



SSP Stockouts National Survey



June 2016



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Photos: Mariska Van Den Brink

Acronyms and abbreviations

MEDICINES

Antiretrovirals

3TC	Lamivudine
ABC	Abacavir
ATV	Atazanavir
AZT	Zidovudine
d4T	Stavudine
ddI	Didanosine
DRV	Darunavir
EFV	Efavirenz
FDC	Fixed-Dose Combination of TDF, FTC and EFV
FTC	Emtricitabine
LPV	Lopinavir
NVP	Nevirapine
RTV or /r	Ritonavir
TDF	Tenofovir

TB-related medicines

E	Ethambutol
ETO	Ethionamide
H	Isoniazid
INH	Isoniazid (for preventive therapy)
Km	Kanamycin
Lvx	Levofloxacin
PN or Vit	Pyridoxine or Vitamin B6
R	Rifampicin
R/H	Rifampicin/Isoniazid
RHZE	Rifampicin/Isoniazid/Pyrazinamide/Ethambutol
Z	Pyrazinamide

Vaccines

DTaP	Diphtheria, Tetanus and acellular Pertussis
HBV	Hepatitis B Virus
Hib	Haemophilus influenzae type b
IPV	Inactivated Polio Virus

PROVINCES

EC	Eastern Cape
FS	Free State
GP	Gauteng Province
KZN	KwaZulu-Natal
LP	Limpopo
MP	Mpumalanga
NC	Northern Cape
NW	North West
WC	Western Cape

GENERAL ABBREVIATIONS

3mo	3-month period prior to contact
API	Active Pharmaceutical Ingredient
ART	Antiretroviral Therapy
ARV	Antiretroviral
BRICS	Brazil, Russia, India, China and South Africa
CC	Carbon Copy
CCMDD	Centralised Chronic Medication Dispensing and Distribution
Day	Day of contact
DHIS	District Health Information System
DM	District Municipality
DOH	Department of Health
DP	District Pharmacist
DTI	Department of Trade and Industry
EML	Essential Medicines List
EPI	Expanded Programme of Immunisation
HIV	Human Immunodeficiency Virus
HOPS	Head of Pharmaceutical Services
IP	Intellectual Property
MCC	Medicines Control Council
MDR-TB	Multi-Drug Resistant Tuberculosis
MM	Metropolitan Municipality
MPP	Medicines Patent Pool
MSF	Médecins Sans Frontières (Doctors Without Borders)
Case Mx	Case Manager
NDOH	National Department of Health
Facility OM	Facility Operations Manager
PEPFAR	US President’s Emergency Plan For AIDS Relief
PHC	Primary Health Care
PMTCT	Prevention of Mother to Child Transmission of HIV
PuPs	Pick-up Points
RuDASA	Rural Doctors Association of Southern Africa
SAHIVSoc	Southern African HIV Clinicians Society
SAHPRA	South African Health Products Regulatory Agency
SSP	Stop Stock Outs Project
TAC	Treatment Action Campaign
TB	Tuberculosis
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children’s Emergency Fund
WHO	World Health Organization
WTO	World Trade Organization
XDR-TB	Extensively Drug-Resistant Tuberculosis

Glossary of terms

ART (antiretroviral therapy): the use of a combination of three or more antiretroviral (ARV) drugs for treating HIV infection. ART involves lifelong treatment.

ARV (antiretroviral) drugs: the medicines used to treat HIV.

Compulsory license: a license issued without the consent of the patent holder for a specified period of time, and often at a defined royalty rate. In the case of medicines, compulsory licenses can allow generic suppliers to enter a national market. Compulsory licenses can be issued upon a number of different grounds, and can be sought by private entities or governmental bodies.

Dosage: the amount of a medicine, drug or vitamin that should be taken at one time or regularly during a period of time.

Drug regimen: a combination of medicines comprising a complete treatment programme for a patient. (e.g. the standard first-line ARV regimen in South Africa is a combination of tenofovir, emtricitabine and efavirenz).

Formulation: the way in which drugs are physically presented in a final pharmaceutical product, or dosage form (e.g. liquid or tablet).

Government use license: when a government exercises their right to issue a compulsory license. The action may be taken in the interest of public health, or to otherwise balance public interest with private privilege.

Last mile delivery: a distribution system whereby commodities are delivered in an organised and systematic way to service delivery points where the commodities reach the end user.

Patents are a form of intellectual property granted on a country-by-country basis, in line with national laws. It allows the patent holder to be the sole supplier of a patented invention in a country for 20 years.

Stock out: the complete absence of a specific formulation and/or dosage of medicine at a given public health facility.

Voluntary license: when patent holders choose to license their patent rights voluntarily, in order to (in the case of medicines) allow generic suppliers to enter a national market. Voluntary licenses can be negotiated in a variety of ways: either on a bilateral basis with generic companies, or through the Medicines Patent Pool (MPP) in Geneva. The latter allows any eligible generic company to take up a license signed with the MPP.

Foreword

The 2015 national survey report is the third annual report published by the Stop Stock Outs Project (SSP). Although there have been some successes over the past three years, and the South African government has undertaken several initiatives to improve the supply chain for medicines, stock outs at primary healthcare facilities remain an undeniable threat to the health of the people of South Africa. Those most vulnerable to the effects of stock outs are usually poor and rural communities who depend on public facilities for health services. When these remote facilities experience stock outs, the impact goes beyond health: Patients often make repeated, costly trips to health facilities to keep up their prescriptions. Pharmacists and nurses spend more time rationing drugs instead of caring for ill patients. Babies are not vaccinated on time, or at all. Ultimately, the quality of patient care is compromised, and lives are lost.

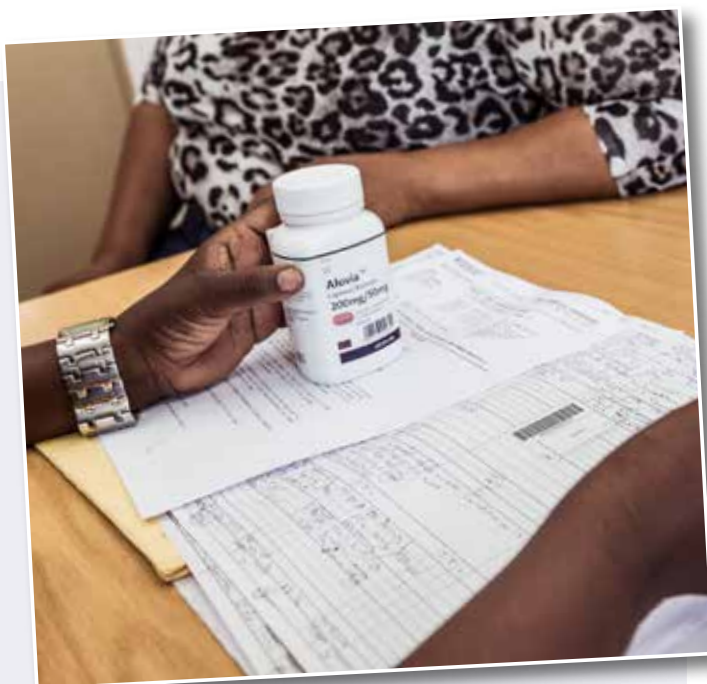
When repeated surveys find that one in four facilities experience stock outs of ARV and/or TB medicines, and more than one in ten facilities are not able to immunise children against preventable diseases, it is undeniable that stock outs are occurring throughout the year, across the

country. All stakeholders, from rural communities to national policy-makers and global health actors, must work together urgently to solve this fundamental problem, if we are to be successful at re-engineering primary healthcare and implementing universal health coverage.

Other struggles are also far from over. In 2001, South Africans took to the streets to protest patent monopolies that prevented the distribution of more affordable generic versions of lifesaving antiretrovirals (ARVs) to people living with HIV. In 2015, patent monopolies and profit-driven pharmaceutical company interests continued to block access to ARVs, and skewed the market for medicines and vaccines, in favour of the wealthy and at the expense of vulnerable populations.

We hope that readers of this report feel compelled to engage with the issue of drug stock outs, take action to report and prevent patients leaving facilities without medicines, and learn more about how global politics and economics influence the ordinary citizen's ability to realise the right to health.

“ I am a 46 year old mother of two. I receive my treatment from Matsulu CHC. I contacted the SSP to report a stock out of Tenofovir tablets in February 2016. Following my report and intervention by the SSP, I have never experienced any medicine stock out constrains. The Facility is giving me 2 months' supply, sometimes I am given 3 months' supply of treatment”
Patient, Mpumalanga



Executive summary

Background

South Africa's human immunodeficiency virus (HIV) and tuberculosis (TB) epidemics continue to rank among the largest in the world, and vaccine-preventable diseases remain significant drivers of mortality in children under five years of age. Without reliable and consistent access to HIV and TB treatment, vaccines and other essential medicines at health facilities, national and international targets to tackle these conditions will not be met.

In 2013, six civil society organisations established a consortium, known as the Stop Stock Outs Project (SSP), to monitor the availability in the South African public sector of antiretroviral (ARV) medicines for HIV, medicines for TB, routine childhood vaccines and other essential medicines. In the past three years, the SSP has established a hotline for patients and healthcare workers to report stock outs, and developed a reporting structure to communicate with the Department of Health (DOH) when stock outs occur. The SSP also collaborates with a variety of stakeholders to resolve stock outs and shortages faced by patients and healthcare workers in facilities across the country, and advocates for policy change that will contribute to strengthening all levels of the supply chain.

3rd Annual National Stop Stock Outs Survey (2015)

In the fourth quarter of 2015, the SSP carried out its third annual telephonic survey to assess the extent and impact of stock outs across South Africa. As in the 2013 and 2014 surveys, the SSP attempted to call all public health facilities in the country.

Participating respondents answered questions about:

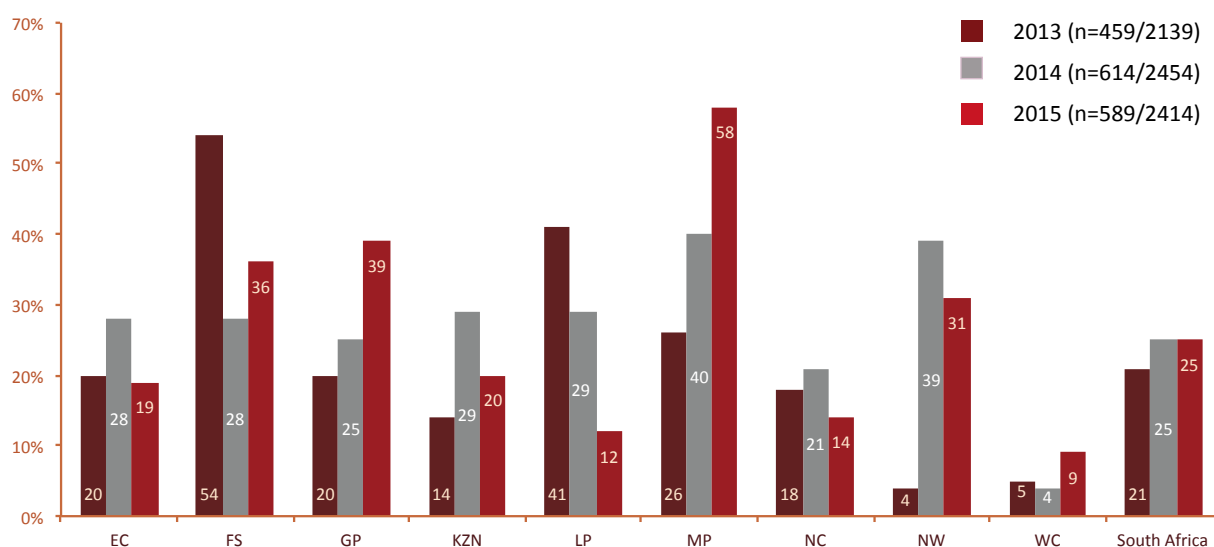
- the availability of ARV and TB medicines on the day of contact (day), and in the three-month period (3mo) prior to contact
- the duration of, and impact on patients of reported stock outs of ARV and TB medicines on the day of contact and in the 3mo prior to contact
- the availability of three routine childhood vaccines and seven essential primary healthcare medicines on the day of contact.

The 2015 survey also introduced a validation sub-study, in which 94% of randomly selected stock outs reported on the day of contact were confirmed by a second person from the same facility through a second telephone call.

Key survey findings

- The proportion of facilities in South Africa experiencing stock outs in 2015 has not changed dramatically compared to 2014, with approximately one in four facilities affected by stock outs of ARV or TB medicines in the 3mo period prior to contact (Figure 1), one in five on the day of contact (Figure 8), and approximately one in ten experiencing vaccine stock outs on the day of contact.

Figure 1: Percentage of facilities reporting at least one ARV or TB medicine stock out (3mo), by province (2013 - 2015)



- Mpumalanga (MP), Gauteng (GP) and Free State (FS) provinces respectively reported the highest proportions of facilities experiencing ARV and TB medicine stock outs (3mo), with the situation in all three provinces deteriorating since 2014. The Western Cape (WC) reported the lowest proportion of facilities with such stock outs, but also saw an increase from 4% in 2014 to 9% in 2015. All other provinces improved, most notably Limpopo (LP) from 29% in 2014 to 12% in 2015.
- Nearly one in five (19.4%) stock outs of ARV or TB medicines in the 3mo prior to contact resulted in patients leaving the facility with no medication.

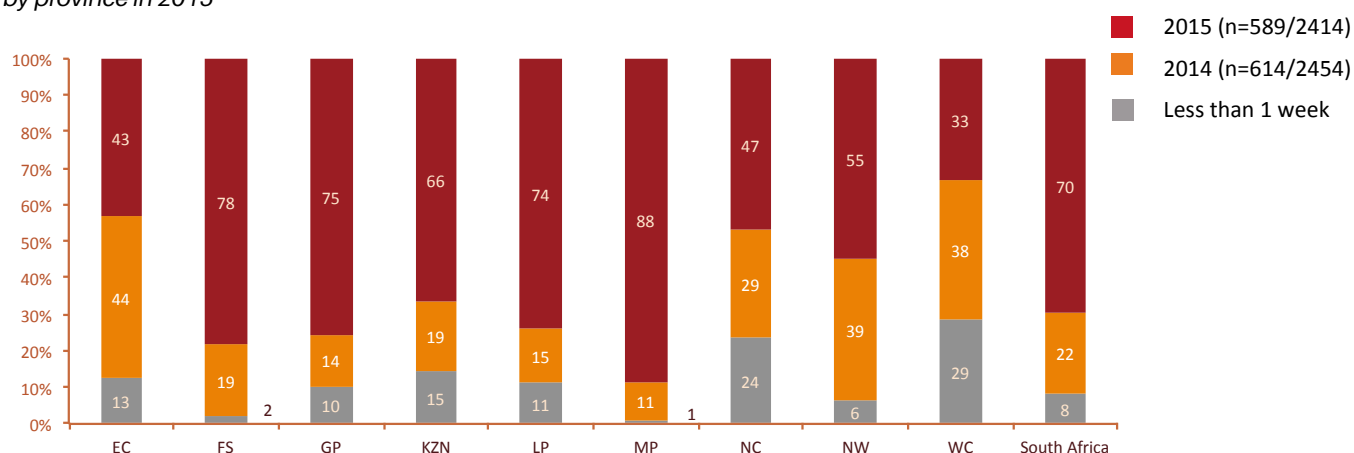
Of 699 stock outs on the day of contact, for which participants provided information about supply given to patients:

23% resulted in patients leaving with no medicines (high impact)	4% resulted in patients leaving with incomplete regimens (high impact)	37% resulted in patients leaving with less supply OR more burdensome treatment (medium impact)	36% resulted in facilities giving patients borrowed supply or appropriate alternative treatment (low impact)

Similar trends in impact were recorded in the 3mo prior to the survey (see Figure 2).

- The duration of stock outs of ARV or TB medicines in the 3mo prior to contact remained unacceptably long, with 70% lasting for longer than one month.
- Provinces with the largest proportion of facilities reporting stock outs of ARV or TB medicines (MP, FS, GP) also reported the longest stock outs (Figure 2), indicating deficiencies in the provincial supply chain, and a lack of emergency response mechanisms.

Figure 2: Percentage of stock outs (3mo) lasting (i) less than one week, (ii) one to four weeks, or (iii) longer than one month, by province in 2015



- The prevalence and duration of stock outs reported varied widely between provinces and districts. Improvements were seen in some districts and provinces – including very rural locations – while in others, stock outs had become more prevalent.
- In eight districts, more than 40% of facilities reported stock outs of at least one ARV or TB medicine in the 3mo prior to contact in 2015. In the 2014 survey, three of these districts similarly saw stock outs reported in over 40% of facilities. Four other districts that performed poorly in 2014 showed an improvement in 2015 (Table 1).

Table 1: Districts with more than 40% of facilities reporting ARV or TB medicine stock outs in 2015 Districts with the highest percentage of facilities reporting ARV or TB medicine stock outs in 2015

District (Province)	Number of facilities with a stock out	% of participating facilities with a stock out
1. Nkangala DM (MP) ●	39	63%
2. Ehlanzeni DM (MP)	62	62%
3. Sedibeng DM (GP)	17	53%
4. Mangaung MM (FS)	8	50%
5. Xhariep DM (FS)	8	50%
6. Ekurhuleni MM (GP)	34	47%
7. G Sibande DM (MP) ●	24	45%
8. Bojanala Platinum DM (NW) ●	30	41%

- Districts with more than 40% of facilities reporting ARV or TB stock outs in 2014

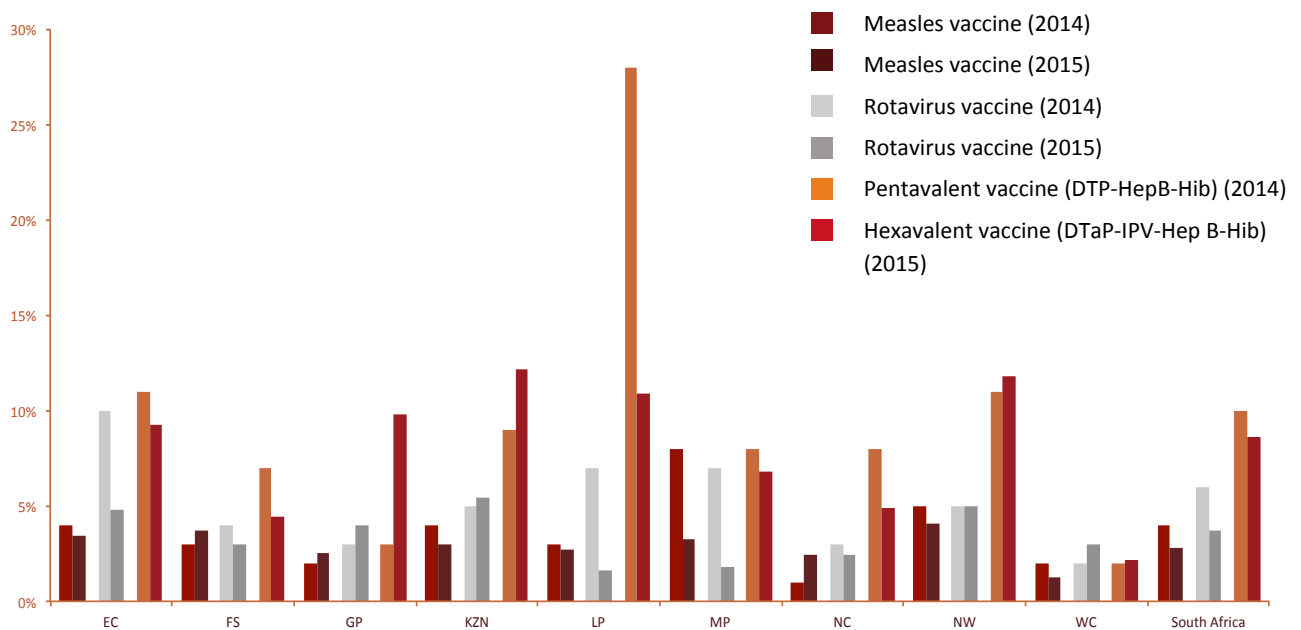
- The ARV or TB medicines most commonly out of stock, and the contributing causes, were different than in previous SSP surveys:
 - In 2013, the three-in-one fixed-dose combination (FDC) was introduced as the first-line ARV regimen of choice for HIV-positive adults. Most stock outs reported in the 2013 survey were of the FDC and other first-line ARVs, suggesting a need for better planning and communication to facilities prior to introduction or scale-up of new treatments for widespread use.
 - In the 2014 survey, facilities reported stock outs of a wide variety of different ARV and TB medicines, but no national trend was evident. This suggested a **need for improved supply chain management**.
 - In 2015, a national shortage of second-line treatment – adult lopinavir/ritonavir (LPV/r) – led to widespread reports of stock outs. Paediatric formulations of LPV/r, as well as substitutes for LPV/r, were also commonly reported as being out of stock. LPV/r shortages

stemmed in large part from a single supplier’s inability to meet demand, and patent monopolies creating barriers to accessing alternative supply sources. This suggests a **need for national policy reforms to avoid over-reliance on single suppliers**. However, the facility-level response to managing LPV/r shortages varied, suggesting that facilities can limit the impact of stock outs regardless of the cause. The number of facilities experiencing stock outs of medicines other than LPV/r, or substitution medicines, suggests

that many facilities still struggle with supply chain management.




- The percentage of facilities reporting stock outs of vaccines used in the routine immunisation schedule for children in 2015 (11%) remained similar to 2014 (12%). The hexavalent DTaP-IPV-Hib-HBV vaccine was most commonly reported out of stock nationally, and in all provinces. The vaccine protects children against diphtheria, tetanus, pertussis, polio, *Haemophilus influenzae* type B and hepatitis B virus (Figure 3).

Figure 3: Percentage of facilities reporting a measles, rotavirus or pentavalent/hexavalent vaccine stock out (day), by province (2014 and 2015)



- Provincial variations were evident in the percentage of facilities reporting stock outs of other essential medicines. Problematic outliers included haloperidol in Limpopo (LP)

(33%) and Mpumalanga (MP) (33%), and ferrous sulphate in KwaZulu-Natal (KZN) (21%) and North West (NW) (16%).

		
<p>472 Facilities had a stock out of at least 1 adult ARV</p>	<p>46 Facilities had a stock out of at least 1 TB-related medicine</p>	<p>274 Facilities had a stock out of at least 1 vaccine</p>



Engagement with the Department of Health

- The National Department of Health (NDOH) established a task team to support development of a national supply chain strategic plan. However, the national plan has not been made public and there has been no consultation with the SSP on this initiative.^[1]
- The NDOH also initiated a number of supply chain reforms in 2015, which may have led to an improved availability of key medicines such as the FDC, which is the current regimen for nine out of ten patients on ART in South Africa.
- Over the course of 2015, the SSP continued to engage actively with the DOH at all levels to solve reported stock outs. During the national shortages of adult LPV/r in particular, this collaboration guided emergency distribution to facilities in need.
- At the time of publication, the SSP had engaged with the provincial DOH in the Eastern Cape (EC), GP, KZN, MP, Northern Cape (NC), NW and FS, for feedback on the survey results. All provinces except FS, MP, LP and WC provided formal responses to the results, which are annexed in this report. A meeting with LP and WC has not yet occurred. An initial meeting and presentation of the results and report to the NDOH has occurred. Regular meetings on managing stock outs, are yet to be arranged.

Why should South Africa act now?

2016 will be a pivotal year for establishing a much-needed response to stock outs, in South Africa and globally. In May, the World Health Assembly discussed how to overcome contributing factors to medicine shortages,^[2] and the United Nations (UN) General Assembly convenes in June for a high-level meeting on HIV/AIDS, to develop recommendations for the next phase of scaling up treatment for HIV.^[3] At a national level, South Africa will embark on the development of its next five-year National Strategic Plan for HIV and AIDS, TB and STIs. South Africa will also host the International AIDS Conference in Durban where a large focus of discussions will revolve around how to improve access to treatment for all people living with HIV.

Conclusions and recommendations

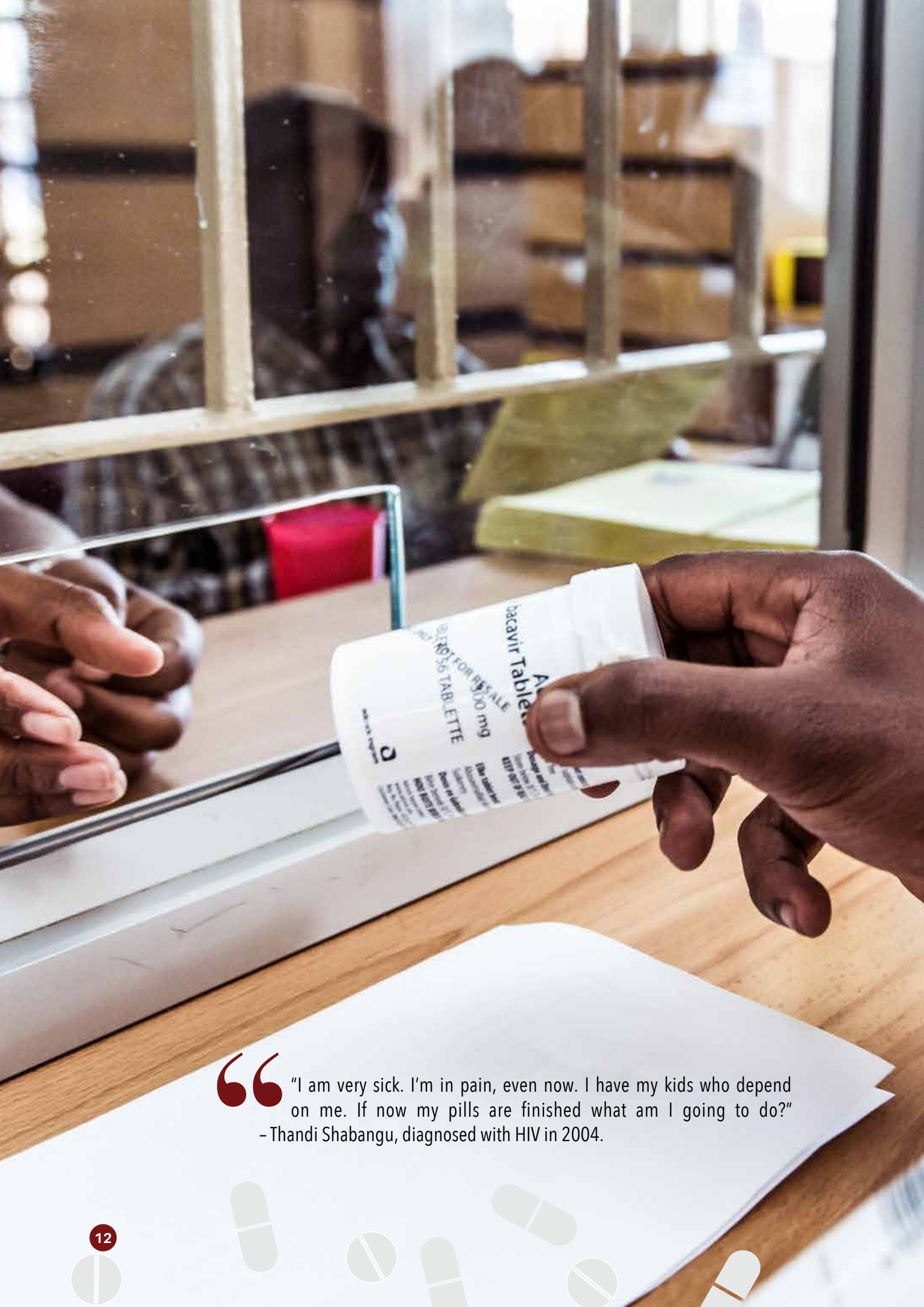
Stock outs remain a serious threat to the South African public healthcare system. When read with results from previous years, the 2015 SSP survey demonstrates the ongoing need to address stock outs at all levels of the supply chain. The common theme remains the need for comprehensive plans that give facilities, provinces, national governments

and international partners the capacity to prevent stock outs from occurring, but also rapidly manage stock outs regardless of cause.

Recommended interventions:

- Address, with urgency, **the eight districts and four provinces reporting the highest prevalence of stock outs**
- **Prioritise finalisation and resourcing of the national strategic plan on the medical supply chain**, in consultation with stakeholders including civil society to: (i) **establish facility- and patient-level indicators** to measure progress of interventions (ii) expand **patient-centred service delivery approaches** to chronic diseases; (iii) improve **monitoring and evaluation tools** at patient and facility level to inform forecasting and supply chain evaluation; (iv) develop and disseminate **implementation plans when introducing new treatments**; and (v) establish **emergency response mechanisms** to ensure a flexible supply chain.
- **Recognise the added value of civil society and use of citizen-reported data** to prevent/solve stock outs, perform quality control and improve supply chain performance.
- **Enhance supply security – adjust legislation** to ensure multiple sources of essential medicines and active ingredients, including: (i) finalisation of a national intellectual property policy and reform of the Patents Act and related legislation to allow effective use of flexibilities enshrined in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); (ii) establishing South African Health Products Regulatory Agency (SAHPRA) regulations for transparent, expedited approval and registration of pharmaceutical products and supplier diversification; and (iii) amending HIV treatment guidelines to include ATV/r as a preferred second-line option in addition to LPV/r.
- **Engage international partners to:** support patients, communities and civil society in resolving stock outs; co-ordinate international exchange of expertise on supply chain models; develop standard indicators; monitor global demand; and support effective implementation of TRIPS flexibilities in the interest of public health.

Universal access to treatment will only be feasible when stock outs can be all but eliminated in the public sector. The only way to ensure stock outs are overcome is to listen to the voices of the people whose lives depend on medicines being available in their health facility.



“I am very sick. I'm in pain, even now. I have my kids who depend on me. If now my pills are finished what am I going to do?”
- Thandi Shabangu, diagnosed with HIV in 2004.



Introduction: 3rd Annual National Stock Outs Survey (2015)

The mission of the Stop Stock Outs Project (SSP) is to ensure that the millions of people who use the South African public health system have access to the medication they need and to which they have a right. The SSP arose to meet a demand: over the last decade, SSP partners saw that chronic stock outs of essential medication hamstrung fulfilment of the right to health and the success of interventions such as the human immunodeficiency virus (HIV) and tuberculosis (TB) treatment programmes.

When medical supply chains fail, stock outs come at a high cost to both the health system and its patients. Stock outs at public health facilities lead to unnecessary suffering, financial loss and an erosion of the users' faith in the ability of the service to meet their needs. Patients with chronic diseases may interrupt treatment, which increases the risk of falling ill, developing drug resistance and transmitting HIV and TB to others.

The SSP formed in 2013 as an organisation dedicated to addressing this crisis. Our approach has focused on the collection of data, through active surveillance by conducting an annual survey, and passive surveillance by receiving stock out reports via our hotline. We attempt to resolve individual stock outs through a protocol agreed upon with the National Department of Health (NDOH), which starts at the district level, and escalates to provincial and national level if stock outs remain unresolved. We also work closely with healthcare workers and communities to inform them of how to report stock outs, and we disseminate information that may help to mitigate or resolve stock outs in facilities. We engage the NDOH on how to overcome policy and programmatic challenges.

This is the SSP's third national survey report. It is the product of a rigorous process and a great deal of work by many hands. Our 2013 report, titled *"Stock Outs in South Africa: a National Crisis"*, found that a shocking 21% of public healthcare facilities in South Africa experienced a stock out or shortage of an HIV or TB medicine in the three-month period preceding the survey. In 2014, our second national survey revealed that this percentage had grown to 25%. In 2015, the situation remained unchanged.

Over the last three years, we have improved upon the methodology and scope of our survey. We have expanded the survey to include vaccines and a selection of seven other essential medicines, to gain insight into the supply chain functionality for other aspects of the health system. The SSP works closely with the NDOH at various levels and appreciates the high priority that government places upon resolving stock outs, but we have far to go. We will not win the battles against HIV and TB if we do not eliminate stock outs. We will fail our children if we do not focus on the supply chain of vaccines. We cannot deliver the right to health if we do not deliver essential medicines.

South Africa has among the largest HIV and TB epidemics in the world, but also one of the largest responses in the world, with over 3.3 million people initiated on antiretroviral therapy (ART) and more than 300 000 people treated for TB every year.^[4] South Africa's HIV treatment programme accounts for over 10% of the global population on antiretrovirals (ARVs)^[5] This programme saves millions of lives, but must double in capacity in the coming years to achieve new international targets, to start and retain approximately 6.8 million people on treatment. Any threat to its success, including stock outs, must be overcome.

STOP
STOCKOUTS

The SSP is an independent civil society consortium dedicated to a health system free of stock outs of medicines and vaccines. SSP is comprised of six members: Doctors Without Borders (MSF), the Rural Doctors Association of Southern Africa (RuDASA), the Rural Health Advocacy Project (RHAP), SECTION27, the Southern African HIV Clinicians Society (SAHIVSoc), and the Treatment Action Campaign (TAC).



