy and TB programme staff. All variances need to be explained and performance management systems are linked to financial compliances. (WC – Eden);
- Verification or procurement officer at depot monitors a sample of critical line items per day for actual stock versus system generated stock or bin card stock levels (Gauteng, FS, WC, Mpu, NW, Limpopo);
- Pickers are pharmacy staff who ensure that correct drugs are picked from depot and also they verify stock is correct before it is placed in boxes for distribution (Gauteng, FS, WC);
- Efficient general assistants pick stock and do fine checks to ensure correct stock and expiry dates are issued to facilities (NW);
- The depot ordering a similar volume of drugs on a regular basis in order to get to a three month stock holding ensures that constant orders are placed with suppliers and improve the ability of suppliers to forecast their manufacturing needs (WC );
- If the depot is monitoring its consumption levels accurately, is vetting the orders coming in from the facilities for critical items to manage over ordering and under ordering, then it will be in a position to identify a drug supply shortage concern well in advance of any stock outs.
- Separating out critical items into a separate depot brings with it efficiencies which a large depot is unable to provide. Firstly a specialised store has a limited number of product lines allowing the staff to have a better handle on stock issues. The limited line also means that facility orders can be vetted by the pharmacists for consistency and correctness therefore managing the stock in a much more appropriate fashion. Smaller depots also require fewer staff and provided they have the necessary competencies they will work closer as a team and the risk of stock theft is limit. (ARV depot in WC)

#### **D. Distribution model to facilities**

- Direct deliveries from the suppliers direct to hospitals and some clinics occurs for large volume items ensuring effective stock availability at facilities and limiting depot stock holding levels (FS, Mpu, Limpopo, WC)
- Vaccines are delivered even to clinics on direct delivery from the suppliers and cold chain is thus maintained (FS – Thabo, Wc – Eden)
- Direct deliveries from suppliers of large volume items to the depot rather than facilities improves the management of proof of deliveries and therefore payment processes (WC, NW)

- Outsourced delivery logistics suppliers with tracking of boxes and deliveries through bar-coded system. All missing boxes can immediately be sourced. Flexibility to deliver emergency orders reducing the hassles from facility staff to arrange these pickups. (WC – Eden, NW, Limpopo)
- Effective returns policy enabling facilities to return stock that is over ordered or over delivered immediately on receipt (FS, WC)

#### **E. Stock availability and uninterrupted supply**

- Stock levels well managed in hospitals with electronic stock management systems with few discrepancies in stock on shelf and systems amounts (most hospitals except TB hospitals).
- Depot and subdepot buffering with 3 months stock holding combined with efficient redistribution between facilities ensures that patients do not experience stock shortages when suppliers are out of stock (FS, WC);
- Adjustment to issuing quantities of medicines when stock is in short supply to limit the probability of stock outs. This includes reducing the amount of medication that patients are able to take out during their usual monthly visits i.e only get 2 weeks instead of 1 months supply (WC- Eden);
- Weekly or bimonthly reporting of stock availability by facilities and distribution of this information to provincial TB/HIV directorates, pharmacy directorates and Head of Departments and executive committees with hospital directors and district managers. Allows a weekly assessment of problems prior to them occurring (FS, WC, Mpu, NW)
- District management meetings include program staff, finance and pharmacy in which stock availability, financial variances and consumption data is reviewed and initiatives to prevent a situation of stock outs being reached are agreed. Communication of these meetings outcomes to PTC committee as district and sub district level to change clinical behaviour and prescribing patterns. (WC – Eden, Mpu)
- Active contract management of suppliers, both over shortages and over quantification and forecasting including depot meetings with suppliers (WC, Mpu in process, FS on process);

#### **F. Governance of the selection of TB medicines and Procurement process**

- Good governance systems are in place within provincial PTC structures and the national EDL committee to ensure that no undue influence occurs from suppliers into the choice of TB medicines for the national EDL (NDOH, WC, FS, Mpu, NW);
- Separation of functions of procurement and National EDL although the chair person of both committees is the same;



## **SOLUTIONS**

Now that we have highlighted the challenges and best practices across the provinces in the management of TB medicines, we can propose a solution. We have taken the stance of proposing a solution which will work within the current resources available in the provinces and the facilities we visited with a focus on driving quality controls, efficient processes and management systems to improve the current shortcomings identified. This solution should be viewed as a bottom up solution to be integrated with the more top-down solution being proposed by the NDOH and SCMS as part of the Central Procurement Unit. We feel that the bottom up solution will effectively compliment the CPU concept and further enhance its outcomes.

