

EMPTY SHELVES COME BACK TOMORROW

**ARV STOCKOUTS UNDERMINE
EFFORTS TO FIGHT HIV**

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“Once I was two weeks without my ARVs. No one at the health center found an alternative solution for me, so I went back home empty handed and desperate. I know that without drugs the virus will multiply in my body, I will get sick and could die eventually. It also forces me to walk long distances to return to the health center again and again”.

Sanculani Langui, patient on ART, Tete, Mozambique

ABBREVIATIONS

| | |
|--------|--|
| AIDS | Acquired Immunodeficiency Syndrome |
| ARV | Antiretroviral (medication) |
| ART | Antiretroviral treatment |
| CAG | Community ART group |
| CBO | Community based organisation |
| CMAM | Central of Medicines and Medical Articles |
| CMS | Central medical store |
| CPP | Coordinated Procurement Planning Unit |
| DRC | Democratic Republic of Congo |
| DR-TB | Drug-Resistant Tuberculosis |
| GFATM | Global Fund to Fight AIDS, TB and Malaria |
| HIV | Human Immunodeficiency Virus |
| MMR | Multiple Months Refill |
| MoH | Ministry of Health |
| MSF | Médecins Sans Frontières/ Doctors Without Borders |
| NGO | Non-Governmental Organisation |
| PEPFAR | The United States President's Emergency Plan for AIDS Relief |
| PFSCM | Partnership for Supply Chain Management |
| PLHIV | People Living with HIV/AIDS |
| PMTCT | prevention of mother-to-child HIV transmission |
| STI | Sexually Transmitted Infection |
| TB | Tuberculosis |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| WHO | World Health Organisation |

Medicines

| | |
|-------|-------------------------------|
| ABC | Abacavir |
| AZT | Zidovudine |
| ATV/r | Atazanavir/Ritonavir |
| EFV | Efavirenz |
| FTC | Emtricitabine |
| LPV/r | Lopinavir/Ritonavir |
| NVP | Nevirapine |
| TDF | Tenofovir Disoproxil Fumarate |
| 3TC | Lamivudine |
| CTX | Cotrimoxazole |

Related to medicines

| | |
|-----|------------|
| Tab | tablet |
| mg | milligram |
| ml | millilitre |

DEFINITION OF KEY TERMS

| | |
|-----------------------------|---|
| Last mile delivery | Distribution system whereby commodities are delivered in an organised and systematic way to service delivery points where the commodities reach the end-user. |
| Lay cadre | A health care worker who performs functions related to health care delivery; trained in the context of the intervention, without formal professional or paraprofessional certificate or degree in tertiary education ¹ |
| Pull system | Method whereby commodities are distributed on base of an order made by lower levels, who must determine their commodity needs and have a way of notifying the higher levels of the supply chain of their order ² . |
| Informed push system | Method whereby commodities are distributed on predetermined delivery schedules without an order from the lower levels of the supply chain ³ . |
| Task shifting | A process whereby specific tasks are moved, where appropriate, to health care workers with shorter training and fewer qualifications ⁴ . |
| Stockout | The complete absence of a required drug at a storage point or delivery point for at least one day ⁵ . |

EXECUTIVE SUMMARY

Despite considerable investments in supply chain reforms, wide-spread medicines stockouts negatively constrain patients' ability to have access to their medication. Limited availability of antiretroviral (ARVs) caused by dysfunctional supply chains impedes patient initiation and adherence and poses a major barrier to win the global fight against HIV.

Secured access to antiretroviral treatment (ART) is critical for the realisation of the '90-90-90' objectives, to initiate 90% of diagnosed patients and obtain viral suppression in 90% of those on ART⁶. Scale-up is critical as studies have proven the benefits of starting ART as early as possible, leading to the World Health Organisation (WHO) recommending universal treatment for all HIV positive patients⁷. Optimal adherence is essential to ensure individual treatment success and limit viral resistance. Realising the importance of accessible ART regimens for scale-up of initiation and retention in care demands a greater understanding of the magnitude of the access problem and of existing methods to ensure efficient ART provision.

This report details four case studies of sub-Saharan African countries with different HIV burdens and variable supply chain models, comparing those models in terms of robustness and flexibility to deliver ART. Context-specific methodologies to actively measure patient access and solve stockouts are proposed. Innovative approaches and initiatives are presented and assessed based on their effectiveness in improving ART access and simplifying ART delivery for people living with HIV.