International Targets for HIV/TB Treatment and Immunisation Coverage

The World Health Organization (WHO) now recommends that all people with HIV are started on treatment as soon as they are diagnosed.^[6] The Joint United Nations Programme on HIV/AIDS (UNAIDS) targets seek to accomplish, by the year 2020, that 90% of people living with HIV know their status, 90% of those testing HIV-positive are initiated on ARVs, and 90% of those on treatment are virally suppressed.^[7] BRICS countries (Brazil, Russia, India, China and South Africa) have also established similar 90-90-90 targets for successfully treating TB.^[8] The Global Vaccine Action Plan (GVAP) seeks to attain more equitable access to immunisation for all people, and aims to have all national schedules including all appropriate new vaccines.^[9] Without reliable and consistent access at the facility level to HIV/TB treatment, vaccines and essential medicines, these targets will not be met.

The SSP survey should inform efforts to ensure people receive the medicine they need, and realise the rights guaranteed in our Constitution. Our vision is that the information in this report will enable all stakeholders to work

together to stop stock outs and save lives. We encourage you to read this report with an aim to understanding this crisis and finding a way in which you can contribute to its resolution.



Methods and participation

Methods

Study history and overview

The SSP conducted its third national telephonic survey of public healthcare facilities in South Africa between October 1st and December 11th, 2015. The study design was informed by experience conducting past surveys, and other documentation related to stock outs of essential medicines across South Africa.^[2-4]

Early versions of the survey questionnaire were first piloted in the Eastern Cape (EC) in 2012. The SSP Steering Committee adapted the original questionnaire for use in the first annual survey conducted by the SSP in 2013. In 2014, the questionnaire was shared with the NDOH Affordable Medicines Directorate, and the Head of Pharmaceutical Services (HOPS) or Depot Manager of each province. Feedback from all stakeholders, including relevant national and provincial government officials, was incorporated into the 2015 survey methodology. The main changes to the methodology made for the 2015 survey are summarised in Annex A-I.

Aims and objectives

The survey aimed to generate comprehensive and representative information on the facility-level availability of ARV and TB medicines, as well as a range of relevant 'indicator' medicines, including childhood vaccines and other essential medicines which are categorised as 'vital', or lifesaving, in the NDOH Master Procurement Catalogue.^[10] The relevant South African Guidelines^[11-13] were used to categorise medicines and vaccines according to their indication. See Annexes A-II to A-V for an overview and rationale of our classifications.

Study Aim 1: To determine the availability of ARV and TB medicines

Study Aim 1 was measured using the following outcomes:

- The number and percentage of public health facilities (i.e. primary health clinics and hospitals) experiencing ARV and/or TB medicine stock outs on the day of contact (day) and during the three-month period (3mo) prior to contact.
- The duration of ARV or TB medicine stock outs.
- The number and proportion of public health facilities experiencing high-, medium- and low-impact stock outs. The impact of a reported stock out was determined by assessing both the facility action and resultant supply of medicines given to the patient (Annex A-VI).

Study Aim 2: To determine the availability of vaccines and first-line primary healthcare medicines using indicator vaccines and medicines as a proxy

Study Aim 2 was measured using the following outcomes:

- The number and percentage of public health facilities experiencing each of the following on the day of contact:
- Stock outs of the three selected indicator childhood vaccines
- Stock outs of the seven indicator essential medicines.

Conducting the study

Study population: Who was eligible to participate?

All public health facilities in South Africa were eligible, with the exception of public satellite clinics and mobile clinics, which were excluded. Private health facilities were not eligible for survey participation. The list of facilities to be contacted was completed using information from the District Health Information System (DHIS).^[14] A total of 3 547 facilities were identified as eligible to be contacted for inclusion in the study. (See Annex A-VII for inclusion and exclusion criteria for facilities and participants.)

What we did

Trained interviewers attempted to contact all eligible facilities by telephone. Each facility was contacted up to three times. If no contact was made after three attempts, then the survey team attempted to obtain an alternative telephone number for the clinic. If an alternative telephone number could be obtained, then an additional contact attempt was made. Facilities that could not be reached were considered uncontactable. The participation rate was calculated as the proportion of contactable facilities that agreed to provide information for the survey.

The survey team asked to speak, in order of preference, to the pharmacist, pharmacy assistant, person who orders the clinic medicines or the sister-in-charge. The motivations and aims of the survey were explained to participants, who were asked to respond anonymously to questions about medicine stock outs at their facility. The team obtained informed consent from all participants (see Annex A-VIII) prior to commencing the survey.

What we measured and how we measured it

Data from participating facilities were collected using a standard questionnaire (see Annex A-IX). Questions on ARV and TB stock outs were asked only to participants at those facilities that provide ARV and TB medicines. Information

about ARV and TB medicines was elicited using open-ended questions. Questions on the indicator medicines were asked to all facilities willing to participate. Closed-ended questions were used to elicit information about vaccines and essential medicines.

What is a stock out?

A “stock out” was defined as the complete absence of a specific formulation and/or dosage of medicine at a given public health facility.

ARV and TB medicines

Participants were asked to provide the name of each ARV and TB medicine that was out of stock on the day of contact and in the 3mo prior to contact.

For both ARV and TB medicines, respondents were provided the following three options for the duration of the stock outs: (i) less than one week, (ii) between one and four weeks, and (iii) longer than one month.

Each stock out was classified as having a high, medium or low impact on patients based on: (i) the action of the facility; and (ii) the supply given to the patient (see Annex A-VI for an overview of impact definitions). All stock outs that led to patients leaving the facility without any medicines or with incomplete regimens were considered to be high-impact stock outs. These were considered high-impact stock outs because both scenarios are associated with future treatment interruption or incomplete treatment, as well as lost patient time and increased patient costs.^[15,16] This classification is slightly different from that used in the 2014 survey. Previously, we only considered stock outs in which the patient left with no medication at all as “high impact”. As our 2015 definition of “high impact” was broader than used previously, we would expect to see a higher proportion of high-impact stock outs for this year.

Those stock outs that led to patients receiving less optimal regimens, higher pill burdens, less optimal formulations and/or less than a full supply of medication were considered of medium impact. Patients receiving medications or regimens that are more difficult to take or less well tolerated may incur higher chances of treatment interruption. Receiving a smaller supply of medication requires patients to make more frequent visits to facilities for refills.

When a stock out resulted in a switch to a suitable alternative regimen or formulation, or the facility borrowed

the medication that was out of stock, and it was given in full supply to the patient, it was considered low impact. Low-impact stock outs would typically result in an acceptable outcome for the patient, but could require a facility to take measures to adjust stock levels of alternative regimens used. Vaccines and essential medicines

The availability of vaccines and essential medicines was only evaluated on the day of contact. The three selected vaccines form a significant proportion of the Expanded Programme of Immunisation (EPI) schedule.^[17] The three vaccines protect against diphtheria, tetanus, pertussis, polio, hepatitis B, Haemophilus influenzae type B infections, measles and diarrhoeal disease.

Seven additional medicines, indicated for a variety of conditions, were selected from the NDOH Essential Medicines List (EML) to cover a range of primary healthcare disease groups, including hypertension, diabetes, epilepsy, anaemia, asthma, bacterial infections and psychiatric disorders.

Validation of results

A key change to the 2015 survey methodology was the introduction of a sub-study for validation of the results. To determine the reliability of our measures of stock outs, a simple random sample of facilities was selected to participate in the validation sub-study. The selected validation facilities were surveyed twice on the same day, with two different participants providing answers to the same questions. Where it was not possible to reach a second participant on the same day, the second participant was surveyed on the day following the original survey. In this case, the participant was asked about stock levels of ARV and TB medicines on the preceding day.

Of the 159 facilities that were randomly selected for the validation sub-study, a second participant from 143 facilities (90%) took part. Among those facilities that responded, the validation participant provided the same answer as the primary participant 94% of the time to the question: “Today do you have an ARV or TB medicine unavailable?” The Kappa test for reliability suggests almost perfect agreement between the results reported by the different participants (Kappa coefficient =0.84). The fact that we obtained the same information from more than one person suggests that our self-reported measures of stock-outs are likely to be accurate.



Ethics

The survey protocol received ethical approval from the ethics board of the University of Cape Town in 2015.

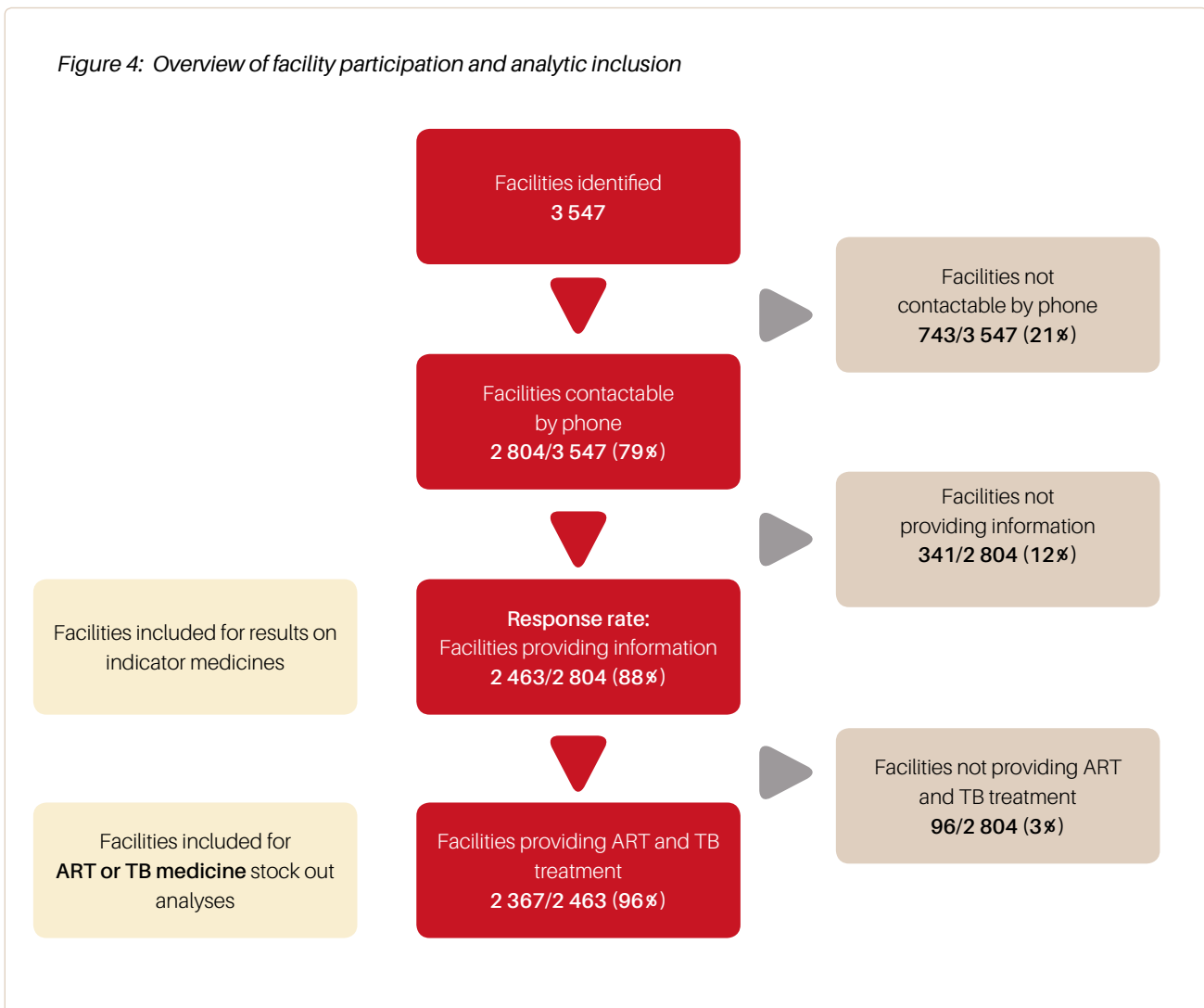
Escalation of stock outs

The SSP has protocols for escalating stock outs as part of the project's regular activities (see Annex A-X). With the consent of facilities, the SSP provided information to the DOH related to stock outs reported through the survey. For facilities that did not agree to have the SSP provide information to the DOH, the participant received information on how to report stock outs through the DOH escalation protocol.

Survey participation

Of the total of 3 547 facilities identified, 2 804 (79%) could be reached telephonically, of which 2 463 (88%) participated in the study (Figure 4). Of facilities that participated, 96 (4%) did not provide ARV or TB treatment and were therefore not included in analyses related to such medicines. As in previous years, participation rates remained high (see Annex B-I), indicating that the survey results are representative of the national situation.

Figure 4: Overview of facility participation and analytic inclusion



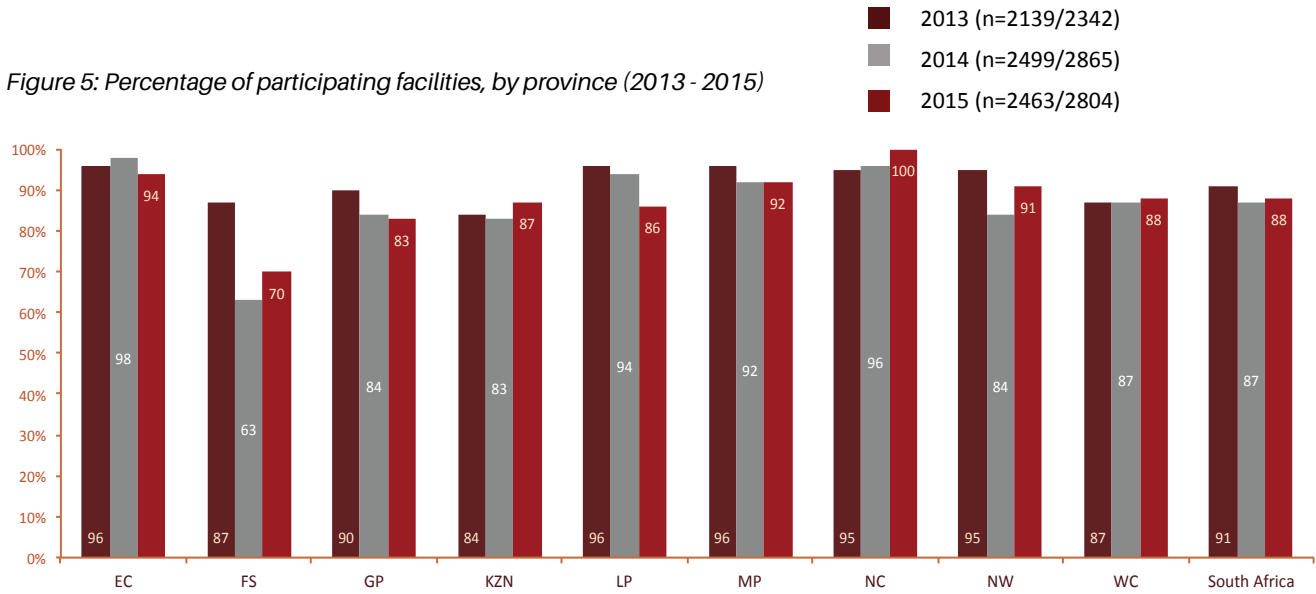
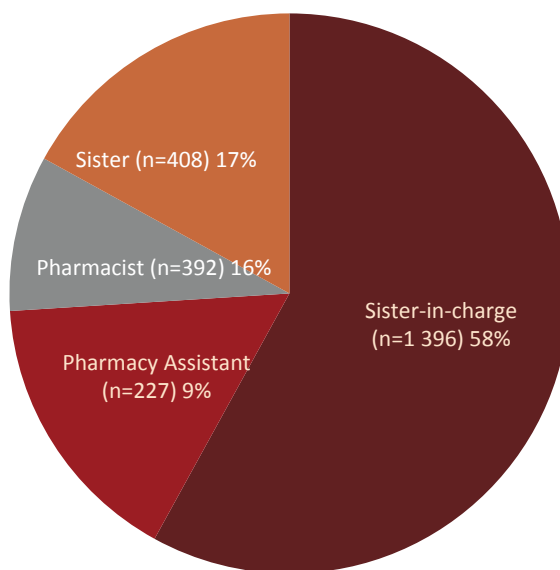


Figure 5 shows the provincial breakdown of participation rates over time (2013 - 2015). Most provinces had consistently high response rates of over 85%, with the Northern Cape (NC) being the first province to record a 100% response rate among contactable facilities in 2015. Limpopo (LP) saw a decrease in participation, from 94% in 2014 to 86% in 2015.


While participation increased in the Free State (FS), the province continues to have the lowest response rate over the

last two years (63% in 2014; 70% in 2015). The 2014 drop in participation in the FS was most likely attributed to fear of identification, following reports of retaliation against facility staff who reported stock outs in the first survey in 2013. While the situation appears to have improved since 2014, fear of retaliation may still exist. FS is also one of the provinces that reported the highest rates of ARV and TB medicine stock outs. The survey might have under-estimated the true stock out situation in FS, particularly if facilities with stock outs were less likely to participate.

Figure 6: Profile of participants in 2015 (N=2 423)

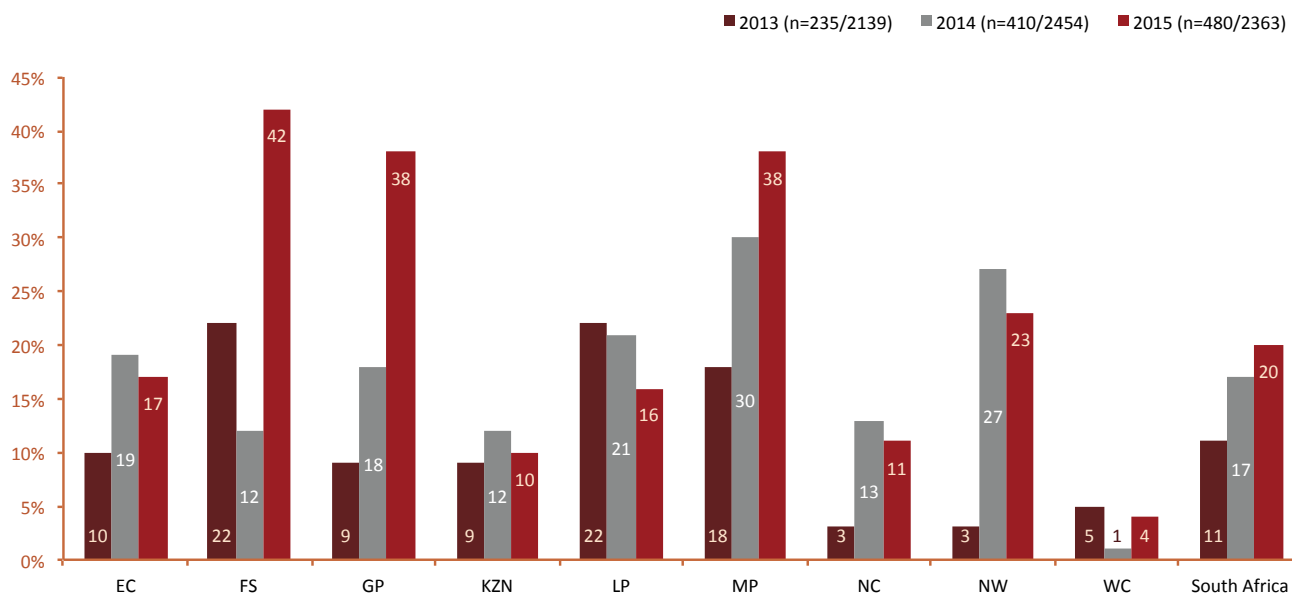


ARV and TB medicines stock outs

A photograph showing a group of people, likely patients or community members, sitting in a line. In the foreground, a man wearing a blue shirt and glasses is looking down. Behind him, a woman in a black jacket and a woman in a red jacket are looking towards the left. The background is slightly blurred, showing other people in a community setting.

Progress in the fight against HIV has largely been facilitated by the massive scale-up of ART, with over 3 million patients initiating treatment in South Africa.^[11] Treatment policies have evolved to include the 2013 introduction of a once-a-day, fixed-dose combination (FDC) tablet of tenofovir/emtricitabine/efavirenz (TDF/FTC/EFV). In 2015, treatment initiation criteria expanded to encompass lifelong ART for HIV-positive people with a CD4 count of 500 cells/ μ l or less, and all pregnant and breastfeeding women regardless of CD4 count. International treatment guidelines now recommend 'test and treat' for all HIV-positive patients, regardless of CD4 count.^[18] A doubling of the HIV patient cohort in South Africa onto lifelong treatment will demand consistent facility-level availability of medicines.




Figure 7: Percentage of facilities reporting at least one ARV or TB medicine stock out (day), by province (2013 - 2015)



On a national level, there was an increase in the percentage of facilities reporting stock outs of ARV or TB medicines on the day of contact, from 11% in 2013 to 17% in 2014 and 20% in 2015 (Figure 7). See Annexes B-II and B-III for further information on stock outs over time and type of stock out

reported on the day of contact. Data on the percentage of facilities reporting stock outs of ARV or TB medicines on the day of contact are consistent with data from 3mo prior to contact (Figure 1; Annexes B-IV and B-V).

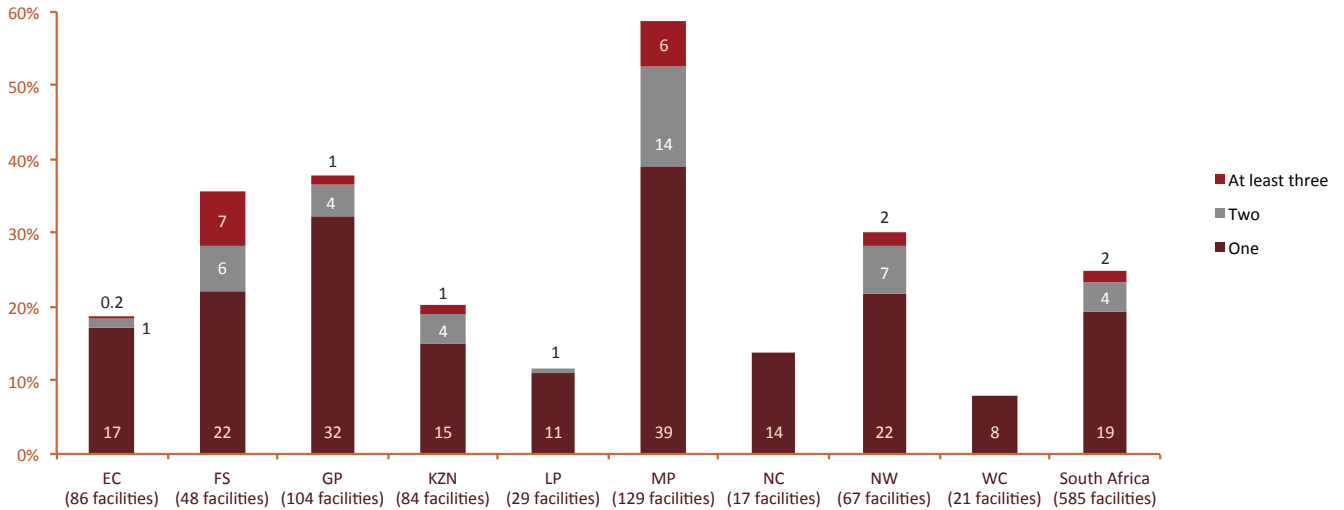
NATIONWIDE, In the three-month period (3mo) prior to contact:

		
1 in 4 facilities reported a stock out (589/2 414)	1 in 5 facilities reported a stock out of adult ARVs (472/1 895)	70% of facilities reported stock outs lasting longer than 1 month (529/760)

The majority of facilities (3mo) reporting a stock out had only one medicine stock out in 2015 (Figure 8).



Figure 8: Percentage of facilities reporting one, two and at least three stock outs (3mo), by province in 2015 (N=2 367)



Lopinavir/ritonavir (LPV/r) and abacavir (ABC) accounted for over two-thirds of the ARV and TB drugs reported out of stock in the 3mo prior to contact (Figure 9). Stock outs of adult formulations were more prevalent than stock outs of paediatric formulations. On the day of contact, of 702 stock outs reported, LPV/r accounted for 23% of all stock outs

(16% adult formulation; 7% paediatric formulations), and ABC accounted for 21% of all stock outs (17% adult formulation; 4% paediatric formulations) (data not shown). The proportion of stock outs attributed to adult formulations of lamivudine (3TC) increased to 17% on the day of contact.

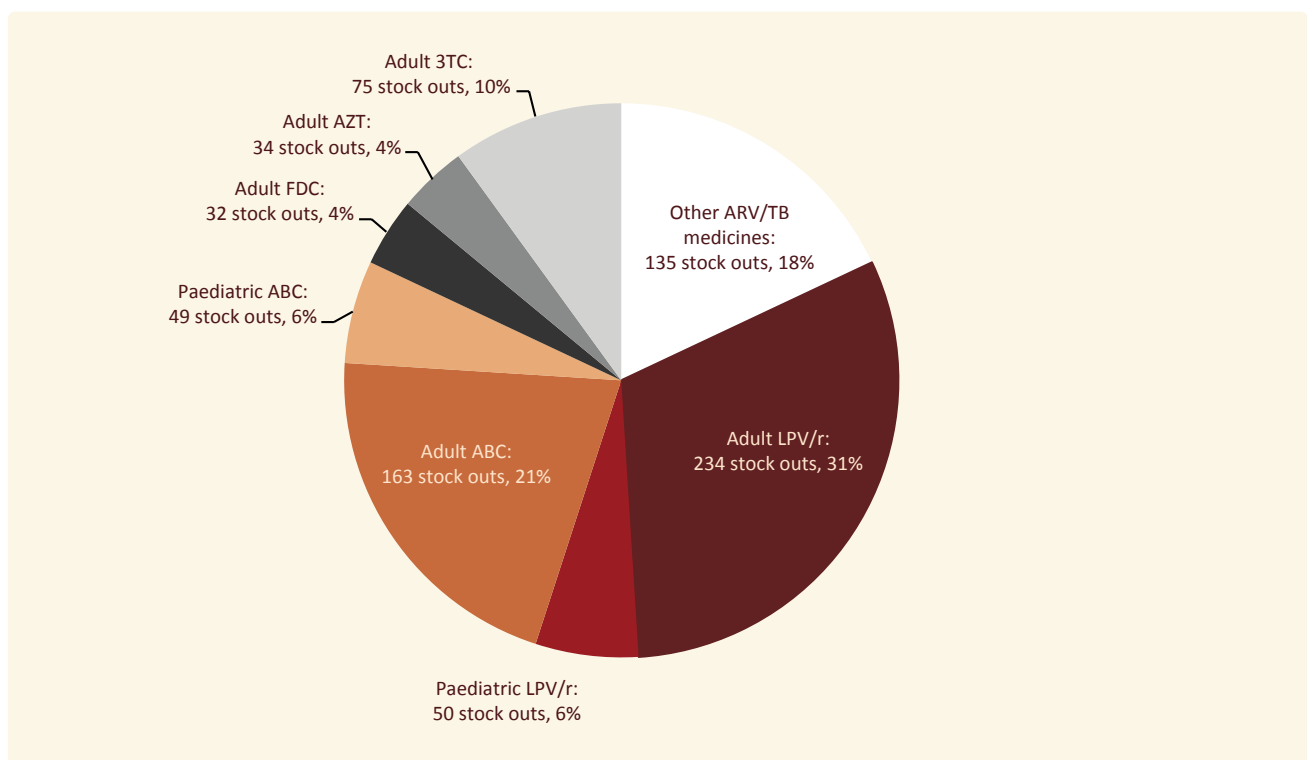
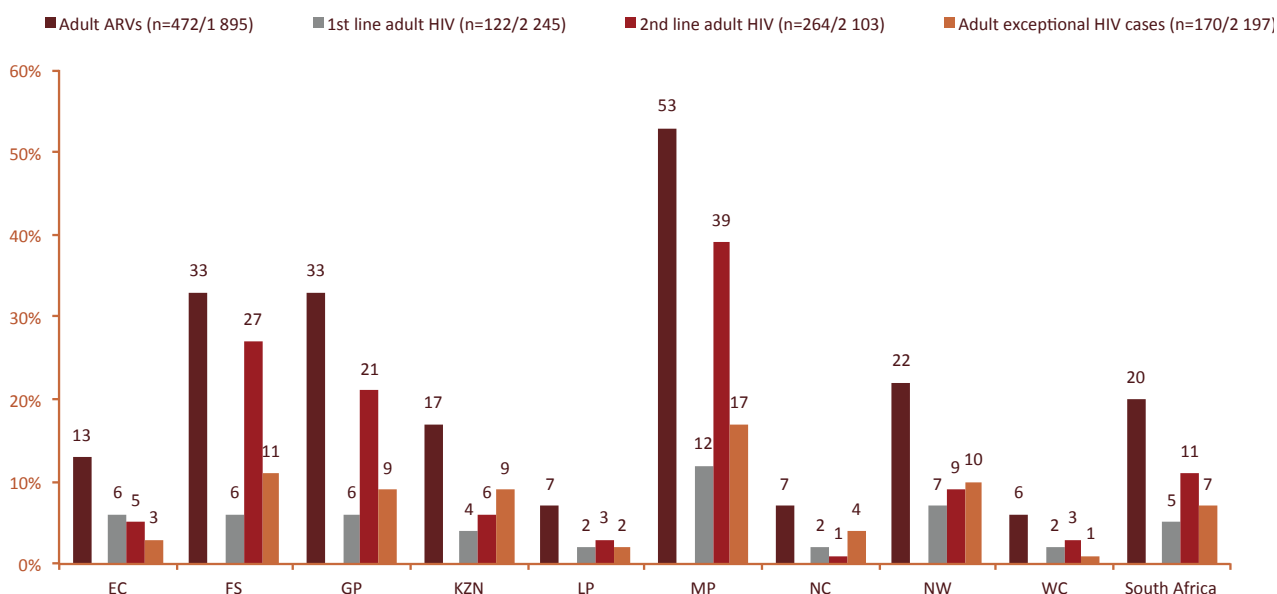


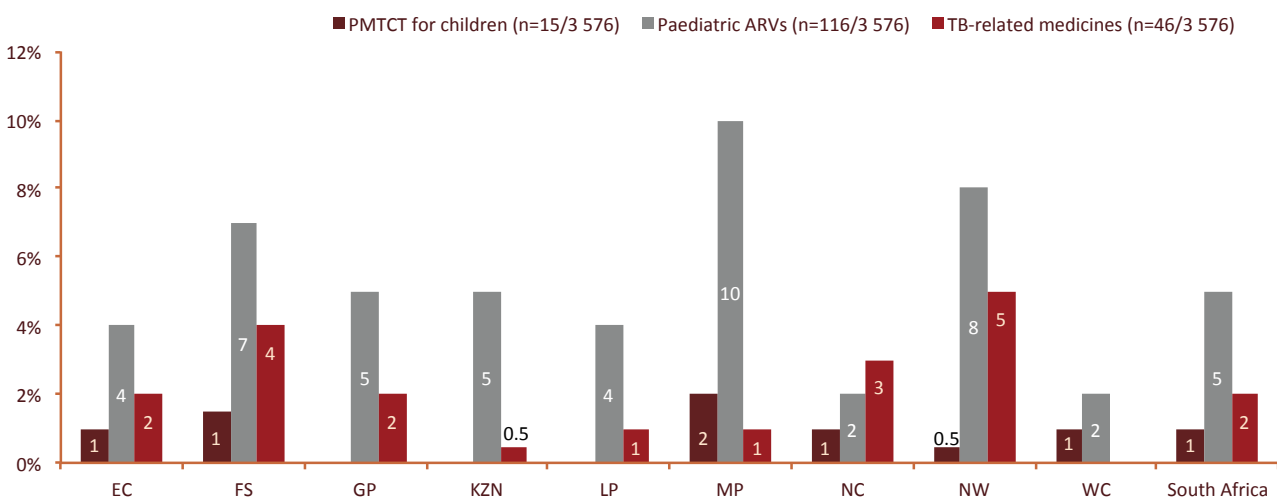
Figure 9: Breakdown of stock outs by ARV or TB medicine (3mo), in South Africa in 2015 (N=767)
 Figure 10: Percentage of facilities reporting adult ARV stock outs (3mo), by province in 2015



One in five facilities nationwide reported stock outs of adult ARVs, with most of these being attributable to second-line ARVs (Figure 10). The main driver of second-line drug stock outs was a national shortage of adult LPV/r (Figure 9). Stock outs of adult ABC, which was used to substitute for LPV/r in

some cases during shortages, contributed to stock outs of ARVs classified as drugs for exceptional HIV cases. Particular provinces were strongly affected by national shortages of LPV/r, and may have managed national stock outs poorly, while others were less affected.