In describing the solution we again are taking it from the point of view of the patient who is provided with the correct TB medicine, at the correct time under supervision.

### **A. Patient treated holistically and empowered to take TB medication**

TB and HIV staff at clinic and hospital level should be working together as an integrated team for patients who have concomitant HIV and other chronic diseases and vice versa. Staff should be skilled to initiate both treatment regimens under the oversight of the other more skilled individual i.e. TB staff should be able to initiate ART under the supervision of the ART clinic staff and then the patient is referred to ART clinics for further management. Integrated TB, HIV and general clinic records should be investigated in settings such as clinics to foster a holistic approach to the patient treatment and remove the silo based system currently in place without placing unnecessary delays on patients waiting for the file daily.

To support and integrated approach we are proposing that the TB patients get given a “**TB Road to health Card**” which forms a completed history of their TB diagnosis, treatment and care including GeneXpert results, referrals performed and feedback from these referrals. So if they attend a clinic where staff are not familiar or are referred the information remains with them in the same way as mothers look after their children’s road to health cards.

Patients who are able to take on the responsibility of their own consumption of TB medication should be encouraged to do so. This requires that the TB DOT staff risk assess which patients are able to perform their DOT under supervision outside of the clinic setting, either through CHW’s and community DOT supporters. Removing the challenge of patients having to access the clinics for TB treatment without increasing infrastructure in areas with poor access requires that more active and effective use is made of CHW’s and community DOT supporters.

In addition allowing the patients to collect their medication from a pharmacy other than the PHC such as a retail pharmacy closer to their place of work and home will increase access to the medicines, reduce the transport costs for patients to attend the clinic and improve compliance. It will also reduce the workload on the clinic and pharmacy staff allowing them to focus on integrated care.

**B. TB coordinators forming the crucial link between facility TB DOT staff and the community.**

The TB coordinator should act as the link between facility DOT staff and the community in which the patients live and work. Their role as link includes:

- Supervising the TB DOT staff to ensure compliance with treatment guidelines through regular audits of patient files;
- Performance management of TB DOT staff against process and outcome indicators for TB;
- Education and informing TB DOT staff of changes to the treatment guidelines, drug dosages or pack sizes. They therefore need to form an integral part of the District and Sub district PTC's and Management meetings in which finance and pharmacy are involved;
- Active contacting of TB patients newly diagnosed and defaulted through their close working relationship with the TB DOT staff at facility level and the community health workers;
- Supporting the patients to transition between clinic based and community based treatment either through CHW's or DOT supporters;
- Monitoring of referrals up and down stream to ensure patients are not lost to the system and the correct treatment information is transmitted between facilities;
- Provision of TB statistics on demand as part of the district TB Stakeholder meetings proposed later in which suppliers and pharmacy staff discuss the forecast and together plan for medication supply to meet the demand in the area.

***Enabling environment for this to happen includes:***

- Competent management skills at TB coordinator level and a passion for caring for TB patients;
- Computers and tools such as email and excel to perform the analysis, supervisory and management functions;
- Access to information through participation in formal structures which discuss TB medicine and clinical issues within the area
- GenXpert machine and other laboratory results available within 24 hours at clinic and hospital level. Results to be SMSed to printers at clinic with sufficient information to allow easy identification of the correct patient to contact.

- Transfer of patients to a higher level of care is monitored by the TB coordinator with an effective referral system through the *TB road to health card* and the communication channels between provider in place.

### **C. District and Sub district TB Stakeholder meetings**

Management of drug supply requires that both the pharmacy staff at all levels as well as the suppliers are able to provide the required drugs to meet the needs. This requires sharing of information between the stakeholders. However, without an IT system that allows for visibility of stock at a facility level, both for the district pharmacists and depot manager this system is almost impossible to achieve.

The solution we are proposing makes use of existing information that is being collected on a daily basis at the clinic level which can impact drug management proactively using a bottom up approach. This data is the number of TB patients, by treatment phase and TB type as part of the eTR register. We propose that district or even sub district level TB Stakeholder meetings are arranged between the district pharmacy staff, district TB coordinators, finance and depot managers. The discussions will utilise the eTr TB data as well as whatever consumption and stock level data is available from the facilities in the area. In addition, the GeneXpert information covering samples taken, positive results and proportion of resistant TB cases in the area can augment any forecasting discussion and are currently available as facility level reports. These various sources of data will form the basis for the following:

- Historical TB demand and drug consumption trends analysis;
- Demand forecasting and projections of needs for the next 3 months;
- Stock availability determinations and identifying critical drug shortage issues proactively;
- Decisions around preventative actions to prevent drug shortages.