The analysis conducted in the four selected countries shows that, due to diverse logistical, managerial and legislative challenges,

country programs fail to offer consistent and timely supplies of ARVs to their patients. None of these countries routinely collect data on ART availability in all facilities that would allow a fast response to stockouts. In South Africa, Mozambique and the Democratic Republic of Congo (DRC), the lack of regular "last mile delivery" poses a chronic problem. The necessary medicines are regularly not available to patients at a health facility despite sufficient stocks being present in the country. In Malawi, ARVs reach the last mile but the system does not have the flexibility needed to allow patients to access ARVs in their community. Finally, acute wide-spread stockouts of ART are exacerbated in all countries due to critical events such as ART regimen switches and scale-up.

Whatever their cause, stockouts have a negative impact on patients' motivation or ability to stay in care, which does not only compromise their health and wellbeing, but also adds to the spreading of resistant virus strains. In contexts where health structures are congested, understaffed and unequipped for necessary scale-up, stockouts undermine both patients and health workers trust in the system. Although supply chains exist for the purpose of serving the patients' needs, currently there are little examples of country chains that are adapted to the patient's reality and are open to their demands.

Access to multiple months refill (MMR) becomes indispensable to allow easy access for growing numbers of increasingly healthy patients and decongest health facilities. To date, few countries have shown their supply to be robust and flexible enough to provide MMR without stockouts. Where human resources are limited, patients successfully participate in medicines distribution and refills through community ART delivery if national legislation

allows it. Patients, civil society and community based organisations have also taken a role in monitoring and resolving stockouts, providing the much needed last level data, while holding the health system accountable. However, many struggle to find the funding and support necessary to perform this role.

Innovations and evidence to guide supply chain reform exist, and governments and donors are investing in context-specific approaches, but little is documented and examples are isolated. Sporadic regional collaboration through sharing of emergency supplies is used as a stop-gap measure, but this occurs only on an ad hoc basis and often when stockouts are already visibly impacting the patients.

Despite its optimised status compared to supply chains of other disease groups, ARV supply chains in the analysed countries still rely on overly complex, rigid and non-adapted procedures with diffuse accountability. The countries were chosen based on data available to MSF in those locations, but it is likely that similar scenarios exist in comparable contexts.

- **In the DRC**, in most sites a bureaucratic four level system persists, not reaching the last mile and with limited visibility of stock levels, resulting in wide-spread facility stock outs. National stockouts in critical periods of treatment changes have resulted in long-lasting facility stockouts with an important impact on patients. Without effective alert and response systems, upcoming regimen transitions and scale-up plans pose a major stock out risk.
- **In Malawi**, a solid two level push system has managed to reach the last mile, and routinely a three-month supply is provided to all stable patients. But quarterly data

collection does not allow an instant facility stock visibility and response, with stockouts occurring in times of regimen scale-up. Legislation does not allow for task shifting of ART distribution to lay cadres for further decentralisation.

- **In Mozambique**, there is no funded regular last mile delivery and stockouts are seen at facility level. National stockouts occur, depleting national buffer stocks in the absence of a defined emergency procurement mechanism. An ambitious supply chain restructuring plans was approved but currently there is no earmarked funding to implement it.
- **In South Africa**, the fragmented ART supply chain, managed by the provinces, allows limited visibility of facility stock levels and no regular last mile delivery. Chronic stockouts are wide-spread, although major provincial differences exist. Occurring national stockouts with a nationwide impact could be prevented or solved by overriding patent barriers.

This report highlights facility medicines stockouts as a regional problem with a negative impact on the health of patients. Urgent action to establish supply chain systems that deliver is essential in order to successfully treat growing patient numbers. We call on national and global actors to prioritise adapting the supply chain to respond to the patients' realities, needs and demands as a condition to provide a quality response against the HIV epidemic.

KEY RECOMMENDATIONS

ENSURE QUALITY SUPPLY CHAIN PERFORMANCE FOR THE ACHIEVEMENT OF GLOBAL HIV TARGETS

- Develop standard indicators to monitor access to ART at the patient level and measure impact on patient outcomes. Patient level access indicators should serve as an objective representation of supply chain efficiency and improvement and as an early warning indicator for ART resistance.
 - Develop and implement robust data collection systems at patient level to support forecasting and quantification by combining data on ART stock levels with patient access data, and for effective early warning on stock out risks.
 - Include supply chain in all funding initiatives for ART, including all related operational costs required for medicines provision. This includes, but is not limited to, last mile delivery costs, national and/or regional buffer stock and emergency distribution mechanism to respond quickly to local and/or national shortages.
-

FACILITATE COMMUNICATION AND EXCHANGE BETWEEN KEY STAKEHOLDERS

- Initiate or strengthen national forums for data exchange and information sharing between all key stakeholders, including patient representatives. The forum should highlight potential or current ruptures and facilitate efficient replenishment with in country solutions where possible.
 - Initiate regional forums for neighbouring countries to identify and exchange best practices, common constraints, and facilitate swift cross-border solutions to respond to stockouts and overstock in emergency situations.
 - Ensure international coordination to pool information on global demand for medicines and ensure global supply security, including the creation of mechanism for transparent and rapid information sharing between suppliers, country programs and international stake holders.
-