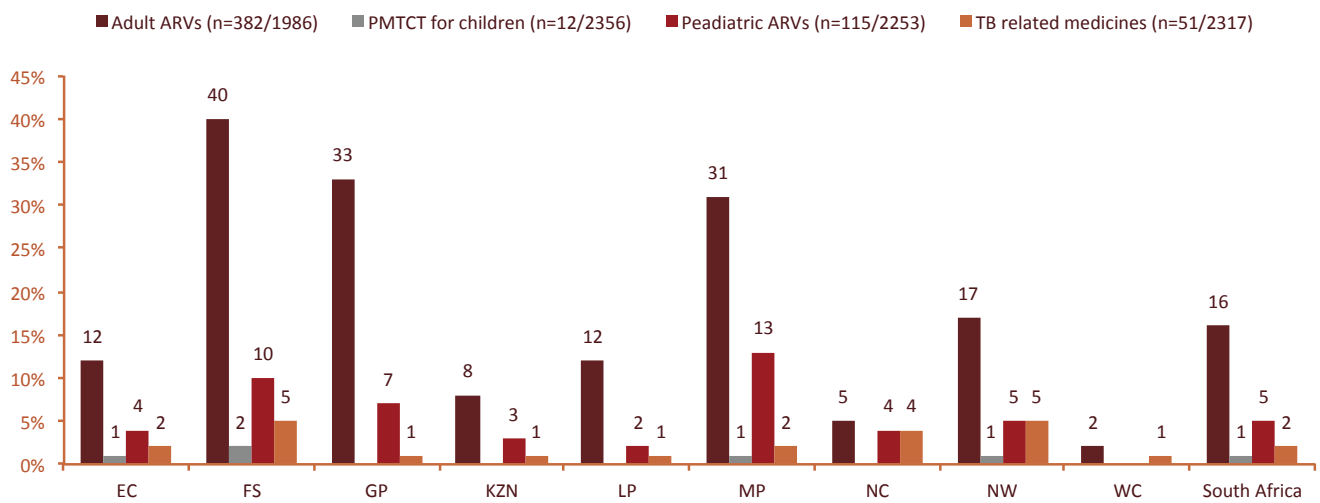
Figure 11: Percentage of facilities reporting stocks outs (3mo) of paediatric ARVs, PMTCT for children and TB medicines (TB treatment, IPT and PN) stock outs (3mo), by province in 2015



Stock outs of nevirapine (NVP) syrup for children for prevention of mother-to-child transmission of HIV (PMTCT) were reported in only 1% of facilities across the country in the 3mo prior to contact (Figure 11). This is a notable improvement compared to 2014, when NVP was the most reported ARV out of stock, due to national shortages. TB-

related medicines, including isoniazid preventive therapy (IPT) and pyridoxine (PN)/vitamin B6 (VitB6), were only reported out of stock by 2% of facilities. Only 5% of facilities nationally reported stock outs of paediatric ARVs, primarily ABC and LPV/r (Figure 9).

Figure 12: Percentage of facilities reporting stock outs (day) of adult ARVs, paediatric ARVs, PMTCT for children and TB medicines (TB treatment, IPT and PN), by province in 2015

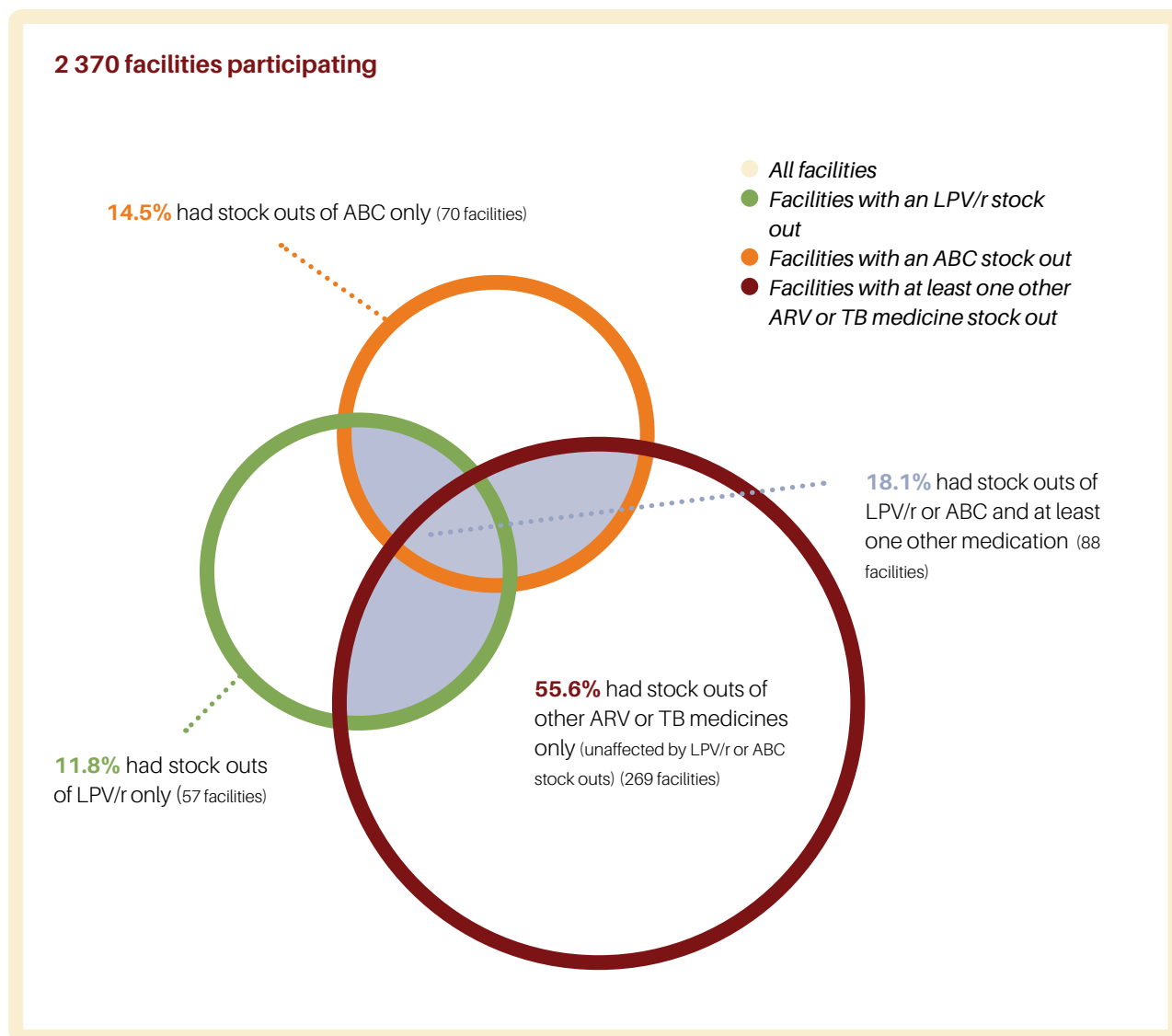


The picture for stock outs on the day of contact is very similar to the scenario seen in the 3mo prior to contact (Figure 12). Most stock outs reported were adult ARVs, driven by the large proportion of facilities reporting LPV/r and ABC

stock outs. Very few facilities reported stock outs of PMTCT medicines or TB medicines. Paediatric ARV stock outs were reported by 5% of facilities nationally, with some variation across provinces.

On the day of contact, of 484 facilities experiencing ARV or TB medicine stock outs:

Figure 13: Percentage of facilities with LPV/r, ABC and other stock outs (day), in 2015 (484 facilities with stock outs)



Duration and impact

Unplanned treatment interruptions that occur as a result of stock outs increase the risk of death, treatment failure, drug resistance and opportunistic infections, and also increase the likelihood of HIV or TB transmission to others.^[19-21] When stock outs occur, patients may lose their trust in the health system, or be unable to afford to return to a clinic on multiple occasions to collect medication.

Stock outs can result in patients being sent home without medicines, administration of regimens or dosages that are more complicated for patients to take, or provision of incomplete regimens. In some cases, providing an

incomplete regimen can pose greater risk to a patient of developing drug resistance than not giving any ARV or TB medications at all.^[22] Patients who develop drug resistance – either following treatment interruptions, or who are directly infected with resistant strains of HIV or TB – rely on more specialised diagnostics. They must also take medicines that are typically more difficult to administer, have a greater number of side-effects and are more expensive to purchase.^[13] Not all facilities may have the capacity to diagnose and treat more complicated strains of HIV and TB, suggesting that stock outs can enhance inequalities in accessing healthcare services.



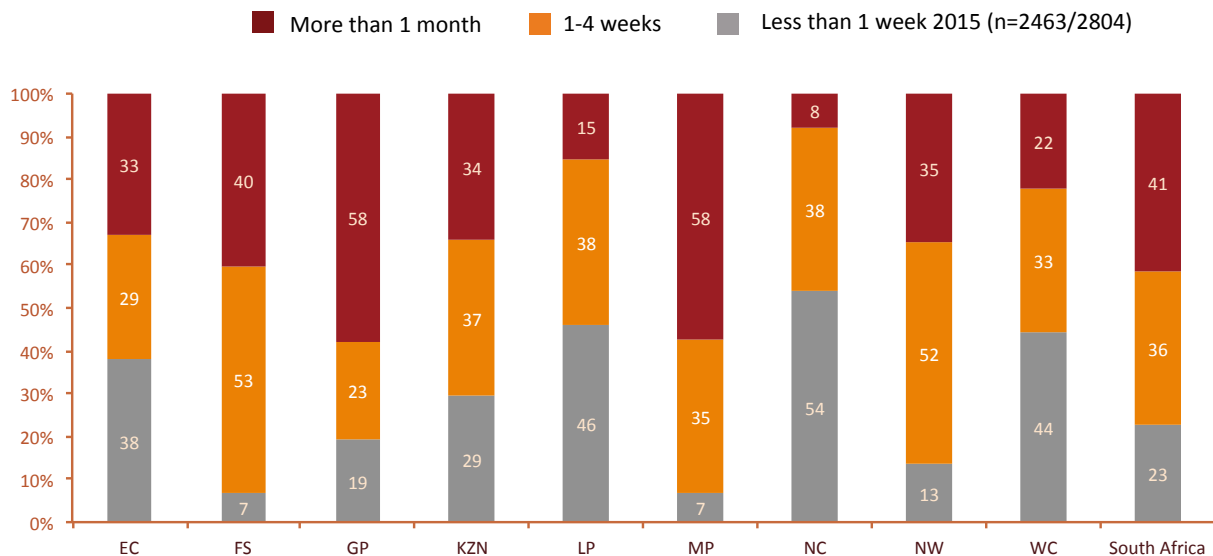
I've been diagnosed with MDR-TB in September 2015. The facility where I get my medicine is always out of stock and I'm concerned that I will default on my treatment. I try to go to the clinic 7-10 days before my medicine is finished to inform the clinic, but this has not helped and I've been told to go somewhere else to get my medication. I'm unemployed and cannot afford to go there. After contacting the Stop Stock Outs Project, it was discovered that my facility needs to request my medication from the nearby hospital. Unfortunately though even if the clinic does this, sometimes there are transport issues and there is no one with a car from the facility who can collect the medication"

- Patient from Mpumalanga



Stock out duration

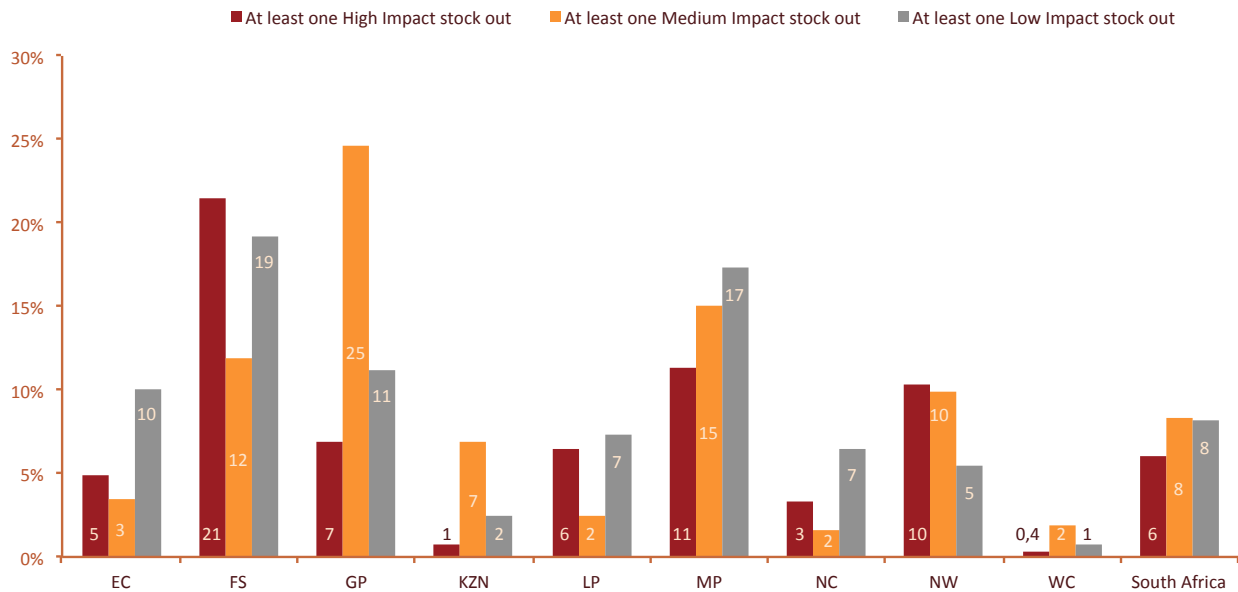
Figure 14: Percentage of stock outs (day) lasting (i) less than one week, (ii) one to four weeks, or (iii) longer than one month, by province in 2015



At a national level in the 3mo prior to contact, 8% of stock outs lasted less than a week, 22% between one and four weeks and 70% lasted longer than one month (Figure 2). On the day of contact, a smaller proportion of stock outs had been occurring for longer than one month (Figure 14); however, the final duration of the stock out was not yet known – the stock out could have been resolved the following day, or in two months' time. In contrast, the longer duration of time encompassed during the 3mo period allowed more opportunity to observe lengthier stock outs. Further detail on the duration of stock outs by province is provided in Annexes B-VI and B-VII.

The majority of provinces showed similar distributions of length of stock out in the 3mo prior to contact. It is concerning that those **provinces with the highest percentage of longer duration stock outs (MP, FS and GP) were also the provinces with the highest overall proportion of facilities reporting stock outs.** Stock outs in the 3mo prior to contact lasted longer than in the 2014 survey. This could be due to national shortages of LPV/r limiting options for quick stock out resolution. However, as observed in 2014, there was variation in the time to resolve the stock outs between provinces.

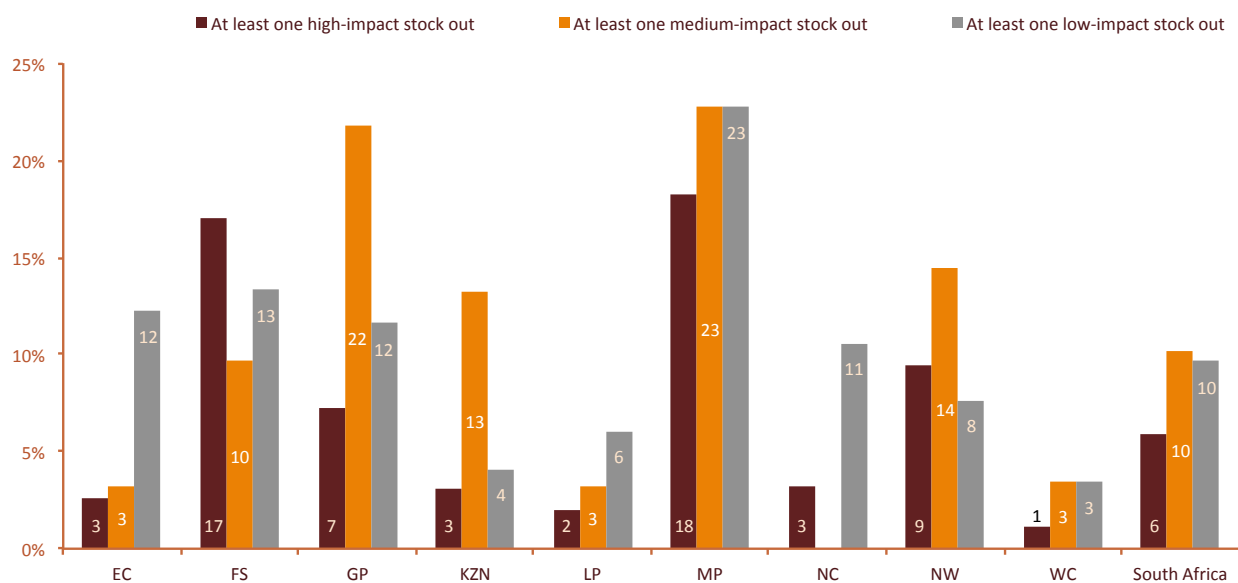
Figure 15: Percentage of facilities reporting at least one high-, medium- or low-impact stock out (day) by province in 2015



The FS had the highest provincial proportion of facilities reporting high-impact stock outs on the day of contact (21%) (Figure 15), which was nearly double that of MP (11%) and triple that of GP (7%). This is concerning, as FS also had a high proportion of facilities reporting stock outs. GP had a

high proportion of facilities with medium-impact stock outs (25%), which could be due to urban facilities being located in closer proximity to suppliers or depots that could provide alternative regimens, or to a more efficient emergency response capacity to stock outs in general.

Figure 16: Percentage of facilities reporting at least one high-, medium- or low-impact stock out (3mo), by province in 2015



In the 3mo prior to contact (Figure 16), MP had the highest percentage of facilities in each impact category, though FS also struggled with a high rate of high-impact stock outs (17%), suggesting these provinces require the greatest

support in learning how to manage and mitigate stock outs. GP maintained a tendency toward medium-impact stock outs (22%).

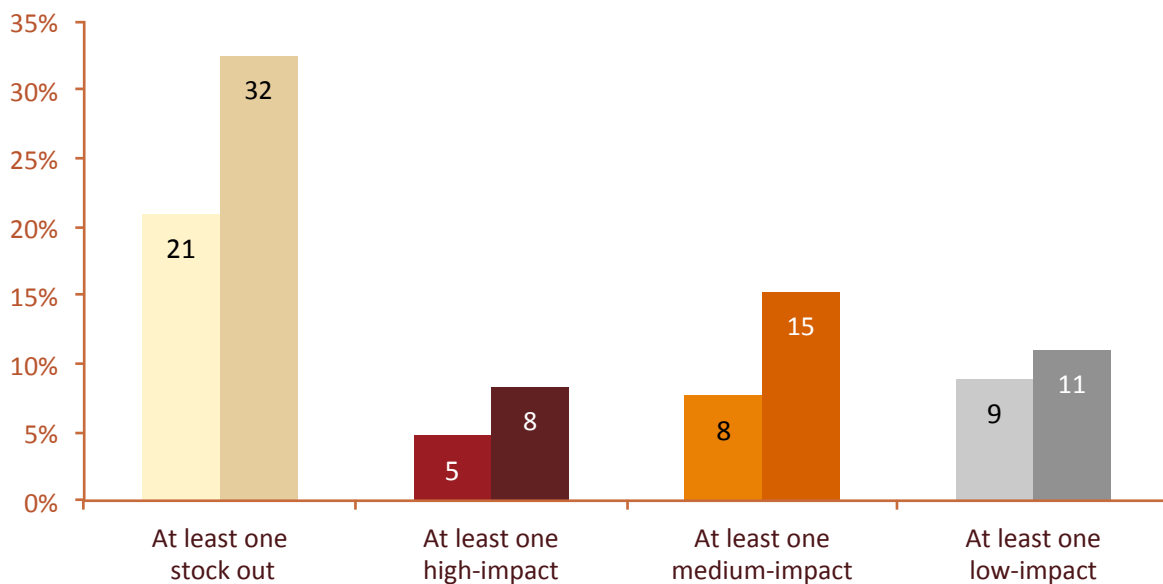
“ When there are stock outs, patients and health care workers often get creative in order to find ways around them. Patients will lend from friends and colleagues who are on similar regimens. That’s a good short-term solution, but long-term is problematic, because it means the patient could fail, and have to go onto third-line treatment. All because of lack of supply, not lack of adherence.” – Lauren Jankelowitz, Southern African HIV Clinicians Society

Impact by facility cohort size

Details on the prevalence and impact of stock outs by facility cohort size are found in Annexes B-VIII to B-XI. Trends in the impact of stock outs by facility cohort size were similar on both the day of contact and the 3mo prior to contact. Here we

report data for the 3mo prior to contact. Facilities with more than 1 000 patients in their ART cohort were considered to be large; facilities with less than 1 000 patients in their ART cohort were considered to be small.

Figure 17: Percentage of facilities with at least one stock out (3mo), by impact of stock out and facility size, in 2015



The percentage of facilities with at least one stock out was significantly higher among large facilities (32%) than among small facilities (21%) (Figure 17). This was primarily driven by medium-impact stock outs, though the proportion of large facilities with at least one high-impact stock out was also significantly greater than among small facilities. There was a significant trend towards higher numbers of stock outs in large facilities than in small facilities.

It is plausible that large facilities were more prone to higher-impact stock outs because they stock larger quantities and

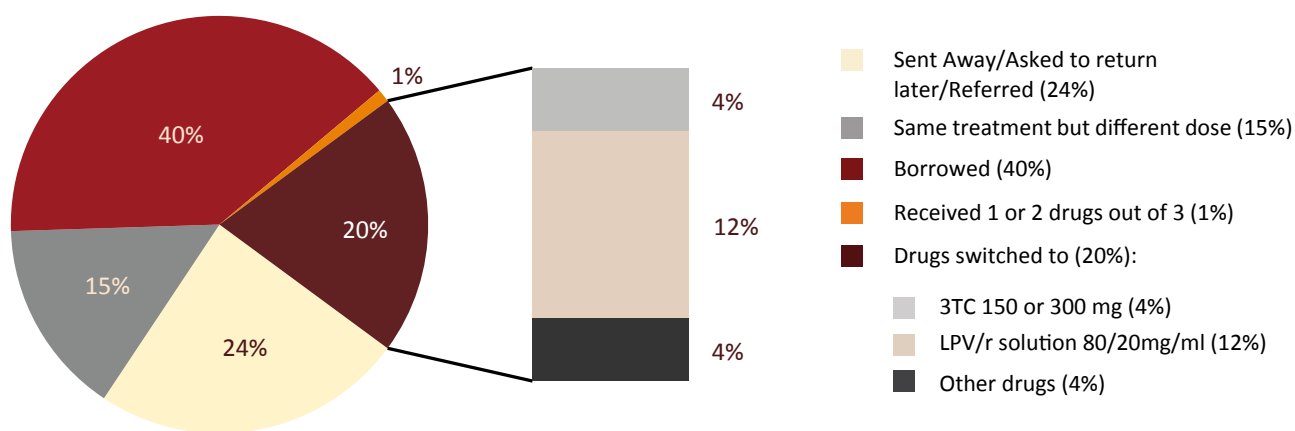
more diverse regimens than smaller facilities, to meet the needs of their patient cohorts. Large facilities may also have been more likely to stock medicines that were in short supply nationally, as they may have more patients identified in need of second-line and exceptional case ARVs. There are fewer alternatives for these medications, and unless a facility had borrowed adult LPV/r from another facility, all LPV/r stock outs reported would at the least have had a medium impact, as most alternative regimens are more burdensome on patients.

Outcomes in the event of adult LPV/r and ABC stock outs

Given national shortages of LPV/r, we analysed how facilities responded in the event of adult LPV/r stock outs, or in the event of ABC stock outs, as ABC appears to have been widely used as part of a substitution regimen for LPV/r. The use of other LPV/r or ABC dosages or formulations would have had the same clinical effect if dosed correctly. However,

this action also likely jeopardised the supply of paediatric formulations, and contributed to stock out reports of these medicines. Furthermore, the increased pill burden or switch to syrup formulations – such as to LPV/r syrup, which is 42% alcohol and renowned for its lack of palatability – would likely have been cumbersome or unpleasant for patients^[23]

Figure 18: Action taken for adult LPV/r stock out (3mo), in 2015

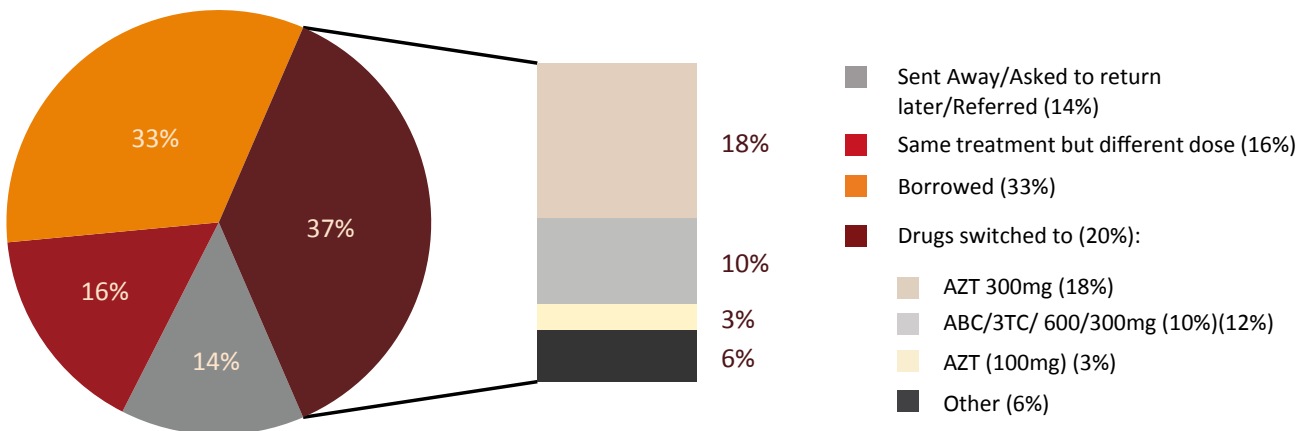


In instances of LPV/r adult formulation stock outs in the 3mo prior to contact, patients were sent away without medication 24% of the time (see Figure 18). In 39% of the reported stock outs, the adult formulation medication was borrowed. In 12% of stock outs, patients were switched to

the LPV/r paediatric solution, 4% to adult 3TC tablets and 4% to other drugs. This distribution of the facility action taken for stock outs on the day of contact was similar to that observed in the 3mo prior (data not shown).

● Other = 1 to (D4T) Stavudine 30mg; 3 to (TDF/FTC/EFV (FDC)) Tenofovir/Emtricitabine/Efavirenz 300/200/600mg
 2 to (3TC) Lamivudine 150 or 300 mg;
 3 to (AZT) Zidovudine solution 50mg/5ml; 1 to (D4T) Stavudine 15mg or 20 mg

Figure 19: Action taken for adult ABC stock out (3mo), in 2015



Of ABC adult formulation stock outs in the 3mo prior to contact: 14% resulted in patients being sent away from facilities without medication (Figure 19); in 33% medication was borrowed; in 16% patients were given an alternative dosage of ABC; and in 37% patients were given an alternative medication, namely AZT 300 mg, or ABC/3TC combination 600/300 mg. On the day of the call (data not shown), a greater proportion of stock outs (22%) resulted in patients being sent away as a result of adult ABC stock outs than in the 3mo prior to contact. A greater percentage (23%) resulted in patients being switched to a different dose of ABC, while smaller percentages of stock outs resulted in borrowing or switching to alternative therapies.

Our findings suggest that in many instances, supplies of all

LPV/r formulations were limited in the event of a stock out, as were supplies of medicines such as ABC, used in alternative second-line regimens. However, it also suggests that clinical guidance issued by the SAHIVSoc in August 2015 had been well disseminated, and followed by clinicians.^[24] The fact that several provinces reported alternative therapies for ABC adult formulation as also being commonly out of stock, suggest an important generalised knock-on effect of national stock outs of LPV/r. Findings suggest that adult ABC shortages were more acute by the end of 2015, with fewer opportunities to find alternative supplies, or clinics were not well-informed on how to manage such stock outs.

“ They told me the pills were not available in the clinic. They said they were not even available in the hospital. They told me to come back on the 13th. I was daunted by the thought that I would have to go back again. Walking is a struggle.” – Khaya Mkhize* (*not his real name), experienced LPV/r stock outs.



● Other = 1 to (D4T) Stavudine 30mg; 1 to (EFV) Efavirenz 600mg; 2 to TDF/FTC/EFV (FDC)) Tenofovir/Emtricitabine/Efavirenz 300/200/600mg; 1 to (TDF/FTC) Tenofovir/ Emtricitabine 300mg/200mg; 2 to (AZT) Zidovudine 300mg; 1 to (NVP) Nevirapine 200mg; 2 to (ABC) Abacavir 600mg; 3 to (LPV/r) Lopinavir/Ritonavir 100mg/25mg



Provincial overview

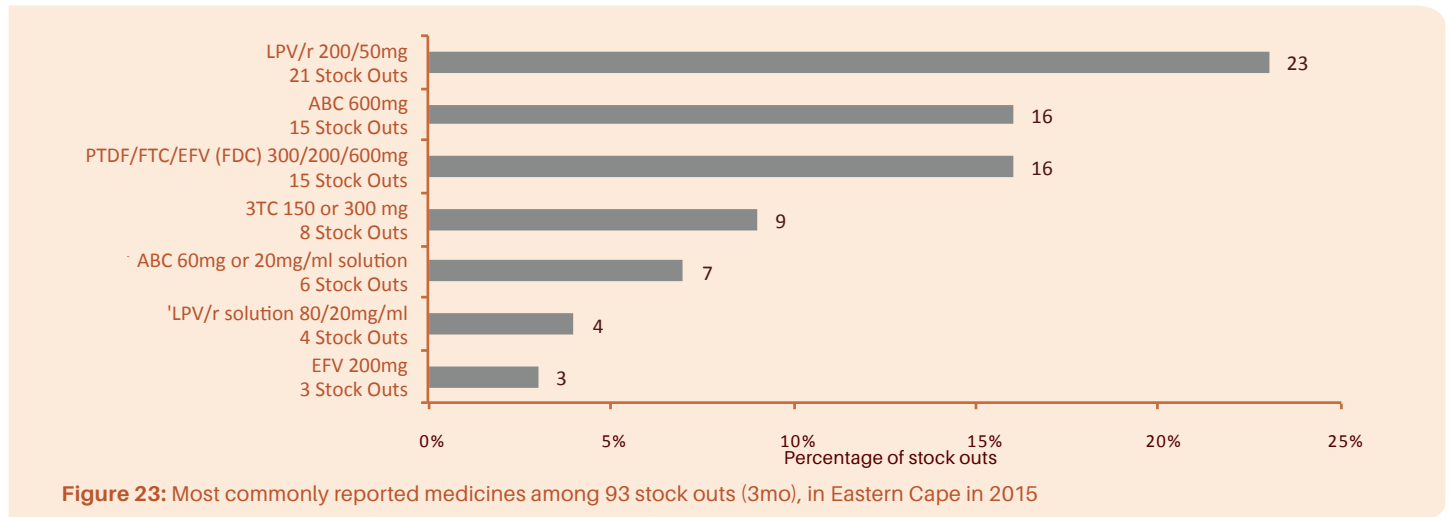
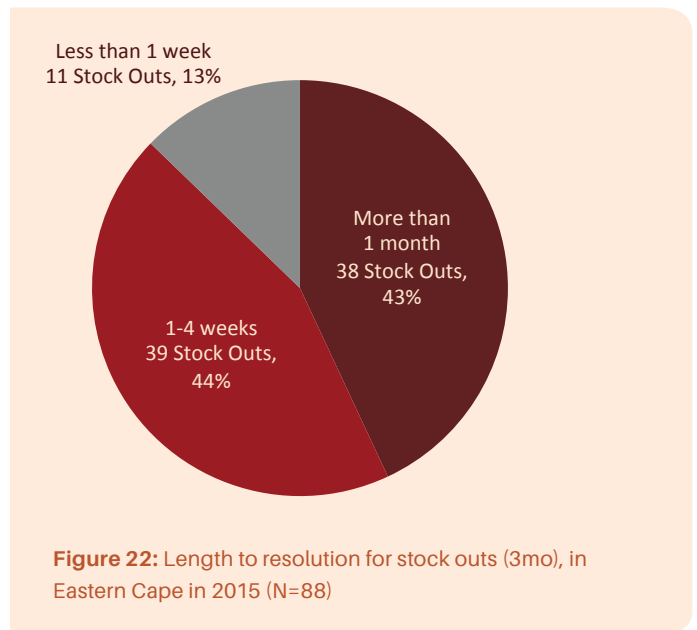
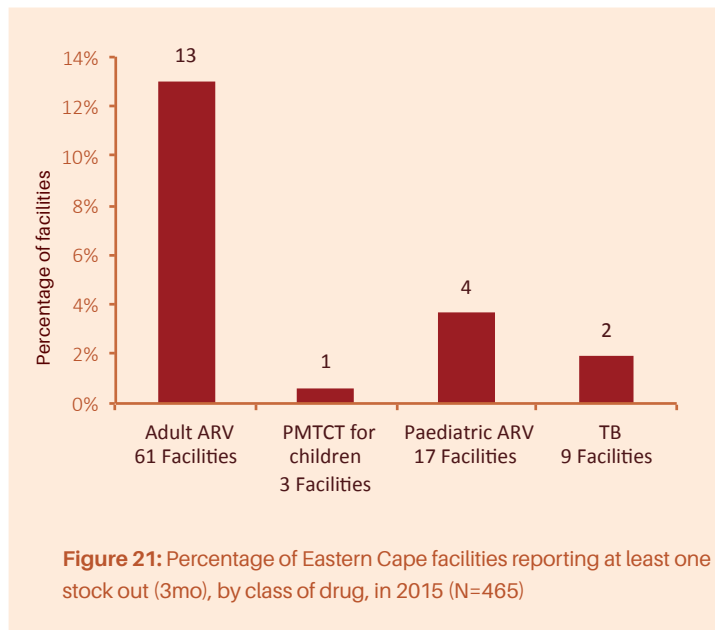
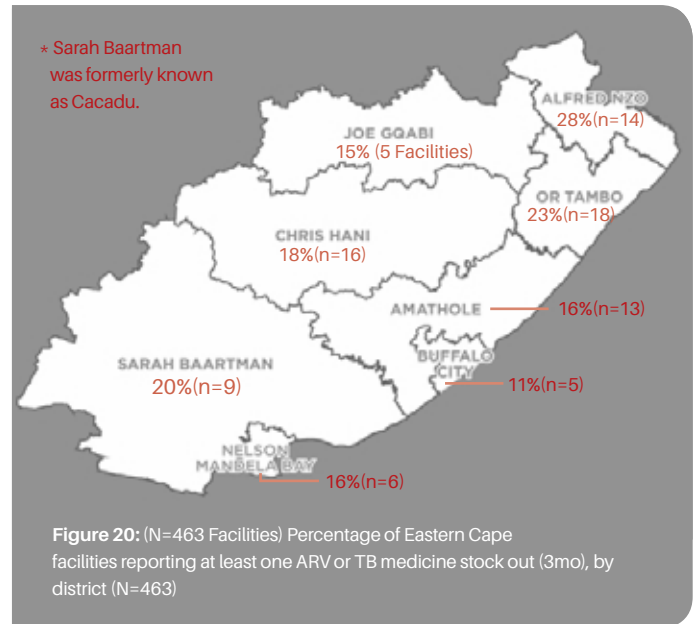
The SSP surveys have consistently shown that wide variation exists in the proportion of ARV or TB medicine stock outs reported by facilities in different provinces, and in different districts within provinces. A province that has not adequately planned for a change in treatment regimen could result in pharmacists having limited information on how to order sufficient supplies, or healthcare workers making suboptimal decisions for mitigating the impact of stock outs when they occur. A single district with a poorly functioning supply chain and many stock outs can skew the results for an entire province.