These same meetings should be repeated at provincial and national levels with the same relevant directorates to ensure that from the bottom up the drug supply is managed more actively and on a more scientific basis.

These meetings do not need to happen face to face every time but can be over teleconference or data can be sent to the stakeholders regularly.

### D. Stock management at facility level

The current pull system requires a certain level of stock management understanding from staff to enable them to place the correct order which the depot then fulfils. Moving towards a push system may result in better management of stock whereby the depot determines the order for each facility based on a number of factors (including number of TB patients by type and phase of treatment, past consumption history, min and max levels, order frequency, stock holding capacity etc). We would phase this in over 3 phases:

#### Phase 1 – ordering based on TB regimen and not drug

By requiring Nursing staff managing clinics to order against a specific drug it requires them to think like a pharmacist. We should be working within their level of competency which is as nurses treating TB patients. Daily, the numbers of TB patients by treatment type and phase are collected as mentioned before for the eTr. Using this information the staff can generate an order which is regimen based. So instead of determining min/max levels of the FDC drug they complete an order detailing how many patients they have in initiation phase for non resistant pulmonary TB or continuation phase by weight bands – see example below.

Figure 48 – Ordering by treatment regimen example

Regimen 1 (New Cases) For adults and children > 8 yrs						Pharmacists only				
Intensive phase 7 days a week for 2 months		RHZE (150, 75, 400, 275)				number of units by pack size			Buffer stock	Total stock issued
Tabs	2 tabs	3 tabs	4 tabs	5 tabs	Pack size	56	84	100		
Pre-treatment body weight	30 - 37 kg	38-54 kg	55 - 70 kg	>70kg g						
Number of patients seen										
Period	1 - 7 Dec	1	2	3	5	4	5	1	5	15
	8 - 14 Dec		2	3	4		5	4	5	14
	15 - 21 Dec	1	1	4	5	2	9		5	16
	22 - 29 Dec	2	7	2	3	2	7	5	5	19

This allows them to translate their daily work into a pharmacy order without having to think like a pharmacist. The thinking happens at the pharmacy where the order is captured, verified

and placed. The pharmacists will determine the buffer stock required for the clinic based on all the data available to them and place the order.

To get this system working would require some effort on the part of the staff to design an ordering form that works for both nursing and pharmacy and then test it in the field. Close monitoring and supervision for the first few months is needed to ensure that the system does not overstock or understock the facilities. Once the system is stable the next phase can be implemented.

### ***Phase 2 – Push system introduced***

Now that we are getting more accurate estimates from the clinics based on the number of patients they have we can implement a more pharmacy driven push system. This process again requires the information to be available to allow the depot to determine the best order to place for the facility. It should be informed by issues identified at the regular district TB stakeholder meetings as well as information that the facilities are submitting regularly.

The depot would generate an order and inform the facility staff who check if it meets their needs and agree to it. Should they have a specific need that requires more or less they may adjust the order which is authorised by the district pharmacists before being confirmed at the depot.

This way the order form touch points are reduced as the flow is only from the depot to the clinic. If the system has been set up correctly in phase 1 then there should be minor changes to push orders with the result that limited flow of paper occurs through the system. Nurses can then just phone in confirmation or be phoned by the client services division of the depot.

A tight performance management process should be put in place with the push system. This will grade the clinics as to their risk of over or under supplying based on site visits and analysis of adjustments made to the push orders. Facilities performing well continue on the system, those performing poorly are put onto phase 1 again with sufficient supervision until their drug supply levels are stable again.

Using a risk based grading of clinics will also limit the amount of supervision required by the pharmacy staff. Pharmacy staff can focus on the clinics requiring support the most and provide only ad hoc support to those performing well. This makes far better use of the limited resources in the system.

### ***Phase 3 – stock visibility at all levels***

Now we can implement the IT system at all clinic levels as part of the roll down of the Central Procurement Unit. Again a push system would be initiated but it will be mainly driven by more accurate stock levels which the depot can view from its point without relying on information submitted by the facilities. Into this system the necessary TB demand data and historical consumption can be added to create a robust push system.

### **E. Depot stock management and distribution**

Systems to manage the depot stock and distribution process have been proposed by SCMS as part of their Central Procurement Unit project and we are not going to propose something different. We believe that making use of direct deliveries to larger facilities where the logistics is suitable is the correct model as it limits the amount of stock holding at depot, improves stock availability and improves the frequency of orders at facilities with capacity constraints.