Districts and provinces with a high proportion of facilities reporting stock outs require urgent intervention, and should create action plans to overcome their unique challenges (Table 1). No districts are the same, and no provinces are the same, but poor performers can learn from others that have been successful in reducing the occurrence of stock outs. Dialogue should be encouraged to help districts and provinces overcome supply chain limitations, and ensure medicines reach the patients for whom they are intended.

Unless otherwise noted, results in the provincial overview provided here refer to stock outs of ARV and TB medicines in the 3mo prior to contact.

Eastern cape

- Achieved a 9% reduction in the percentage of facilities reporting at least one stock out, from 28% in 2014 to 19% in 2015—similar to the proportion observed in 2013 (20%).
- Two districts, where over 40% of facilities reported at least one stock out in 2014, reported large reductions in 2015: in Alfred Nzo District the proportion fell from 50% in 2014, to 28% in 2015. In Joe Gqabi District, the proportion fell from 46% in 2014 to 15% in 2015.
- Limiting the duration of stock outs remains a challenge in the EC, with 43% of stock outs lasting more than one month, and a further 44% of stock outs lasting between one and four weeks.
- First-line FDC comprised 16% of stock out cases in the province—a rate approximately four times higher than the national average.



Free State

- A large increase between 2014 (28%) and 2015 (36%) in the percentage of facilities reporting at least one stock out in the three months prior to contact, and on the day of the call (12% in 2014; 42% in 2015) (Figure 9, page XX).
- A majority (54%) of facilities reporting stock outs on the day of the call reported at least two ARV or TB medicines out of stock.
- Two districts (Fezile Dabi DM and Lejweleputswa DM) with high proportions of stock outs in 2014 managed to substantially reduce the percentage of facilities reporting stock outs, though rates of over 30% were still reported. Both districts had 42% of facilities reporting stock outs in 2014, and 33% reporting stock outs in 2015.
- The duration of stock outs remains unacceptably high, with 78% of stock outs lasting more than one month.

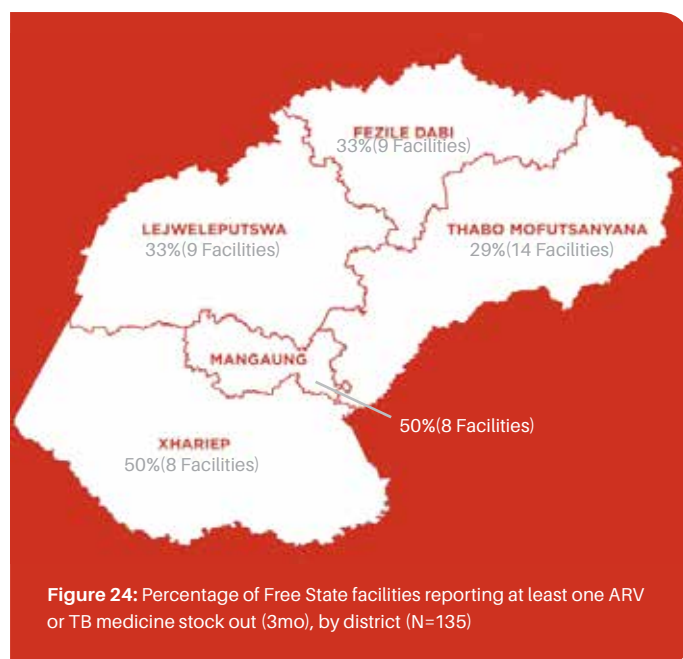


Figure 24: Percentage of Free State facilities reporting at least one ARV or TB medicine stock out (3mo), by district (N=135)

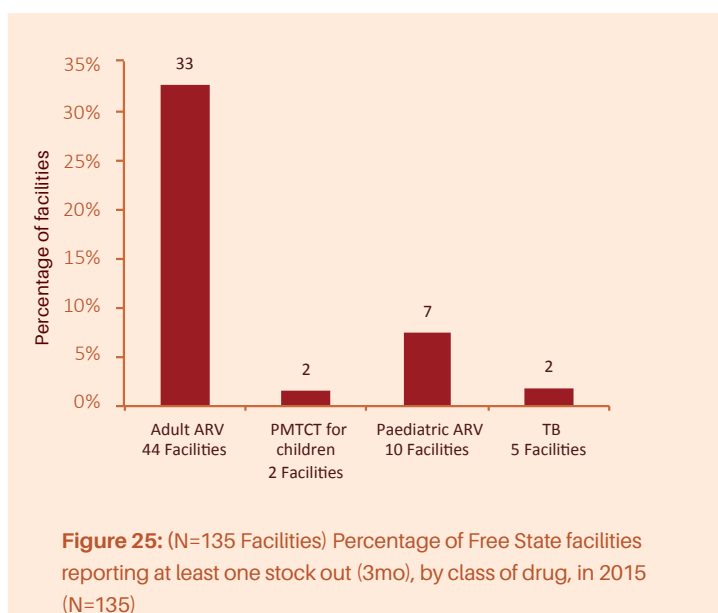


Figure 25: (N=135 Facilities) Percentage of Free State facilities reporting at least one stock out (3mo), by class of drug, in 2015 (N=135)

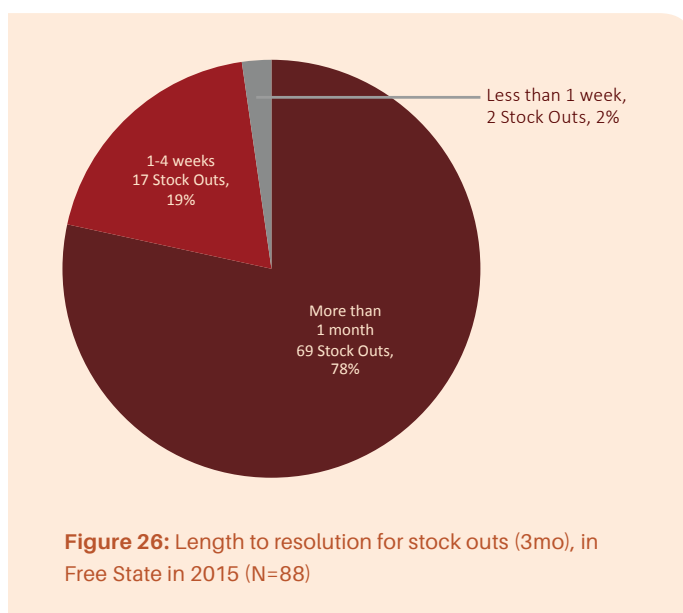


Figure 26: Length to resolution for stock outs (3mo), in Free State in 2015 (N=88)

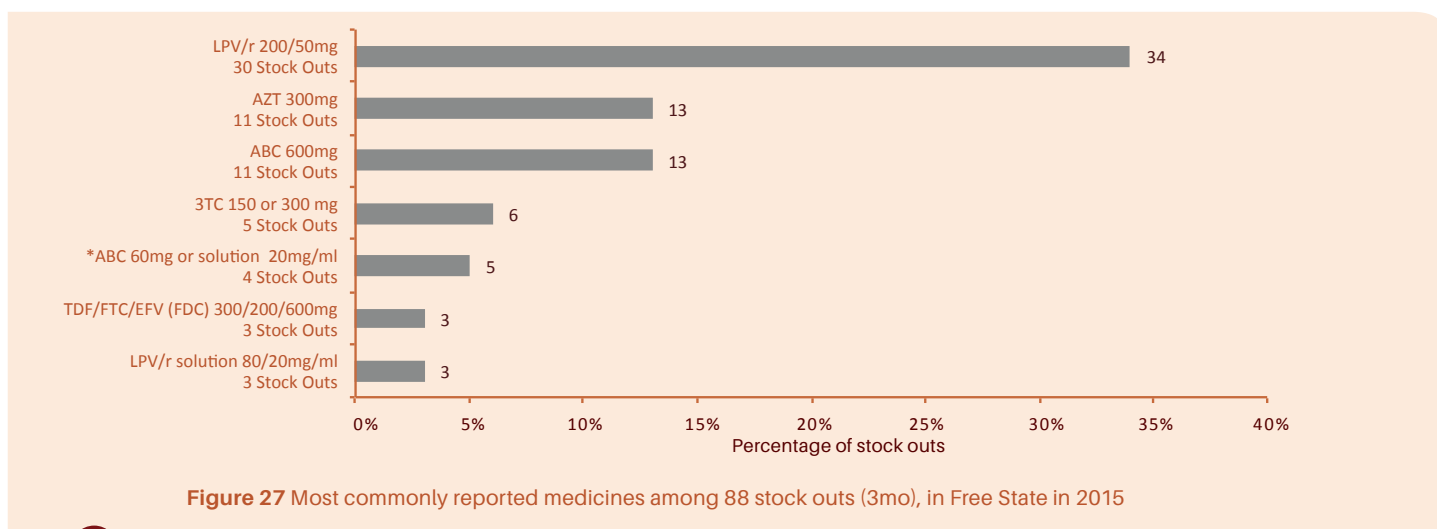


Figure 27 Most commonly reported medicines among 88 stock outs (3mo), in Free State in 2015

Gauteng

- The percentage of facilities in the province reporting at least one stock out in the three months prior increased steadily since 2013 (20%), to 25% in 2014 and 39% in 2015. Compared to 2014, the proportion of facilities reporting at least one stock out on day of survey more than doubled in 2015, from 18% to 38% (Figure 9, page XX).
- Urgent intervention is needed in Sedibeng DM and Ekurhuleni MM, where the proportions of facilities reporting stock outs are 53% and 47%, respectively. All districts in GP saw an increase since 2014 in the proportion of facilities reporting stock outs.
- The duration of stock outs remains unacceptably high, with 75% of stock outs lasting more than one month.

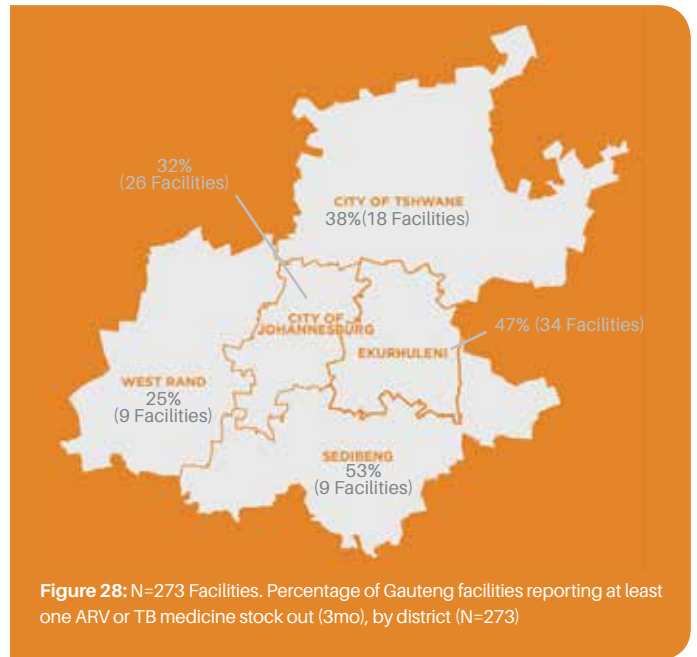


Figure 28: N=273 Facilities. Percentage of Gauteng facilities reporting at least one ARV or TB medicine stock out (3mo), by district (N=273)

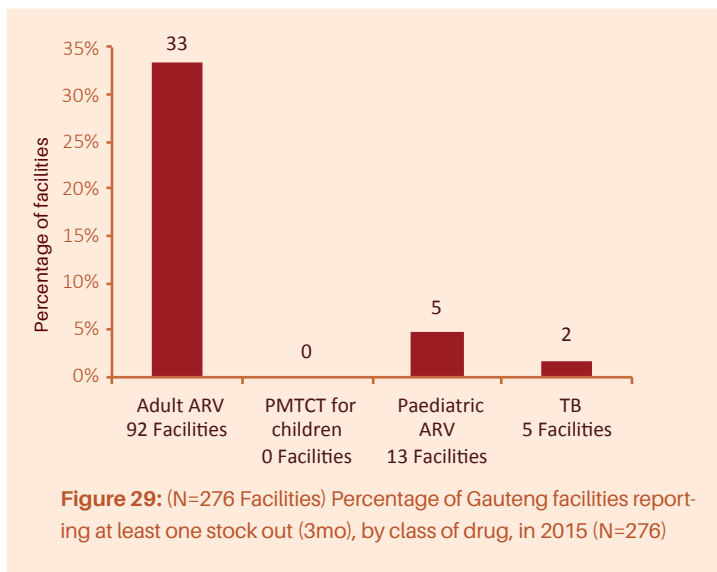


Figure 29: (N=276 Facilities) Percentage of Gauteng facilities reporting at least one stock out (3mo), by class of drug, in 2015 (N=276)

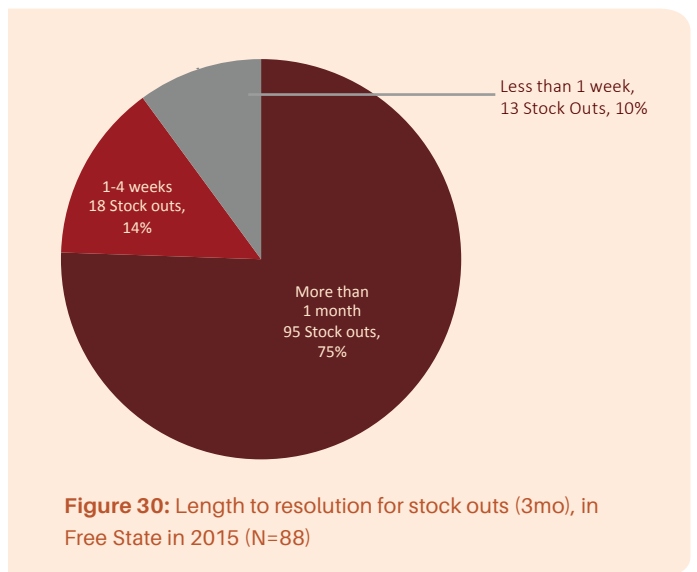


Figure 30: Length to resolution for stock outs (3mo), in Free State in 2015 (N=88)

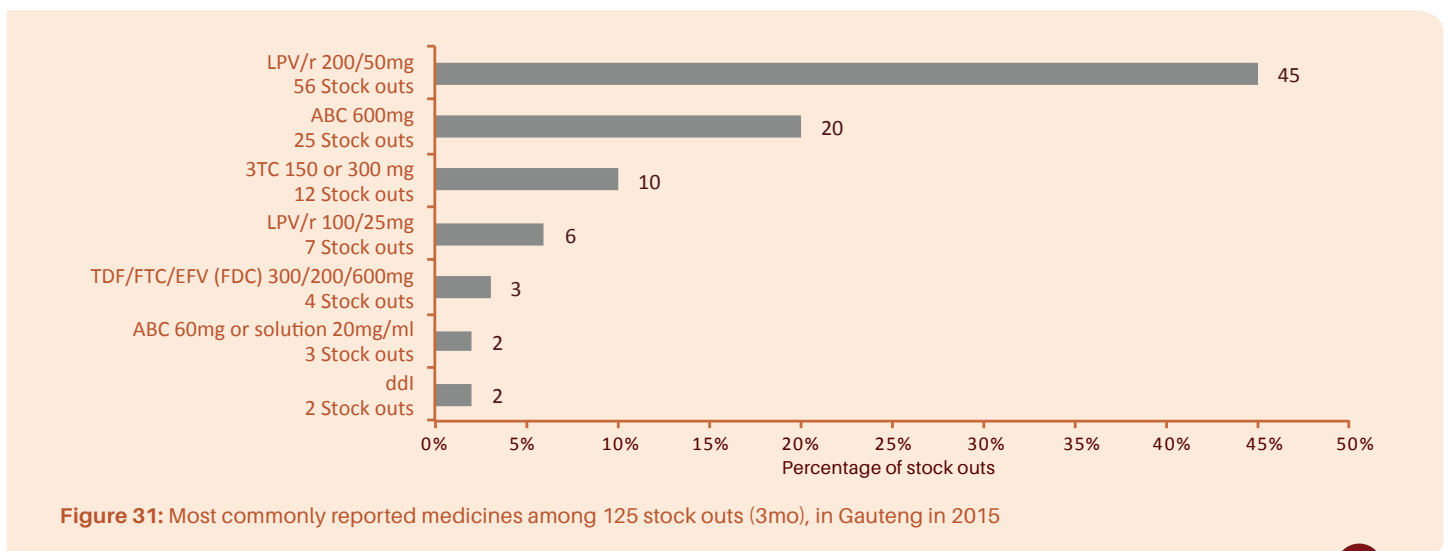


Figure 31: Most commonly reported medicines among 125 stock outs (3mo), in Gauteng in 2015

KwaZulu-Natal

- Decrease in the percentage of facilities reporting at least one stock out, from 19% in 2014 to 12% in 2015. KZN was one of the better-performing provinces in 2015, where stock out rates reported were approximately half the national average.
- Only two districts (Umkhanyakude DM and Umzinyathi DM) reported more than 30% of facilities experiencing stock outs.
- The duration of stock outs remains unacceptably high, with 66% of stock outs lasting more than one month.

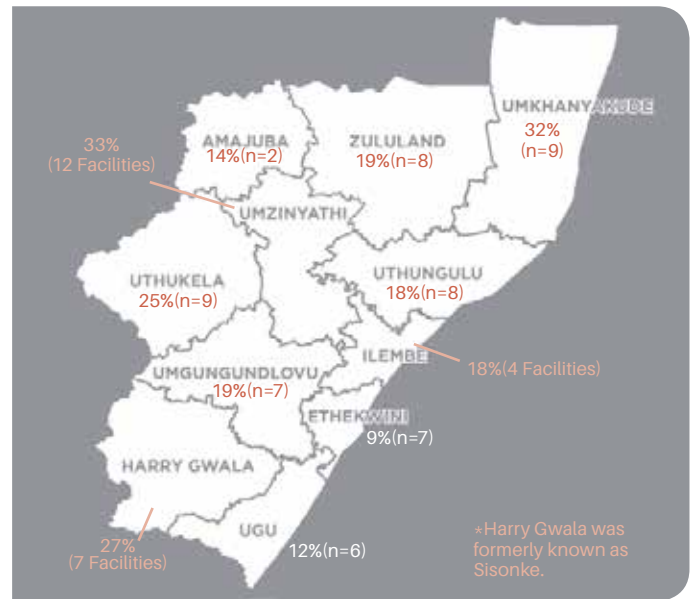


Figure 32: N=413 Facilities. Percentage of KwaZulu-Natal facilities reporting at least one ARV or TB medicine stock out (3mo), by district (N=413)

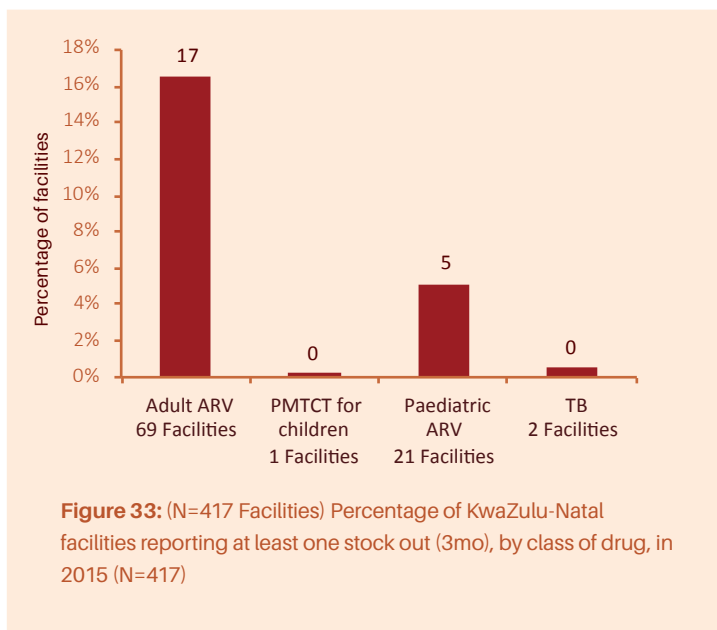


Figure 33: (N=417 Facilities) Percentage of KwaZulu-Natal facilities reporting at least one stock out (3mo), by class of drug, in 2015 (N=417)

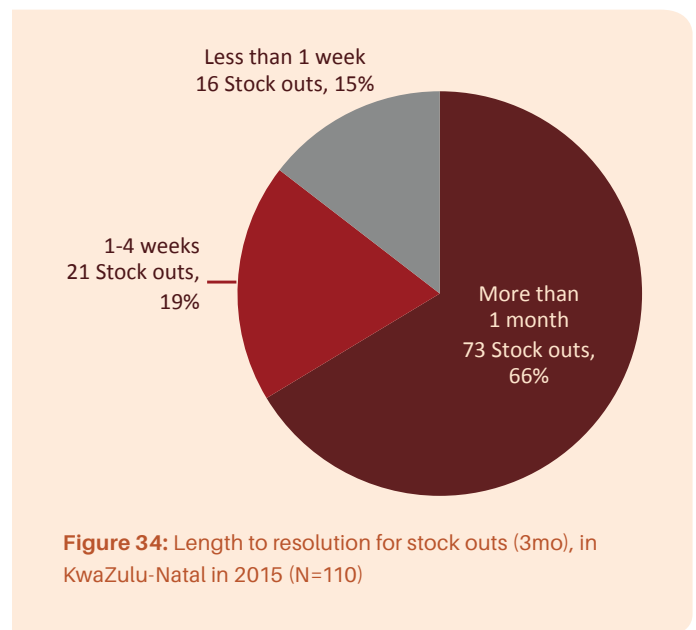


Figure 34: Length to resolution for stock outs (3mo), in KwaZulu-Natal in 2015 (N=110)

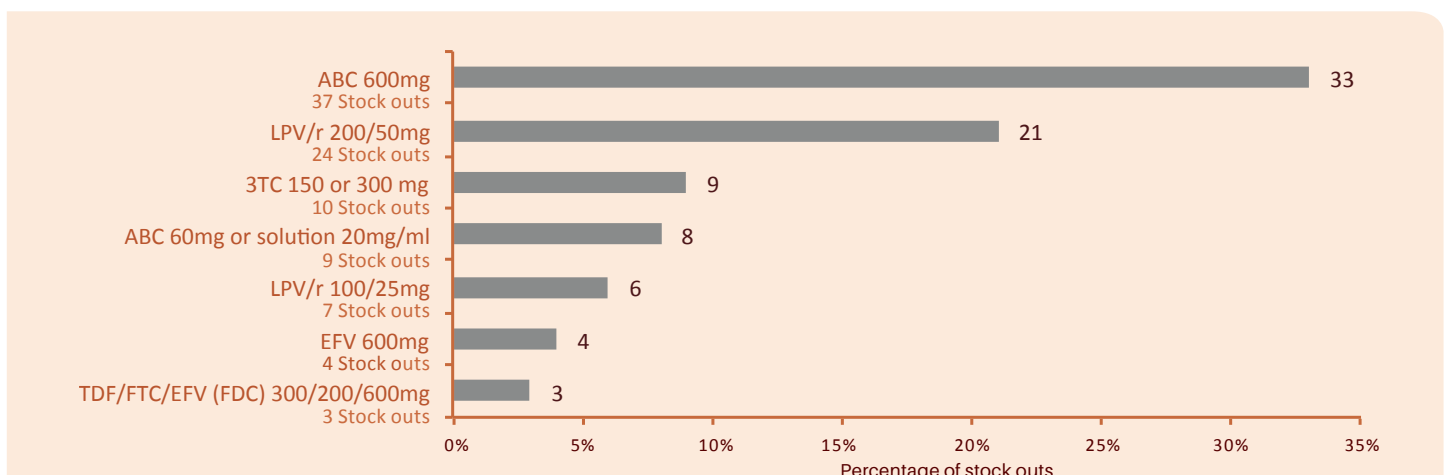


Figure 35 Most commonly reported medicines among 112 stock outs (3mo), in KwaZulu-Natal in 2015

Limpopo

- Steady improvement in reducing proportion of facilities with stock outs (41% in 2013, 29% in 2014, 12% in 2015). LP was one of the top-performing provinces in 2015, where stock out rates reported were approximately half the national average.
- Only one district (Vhembe DM) reported more than 15% of facilities with stock outs. All other districts had five or fewer facilities reporting stock outs.
- The duration of stock outs remains unacceptably high, with 74% of stock outs lasting more than one month.

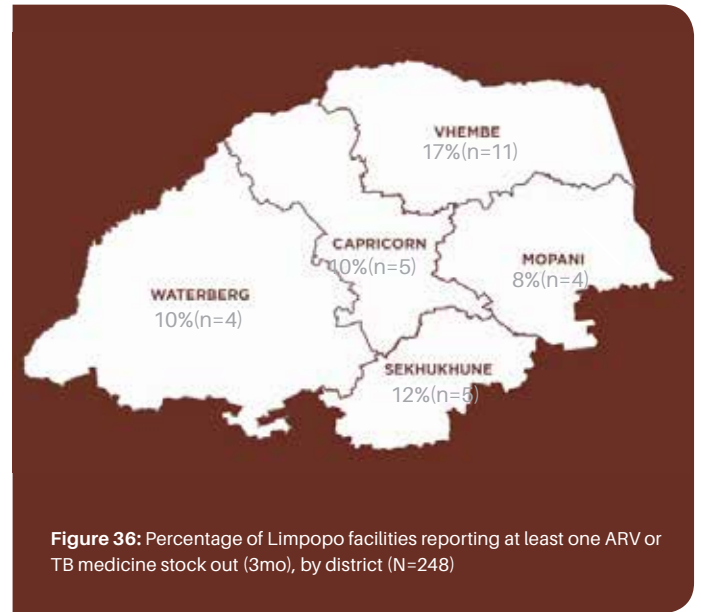


Figure 36: Percentage of Limpopo facilities reporting at least one ARV or TB medicine stock out (3mo), by district (N=248)

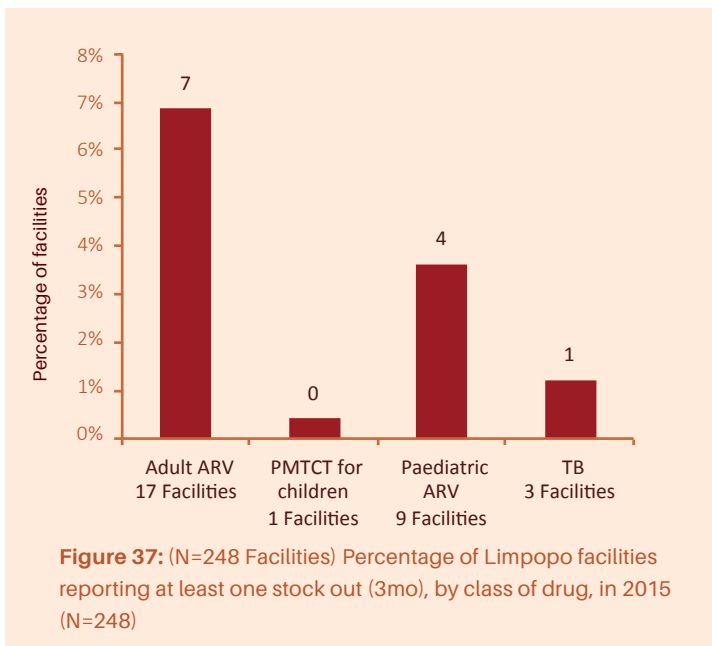


Figure 37: (N=248 Facilities) Percentage of Limpopo facilities reporting at least one stock out (3mo), by class of drug, in 2015 (N=248)

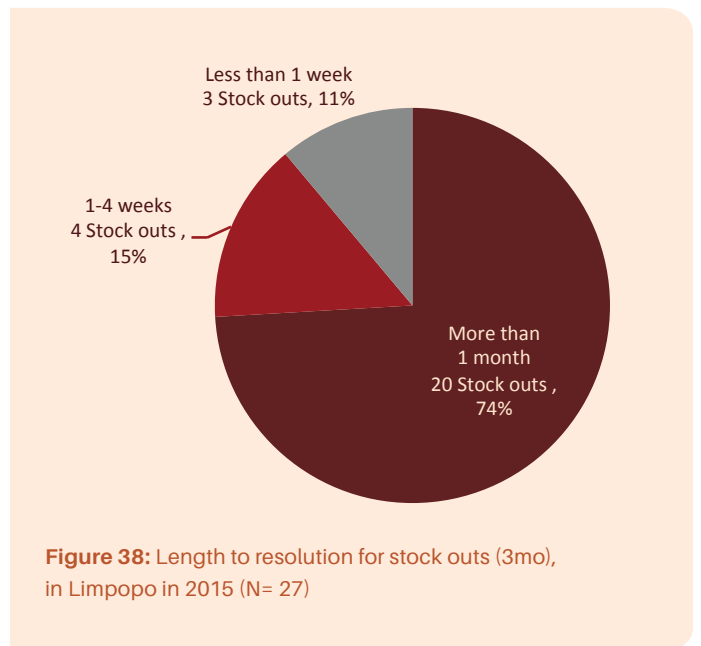


Figure 38: Length to resolution for stock outs (3mo), in Limpopo in 2015 (N= 27)

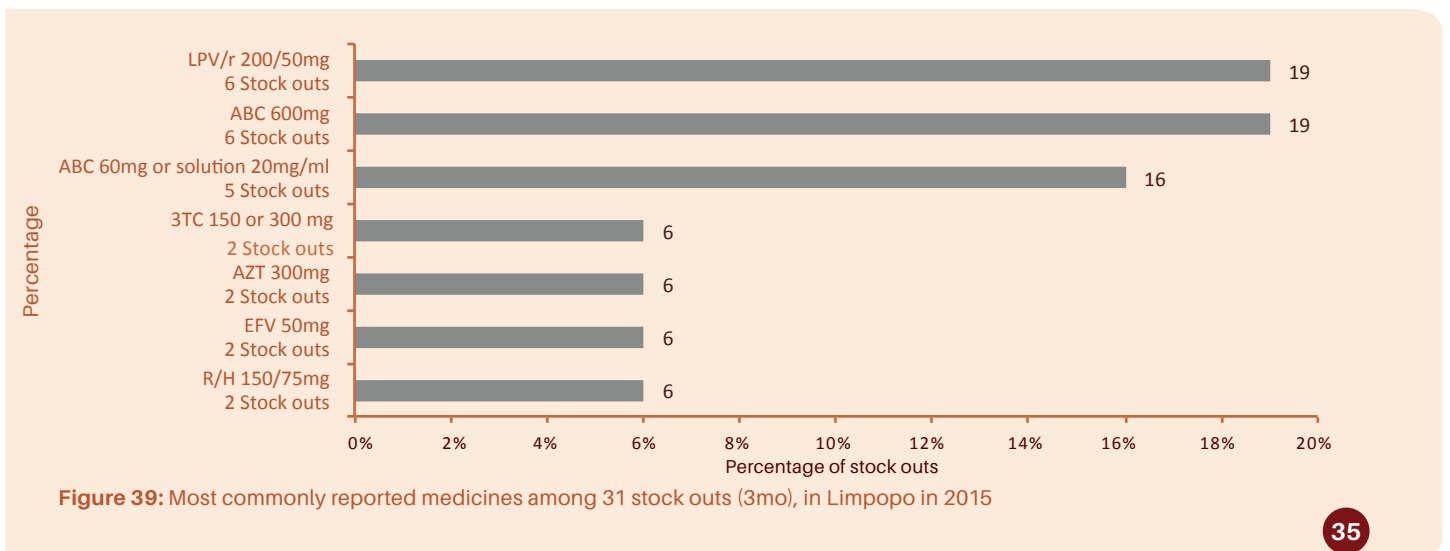
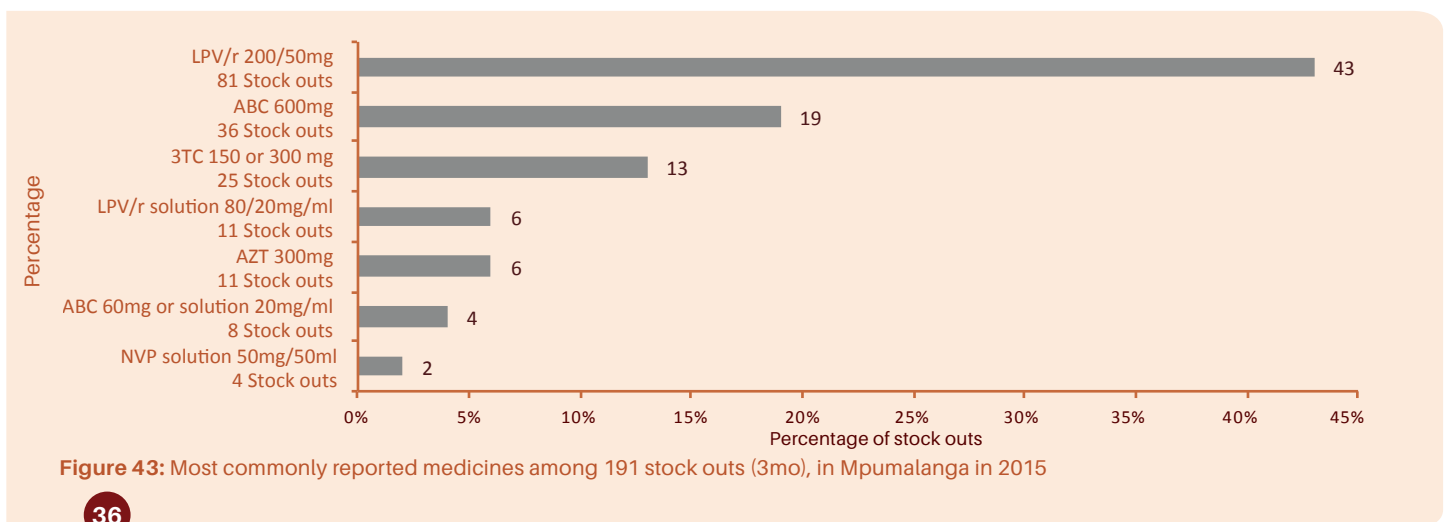
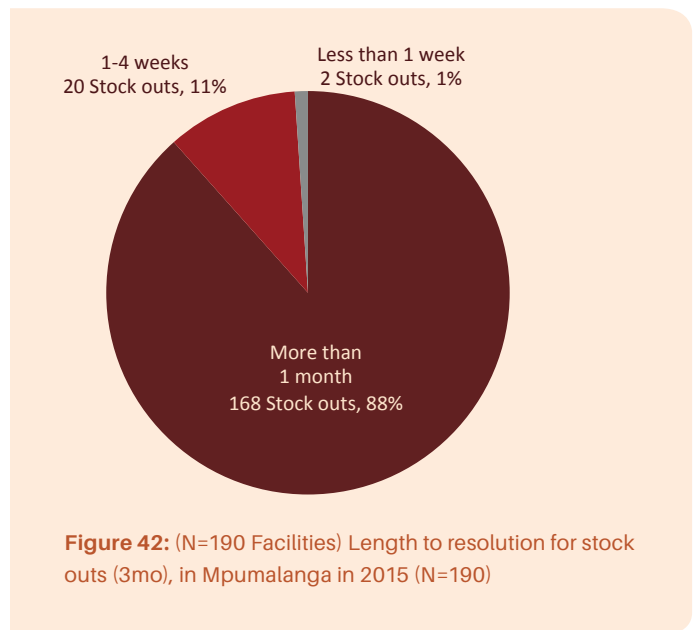
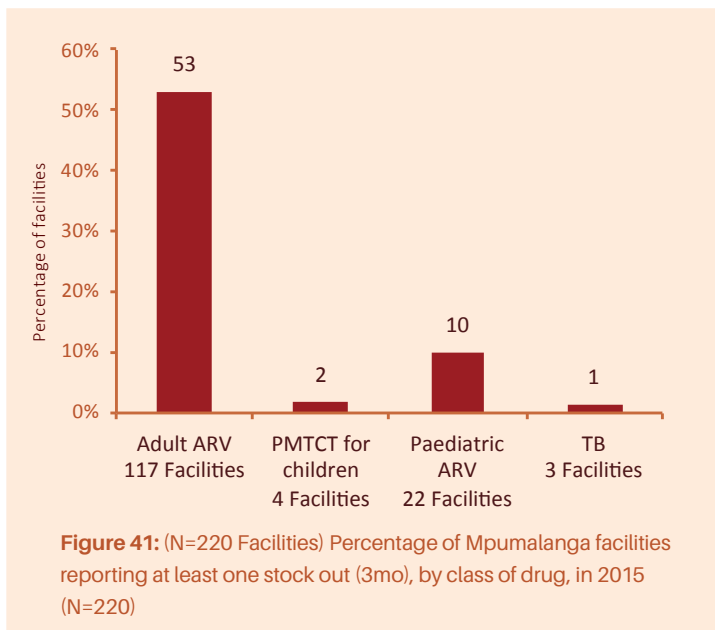
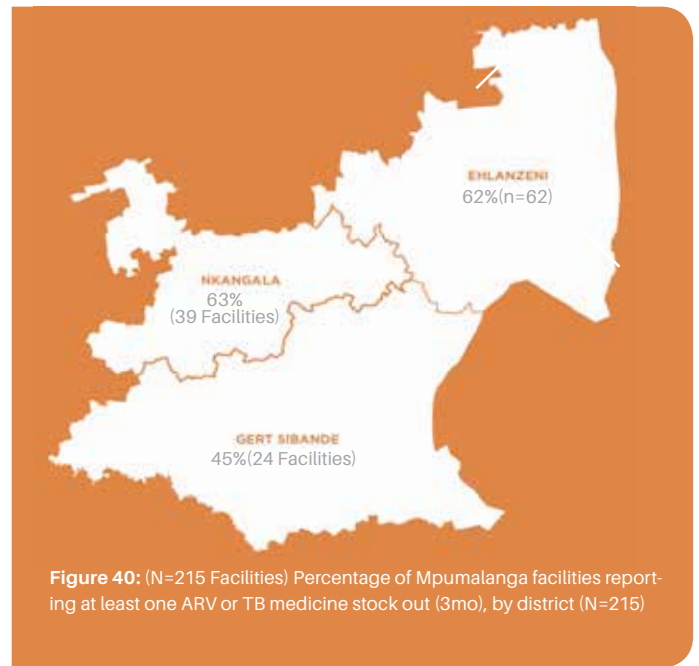


Figure 39: Most commonly reported medicines among 31 stock outs (3mo), in Limpopo in 2015

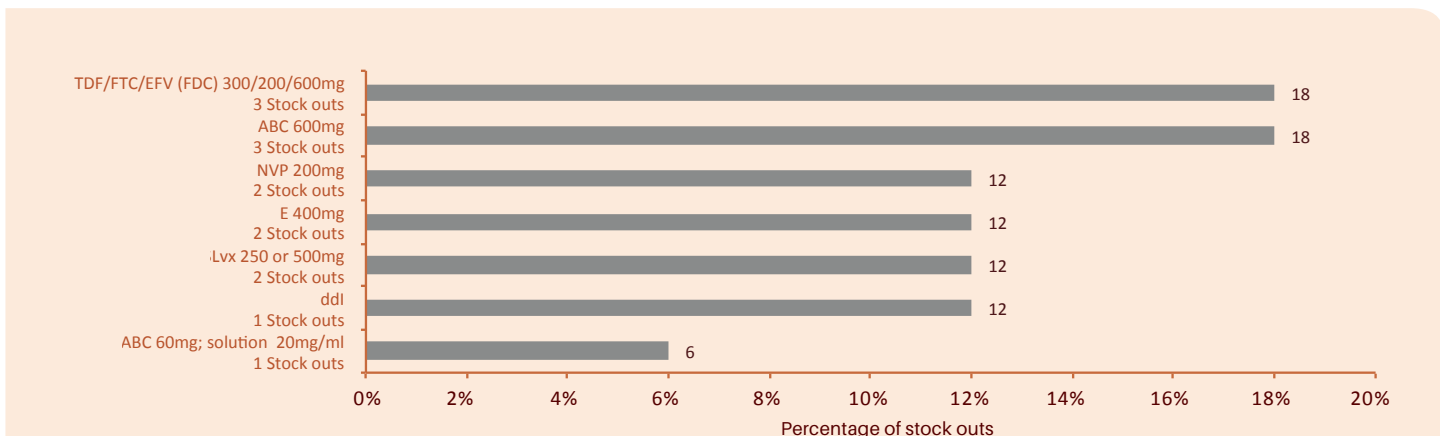
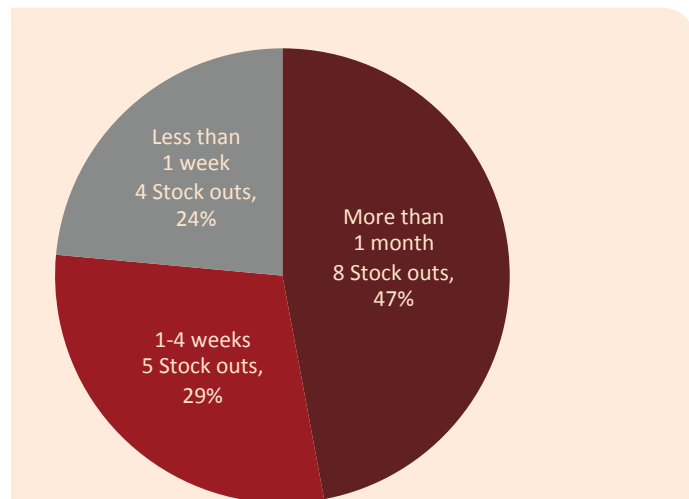
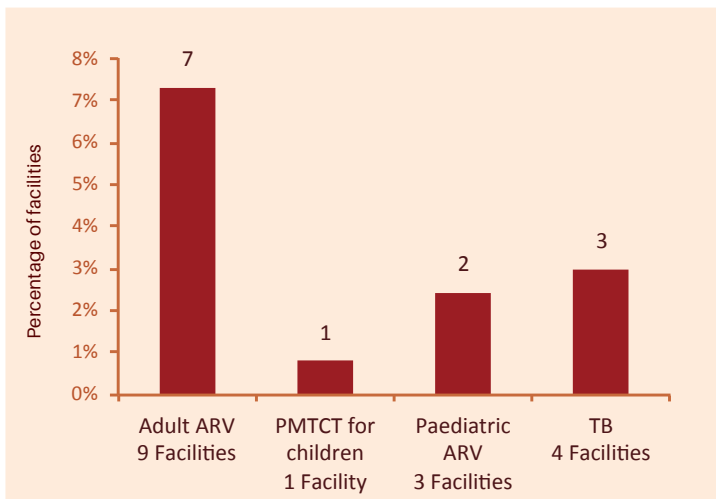
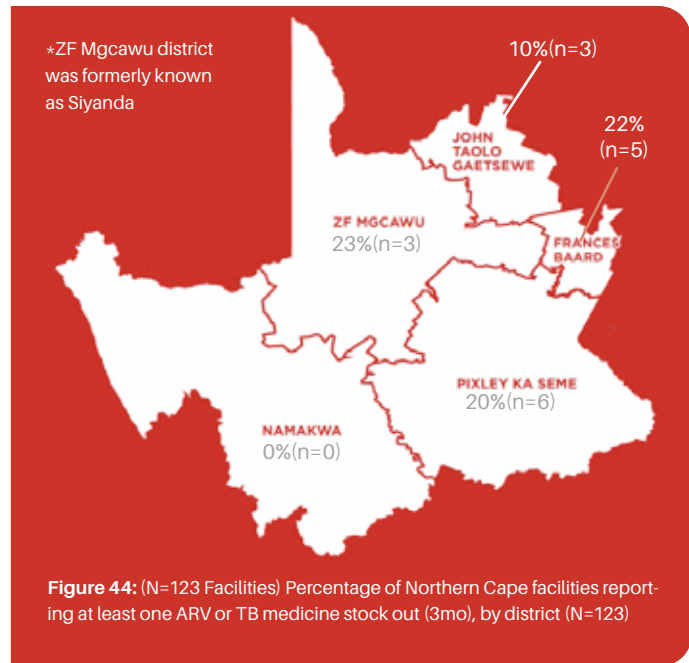
Mpumalanga

- Province with highest proportion of facilities reporting stock outs in the previous three months, with increases since 2014 from 40% to 58%. On the day of the call, more than one in three facilities (38%) reported a stock out.
- Urgent intervention is needed in all districts where more than 40% of facilities reporting stock outs: Ehlanzeni (62%), Gert Sibande (45%), and Nkangala DM (63%). The proportion of facilities reporting stock outs increased in all districts. Gert Sibande and Nkangala DM were also reporting high rates of stock outs in 2014, though the situation has deteriorated in the past year.
- The duration of stock outs remains unacceptably high, with over 88% of stock outs lasting more than one month—the worst rate in the country.



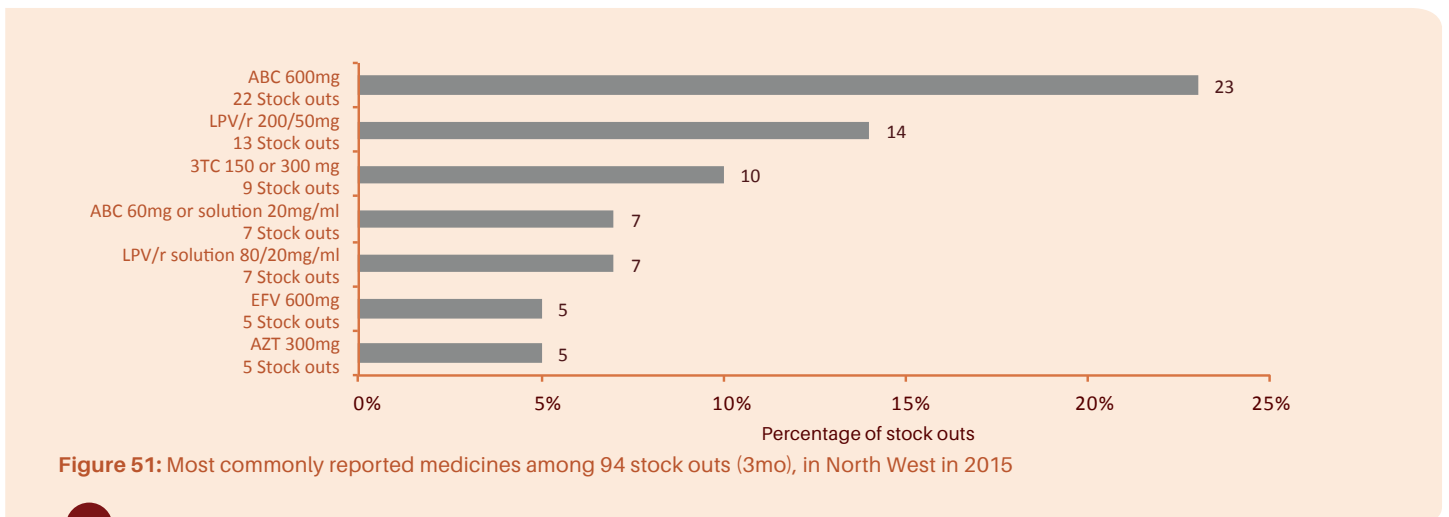
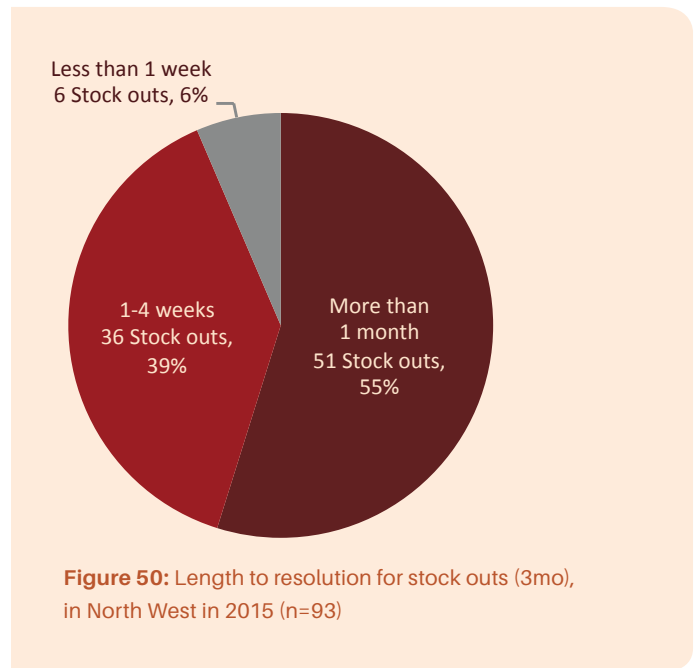
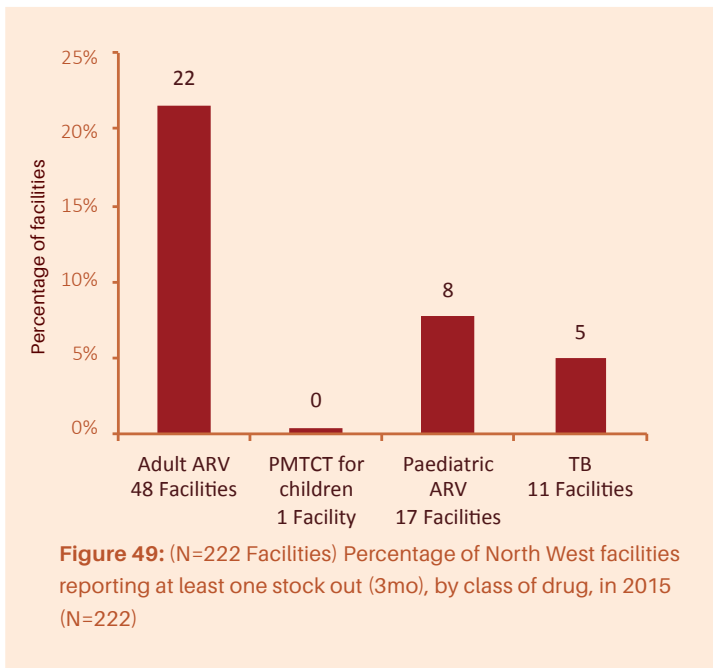
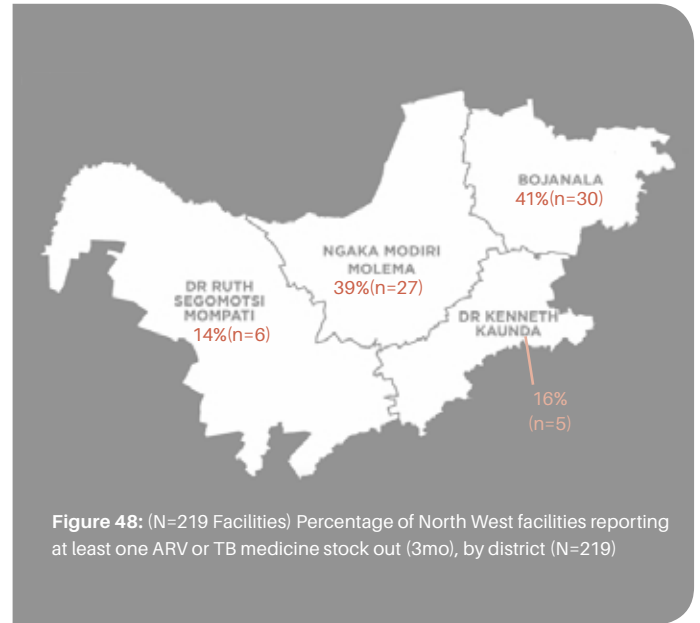
Northern cape

- First province ever to achieve 100% response rate among contactable facilities.
- Substantial reduction since 2014 in percentage of facilities in the province reporting at least one stock out—from 21% in 2014, to 14% in 2015.
- While having one of the lowest provincial rates of long-duration stock outs, nearly half (47%) lasted more than one month, with a further 29% lasting one to four weeks.
- NC was the only province where the FDC was the most commonly reported drug out of stock, and multiple TB drugs were also reported as commonly out of stock.



North West

- Province reported 8% reduction in proportion of facilities with at least one stock out since 2014 (39%), but the 2015 rate of 31% is higher than the national average.
- Bojanala District continues to require urgent intervention, and for the second year remains the one district in the province with more than 40% of facilities reporting stock outs.
- Dr K Kaunda and Ruth Segomotisi Mompoti districts have more than halved the percentage of facilities experiencing stock outs from 2014 to 2015.
- More than half (55%) of the 93 stock outs reported in NW lasted more than one month.



Western Cape

- Consistently the province with the lowest proportion of facilities reporting at least one stock out, though the rate has more than doubled from 4% in 2014 to 9% in 2015.
- Of all provinces, had the lowest proportion of stock outs lasting more than one month (33%)



Figure 52: (N=260 Facilities) Percentage of Western Cape facilities reporting at least one ARV or TB medicine stock out (3mo), by district (N=260)

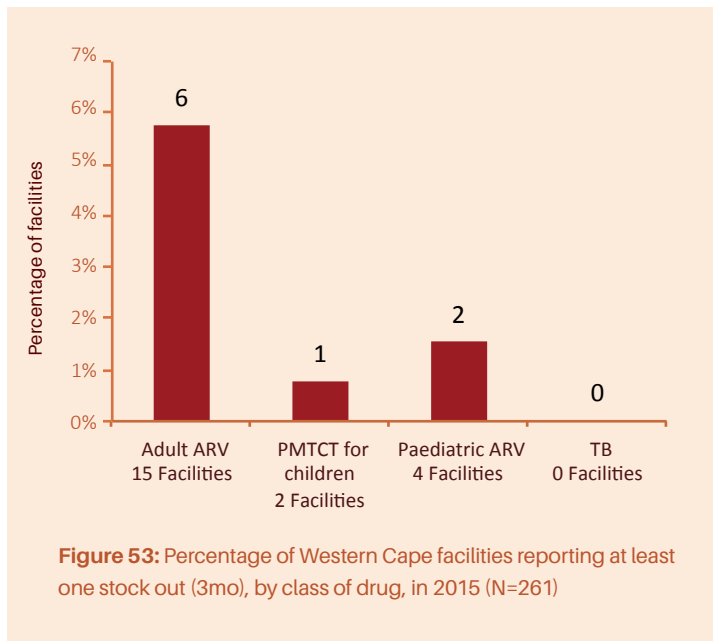


Figure 53: Percentage of Western Cape facilities reporting at least one stock out (3mo), by class of drug, in 2015 (N=261)

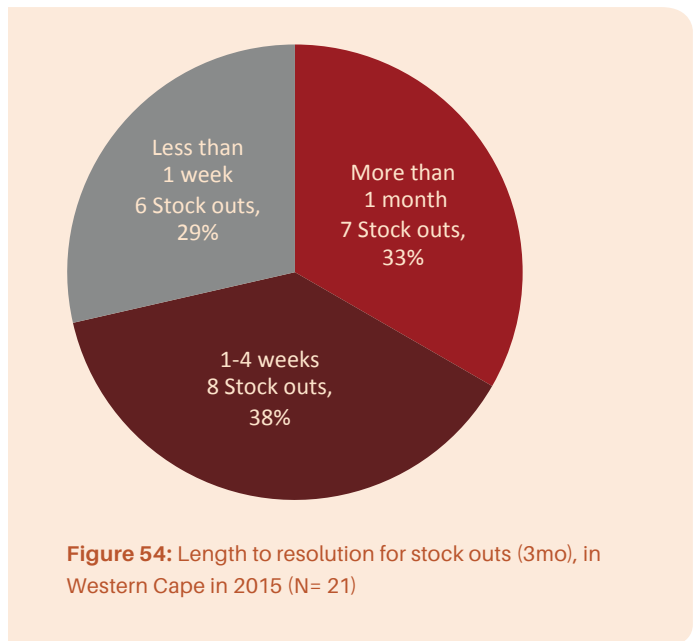


Figure 54: Length to resolution for stock outs (3mo), in Western Cape in 2015 (N= 21)

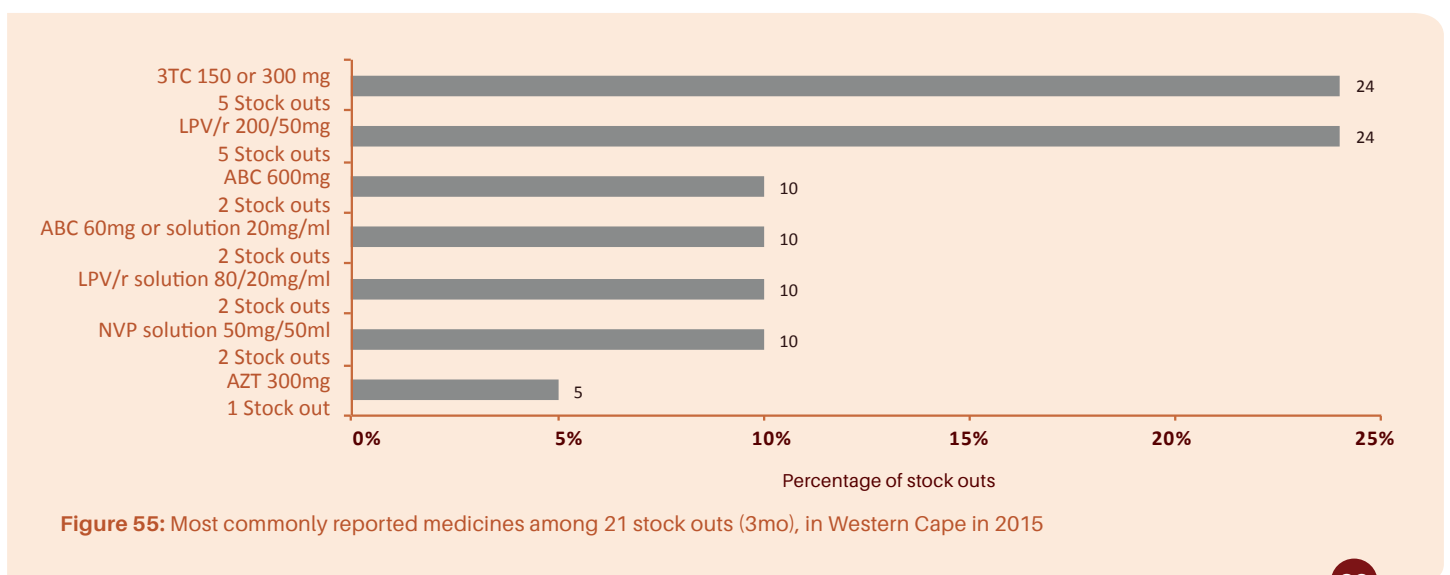


Figure 55: Most commonly reported medicines among 21 stock outs (3mo), in Western Cape in 2015

Vaccine and essential medicine stock outs



P725
S4
Aluvia™
Lopinavir/Ritonavir
200mg/50mg
112 film-coated
112 film-coated
take

Supply chain problems affect the availability of a range of vaccines and other essential medicines. These stock outs can lead to diseases in children or adults that could have been prevented through timely vaccination, or create life-threatening situations for patients who do not receive the medicines they need. The 2015 survey included questions on the availability of childhood vaccines – measles, rotavirus and DTaP-IPV-Hib-HBV – as well as a number of indicator medicines from the EML important in the management of a variety of conditions at primary healthcare level.

Despite evidence of some improvement in 2015, an overall rate of one in ten facilities with a stock out of childhood vaccines – the most cost-effective primary healthcare intervention – is extremely concerning. The unavailability of essential medication in up to 33% of facilities in some provinces indicates an alarming level of health system dysfunction and undermines the NDOH goal of a “long and healthy life for all”. It is difficult to estimate the full extent of the problem, but it is likely that stock outs also extend to other important medicines and vaccines that were not included in the SSP survey.

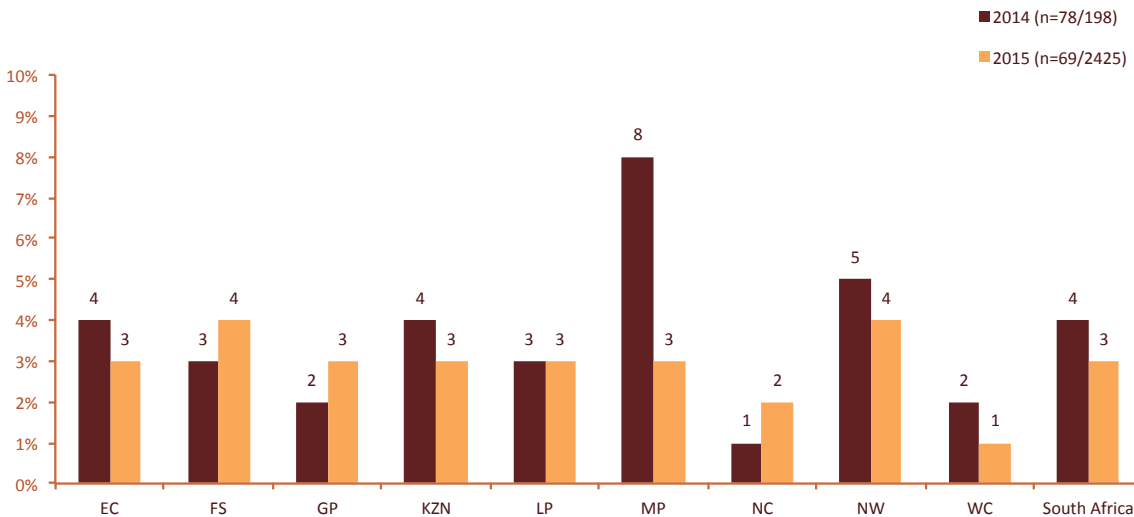
(See Annexes A-IV and A-V for indications and selection process of childhood vaccines and essential medicines.)

Vaccine stock outs

Nationally, the percentage of facilities with at least one vaccine out of stock improved only marginally (Figure 3: 12% in 2014; 11% in 2015). There were fewer provincial outliers than in 2014 – when, for example, 28% of facilities in LP had

no stock of the pentavalent vaccine on the day of contact. (See Annex B-XII for further information on vaccine stock outs over time and type of stock out reported on the day of contact.)