A more customized solution is needed for facilities that are very far and are hard to reach in terms of roads and distance or small and require more regular deliveries to meet their infrastructure constraints.

We also believe that a more efficient process of receiving the proof of deliveries is required and the provisions in the contract whereby the suppliers are required to provide these back to the depot should be implemented and enforced.

Ensuring uninterrupted supply is an essential element of good supply chain management. Provinces that did not feel the INH supply issues are distinguished by having regional sub depots which added an additional buffer layer, good stock holding compliances within the depots and good redistribution policies between facilities. Additionally policies of changing the issuing quantities for patients and requiring them to come back more frequently assists in stretching the short supply. Issuing policies allowing pack sizes to be split by designated individuals or in times of supply constraints may also assist. These ideas should be integrate within the CPU proposal.

### **F. Budgeting for TB medicines**

All provinces should be encouraged to develop separate medicine budgets detailing the critical programmatic elements as separate line items. Ring fencing these medicines budgets to prevent provinces dipping into them to solve budget deficiencies elsewhere should not be acceptable. The entire budgeting process and assumptions should be overhauled to ensure that the budget reflects actual demand and forecasted requirements based on programmatic initiatives, incidences and needs. This requires the financial, pharmacy, programmatic and district management staff to jointly determine drugs budgets based on all the data already collected.

Although this is a provincial responsibility, we feel that national should lend their hand to assisting provinces to get there. In addition, measures should be added to the National Core Standards which monitor compliance to programmatic demand based budgeting, ring fencing and budgets being adequate to meet clinical needs.

## **G. Contract management**

### ***Contract management - National***

A more efficient system for providing bimonthly stock information to the NDOH should be investigated. The data submission process needs to be automated from the provinces IT system to prevent the time consuming, non value adding manual manipulation of the depot information into the NDOH format for their analysis. More importantly the data should be used as an alert to impending stock shortages or concerns rather than just collection of data.

Each province should have a person responsible for the communication between themselves and the suppliers. This may be fulfilled by the new monitors proposed by Affordable Medicines. However, some provinces have already got this gap filled internally through their own staff so in these instances the monitor can be used to help close the gaps of communication between the depot and the facilities.

### ***Contract management provincial***

Contract management should be a provincial function as they are accountable for their budgets and therefore it would be their incentive to get it back. It should be an outcome based process for suppliers with follow up of breaches in lead times and order quantities. Implementation of warnings and penalties and full enforcement of the terms of the contract should occur for relevant breaches. Contracts with suppliers should include a clause that states in the event of a breach in supplier terms of delivery the province is authorized to deduct a penalty directly from the next invoice and the same should apply for buy outs against that supplier. This would enable the provinces to better manage this process.

At the same time the reporting of these breaches in contractual terms needs to occur to NDOH on a regular basis so they too may contract manage suppliers across the country and use this data to in the prequalification process for new tenders. This way poor suppliers can be eliminated from the tender process improving the efficiency of the system.

## **H. Tendering process**

Various solutions for the tendering process have been proposed, many have already been implemented with the latest ARV tender in September 2012. We however have included them for completeness sake.

- Tender management should be an ongoing function of the District TB Stakeholder meetings and only national concerns should be addressed at the national level quarterly meetings;

- Tender contracts should be split irrespective of the points scored by the company. This was performed for the ARV tender in September 2012 whereby the special conditions of the contract which allowed for splits only if a points difference of up to 20% in price occurred was waived. The reasons cited were for critical drugs like the FDC's which improve compliance in patients consideration should be given to ensuring constant supply rather than only on price. In such instances the suppliers have been negotiated with to come to a more acceptable price and ensure split suppliers.
- The tender contracts should be finalized and published 8 weeks before they are due to start to allow for a proper transition between the contracts.
- Potentially the contracts should be staggered I.e. old contract ends in December 2012 but new one starts in October 2012 to allow the new supplier time to get set up while not compromising stock levels.
- The start times can also be staggered between the provinces to allow the new supplier to slowly ramp up their volumes for the new contract i.e. first 4 provinces start in Oct 2012 and then the next lot in Nov 2012 etc.
- The critical aim is to prevent a situation whereby there are no contracts in place forcing either extensions or buy outs to occur or emergency stock shortages.
- Contracts should stipulate that suppliers are required to fill orders placed within the contract period even if the volumes are larger than those estimated initially. Without this no supplier is required to honor the end period of the contract compromising the province's ability to secure bridging stock.
- Better quantification of needs is therefore essential to ensure estimates are more accurate and don't impact on suppliers towards the end of the contract period.
- To reduce the set up time suppliers should make plans around a standardized template for the patient ready packs I.e. NDOH could prescribe a patient ready pack template into which the supplier can just add their logo and specifics of the drug. For boxes this may not be possible.
- With effective provincial contract management and submission of breaches to the Affordable Medicines, the NDOH will be able to use this data for future pre qualifications of suppliers. Breaches in previous contracts should reduce the points of that supplier in the next tendering process thereby limited poor performing suppliers from getting contracts within the public sector.