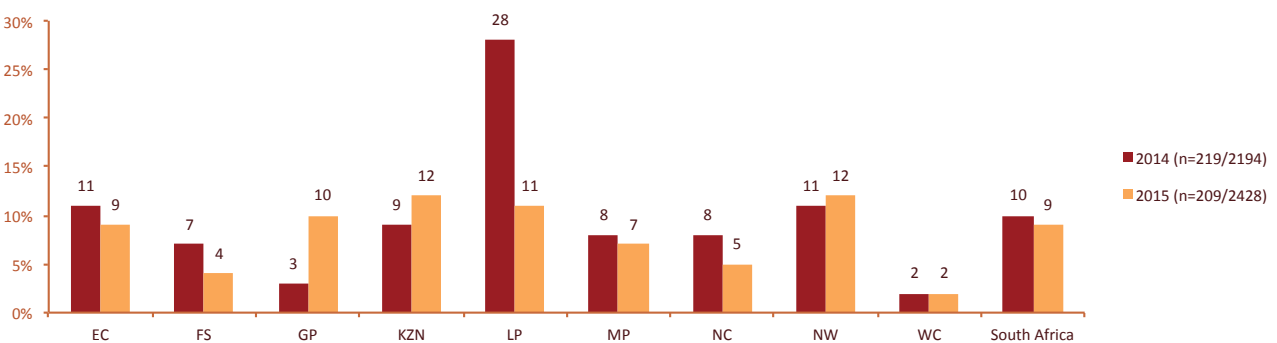
Figure 56: Percentage of facilities reporting a measles vaccine stock out (day), by province (2014 and 2015)



Measles vaccine: Nationally and per province, stock outs remained mostly stable, with the exception of MP, which saw

a reduction in reported stock outs on the day of contact (8% in 2014; 3% in 2015) (Figure 56).

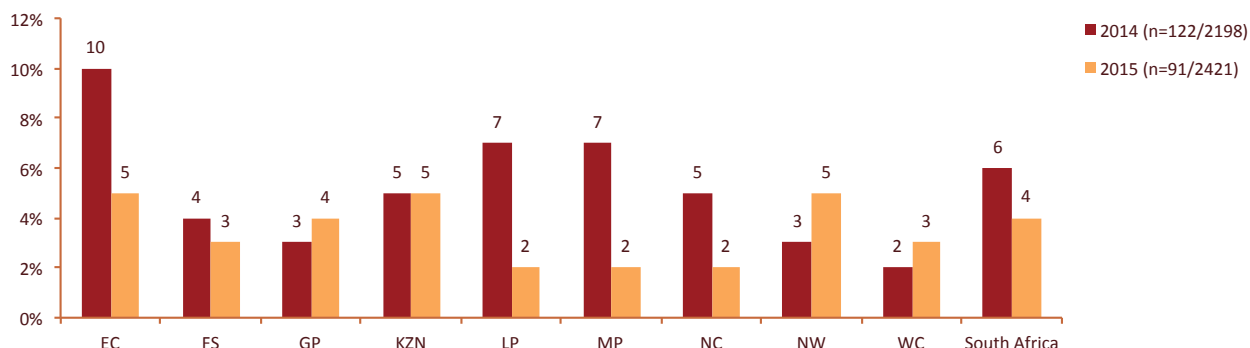
Figure 57: Percentage of facilities reporting a pentavalent (2014) or hexavalent (2015) vaccine stock out (day), by province



Hexavalent vaccine (DTaP-IPV-Hib-HBV): In 2015, the national EPI schedule switched from a pentavalent DTaP-IPV-Hib) to a hexavalent vaccine, incorporating the hepatitis B antigen, but the proportion of facilities reporting stock outs

remained relatively stable compared to 2014 (Figure 57). Provincial differences existed, with a large improvement in LP, but an increase in stock outs in GP.

Figure 58: Percentage of facilities reporting a rotavirus vaccine stock out (day), by province (2014 and 2015)



Rotavirus vaccine: There was a reduction in the proportion of facilities reporting stock outs nationally in 2015 (4% versus

6% in 2014), driven by reductions in EC, LP and MP (Figure 58).

Essential medicines stock outs

“ I have an 11-year-old child who takes psychiatric medication. When I recently went to collect my son’s treatment, I was told that her child’s regular medication is out of stock and she was given Ritalin instead of Concerta as an alternative treatment. My child tends to react to alternatives offered instead of his regular medication. It feels like lots of attention is given to ARVs and TB medicines and not to other essential medicines.” - Mother from Gauteng

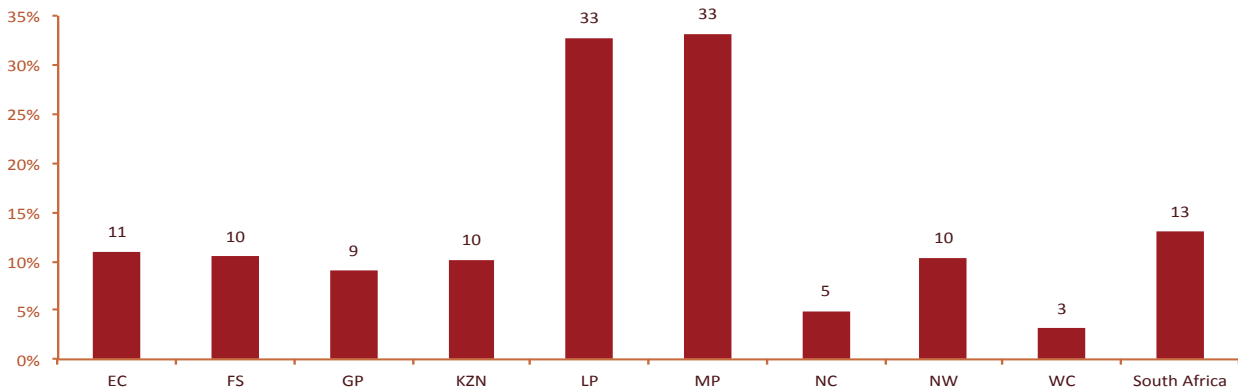


At a national level, stock out rates remained consistent or decreased for essential medicines, but ranged from 3 - 13% among facilities nationwide on the day of contact. See Annex B-XIII for further information on essential medicine stock outs over time and type of stock out reported on the day of contact.

Province-specific differences were clearly evident, however, with notable improvements in sodium valproate availability in KZN and salbutamol inhaler in NW and MP, and the greatest overall improvements in the EC. Haloperidol stock

outs were reported by 33% of facilities in MP and FS (versus 13% nationally), while NW had the highest proportion of stock outs of sodium valproate (12% versus 4% nationally), metformin (6% versus 3% nationally) and ferrous sulphate (16% versus 11% nationally). In FS, ceftriaxone stock outs nearly quadrupled (13% in 2015 versus 3% in 2014) and salbutamol stock outs nearly doubled (10% in 2015 versus 6% in 2014). Urgent attention should be given to poorly performing provinces, to better understand and address the root causes of specific medicine stock outs.

Figure 59: Percentage of facilities reporting a haloperidol tablet stock out (day), by province in 2015 (n=325/2 422)

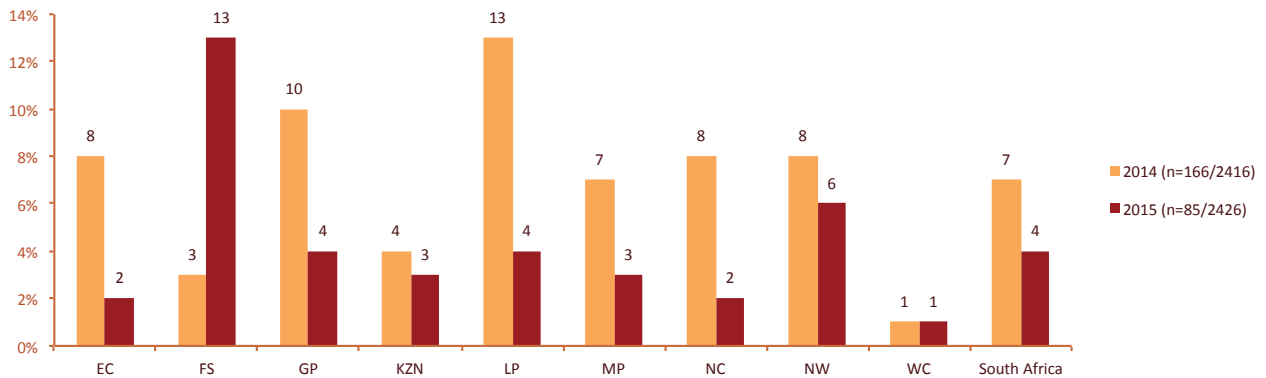


Haloperidol (psychosis)

Haloperidol (psychosis): Of all essential medicines surveyed, stock outs of haloperidol were the most prevalent nationally

(13%) (Figure 59). Of facilities in MP and LP, 33% reported haloperidol out of stock on the day of contact.

Figure 60: Percentage of facilities reporting a ceftriaxone injection stock out (day), by province (2014 and 2015)



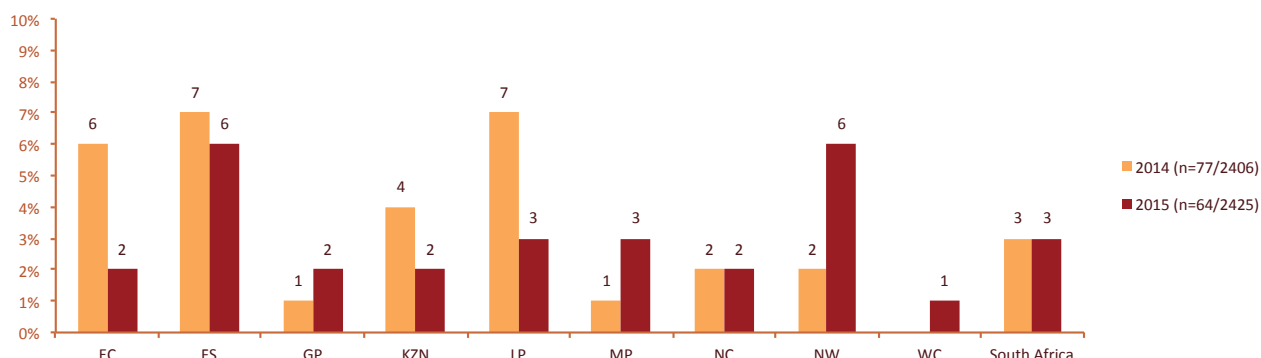
Ceftriaxone (paediatric infections)

Ceftriaxone injection (paediatric infections): Most provinces saw a reduction from 2014 to 2015 in facilities reporting stock

outs on the day of contact (Figure 60), with the exception of FS.

Figure 61: Percentage of facilities reporting a metformin tablet stock out (day), by province (2014 and 2015)

Metformin (diabetes)

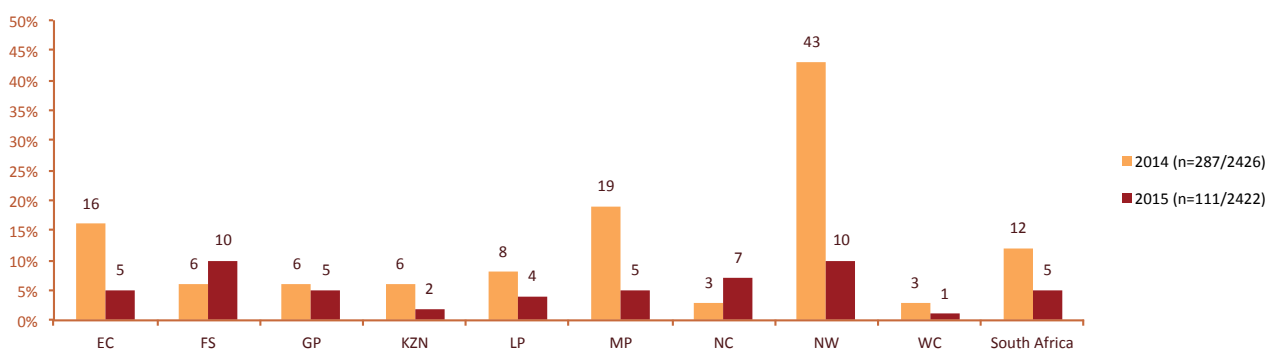


Metformin (diabetes): Nationally, the percentage of stock outs was consistent with 2014 (Figure 61); however, some

provinces saw a decrease (e.g. EC and LP) and others an increase (e.g. NW and MP).

Figure 62: Percentage of facilities reporting a salbutamol inhaler stock out (day), by province (2014 and 2015)

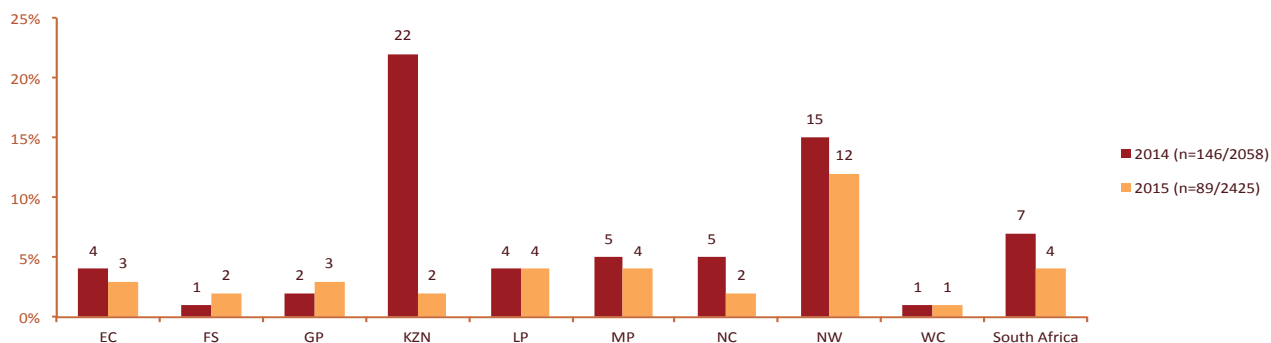
Salbutamol inhaler (asthma)



Salbutamol inhaler (asthma): The reduction in stock outs (Figure 62) was driven by large decreases in the NW, MP and EC.

Figure 63: Percentage of facilities reporting a sodium valproate tablet stock out (day), by province (2014 and 2015)

Sodium valproate (epilepsy)

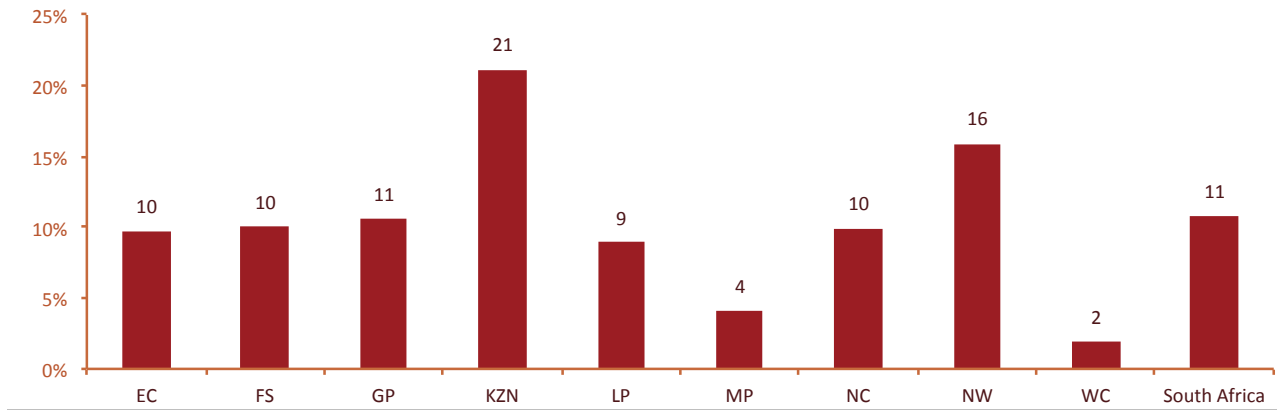


Sodium valproate (epilepsy): The prevalence of stock outs has seen a reduction (Figure 63), most notably in KZN.



Figure 64: Percentage of facilities reporting a ferrous sulphate

Ferrous sulphate (anaemia and maternal/fetal health)

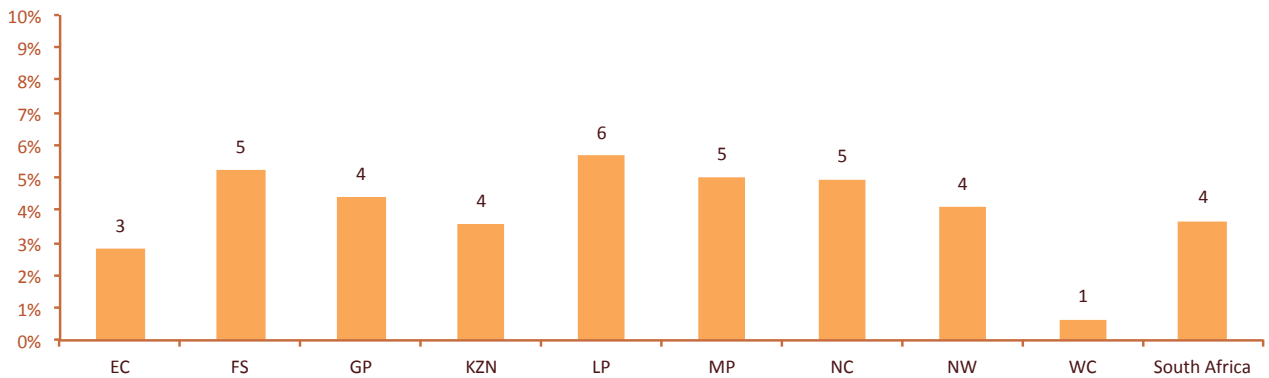


Ferrous sulphate (iron) tablets (anaemia and maternal/fetal health): More than one in ten facilities in South Africa

reported a stock out on the day of contact; with the highest percentages in KZN (21%) and NW (16%) (Figure 64).

Figure 65: Percentage of facilities reporting a furosemide tablet

Furosemide (oedema and high blood pressure)



Furosemide tablets (oedema and high blood pressure): Included for the first time since commencement of the SSP

surveys, furosemide was reported to be out of stock in less than 5% of facilities on the day of contact (Figure 65).



DISPENSARY

Department of Health : Discussion



In the past year, the SSP has seen the DOH and its partners take measures to address and overcome stock outs of medicines in South Africa. An NDOH task team is currently developing a comprehensive overview of planned interventions within a national procurement and supply chain plan. Progress in reducing the prevalence of stock outs in some provinces could be the result of some of the innovative models being piloted to improve the supply chain.

The missing link in these national discussions is an open and transparent dialogue with civil society organisations such as the SSP. To date, the SSP has not been invited to collaborate in the elaboration of the national procurement and supply chain plan, or included on the ministerial task team. Provincial DOHs have been willing to collaborate with the SSP in some instances, and not yet responded to meeting requests elsewhere. Yet, nationwide shortages of LPV/r in 2015 proved the value of dialogue between the NDOH and SSP, as end-user data provided by the SSP was used to guide emergency redistribution of supplies. The SSP provides valuable information from patient and healthcare worker reports about the effectiveness of the supply chain in delivering medicines to patients, and contributes to the dissemination of information to healthcare workers and patients on how to manage stock outs.

Going forward, all levels of the DOH should attempt to live up to the spirit of the Deputy Minister's statement in the 2014 - 2015 NDOH Annual Report, which noted, "Among our key priorities ... is to continue to work with our partners and civil society to achieve the highest quality standards of care across the system." The SSP will continue in its efforts to engage with the DOH at all levels, to ensure that the voices of healthcare workers and patients reporting stock outs are represented, and supply chain bottlenecks are overcome.

Key progress shown by the survey data

- Consistent high participation rates nationwide suggest a willingness to collaborate among healthcare workers in a large majority of public health facilities.
- Five out of nine provinces (EC, KZN, LP, NC and NW) have seen a decrease in the proportion of facilities reporting stock outs of ART and TB medicines (3mo and day), compared to 2014.
- There is a marked improvement since 2014 in the availability of the three-in-one FDC used by the large majority of patients on ART: only 32 facilities

(4%) reported stock outs in 2015, compared to 75 facilities (9%) in 2014. In 2013, the first year of FDC roll-out, it was among the most frequently reported ARVs out of stock.

- National shortages of LPV/r contributed substantially to stock out reports in 2015, and to reports of medicines used to substitute for LPV/r (ABC, 3TC, AZT). While provinces and districts managed stock outs with varying degrees of effectiveness, shortages were due in part to the inability of suppliers to provide adequate quantities. In the absence of national shortages, fewer stock outs might have occurred, suggesting that in-country supply chain management might have improved overall, compared to 2014.

NDOH engagement, actions and opportunities for collaboration

The NDOH has been provided with the interim results of the survey. A session at the third annual Southern African HIV Clinicians Society Conference in April 2016 included a presentation of the interim results of the SSP 2015 survey, as well as a presentation from the NDOH on supply chain reforms. As of 1 June 2016, a formal meeting between the SSP and NDOH to discuss the results and way forward had yet to occur.

In the past year, the NDOH has engaged in a number of supply chain reforms, which are at various stages of implementation at national and provincial levels. The list below is not exhaustive. However, to date, the SSP has not been involved in the process of developing a national supply chain strategic plan, which may provide greater detail on these and other initiatives.

NDOH task team on stock outs

In September 2015, the NDOH appointed a task team “to review the various reports on medicine availability and advise the Department on the interventions that should be implemented to address the challenges”.⁶ This task team is contributing to the development of the national procurement and supply chain plan. This initiative indicates that the NDOH places significant importance on addressing stock outs, and this intention is welcomed by the SSP. However, while the task team has included SSP surveys in its reviews, SSP representatives have not been invited to participate on the task team.

Based on the limited information placed in the public domain on task team activities, however, the SSP is concerned that the task team has failed to identify all contributing causes of stock outs. There is no mention of a lack of accountability along the supply chain, nor of the lack of regularly organised last mile delivery.

While in support of some of the task team’s potential solutions, the SSP does not agree with others. The proposed ring-fencing of medicine quantities at the start of a tender, for example, will bind provinces to two-year forecasts, and leave little flexibility for adjustment if patient cohort numbers or regimens change in that timeframe.

Innovations to improve patient access to chronic disease medications

The National Health Insurance (NHI) White Paper of 2015 outlines plans to improve patient access to needed medicines.^[25] The White Paper specifically notes the importance of efficient prescription refill options for patients on chronic medication, in order to decongest public health facilities, and save time for patients and healthcare workers alike.^[18]

One proposed solution to reduce the frequency of clinical visits is the DOH implementation of the Centralised Chronic Medication Dispensing and Distribution (CCMDD) programme. The CCMDD consists of a centralised facility that pre-packs prescriptions of chronic medications, then dispenses and distributes the packages to decentralised Pick-up Points (PuPs) at facilities or other locations in the community (e.g. private pharmacies, churches, etc.). All CCMDD facilities and PuPs are registered with the DOH.

The implementation of the CCMDD programme has initially focused on the provision of ARVs, and the FDC in particular, to HIV-positive patients who are stable on treatment. Over 400 000 patients have been registered on the programme, which is eventually intended to serve all patients with chronic

conditions who are clinically stable on treatment.^[26]

Successful implementation of the CCMDD will depend on community consultation to identify PuPs, effective data management systems, quality assurance of less frequent clinical visits and, of course, an uninterrupted national and provincial medicines supply.



“ There are frequent stock outs of ritonavir and I am concerned as this is a third-line treatment for exceptional adult cases; its non-availability is critical and unacceptable. We contacted the Stop Stock Outs project and they spoke to the manufacturer AbbVie. We discovered that the drug is not on a DOH tender list and not widely used. Therefore, orders for the drug involve a process that require authorisation at provincial level. This process can take time, leaving patients in a situation with no alternative treatment.” – Healthcare worker from Free State

Further patient-centred innovations can be rolled out within the CCMDD, and have the potential to improve cost savings for both patients and the health system. At present, patients enrolled in the CCMDD programme still rely on monthly trips to a PuP to access their medicines. The WHO recommends the provision of multiple months' refills of chronic medication such as ARVs – a practice that has been implemented in a few sub-Saharan African countries (e.g. Zimbabwe, Malawi, Kenya).

Electronic medicine stock management system

In his February 2016 budget speech in Parliament, the Minister of Finance announced the allocation of R300 million for the development of a national electronic medicine stock management system. The SSP welcomed the announcement, as such a system could help reduce facility-level stock outs, by improving pharmacy data management and forecasting efforts at a district, provincial and national level.

A significant amount of time, effort and training will be required, however, to integrate the electronic system into the current medicine supply chain. In the interim, emergency reporting and distribution strategies are necessary to respond rapidly to stock outs. The SSP hotline provides healthcare workers and patients with a mechanism for reporting end-user data, so that the functionality of the supply chain can be monitored before the establishment, and during the rollout, of improved stock management tools.

Joint response to lopinavir/ritonavir stock outs

Over six months in 2015, nationwide shortages of LPV/r affected health facilities and patients across South Africa. The SSP received 73 reports of LPV/r stock outs through its national hotline during 2015, with additional facilities reporting LPV/r stock outs in the national survey. The SSP worked closely with the NDOH to communicate with AbbVie, the sole supplier of LPV/r in South Africa, and address stock outs.

In the second and third quarters of 2015, when LPV/r stock outs were particularly acute, the SSP escalated consolidated LPV/r stock out reports to send to the NDOH on at least a weekly basis. In turn, the NDOH regularly informed the SSP of steps being taken by the Department and LPV/r supplier, AbbVie, to respond to stock out reports. The NDOH response to the LPV/r stock out crisis has demonstrated willingness by government to reactively resolve supply chain challenges reported by the SSP. The collaboration helped to resolve 37 LPV/r stock out cases in six provinces, including at major facilities such as Chris Hani Baragwanath Hospital, Charlotte Maxeke Hospital and Mamelodi Hospital. Further communication and data sharing initiatives between the SSP and DOH could similarly identify stock out trends or hotspots and guide an appropriate response.

Provincial engagement

- **Eastern Cape (EC):** In January 2016, SSP attended a meeting with the EC pharmaceutical management team. The DOH appreciated the work of the SSP, and proposed collaboration for the revision of EC DOH facility stock management cards. A further meeting with the EC Head of Pharmaceutical Services (HOPS) and pharmaceutical management team was held in June 2016, they appreciated the improvements in certain aspects stock outs in EC, as found in the survey, and have included attributes to these improvements in this report. The HOPS recommended a re-introduction of the SSP and present the survey results to the MEC for Health and Head of Department (HOD). At the time of writing of this report, the SSP were awaiting a date for this meeting to take place.
- **Gauteng (GP):** In April 2016, the SSP presented the survey results to the GP HOPS team. GP expressed satisfaction with the work of the SSP, and made suggestions for future survey methodology, which will be considered.
- **KwaZulu-Natal (KZN):** In April 2016, the SSP provided interim survey results to the KZN DOH. The HOD outlined processes that the KZN DOH has in place for monitoring medicine availability at facilities (included in this report) and emphasised that all efforts are made to ensure that patient care is not compromised by supply chain constraints. The SSP requested a meeting to discuss these processes further; at the time of writing of this report, the SSP were awaiting a date for this meeting to take place.
- **Mpumalanga (MP):** In April and June 2016, the SSP met with the HOD and pharmaceutical management team. They indicated that the results were truly reflective of the current situation in MP and were in agreement that urgent attention was needed in the worst-performing districts. To improve communication between the DOH and SSP, the province requested a re-introduction of the project, and the establishment of a memorandum of understanding. These processes are ongoing.
- **Northern Cape (NC):** In February 2016, SSP presented interim survey results to the NC HOPS and district pharmacists. They identified some of the contributing factors to stock outs and expressed willingness to investigate certain stock outs further. Opportunities for future collaboration were discussed, and recommendations for changes to the survey methodology will be considered. NC investigations and its response to survey results are part of this report.
- **North West (NW):** In March 2016, the SSP presented interim survey results to the NW HOD, HOPS and their respective teams. They commended the work of the SSP and showed great interest in the results. The department outlined factors contributing to stock outs and action points to resolve stock outs, which are included in this report.
- **Free State (FS):** In June 2016, The SSP met with some of the FS DOH management team, survey results were presented and an overview of the project was provided. The province requested a re-introduction of the project, and the establishment of a memorandum of understanding, to be presented to the HOD and MEC. At time of writing the SSP were awaiting a meeting date. We anticipate that this meeting will take place as soon as the FS is the province with the lowest respondent rates, high proportions of long-lasting and high-impact stock outs, and some of the most poorly performing districts in the country.
- **Limpopo and Western Cape** have been provided with the interim results of the survey, however attempts to establish a meeting prior to the publication of this report were unsuccessful. Meetings with the two provinces and SSP are scheduled to take place later in June/July 2016.

National policy reform: Case studies

As countries start to adopt recent WHO guidelines, which recommend starting all people living with HIV on treatment, the demand for ARVs in general, and certain regimens in particular will increase. Ensuring security of supply will require global coordination to ensure production of adequate quantities of the ARVs countries introduce into national guidelines. At a national level, South Africa must create contingency plans and take measures to ensure that ARVs, and the active ingredients used in their production, are sourced from multiple quality-assured suppliers. Dividing the market between multiple suppliers improves the likelihood that if one supplier faces constraints in its production line, quality-assured alternatives can be accessed quickly, and the country will not face shortages.

Intellectual property (IP) rights or the time required for regulatory approvals can create barriers to accessing multiple supply sources. Appropriate legislative framework must therefore be established if South Africa is to create an environment of supply security for ARV, TB and other essential medicines. In cases where pharmaceutical manufacturers lack appropriate incentives to develop adequate quantities of ARVs, better guaranteeing supply security may require the introduction of new treatment regimens. The following two case studies illustrate the urgency of codifying certain reforms into national laws, regulations and clinical guidelines, if South Africa is to successfully scale up treatment for HIV, TB and other diseases.



“ I went to the clinic, they told me, ‘no, we don’t have Aluvia, so you’re supposed to go to the chemist to buy [it]’... If now my pills are finished, what am I going to do? [Because] I don’t have money.” – Thandi Shabangu, affected by national LPV/r shortages.

The cost of a one-month supply of adult LPV/r at a private pharmacy in South Africa is R391 – more than 2.5 times what the government pays (R149) for the same formulation provided in public facilities at no cost to the patient.^[27,28]

LPV/r shortages: A case for patent law reform and new regimens

South Africa is one of the largest global users of LPV/r. As of November 2015, approximately 160 000 people in the country take LPV/r as part of their ARV regimen.^[29] In 2015, pharmaceutical company AbbVie was unable to fully meet the growing demand for LPV/r in South Africa, which led to national shortages.

“ Things could be changed for the better if we looked at our patent laws, if we allowed many more suppliers into the market so there was more competition. It would ultimately only benefit the patient.” – Lauren Jankelowitz, Southern African HIV Clinicians Society

Patent monopolies held by AbbVie on LPV/r and ritonavir (RTV) in South Africa contributed to national supply shortages, by hampering responses that would have involved sourcing alternative generic suppliers of LPV/r or possible alternative treatments like atazanavir/ritonavir (ATV/r). (See *Timeline of LPV/r Stock Outs in South Africa*)

AbbVie’s patent rights mean that it is the sole supplier in the country of all LPV/r and RTV products, including adult and paediatric tablets, marketed as Aluvia®. Several generic versions of LPV/r and ATV/r are pre-qualified by the WHO.^[12] Some WHO pre-qualified manufacturers also have LPV/r or ATV/r products registered, or pending registration, in South Africa. However, patent barriers have meant that generic manufacturers were unable to supply these products. (See *Overview: Patents and Licensing*).

After months of LPV/r shortages, SSP consortium members increasingly vocalised the need for AbbVie’s patent rights to be licensed to generic companies. AbbVie eventually signed a voluntary licensing agreement with the Medicines Patent Pool (MPP) in December 2015. Unfortunately, no generic companies have taken up the MPP license to date.

There are several potential explanations for the lack of interest in the MPP license. Firstly, companies signing the license can only supply their products to countries on the African continent. This may not be as appealing to LPV/r manufacturers as other emerging or high-income markets, where sales revenues could be higher.

Furthermore, some generic manufacturers have claimed that the low price AbbVie charges for LPV/r to the NDOH in South

Africa and other developing countries is lower than the cost of production.^[30] This creates disincentives for generic manufacturers to invest in additional production capacity for LPV/r. It also leads to reluctance on the part of the NDOH to secure supplies that it can purchase more affordably from AbbVie. Instead, several manufacturers have invested greater resources in ATV/r production, and claim sufficient capacity to support treatment scale-up of this combination.

More people will require second-line treatment as countries introduce expanded eligibility criteria for ARVs, and improve access to viral load monitoring. The global supply situation for LPV/r is not expected to improve, however, unless AbbVie is willing to scale up LPV/r production capacity, or market conditions become more favourable to generic manufacturers.

ATV/r is recommended by the WHO on equal footing with LPV/r as a preferred second-line adult treatment option.^[18] In the interest of supply security, it is critical that the NDOH moves **to introduce ATV/r as an additional, preferred second-line ARV option** in South Africa. The NDOH should **continue to procure LPV/r**, both for patients who cannot be initiated on regimens with ATV (namely, patients co-infected with TB), but also to avoid having the availability of the majority of second-line treatment dependent on a single supplier.

Many of the patent-related problems that have led to shortages of LPV/r could have been avoided if South Africa took more urgent measures **to amend its patent laws** to work better in the interest of public health and supply security. If South Africa examined patent applications, for example, then AbbVie might not have been granted multiple patents for a prolonged monopoly on LPV/r. If the process for issuing compulsory licences was less onerous, then alternative suppliers could have been on the market years ago.

More than two years after the public comment period closed on a 2013 draft national IP policy, the Department of Trade and Industry (DTI) has failed to finalise it or embark on proposed reform of the Patents Act. The SSP, together with 17 other patient groups in the Fix the Patent Laws coalition, have called on the DTI on numerous occasions to **prioritise IP reform** in South Africa more urgently.

Overview: Patents and licensing

Patents are a form of IP granted on a country-by-country basis, in line with national laws. It allows the patent holder to be the sole supplier of a patented invention in a country for 20 years. As a member of the World Trade Organisation (WTO), South Africa has signed the Agreement on Trade-Related aspects of Intellectual Property (TRIPS), and is required to grant patents on pharmaceuticals. It can, however, also establish legal safeguards to limit patent monopolies compromising access to medicines and public health.

South Africa has put in place some of the **legal safeguards permitted by TRIPS**, but has failed to establish a number of important laws and practices. For example, in South Africa, patent applications are not substantively examined prior to being granted. As a result, South Africa grants an extraordinary number of patents on medicines – an estimated 80% of pharmaceutical patents in force in the country would not have been granted, had they been examined in line with national patentability criteria.^[31]


If a generic company receives a license to do so, then it can market patented products prior to patent expiration. Licenses will specify certain terms and conditions, most notably including the scope of patents that are covered, any royalty rates on generic sales that must be paid to the patent holder, and the geographic territories where the license is valid. The terms of licenses signed with the Geneva-based MPP are published online, whereas the terms of bilateral licenses, or licenses issued by the government, are not necessarily shared beyond the parties signing the license. There are several types of licenses that can be used to access generic suppliers. Patent

holders can choose to license their patent rights voluntarily, in order to allow generic suppliers to enter a national market. **Voluntary licensing** can occur in a variety of ways: either on a bilateral basis with generic companies, or through the MPP. The latter allows any eligible generic company to take up a license signed with the MPP.

The TRIPS Agreement also allows for licenses to be issued without the consent of the patent holder for a specified period of time, and often at a defined royalty rate – this is called a **compulsory license**. Compulsory licenses can be issued upon a number of different grounds, and can be sought by private entities or governmental bodies. When governments exercise their right to issue compulsory licenses, it is known as a **government use license**, and the action may be taken in the interest of public health, or to otherwise balance public interest with private privilege. Compulsory licenses have been issued in numerous countries, such as Brazil, India, Thailand, Malaysia and Indonesia, to improve access to generic sources of lifesaving medicines.

Licensing of patent rights, be it compulsory or voluntary, is among the full TRIPS flexibilities that countries can use in order to overcome patent monopolies and improve access to more affordable generic sources of medicines. The establishment of the world's largest ARV programme in South Africa has relied heavily on voluntary licenses for access to generic ARVs. The presence of multiple suppliers on the market is not only beneficial for accessing lower prices, but can have added benefits in terms of supply security – if one supplier is unable to meet demand, other suppliers can be approached in an attempt to fill supply gaps.

Timeline of LPV/r stock outs in South Africa



December 2014

- AbbVie signs voluntary license with MPP on two LPV/r paediatric formulations (40/10 mg tablet and suspension). No generic companies take up these licenses. Two other, more widely-used formulations – LPV/r 100/25 mg paediatric tablets for older children and 200/50 mg tablets for adult patients – are excluded from the license.

April 2015

- SSP starts receiving facility reports of stock outs and insufficient buffer stocks of LPV/r tablets and syrup. Some facilities halt new treatment initiations of children.
- Global players purchasing large volumes of ARVs, including MSF, report having limited supplies of LPV/r and longer ordering lead times. These players also receive reports of limited international availability of the active pharmaceutical ingredient (API) used in LPV/r production.

May 2015

- LPV/r and RTV stock out reports continue. Global health players – including the WHO, United Nations Children's Emergency Fund (UNICEF), UNAIDS, the Global Fund and the US President's Emergency Plan For AIDS Relief (PEPFAR) – are alerted to shortages by SSP consortium members.

July - August 2015

- AbbVie claims they have adequate LPV/r supply to meet demand, but shortages of LPV/r 200/50 mg tablets and RTV continue. Facilities across the country report complete stock outs lasting longer than a month. Back orders are outstanding at provincial depots.
- SAHIVSoc issues a national circular to guide regimen switches in the case of LPV/r shortages.
- NDOH and AbbVie issue controlled supply quantities of LPV/r to locations reporting stock outs. NDOH requests facilities to limit patient refills to one month, rather than the usual two months. This action places an additional burden on people who must travel long distances to reach a health facility.

July - August 2015

Medicines Control Council (MCC) approves exceptional use of AbbVie LPV/r products with French labelling to alleviate shortages. Letter sent to the Minister of Health by SECTION27 outlines the extent of recent stock outs. It calls attention to the fact that alternative suppliers are blocked from alleviating shortages in South Africa, due to AbbVie's patents. The letter offers potential solutions that would allow generic suppliers on the market, including a voluntary agreement where AbbVie does not enforce or licenses its patent rights, or the issuing of a compulsory license by NDOH, requiring AbbVie to license its patent rights.

October - November 2015

LPV/r shortages continue, and stock outs are reported in the SSP survey. AbbVie makes no effort to sign a non-enforcement agreement or voluntary license. MSF issues a public call for the South African government to issue a compulsory license in order to alleviate shortages. The NDOH responds by stating its preference for AbbVie to voluntarily license LPV/r to the MPP in Geneva. AbbVie indicates it has a supply plan to deliver 1.1 million units of LPV/r before the end of 2015, and the NDOH says it has adequate quantities of LPV/r in stock.

December 2015

- Revised MPP license announced, which would allow any generic company taking up the license to supply adult or paediatric formulations of LPV/r, or other RTV combinations, to any country on the African continent. To date, no manufacturers have taken up the license.

Paediatric abacavir shortages: A case for expedited regulatory approvals

In the first half of 2015, generic companies in South Africa reported inadequate supply of the API used to manufacture ABC 20 mg/ml oral solution. Abacavir (ABC) is recommended by the WHO as the first choice for HIV treatment in children and adolescents. South Africa has an estimated 340 000 children aged 0 - 14 years living with HIV.^[32]

ABC 20 mg/ml paediatric oral solution is supplied on contract to the NDOH by several generic companies, including Aspen, Adcock Ingram and Aurobindo.^[28] Mylan also produces 60 mg tablets for children, as well as 300 mg tablets for adults. During the time of the shortages, all three manufacturers of the oral solution sourced the API for ABC solution from a single supplier. When this supplier experienced several batch failures, it triggered supply shortages.

Once news of ABC paediatric shortages reached the media in May 2015, the NDOH and MCC took rapid action to register a second API source that was already pre-qualified by the WHO.^[33] Shortages of the oral solution were mostly resolved the following month, in mid-2015.

As the MCC transitions into a new body known as the South African Health Products Regulatory Agency (SAHPRA), rapid approval mechanisms should be adopted as a best practice for supporting the alleviation of stock outs, and enshrined in the regulations of the new agency. Rapid approval can be applied not only to API sources, but also toward rapid

registration of finished pharmaceutical products in short supply. By limiting emergency approval to products already qualified by the WHO, or a stringent regulatory authority, SAHPRA can continue effectively to regulate the efficacy, safety and quality of medicines, while also responding in a timely manner to urgent public health needs.

The creation of SAHPRA is also an opportunity to review the prioritisation of products designated for expedited registration. As discussed by Leng et al., products with a limited number of registered sources should be considered a priority for registration in order to promote supplier diversification, while applications for products that already have multiple registered sources of API or finished products can be de-prioritised, in order to allocate the time of the regulatory authority more effectively to work in the interest of public health.^[34,35]

NOTE: Shortages of ABC tablets at the time of the survey appear unrelated to the shortages of paediatric formulation earlier in the year, and are more likely due to ongoing LPV/r shortages placing an unexpected high demand on ABC supplies as an alternative medication. The single supplier of ABC tablets to the NDOH, Mylan, informed the SSP in March 2016 that it “has had no ABC API or finished dose supply challenges in the past nine months ... and has sufficient stock to supply all formulations on tender”.

Timeline of abacavir stock outs in South Africa



January 2015

- Suppliers of ABC oral solution start reporting under-delivery of API supplies, limiting their production capacity.

February 2015

- NDOH issues clinical guidance for managing patients when ABC stock outs occur, suggesting a switch to ABC/3TC for eligible adult patients and a switch to AZT or stavudine (d4T) as a last resort for children.

month supply of paediatric ABC costs a minimum of R340. In some cases, facilities send away children without medicines.

- Global health players – including the WHO, UNICEF, UNAIDS, the Global Fund and PEPFAR – are alerted to ABC shortages in South Africa by SSP consortium members.
- The Minister of Health calls a press conference in Pretoria, stating that stock outs of ABC would be resolved by the following month.^[36]
- Suppliers of ABC oral solution seek to register an additional API source for ABC with the MCC, via a Section 21 urgent application for an import waiver.

June 2015

- After requesting additional documentation about the product's quality, MCC approves a Section 21 import waiver application to establish a second source of ABC API in the country.
- As a result of the ABC oral solution shortages, the MCC resolves to “allow for the sourcing of APIs from alternative manufacturing sites that have been pre-qualified by the WHO.”^[33]
- Manufacturers of ABC oral solution also filed additional paperwork with the MCC to allow the second API source to be used on a more permanent basis.
- Supply of ABC oral solution stabilises by the end of June.

May 2015

- ABC crisis reaches acute levels, though the single API supplier claims to have adequate quantities to meet demand.
- Facilities use a variety of tactics to compensate for ABC shortages. These include switching to AZT and d4T, borrowing supply from other facilities, or giving patients prescriptions to fill at private pharmacies, where a one-

Strengths and limitations

Sampling bias occurs when some members of the population are more or less likely to be included in the study than others. As this study was a census that attempted to reach the entire population, rather than a sample, there should not be limited sampling biases and results should reflect what is seen at primary health facilities in South Africa. In this telephonic survey we reached 79% of the facilities on the list of South African public health facilities. While there was some variation in the participation rate across provinces, the overall participation rate was high at 88% among facilities reached.

There were multiple reasons why a facility could not be reached: no one picked up the phone; phone line no longer active; phone number associated with a different business or person. Non-respondents may have decided against participation for a variety of reasons (e.g., fear of retaliation from a superior (as noted previously), lack of time due to competing job demands and/or staff shortages at facilities).

Facilities that could not be reached or did not participate may be different from those that did participate and this might have impacted our results. For example, if facilities with a greater number of stock outs were less likely to be reachable or participate, then our estimates would be under-estimates. If facilities do not stock certain medicines, then they cannot report them as being out of stock. Although facilities that did not participate may be different from those that did, the effect of this will be minimal because of the high participation rate.

The data in this study were collected by self-report; that is, we asked people to tell us about the stock in their facilities. Self-report has been used to collect information about a variety of health and health system-related issues and has generally been found to be a reliable method of data collection.^[37-39] However, it may have introduced some bias into our study. We used multiple methods to minimise the risk of self-report, including: eligibility for staff participation, collecting information for multiple time points, and conducting a validation sub-study.

We acknowledge that participant characteristics and context may contribute to inaccurate reporting of stock outs, duration and impact. The position and level of knowledge of the participant contribute to awareness of which medicines should be in stock as well as awareness of stock outs. The expertise of staff may vary by clinic size and/or location. Busier clinics may have more experienced staff, but these

staff may have less time in the day to keep up with stock needs and levels. To minimise the overall risk of misreporting of stock outs, we only interviewed people in positions (e.g., sisters-in-charge, pharmacists) that should necessitate a full understanding of the stock levels of all medicines, including those not commonly used, at their facility. To validate and determine the reliability of our findings, we randomly selected a sub-set of clinics that participated and interviewed a second staff member. Agreement between the participants from the same facility was high at 94% and had near-perfect reliability.

Recall bias, a specific form of reporting bias, occurs when participants cannot accurately remember the information requested. In our study, the risk of recall bias is minimal because of the reporting time periods selected. For stock outs on the day of the call, no recall was required. However, this only provides a snapshot of the stock conditions at the clinics. For example, if the call was received just prior to ordering new stock, then a stock out might have been more likely to be reported. In contrast, if the call was received just after a delivery of stock, then a stock out might have been less likely to be reported. To compensate for this, we also asked for participants to report stock outs of ARV and TB medicines in the 3mo prior to the call. Stock outs reported during the 3mo prior to the call may provide a more accurate representation for the average levels of stock at a particular clinic, though under-reporting of stock outs could have occurred if participants could not remember certain stock outs. Recall over the preceding three months is relatively short, however, and staff should be able to recollect stock outs during this period.

We understand and acknowledge that not all stock outs are equivalent in terms of impact on patient care and quality of life (e.g., patient health outcomes, excess cost and time related to returning to the clinic or going to another clinic when confronted with stock outs) and that impact is an important aspect of a stock out. Therefore, we were interested in describing not only the number of stock outs, but also the impact of the stock outs on patient care. However, we collected facility-level data; thus, it was not possible to assess the patient-level consequences of the stock outs. We created a measure of impact derived from the action that the facility took to mitigate the stock out and the supply given to the patient. We acknowledge that, in a certain facility, different actions might have been proposed to different patients. These decisions might have been affected by several





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different factors that we were not able to capture: e.g. the expertise of the clinical staff member providing the patient care; knowledge and availability of the medicines in a nearby facility; patient need; and ability to access medicines through other sources. However, we assume that most facilities have a standard strategy or protocol to deal with stock outs and the options reported by participants were those offered to the majority of patients confronted with stock outs.

In this study, as with all surveys, there is an opportunity for bias to be introduced. The protocol developed was based

Conclusions

The anticipated introduction of a 'test and treat' policy for HIV and reaching UNAIDS 90-90-90 targets will mean an increasing number of people need uninterrupted supplies of chronic medication. A strong but flexible supply chain system, with regular last mile delivery, emergency mitigation mechanisms and robust data management systems, is necessary to make this happen. Innovative new models of care that outsource dispensing and distribution of medical supplies can help reduce the prevalence of stock outs, while also providing patients with accessible options for prescription refills closer to their homes.

The likelihood of stock outs increases during the introduction of new regimens or the scale up of treatment, as evidenced by increased stock out reports during the FDC introduction, as reported in the 2013 survey, and LPV/r in the 2015 survey. Scale up to a 'test and treat' policy will require adequate preparation of the supply chain by all levels of the DOH.

In 2014, stock outs occurred for a variety of different regimens and with stark differences between provinces, suggesting that province-specific supply chain management problems were the root cause. ARVs used by a large proportion of the patient cohort, such as NVP solution for PMTCT, adult AZT tablets and FDC, were commonly reported to be out of stock. Even though valid alternatives were available in the country, patients were sent away without medicine in over one in five instances of stock outs. Provincial differences show the persisting contribution of localised supply chain

on our previous experience conducting stock out surveys, was developed in collaboration with several organisations, and underwent scientific review through the ethics review process. As outlined above, we recognised the potential sources of bias and error and took steps wherever possible to minimise these. Increased and ongoing support and buy-in from primary health facilities, as evidenced by high participation rates, suggests a general trust in our survey and reporting.

problems, as the most problematic provinces score poorly at all levels. Supply chain issues are not limited to ARV and TB medicines, but affect vaccines and medicines for a wide range of conditions.

In the most recent survey in 2015, the overall stock out situation in the country had not changed from 2014, but many stock outs were attributed to national shortages of adult LPV/r, which weighed heavily on supplies of other ARVs used as substitutes. Although fewer patients are likely to be affected by these stock outs, the lack of valid alternatives makes these patients more vulnerable to interrupt treatment or develop further resistance. Shortcomings in current legislation hindered the ability to source alternative suppliers, and prevented a rapid response to LPV/r stock outs.

At the same time, success stories exist, and can take place in even the most rural, or resource-limited settings. Proper planning can overcome supply chain challenges, and numerous players, including the Global Fund,^[40] PEPFAR,^[41] UNAIDS^[7] and South African government, recognise that success is more likely when the community is involved in the development, implementation and monitoring of the response. Civil society and the communities it represents provide an independent opinion on the effectiveness of service delivery and have a right to demand transparency on the spending of public funds destined to ensure that people's right to healthcare services is delivered.





“ I suffer from anxiety, depression and I am HIVpositive. I am taking citalopram 20 mg, propranolol 20 mg and FDC 300/200/600 mg. I started my ARVs in 2007. I have never had any problem with them at the clinic. I started citalopram 20 mg and propranolol 20 mg in 2013. However citalopram 20mg has been out of stock ... since 2013. Nurses informed me to go and buy it in the private pharmacy. I used R122.00 to buy the citalopram, which lasts for 10 days.’ – Patient, Johannesburg

Recommendations

Causes of stock outs are diverse and should be addressed at all supply chain levels, but the following interventions should be prioritised to decrease impact in the short term and allow adequate preparation for critical periods, such as the move to a ‘test and treat’ policy for all HIV-positive people:

- **The DOH and partners should address with urgency the eight worst-performing districts for ARV and TB medicine stock outs** and the four worst-performing provinces:
 - Gauteng: Ekurhuleni (47%) and Sedibeng (53%)
 - Free State: Mangaung (50%) and Xhariep (50%)
 - Mpumalanga: Ehlanzeni (62%), Gert Sibande (45%) and Nkangala (63%)
 - North West: Bojanala Platinum (41%)
- **Prioritise finalisation of the NDOH national strategic plan on medical supply chain**, with clear indicators and an ambitious timeline to reduce patient-level stock outs in the short- and long term. The action plan should include but not be limited to:
 - Ensure **timely consultation** with all relevant players, and **include civil society on the NDOH task team on non-availability of medicines**, as representatives of the end-users.
 - Ensure a **clear budget for implementation**, which is urgent in the light of the pending expansion of HIV treatment criteria.
 - **Prioritise support for struggling districts and provinces.**
 - Ensure implementation of clear **facility- and patient-level indicators** to measure progress of supply chain interventions and serve as early warning indicators to limit stock outs.^[22]
 - Utilise innovations such as the CCMDD and community models of care to expand **patient-centred service delivery approaches** to chronic diseases; offer minimum three months’ supply of chronic medicines for all stable patients and clinic appointment spacing
 - Improve **monitoring and evaluation tools** at patient level to inform forecasting and supply chain evaluation (i.e. pharmacy software, cohort follow-up tools).
 - **Establish guidance to ensure DOH implementation plans** when introducing new treatment policies or scaling up new regimens, including: (i) an elaborated

transitional plan; (ii) sufficient national and local buffer stocks; and (iii) clear clinical guidance, distributed to all clinicians.

- o Establish **emergency response mechanisms** for importation and distribution alongside robust, simplified (i.e. direct delivery) and reliable supply chain channels – to ensure the supply chain remains dynamic enough to respond to changing ARV regimens, growing cohorts and unexpected circumstances.
- **Recognise the complementary role and added value of civil society in reporting on and addressing stock outs:** Data collected from patients and healthcare workers by local civil society should be used to complement government monitoring mechanisms, inform the DOH whether services have reached the end-user, and catalyse subsequent action. The availability of SSP end-user data should allow for synergies with government systems to: (i) confirm lack of medicine availability in areas where there are functional DOH supply monitoring systems, and (ii) provide information from areas where DOH does not have the necessary supply chain visibility.
- **Enhance supply security** by having multiple available sources of finished products and their active ingredients, for all essential medicines. Adjust legislation and guidelines to facilitate this:
 - o **Fix the patent laws:** The DTI should finalise a national IP policy that balances the Constitutional right to access healthcare with private privilege. Reform by Parliament of the Patents Act and related legislation should allow for effective and timely use of TRIPS flexibilities to improve supply security.
 - o **New SAPHRA regulations should:** (i) ensure fast-

track registration procedures for finished products and API with no/only one registered source – recognition of approvals by internationally recognised quality assurance sources (WHO pre-qualification, stringent regulatory authorities) can expedite this process; (ii) actively pursue and engage suppliers of priority products if insufficient applications are received; (iii) ensure full public transparency of drug application status and decisions made on the SAHPRA website.

- o **Amended HIV treatment guidelines** from NDOH should include ATV/r as a preferred second-line treatment option in addition to LPV/r, to diversify supply sources.
- **International stakeholders and partners:**
 - o Support **patients, communities and civil society** with funding, technical support and by giving access to relevant forums, to allow them to fulfil the dual roles of observer of supply chain functioning and participant in efforts for its improvement.
 - o Coordinate **international exchange of expertise** on lessons learned from: different supply chain models, including community delivery models; and the introduction or scale-up of new regimens.
 - o Develop standard **indicators** and tools to monitor facility- and patient-based access indicators, and evaluate, adjust and predict outcomes of treatment programmes.
 - o Monitor global demand for **essential medicines** to improve international forecasting and inform proactive measures to promote supply security
 - o Support effective implementation of **TRIPS flexibilities** to promote public health, including technical and political assistance to enable their timely application and use.



Department of Health narratives and action plans



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7 JUNE 2016

ATTENTION: SUE
STOP STOCK OUTS PROJECT

IN RESPONSE TO YOUR SURVEY RESULTS PRESENTATION, STOCK OUTS IMPROVEMENTS IN EC, CAN BE ATTRIBUTED TO THE FOLLOWING:

- Closure of sub depots and promote direct deliveries to health facilities using an ordering and delivery schedule
- Employment of Sub District Pharmacists to manage medicine supply within a sub district
- Strengthened management of each depot to Director Level with delegations
- Payment of suppliers within 30 days
- Maintain 12 week buffer stock in the depots and 6 weeks in PHC clinics
- *Whatsapp* stock movement group in case of excess or shortages
- Appointment of Pharmacist Assistants for PHC clinics
- Improve staffing in the depots
- Implement the Stock Visibility System across all PHC facilities

MR S ZUMA
GENERAL MANAGER: CLINICAL SUPPORT SERVICES
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**OFFICE OF THE HEAD OF
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Reference: 17/1/R
Enquiries: Dr ST Mtshali
Tel No: (033) 395 3176

Ms. S Tafeni
Project Manager
Stop Stockouts

Email: sue@stockouts.org

Dear Ms. Tafeni

Re : STOP STOCKOUTS PROJECT: 2015 SURVEY RESULTS

The above-mentioned subject refers.

It must be noted that thirty (30) clinics from KwaZulu-Natal participated in the survey for stockouts during the period 05th October 2015 to 09th November 2015 however; no feedback had been provided to Stop Stockouts Project on verification of the responses. Furthermore, context had not been provided as many clinics reported to have had either alternative strengths and/or Fixed Dose Combination ARVs.

The KwaZulu-Natal Department of Health has systems and processes in place for monitoring medicine availability at facilities which assist with interventions when the need arises. The following processes are:

- Head Office communicates any contingency for products with supply constraints e.g. advising on therapeutic alternatives;
- Head Office liaises with the National Department of Health with regard to the management of Pharmaceutical Contracts;
- Each district has a District Pharmacy Manager who coordinates medicine availability data collation within the district. This data is submitted to Head Office for decision making and for further interventions if required;
- The District Pharmacy Manager facilitates the redistribution of stock between the district facilities;
- In cases where there is a definite stock out at a facility, patient contact details are recorded for follow-up with the patient when the stock becomes available (for catch-up vaccination).

All efforts are made to ensure that patient care is not compromised by supply constraints.

Yours sincerely


DR ST MTSHALI
HEAD OF DEPARTMENT
DEPARTMENT OF HEALTH: KWAZULU-NATAL

Date: 2016 -04- 08

Fighting Disease, Fighting Poverty, Giving Hope





health

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PHARMACEUTICAL SERVICES

12 April 2016

Project Manager
Stop Stock-Out Consortium

Attention: Dr Sue Tafenni
E-mail: sue@stockouts.org

RE: 2015 SURVEY REPORT / FINDINGS

We acknowledge the above mentioned report and findings. However, in the absence of detailed facility information, we could not verify the information provided and do a thorough investigation of what the actual root causes could have been. We further acknowledge the reasons provided as to why this information cannot be made available.

Response to the findings:

During the period of the survey, there was National shortage of the following items:

- ❖ Abacavir 300g tablets – Abacavir and Lamivudine combination or Abacavir 60mg tablets were available as alternatives.
- ❖ Lopinavir/Ritonavir (Aluvia) tablets – stock was received mid-October, initially in part supplies which could not fully satisfy the demand.
- ❖ Zidovudine 300mg tablets – problems experienced since September 2015, substituted with a combination of Lamivudine and Zidovudine.
- ❖ Ferrous sulphate tablets – Ferrous Fumarate tablets were available as alternative.


During the period of the survey, supply of the following items to the Province was in-consistent and this affected their sustained availability at the facilities:

- ❖ Ceftriaxone injection
- ❖ Haloperidol tablets
- ❖ Metformin tablets
- ❖ Sodium Valproate tablets.
- ❖ Furosemide tablets 40mg

Supply of these items has since stabilized and they are available.

Even though the detailed facility information was not available, assessment of the situation during the period of the survey indicates the following as possible root causes of the findings:

- ❖ National shortage of certain items e.g Abacavir and Aluvia tablets e.t.c
- ❖ Supplier challenges i.e inconsistent supply e.g Haloperidol tablets e.t.c
- ❖ Drug supply management challenges:



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15 April 2016

Dear Ms Sue Tafeni

RE: 2015 SURVEY RESULTS

To alleviate the stock-out situation going forward, the Pharmaceutical Directorate did an analysis on the root causes for stock-outs and came up with the following:

- Lack of Pharmaceutical staff.
- No electronic stock management system up to facility level.

The fact that most of the facilities are nurse-driven (and also huge shortages are being experienced in this profession at facilities) inadequate or no stock management on pharmaceutical stock is applied. This is clearly evident in the lack of stock cards (in the absence of electronic systems), huge wastage (redundant/expired stock), incorrect ordering or no ordering at all, that is currently being experienced.

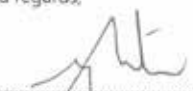
To mitigate the aforesaid a needs analysis was done on the cadre and number of pharmaceutical staff that is needed. This was encapsulated in a submission to the Head of Department and an alternative option was provided in the numbers as to the total that is actually needed. I was reliably informed that it is being considered to possibly fill SOME of these positions.

The roll-out of the Rx Solution stock management system as the electronic system in the Province is also being considered (with the help from NDoH) which would address this challenge.


The reason for first having the staff in place would assist IF the electronic system is not installed at facility level then dedicated staff in the form of Post Basic Assistants can tend to stock management.

Please contact me should you need additional input or clarity.

Kind regards,



Mr. G. Mentoor
Director: Pharmaceutical Services



We are committed to achieving our vision through a decentralized, accountable, accessible and constantly improving health care system within available resources. Our caring, multi-skilled, effective personnel will use evidence-based, informative health care and maturing partnerships for the benefit of our clients and patients.





**FIX THE
PATENT
LAWS!**

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Annex A: Methodology tables and definitions

Annex A-I: Summary of changes in methods between the 2014 and 2015 national stock out survey

Survey aspect	2014	2015
Respondent	Pharmacist, pharmacy assistant or person who orders facility medicines	Aged 18 years or older Pharmacist, pharmacy assistant or person who orders medicines, sister-in-charge
Use of medicines	No specification of medicines use	Added question on whether the facility 'does usually stock' ARVs, TB-related medicines and specific vaccines and other essential medicines
Selected childhood vaccines	Measles vaccine, rotavirus vaccine, pentavalent vaccine	Measles vaccine, rotavirus vaccine, hexavalent vaccine
Selected essential medicines	Salbutamol inhaler, metformin tablets, sodium valproate tablets, enalapril/perindopril tablets, ceftriaxone injection	Salbutamol inhaler, metformin tablets, sodium valproate tablets, ceftriaxone injection, haloperidol tablets, furosemide tablets, ferrous sulphate tablets
Validation	No validation of results	Validation of results by second interviewer to alternative respondent in the same facility

Annex A-II: Classification of ARVs and rationale for inclusion in stock out analysis

Adult first-line ARVs ●	Adult second-line ARVs ●●	Adult ARVs for exceptional cases ●●●	Paediatric ARVs ●●●●	PMTCT for children ●●●●●
TDF/FTC/EFV 300/200/600 mg, FDC tablets	AZT 300 mg, tablets	NVP 200 mg, tablets	ABC 60 mg, tablets or 20 mg/ml, solution	NVP 50 mg/50 ml, solution
TDF/FTC 300/200 mg, tablets	LPV/r 200/50 mg, tablets	ABC 600 mg, tablets	AZT 100 mg, tablets	
3TC 150 mg or 300 mg, tablets	ATV 300 mg, tablets	ABC/3TC 600/300 mg, tablets	RTV 80 mg/ml, solution	
d4T 30 mg, tablets	ddI 400 mg, tablets	DRV 600 mg, tablets	3TC 10 mg/ml, solution	
EFV 600 mg, tablets	RTV 100 mg, tablets	AZT/3TC 300/150 mg, tablets	LPV/r 80/20 mg/ml, solution	
TDF 300 mg, tablets			LPV/r 100/25 mg, tablets	
			AZT 50 mg/5 ml, solution	
			d4T 15 mg or 20 mg, tablets	
			EFV 50 mg or 200 mg, tablets	

3TC – Lamivudine; ABC – Abacavir; AZT – Zidovudine; ATV – Atazanavir; ddI – Didanosine; DRV – Darunavir; d4T – Stavudine; EFV – Efavirenz; FTC – Emtricitabine; FDC – Fixed-Dose Combination of TDF, FTC and EFV; LPV – Lopinavir; NVP – Nevirapine; RTV or /r – Ritonavir; TDF – Tenofovir.

- Medicines prescribed as first-choice treatment for the large majority of the patient cohort with no demonstrated resistance to ARVs, were classified as “first-line ARVs.”
- ARVs prescribed for the majority of patients who demonstrated resistance to first-line ARVs were classified as “second-line ARVs”.
- ARVs used for patients who experienced side-effects or resistance to the most frequently used first- and second-line treatment – generally a small proportion of the cohort – were classified as “ARVs for exceptional cases”.
- All medicines for which the formulation and/or dosage has been adapted for administration to children were classified as paediatric ARVs. These adaptations allow for the variation in children’s weights and ability to swallow pills.
- For the purposes of this analysis, only NVP solution for children was classified as an ARV for PMTCT, as it is mainly used in infants of HIV-positive mothers. Initiating an HIV-positive mother on lifelong ART is also part of the standard PMTCT care, but these ARVs were classified under adult ARVs, as we could not differentiate between a stock out of adult ARVs being used for PMTCT from a

Annex A-III: Classification of TB medicines and rationale for inclusion in stock out analysis

First-line TB ●	Complicated (second-line) TB ●●	IPT for TB prophylaxis ●●●	Prevention of side-effects caused by TB medicines ●●●●
R/H 150/75 mg, tablets	Z 150 mg or 400 mg, tablets	INH 300 mg, tablets	PN/Vit B6 25 mg or 50 mg, tablets
R/H 300/150 mg, tablets	R 150 mg or 300 mg, tablets	INH 100 mg, tablets	
R/H 60/60 mg, tablets	E 100 mg or 400 mg, tablets		
RHZE 150/75/400/275 mg, tablets	ETO 250 mg, tablets		
	Km 500 mg/2 ml, injection		
	Lvx 250 mg or 500 mg, tablets		
	R/H 10 mg/ml, suspension		

IPT – Isoniazid Preventive Therapy; R/H – Rifampicin/Isoniazid; RHZE – Rifampicin/Isoniazid /Pyrazinamide/Ethambutol; E – Ethambutol; ETO – Ethionamide; INH – Isoniazid (for preventive therapy); Km – Kanamycin; Lvx – Levofloxacin; R – Rifampicin; Z – Pyrazinamide; Vit B6 – Vitamin B6 or pyridoxine.

TB is an infectious disease caused by the bacillus *Mycobacterium tuberculosis*. People living with HIV have a much higher chance of developing TB. Without treatment, the death rate from TB is high. The recommended treatment for new cases of drug-susceptible TB is a six-month regimen of four first-line medicines: rifampicin (R), isoniazid (H), pyrazinamide (Z) and ethambutol (E). Treatment for multi-drug-resistant TB (MDR-TB), defined as resistance to R and H (the two most powerful anti-TB drugs) is longer, and requires more expensive and more toxic medicines.