### **I. Quantification**

A more scientific approach is required to improve the ability of the country to estimate the needs for TB medicines which will enhance the suppliers ability to price more effectively and deliver against needs. TB statistics and weight data should be taken into account. This requires improvements in the data collection processes including the collection of weight based treatment regimens through the eTr. This same information can then be used for the district stakeholder meetings with suppliers to plan and forecast TB demand and better manage drug supply.



## **J. Communication and cross directorate working relationships**

Closer working relationships is needed between the national programme directorates (TB and HIV/TB), Affordable Medicines and MCC in development of new treatment guidelines for TB based on the research and clinical effectiveness information collected within the various directorates. This would improve the development of clinical practical guidelines for TB medicine administration especially with difficult protocols such as the paediatric one. Having the insights of the MCC on bioavailability and quality of product for protocol formulation and their knowledge of the suppliers manufacturing and capacity constraints may improve the ability to provide access to the best quality medicines in the country through enhanced prequalification criteria.

Investigation of the concurrent jurisdiction of SAPC and MCC for compliance of GWP and GPP for depots and regional pharmacies should be occur with a view to harmonizing to ensure correct governance of the depots standards of quality

Closer working relationships within provinces between provincial and district program directorates, pharmacists, depot managers and finance in estimating quantities for tender based on all available information. This same process should then be replicated for the budgeting processes and should again continue into the monitoring of variances.

## **K. Distribution enhancement at provincial depot and facility level**

We understand that the NDOH has already investigated a Central Procurement Unit for the country for ARV's and TB medicines. We believe that in the interim a solution within the provinces is achievable with existing resources using a more bottom up approach. We have focused on the distribution part for now and have indicated where there are some immediate solutions needed to impact distribution systems now before the CPU is implemented in full. These include:

- Enhancing the use of direct deliveries from suppliers to reduce stock holding in warehouses should be encouraged in all provinces and enhanced in those that currently use this system (part of CPU proposal by SCSM). Depots should be used to manage the smaller volume items and hold a safety buffer stock for the facilities in the event of supplier manufacturing constraints. Suppliers should be engaged to determine which facilities (both from size, order quantity and rural position) may not be appropriate for direct deliveries. The depots then can serve these facilities with a more specialised distribution and logistic system taking into account the vast distance and inaccessibility of some of the clinics.
- Fit for purpose built facilities should be investigated for all depots where there is an infrastructure concern to enable them to meet SAPC and MCC compliance and standards of quality GWP and GPP.

- This includes the availability of a storage solution that allows sufficient space, accurate placement, correct rotation and management of stock. The solution may be a warehousing shelving system or an IT system like is function in NW and Mpumalanga with improvements.
- Capacity of clinics and some hospital to manage the large volume of ARV medicines and stock of TB medicines needs to be investigate and improvement made. These improvements may be larger facilities or increased frequency of orders and deliveries to the facilities. In addition the solution of ARV's being prepacked and distributed to pharmacies in clinics or even to retail pharmacies to relieve pressure on public sector staff should be investigated further.

#### **L. Supplier Proposed Solutions**

At a national level the proposed Centralised Procurement Unit is a good idea. There are some suggestions in terms of how it should function:

- It should function as a safety gap for the country and not be the sole distributor for the provinces. It therefore should only hold the safety stock for the ARV's and TB medicines and maybe in the future the chronic medicines.
- Provinces to have control over their budgets for these drugs and ordering to be centralized through the CPU;
- Provinces ability to purchase drugs and in the future consumables should be strengthened through:
  - a single stock management system at each depot with the pharmacies of each facility linked;
  - Adequately qualified staff in the depot's and pharmacies who understand stock management processes and are able to assist with the quantification of needs
- Provincial depots should be maintained as well as regional pharmacies which can take the strain off the depot in terms of managing the stock for the small facilities (PHC's and CHC's);
- A culture of enhanced service delivery and an understanding of the impact that drug shortages has on patients should be driven at all levels of the supply chain;
- Good sound data should be used at all levels in the supply chain to ensure that the drug needs of the patients are being met and supplied to the pharmaceutical companies to help them manage the manufacturing and delivery processes better.