- “First-line TB medicines” are those prescribed for patients who are being treated for TB for the first time, and who have no demonstrated resistance to these drugs.
- TB medicines most commonly used among patients with drug-resistant TB were classified as “second-line TB medicines.”
- A single drug, isoniazid (H), comprises the “Isoniazid Preventive Therapy (IPT)” category – and is used for the prevention of TB in HIV-positive patients.
- Pyridoxine/Vitamin B6 (PN or Vit B6) is a vitamin used by patients receiving TB treatment, to prevent associated side-effects.

Annex A-IV: Selected vaccines and rationale for inclusion in stock out analysis

Name of vaccine	Vaccination against	Rationale for inclusion
Measles vaccine	Measles	Since the South African measles epidemic of 2010, there has been a redoubling of efforts to reach the goal of 95% coverage of the measles vaccine in South Africa ^[4] – a lofty aim which will be impossible to achieve unless the measles vaccine is always in stock in facilities.
Rotavirus vaccine	Rotavirus diarrhoea	Introduced in South Africa in 2009, the vaccine protects against rotavirus, the most common cause of severe diarrhoea in children. ^[2] Diarrhoea and pneumonia are among the top three causes of death among infants in South Africa. ^[3] The vaccine is fairly new on the schedule, its administration is time-sensitive, and a stock out would mean that children would not receive protection (it is not recommended to provide a catch-up dose beyond 24 weeks). ^[2]
DTaP-IPV-Hib pentavalent vaccine OR DTaP-IPV-HBV-Hib hexavalent vaccine	Diphtheria, Tetanus, acellular Pertussis, Polio and <i>Haemophilus influenzae</i> type b OR Diphtheria, Tetanus, acellular Pertussis, Polio, <i>Haemophilus influenzae</i> type b and Hepatitis B	Population coverage of immunisation with the combination diphtheria-tetanus-pertussis vaccine has historically been considered by WHO as an important marker of health system functioning. ^[1] In recent years, additional antigens have been added to the DTP combination to protect against other vaccine-preventable diseases. In 2015, South Africa switched from using a pentavalent vaccine to a hexavalent vaccine.
DTaP – Diphtheria, Tetanus and acellular Pertussis; HBV – Hepatitis B Virus; Hib – <i>Haemophilus influenzae</i> type b; IPV – Inactivated Polio Virus.		
Although additional vaccinations are included in the South African Expanded Programme of Immunisation (EPI) schedule, the number of vaccines enquired about in the survey was limited to three.		

Annex A-V: Selected essential medicines and general indications, and rationale for inclusion in stock out analysis

Medicine, formulation	Indication (general)	Rationale for inclusion ^[5]
Ceftriaxone, injection	Bacterial infections	Important in the treatment of paediatric infections.
Ferrous sulphate, tablets	Anaemia, prevention of anaemia in antenatal care	Used to prevent or treat iron-deficiency anaemia – an indicator of poor nutrition, poor health and socio-economic disadvantage in many settings, and which mostly affects children and women of reproductive age. Pregnant women and patients being treated for cancer and chronic infectious diseases, such as TB and HIV, are usually given dietary iron supplements in the form of ferrous sulphate. Untreated anaemia has far-ranging health consequences and affects school performance and work productivity.
Furosemide, tablets	Heart disease	Predominantly used at primary healthcare level by patients with chronic oedema and high blood pressure, which can be life-threatening if left untreated.
Haloperidol, tablets	Psychosis	As chronic treatment, the oral tablets are used as the first-line treatment for schizophrenia in adults. The intramuscular injection is widely used to sedate agitated and acutely disturbed patients suffering from psychosis or bipolar mood disorder.
Metformin, tablets	Type 2 diabetes mellitus	The most common first-line medication used in diabetes mellitus. Can be used in conjunction with insulin.
Salbutamol, inhaler	Asthma	Used first-line as a reliever at primary care level for patients suffering from asthma.
Sodium valproate, tablets	Epilepsy	Used to treat all forms of epilepsy; it is the preferred treatment for HIV-infected children on ARVs and one of the first-line treatments for generalised tonic and/or clonic seizures in all children. Sodium valproate is also used to treat the acute manic phase of bipolar disorder.

Annex A-VI: Definitions of stock out impact

Impact category	Facility action	AND	Patient supply
High	Referred OR turned patients away	AND	No medication at all
	Received one or two out of three drugs	AND	A smaller OR full supply
Medium	Referred OR turned patients away	AND	A smaller supply
	Borrowed	AND	A smaller supply
	Switched to same drug but a less optimal dosage OR a less optimal formulation OR pill burden increased	AND	A smaller OR full supply
	Switched to a less optimal regimen	AND	A smaller OR full supply
Low	Switched appropriately to a different regimen, dosage or formulation	AND	A full supply
	Borrowed	AND	A full supply

Regimens were assessed to contain only one or two out of three drugs, and switches were determined as less optimal or appropriate, according to regimen choices outlined in the *National Consolidated Guidelines for the prevention of mother-to-child transmission of HIV (PMTCT) and the management of HIV in children, adolescents and adults*.^[11]

Annex A-VII: Inclusion and exclusion criteria for facilities and participants in 2015 survey

	Facility level	No medication at all
Inclusion criteria	Public health facility located in South Africa	18 years of age or older Pharmacist, pharmacy assistant, person responsible for ordering the facility's medicine, or sister-in-charge
Exclusion criteria	Public satellite and mobile clinics; private health facilities	



Annex A-VIII: Consent form

Hello, My name is [interviewer's name]. I'm currently conducting a survey of facilities across the country asking about medicine availability in public health facilities. I'd like to ask some questions about medicines in your clinic. This is completely anonymous, you will not be identified. May I tell you more about the study to see whether you would be interested in taking part?

(If the patient says "Yes" → continue. If the patient says "No" → stop here.)

Who is conducting the study? *The study is being conducted by the Stop Stock Outs Project, a consortium of organisations monitoring essential medicines availability in South Africa.*

How will my confidentiality be protected? *This survey is completely anonymous. All the responses you provide will be confidential and you will not be identified. We will not ask you for your name.*

What is the purpose of this study? *The purpose of the study is to find out medicine availability across the country at public health facilities.*

Who can take part in the study? *Only those who want to and consent to take part in this study will proceed. In order to take part in the study you must be at least 18 years old.*

1. Are you 18 years old or older?

If the patient says "Yes" → continue.

If the patient says "No" → stop here.

What does taking part in the study involve? *We will be asking you questions about medicine availability in your clinic. The survey will take about 5 - 10 minutes of your time.*

Has the study been approved? *The study has been approved by the **Faculty of Health Science's Human Research Ethics Committee** of the University of Cape Town.*

Can people choose not to take part? *People are free to choose whether or not to take part in the study for any reason. There will be no negative consequences. Those who agree to take part in the study are free to choose to stop taking part in the study at any time by telling us or hanging up the phone.*

What are the benefits of taking part in the study? *Medicine availability is important for patients to prevent mortality and morbidity and for health care workers to have the basic tools they need to do their job. Assessing the availability of medicines in different health clinics will help us understand which areas are more affected and less affected and allows those improving the supply to direct their attention to districts and provinces that require more improvement in the supply chain. It's important for the problem to be identified in order for actions to be directed.*

What are the risks of taking part in the study? *You will need to decide if it is safe for you to respond to the questions that we ask and weigh the risks of others finding out that you may have answered some of our questions. You may choose not to answer any of our questions at any time.*

Will respondents be rewarded for taking part in the study? *Respondents will not be paid to be in the study, and will not be given cell phones or air time vouchers. It will not cost respondents anything to be in the study.*

Is there anyone who respondents can contact if they have questions or concerns about the study? *Respondents can contact Bella Hwang, study co-ordinator at 079 897 8518 if they have questions or want more information about the study.*

Respondents can also report stock outs by sending a free “Please call me” message to 084 855 7867.

Anyone who has concerns about the study or thinks that their rights have not been respected because of the study, can contact Professor Mark Blockman, the Chairman of the University of Cape Town Human Research Ethics Committee, on 021 406 6492. If they contact Professor Blockman, they will need to give the study reference number. The study reference number is XXXXX.

Do you have any questions about what I have told you about the study? Is there anything else that you would like to know before deciding whether to take part? [The recruiter should answer all questions.]

Are you willing to take part in the study?

If the patient says “Yes” → verbal consent obtained and proceed to questionnaire.

If the patient says “No” → stop here.

Annex A-IX: Questionnaire

Hello, my name is -----

Can I speak to you, or can I please speak to the Pharmacist > Pharmacy Assistant > Person who orders the facility's medicine > Sister-in-charge?

1. No
2. Yes
3. Not reachable
4. Not ARV/TB clinic

< Information and Informed Consent Procedures >

The person was willing be interviewed

1. Yes
2. No

At your facility, how many patients do you have on ARVs?

1. Less than a 1 000
2. More than a 1 000

Are any ARV or TB medicines out of stock TODAY?

1. Yes
2. No

(The following questions repeated for each item reported out of stock TODAY)**What is the name of the ARV or TB medicine?** (Drop-down menu of medicines provided)**For how long has the item been out of stock?**

1. Less than 1 week
2. 1 - 4 weeks
3. Longer than 1 month

What are you doing for the majority of patients in the mean time?

1. Sent Away/Asked to return later/Referred elsewhere
2. Switching their treatment to a different medicine (To what did they switch them?)
3. Same treatment BUT given another strength/dosage
4. Borrowed
5. Received 1 or 2 out of 3 drugs
6. Received 3 out of 3 drugs
7. Other

Did the majority of patients leave with:

1. No medication?
2. Smaller supply of medication (than would otherwise have been issued)?
3. Full supply of medication?

Is there another HIV or TB medicine out of stock TODAY? (Repeat previous 4 questions for each item out of stock)

1. Yes
2. No

Now I would like you to think about the past 3 months? Can you think back to _____ (provide date exactly 3 months ago (e.g. if 15 October 2015 today, then say 15 July 2015).

Have any other HIV or TB medicines been out of stock in the past 3 months?

1. Yes
2. No

(The following questions repeated for each item reported out of stock in the PREVIOUS 3 MONTHS)

What is the name of the HIV or TB medicine? (Drop-down menu of medicines provided)

During which month did the problem start/was it out of stock?

For how long was the item out of stock?

1. Less than 1 week
2. 1 - 4 weeks
3. Longer than 1 month

When the treatment ran out, what did you do for your patients?

1. Sent Away/Asked to return later/Referred elsewhere
2. Switching their treatment to a different medicine (To what did they switch them?)
3. Same treatment BUT given another strength/dosage
4. Borrowed
5. Received 1 or 2 out of 3 drugs
6. Received 3 out of 3 drugs
7. Other

Did the patient leave with:

1. No medication?
2. A smaller supply of medication?
3. One month's/full supply of medication?

Were there any other ARVs or TB medicines out of stock in the last 3 months? (Repeat previous 5 questions for each item out of stock)

1. Yes
2. No

Now I am going to ask you about the availability of some other vaccines and medicines in your facility TODAY. Can you tell me whether each item I ask is "in stock"; "out of stock"; or your facility "does not usually stock".

Do you have the following vaccines available TODAY?

1. RV (rotavirus vaccine)
2. DTaP-IPV-Hib-HBV vaccine (six-in-one: Diphtheria, Tetanus, acellular Pertussis, Polio, *Haemophilus influenzae* type b, Hepatitis B)
3. Measles vaccine

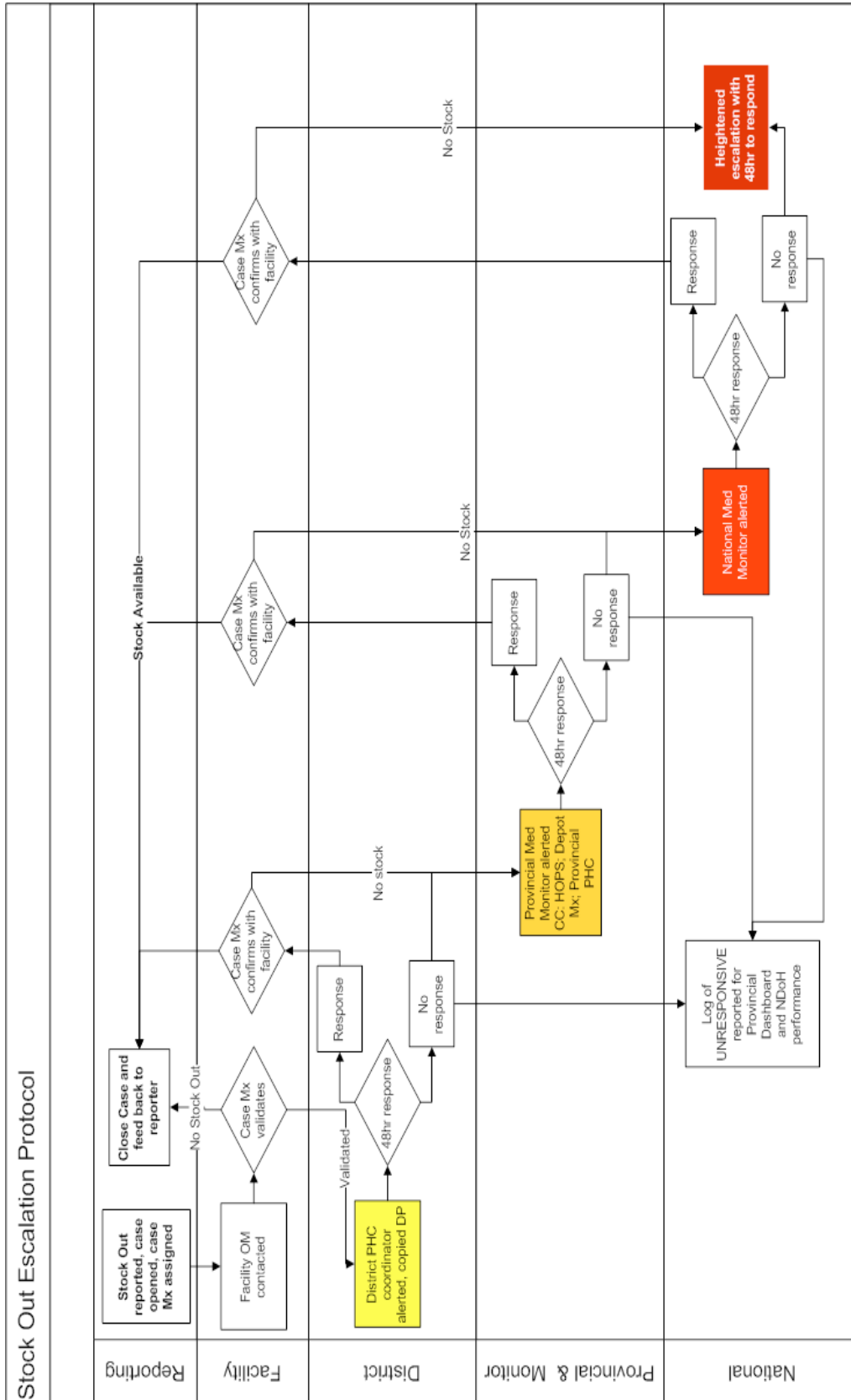
Are the following items available at your facility TODAY?

1. Ceftriaxone (or Kocef® or Rociject®)
2. Epilim® (or sodium valproate) tablets
3. Metformin (or Forminal®) tablets
4. Salbutamol inhaler (or Ventimax® or Ventolin®)
5. Haloperidol tablets
6. Lasix® or furosemide tablets
7. Iron tablets or ferrous sulphate

Thank you for your time and for participating in our survey. If you would like to report a stock out in the future, then please contact us at 084 855 7867.

Annex A-X: Protocol for escalation of stock outs

[If redrawing this, kindly provide access to Illustrator file, so that it can be edited]



Annex B: Results tables

Annex B-I: Facilities that were contactable and provided information on any stock outs, by province (2013 - 2015)

Province	2013 ●	2014		2015		Breakdown of facilities by provision of ARV/TB (2015)	
	Facilities providing information % (n/N)	Facilities contactable by phone % (n/N)	Facilities providing information % (n/N)	Facilities contactable by phone % (n/N)	Facilities providing information % (n/N)	ARV/TB n/N	Not ARV/TB n/N
Eastern Cape	96% (447/468)	75% (519/696)	98% (509/519)	75% (501/669)	94% (469/501)	465/469	4/469
Free State	87% (167/191)	97% (235/242)	63% (147/235)	85% (193/226)	70% (135/193)	135/135	0/135
Gauteng	90% (284/316)	85% (348/409)	84% (294/348)	92% (334/363)	83% (277/334)	276/277	1/277
KwaZulu-Natal	84% (332/393)	74% (532/717)	83% (444/532)	70% (508/726)	87% (443/508)	417/443	26/443
Limpopo	96% (218/228)	76% (282/370)	94% (266/282)	81% (290/357)	86% (248/290)	248/248	0/248
Mpumalanga	96% (224/234)	68% (223/327)	92% (205/223)	80% (240/299)	92% (220/240)	220/220	0/220
Northern Cape	95% (182/192)	79% (112/141)	96% (107/112)	75% (123/163)	100% (123/123)	123/123	0/123
North West	95% (62/65)	80% (265/332)	84% (222/265)	75% (243/322)	91% (222/243)	222/222	0/222
Western Cape	87% (223/255)	70% (349/498)	87% (305/349)	88% (372/422)	88% (326/372)	261/326	65/326
South Africa	91% (2 139/2 342)	77% (2 865/3 732)	87% (2 499/2 865)	79% (2 804/3 547)	88% (2 463/2 804)	2 367/2 463	96/2 463

● Note: In 2013 only ARV/TB clinics were included in the survey.

Annex B-II: Percentage of facilities reporting at least one ARV or TB medicine stock out (day), by province (2013 - 2015)

Province	Facilities reporting at least one ARV or TB medicine stock out % (n/N)		
	2013	2014	2015
Eastern Cape	10% (45/447)	19% (95/509)	17% (81/465)
Free State	22% (37/167)	12% (18/147)	42% (56/135)
Gauteng	9% (26/284)	18% (50/283)	38% (104/275)
KwaZulu-Natal	9% (30/332)	12% (53/436)	10% (43/417)
Limpopo	22% (48/218)	21% (55/266)	16% (39/248)
Mpumalanga	18% (40/224)	30% (62/205)	38% (84/219)
Northern Cape	3% (2/62)	13% (14/107)	11% (13/123)
North West	3% (5/182)	27% (59/222)	23% (51/221)
Western Cape	5% (11/225)	1% (4/279)	4% (9/260)
South Africa	11% (235/2 139)	17% (410/2 454)	20% (480/2 363)

Annex B-III: Breakdown of facilities by type of stock out (day), by province (2014 and 2015)

Province	Facilities reporting at least one adult ARV stock out % (n/N)		Facilities reporting at least one paediatric ARV stock out % (n/N)		Facilities reporting at least one PMTCT stock out % (n/N)		Facilities reporting at least one TB medicine stock out % (n/N)	
	2014	2015	2014	2015	2014	2015	2014	2015
Eastern Cape	7% (36/509)	12% (54/465)	5% (25/509)	4% (20/465)	2% (11/509)	1% (3/465)	8% (39/509)	2% (11/465)
Free State	10% (15/147)	40% (54/135)	3% (5/147)	10% (13/135)	0% (0/147)	1% (2/135)	1% (2/147)	5% (7/135)
Gauteng	10% (29/283)	33% (92/276)	4% (11/283)	7% (18/276)	1% (4/283)	0% (0/276)	5% (14/283)	1% (3/276)
KwaZulu-Natal	5% (22/436)	8% (34/417)	6% (24/436)	3% (12/417)	2% (8/436)	0% (1/417)	1% (6/436)	0% (2/417)
Limpopo	12% (32/266)	12% (29/248)	5% (13/266)	2% (6/248)	8% (20/266)	0.004% (1/248)	1% (2/266)	1% (3/248)
Mpumalanga	21% (28/205)	31% (69/220)	7% (14/205)	13% (29/220)	6% (13/205)	1% (3/220)	9% (19/205)	2% (5/220)
Northern Cape	8% (9/107)	5% (6/123)	2% (2/107)	4% (5/123)	1% (1/107)	0% (0/123)	6% (6/107)	4% (5/123)
North West	21% (46/222)	17% (38/223)	4% (9/222)	5% (12/223)	0.5% (1/222)	1% (2/223)	4% (8/222)	5% (12/223)
Western Cape	0% (0/279)	2% (6/261)	0% (0/279)	0% (0/261)	0% (0/279)	0% (0/261)	1% (4/279)	1% (3/261)
South Africa	9% (217/2454)	16% (382/2368)	4% (103/2454)	5% (115/2368)	2% (58/2454)	0.507% (12/2368)	4% (100/2454)	2% (51/2368)

Annex B-IV: Percentage of facilities reporting at least one ARV or TB medicine stock out (3mo), by province (2013 - 2015)

Province	Facilities reporting at least one ARV or TB medicine stock out % (n/N)		
	2013	2014	2015
Eastern Cape	20% (89/447)	28% (141/509)	19% (86/465)
Free State	54% (90/167)	28% (41/147)	35% (48/136)
Gauteng	20% (58/284)	25% (71/283)	39% (106/274)
KwaZulu-Natal	14% (45/332)	19% (83/436)	19% (79/425)
Limpopo	41% (89/218)	29% (77/266)	12% (30/249)
Mpumalanga	26% (58/224)	40% (82/205)	58% (129/222)
Northern Cape	18% (11/62)	21% (23/107)	14% (17/123)
North West	4% (8/182)	39% (86/222)	31% (68/220)
Western Cape	5% (11/223)	4% (10/279)	9% (26/300)
South Africa	21% (459/2139)	25% (614/2454)	24% (589/2414)

Annex B-V: Breakdown of facilities by type of stock out (3mo), by province (2014 and 2015)

Province	Facilities reporting at least one adult ARV stock out % (n/N)		Facilities reporting at least one paediatric ARV stock out % (n/N)		Facilities reporting at least one PMTCT stock out % (n/N)		Facilities reporting at least one TB medicine stock out % (n/N)	
	2014	2015	2014	2015	2014	2015	2014	2015
Eastern Cape	15% (74/509)	9% (61/669)	7% (34/509)	3% (17/669)	3% (14/509)	0.004% (3/669)	10% (52/509)	1% (9/669)
Free State	21% (31/147)	20% (44/226)	8% (12/147)	4% (10/226)	1% (1/147)	1% (2/226)	2% (3/147)	2% (5/226)
Gauteng	16% (44/283)	25% (92/363)	6% (17/283)	4% (13/363)	2% (7/283)	0% (0/363)	6% (16/283)	2% (6/363)
KwaZulu-Natal	8% (37/436)	9% (69/749)	7% (31/436)	3% (21/749)	3% (11/436)	0.001% (1/749)	3% (14/436)	0.003% (2/749)
Limpopo	17% (46/266)	5% (17/358)	7% (19/266)	3% (9/358)	10% (26/266)	0.003% (1/358)	1% (93/266)	1% (3/358)
Mpumalanga	21% (43/205)	39% (117/299)	10% (20/205)	7% (22/299)	7% (15/205)	1% (4/299)	11% (22/205)	1% (3/299)
Northern Cape	12% (12/107)	6% (9/163)	5% (5/107)	2% (3/163)	1% (1/107)	1% (1/163)	9% (10/107)	3% (4/163)
North West	28% (63/222)	15% (48/322)	6% (14/222)	5% (17/322)	1% (3/222)	0.003% (1/322)	5% (12/222)	3% (11/322)
Western Cape	0.004% (1/279)	4% (15/427)	0.004% (1/279)	1% (4/427)	0% (0/279)	0.005% (2/427)	3% (8/279)	1% (3/427)
South Africa	14% (351/2454)	13% (472/3576)	6% (153/2454)	3% (116/3576)	3% (78/2454)	0.004% (15/3576)	6% (140/2454)	1% (46/3576)

Annex B-VI: Percentage of stock outs (day) lasting (i) less than one week, (ii) one to four weeks, or (iii) longer than one month, by province in 2015 (N=482)

Province	Less than 1 week % (n/N)	1 - 4 weeks % (n/N)	Longer than 1 month % (n/N)
Eastern Cape	38% (31/82)	29% (24/82)	33% (27/82)
Free State	7% (4/57)	53% (30/57)	40% (23/57)
Gauteng	19% (20/104)	23% (24/104)	58% (60/104)
KwaZulu-Natal	29% (12/41)	37% (15/41)	34% (14/41)
Limpopo	46% (18/39)	38% (15/39)	15% (6/39)
Mpumalanga	7% (6/85)	35% (30/85)	58% (49/85)
Northern Cape	54% (7/13)	38% (5/13)	8% (1/13)
North West	13% (7/52)	52% (27/52)	35% (18/52)

Annex B-VII: Percentage of stock outs (3mo) lasting (i) less than one week, (ii) one to four weeks, or (iii) longer than one month, by province in 2015 (N=760)

Province	Less than 1 week % (n/N)	1 - 4 weeks % (n/N)	Longer than 1 month % (n/N)
Eastern Cape	13% (11/88)	44% (39/88)	43% (38/88)
Free State	2% (2/88)	19% (17/88)	78% (69/88)
Gauteng	10% (13/126)	14% (18/126)	75% (95/126)
KwaZulu-Natal	15% (16/110)	19% (21/110)	66% (73/110)
Limpopo	11% (3/27)	15% (4/27)	74% (20/27)
Mpumalanga	1% (2/190)	11% (20/190)	88% (168/190)
Northern Cape	24% (4/17)	29% (5/17)	47% (8/17)
North West	6% (6/93)	39% (36/93)	55% (51/93)
Western Cape	29% (8/21)	38% (8/21)	33% (7/21)
South Africa	8% (63/760)	22% (168/760)	70% (529/760)

Annex B-VIII: Percentage of facilities with at least one stock out (day), by impact of stock out and facility size in 2015

Stock out	Less than 1 000 % (n)	More than 1 000 % (n)	p●
At least one stock out on the day of the call	18.1% (279)	24.9% (201)	<0.0001
At least one high-impact stock out	5.2% (80)	7.7% (62)	0.011
At least one medium-impact stock out	5.9% (91)	13.0% (105)	<0.0001
At least one low-impact stock out	8.3% (128)	7.9% (64)	0.406
● Fisher's exact			

Annex B-IX: Percentage of facilities with at least one stock out (3mo), by impact of stock out and facility size in 2015

Stock out	Less than 1 000 % (n)	More than 1 000 % (n)	p●
At least one stock out in the 3mo prior to contact	20.9% (322)	32.4% (260)	<0.0001
At least one high-impact stock out	4.7% (73)	8.3% (67)	0.001
At least one medium-impact stock out	7.7% (118)	15.2% (123)	<0.0001
At least one low-impact stock out	8.9% (137)	11.0% (89)	0.105
● Fisher's exact			

Annex B-X: Percentage of facilities with 0, 1, 2, 3 and at least 4 stock outs (day), by facility size in 2015

Number of stock outs on the day of contact	Less than 1 000 % (n)	More than 1 000 % (n)	p●
0	81.8% (1 260)	75.3% (608)	<0.0001
1	14.3% (220)	14.7% (119)	
2	2.8% (43)	6.3% (51)	
3	0.7% (11)	2.5% (20)	
At least 4	0.5% (7)	1.2% (10)	

● Wilcoxon ranksum

Annex B-XI: Percentage of facilities with 0, 1, 2, 3 and at least 4 stock outs (3mo), by facility size in 2015

Number of stock outs in the 3mo prior to contact	Less than 1 000 % (n)	More than 1 000 % (n)	p●
0	79.1% (1 219)	67.8% (548)	<0.0001
1	17.4% (268)	23.5% (190)	
2	2.3% (35)	6.6% (53)	
3	0.8% (12)	1.1% (9)	
At least 4	0.5% (7)	1.0% (8)	

● Wilcoxon ranksum

Annex B-XII: Percentage of facilities reporting a measles, rotavirus or pentavalent/hexavalent vaccine stock out (day), by province (2014 and 2015)

Province	2014: facilities reporting at least one vaccine stock out % (n/N)	2015: facilities reporting at least one vaccine stock out % (n/N)	2015 breakdown		
			Facilities reporting a measles vaccine stock out % (n/N)	Facilities reporting a rotavirus vaccine stock out % (n/N)	Facilities reporting a hexavalent (DTaP-IPV-Hib-HBV) vaccine stock out % (n/N)
Eastern Cape	15% (64/426)	14% (64/469)	3% (16/464)	5% (22/461)	9% (43/464)
Free State	7% (9/138)	7% (10/135)	4% (5/134)	3% (4/134)	4% (6/134)
Gauteng	4% (11/252)	11% (31/277)	3% (7/276)	4% (11/276)	10% (27/276)
KwaZulu-Natal	10% (38/392)	14% (60/443)	3% (11/425)	5% (23/423)	12% (52/425)
Limpopo	31% (73/238)	13% (32/248)	3% (8/245)	2% (4/246)	11% (27/246)

Province	2014: facilities reporting at least one vaccine stock out % (n/N)	2015: facilities reporting at least one vaccine stock out % (n/N)	2015 breakdown		
			Facilities reporting a measles vaccine stock out % (n/N)	Facilities reporting a rotavirus vaccine stock out % (n/N)	Facilities reporting a hexavalent (DTaP-IPV-Hib-HBV) vaccine stock out % (n/N)
Mpumalanga	10% (17/173)	8% (18/220)	3% (6/220)	2% (4/220)	7% (15/220)
Northern Cape	8% (7/92)	7% (9/123)	2% (3/122)	2% (3/121)	5% (6/122)
North West	13% (26/201)	17% (37/223)	4% (9/222)	5% (11/222)	12% (26/222)
Western Cape	2% (4/245)	4% (13/326)	1% (4/317)	3% (9/318)	2% (7/319)
South Africa	12% (249/2 157)	11% (274/2 465)	3% (69/2 425)	4% (91/2 421)	9% (209/2 428)

Annex B-XIII: Percentage of facilities reporting essential medicines (non-ARV/-TB) stock outs (day), by province (2014 and 2015)

Province	Facilities reporting a ceftriaxone injection stock out % (n/N)		Facilities reporting a metformin tablet stock out % (n/N)		Facilities reporting a salbutamol inhaler stock out % (n/N)		Facilities reporting a valproate tablet stock out % (n/N)		Facilities reporting a sodium haloperidol tablet stock out % (n/N)		Facilities reporting a ferrous sulphate tablet stock out % (n/N)		Facilities reporting a furosemide tablet stock out % (n/N)	
	2014	2015	2014	2015	2014	2015	2014	2015	2014	2015	2014	2015	2014	2015
Eastern Cape	8% (41/503)	2% (10/463)	6% (28/504)	2% (7/463)	16% (79/501)	5% (23/463)	4% (18/496)	3% (16/463)	11% (51/463)	10% (45/463)	10% (45/463)	3% (13/463)		
Free State	3% (4/141)	13% (18/134)	7% (6/131)	6% (8/134)	6% (8/140)	10% (13/134)	1% (2/134)	2% (3/134)	10% (14/134)	10% (14/134)	5% (7/134)			
Gauteng	10% (27/280)	4% (12/276)	1% (2/284)	2% (5/275)	6% (16/286)	5% (13/274)	2% (6/275)	3% (9/275)	9% (25/275)	11% (29/274)	4% (12/274)			
KwaZulu-Natal	4% (15/429)	3% (12/425)	4% (15/432)	2% (10/425)	6% (24/430)	2% (10/424)	22% (78/354)	2% (9/425)	10% (43/423)	21% (89/421)	4% (15/422)			
Limpopo	13% (35/264)	4% (9/246)	7% (18/263)	3% (7/246)	8% (21/263)	4% (10/246)	4% (4/96)	4% (10/246)	33% (80/246)	9% (22/246)	6% (14/246)			
Mpumalanga	7% (14/191)	3% (6/220)	1% (2/194)	3% (7/220)	19% (35/188)	5% (10/220)	5% (9/190)	4% (8/220)	33% (73/220)	4% (9/220)	5% (11/220)			
Northern Cape	8% (8/99)	2% (2/122)	2% (2/103)	2% (3/121)	3% (3/104)	7% (8/121)	5% (5/104)	2% (3/121)	5% (6/121)	10% (12/121)	5% (6/121)			
North West	8% (18/215)	6% (13/221)	2% (4/217)	6% (14/222)	43% (92/214)	10% (21/222)	15% (21/140)	12% (27/222)	10% (23/221)	16% (35/220)	4% (9/221)			
Western Cape	1% (4/294)	1% (3/319)	0% (0/278)	1% (3/319)	3% (9/300)	1% (3/318)	1% (3/269)	1% (4/319)	3% (10/319)	2% (6/317)	1% (2/318)			
South Africa	7% (166/2 416)	4% (85/2 426)	3% (77/2 406)	3% (64/2 425)	12% (287/2 426)	5% (111/2 422)	7% (146/2 058)	4% (89/2 425)	13% (325/2 422)	11% (261/2 416)	4% (89/2 416)			