RECOGNISE PATIENT REALITIES AND THE IMPORTANCE OF COMMUNITY INVOLVEMENT

- Enable patients, civil society and community-based organisations to actively understand, contribute, develop solutions, and flag issues relating to their access to critical medication. The end-level reporting data should be used to provide end-level visibility or as a parallel source of information to complement internal monitoring mechanisms when these are present.
- Adapt legislation to allow for effective decentralisation of ART supply, including task-shifting for dispensing and distribution to lay cadres and multiple months refill for stable patients.
- Pilot, evaluate and document supply chain innovations that recognise the real constraints of individual contexts and patient realities. Solutions need to take into account easy access for patients, and recognition of human resource capacity in the affected areas.

PART 1.

SUMMARY OF FINDINGS

INTRODUCTION

THE HIV RESPONSE IN SUB-SAHARAN AFRICA

An estimated 36.9 million people are living with HIV (PLHIV) worldwide. Treatment scale-up has made major progress in most countries, with 15 million people on ART across the globe by 2015. However, 22 million, or three out of five people living with HIV, are still not accessing ART⁸.

25.8 million people living with HIV are living in sub-Saharan Africa, or nearly 70% of the global total. Although the number of AIDS-related deaths fell by 48% between 2004 and 2014, the region still accounted for 66% of all the people dying from AIDS-related causes in 2014. This decrease in deaths is largely due to scale-up of ART availability. However, less than half of the people living with HIV in the region are on ART⁹. In 2014 the Joint United Nations Programme on HIV/AIDS (UNAIDS) proposed the new target of '90-90-90', which aims at 90% of people living with HIV to know their HIV status, 90% of those diagnosed to be on ART and 90% of those on ART to have an undetectable viral load by 2020. Concomitantly new ART guidelines were released in 2015 by the WHO which recommends that all people living with HIV be started on treatment at diagnosis¹¹. Hence, countries will have to adapt their targets in the light of these international recommendations.

These new targets remain very ambitious in the current reality. In sub-Saharan Africa, less than half (45%) of people living with HIV know their HIV status¹². A pooled analysis of 37 studies in sub-Saharan Africa indicates that among those knowing their status, only 57% completed ART eligibility assessment, 66% of those eligible initiated ART and 65% of those initiating treatment were retained on ART¹³. Studies show that, on average, only 29% of those people remaining on ART in sub-Saharan Africa have an undetectable viral load¹⁴.

If the world is to achieve the '90-90-90' target, not only will the number of people living with HIV put on treatment need to be doubled, the quality gaps in existing treatment programs will also have to be closed for 90% of the patients on ART to maintain an undetectable viral load. One of the major preconditions to ensure quality of ART programming to achieve these ambitious targets will be the development of flexible and robust supply chains capable of delivering medicines when and where the patients need them.

SHORTAGES AND STOCKOUTS OF ART

Stockouts are wide-spread in sub-Saharan Africa: reports from the Coordinated Procurement Planning Unit (CPP) state that in the first quarter of 2014, 21 out of 22 sub-Saharan countries were at risk of national stockouts in the next 18 months, and 50% (11/22) were at high risk in that same year. Facility level stockouts were reported in 35% of low and middle income countries in 2013¹⁵.

The WHO has defined a stockout as the complete absence of a required drug at a storage point or delivery point for at least one day¹⁶. A stockout of any ARV routinely used in a health facility over a one year period is considered an early warning indicator for development of ART resistance¹⁷, as patients confronted with a lack of availability of their medicine may interrupt their treatment, increasing the risk of insufficient viral suppression, resistance and transmission of (resistant) virus to others. ART stockouts also have a negative impact on retention in care and patient survival¹⁸.

¹ CPP: The Coordinated Procurement Planning Initiative is a multi-stake holder initiative collecting data on availability of medicines in low and middle income countries.

“Once I had to buy two weeks worth of cotrimoxazole on the market because my health center had none in stock. At that time I kept silent because I didn’t know I had the right to report it. But now I would do so. In fact as I’m an activist I’m often approached by those who suffer from stock outs”

Bernardo Suarte Raiva, Changara, Mozambique.

There are several cases where limited availability provides a significant burden on the patient by changing their capacity to adhere. In the case of facility stockouts patients may be referred to other facilities or asked to return later, given no medicines, fewer medicines or other, less appropriate and more complex regimens or formulations. In addition to physical and emotional stress this situation also places an unacceptable financial burden on the patients. Transport cost and time needed to access the medicine increases, potentially discouraging patients from optimal adherence to their treatment. Patients who are sent away are more likely to turn to alternative sources to access ARV, possibly from less reliable suppliers and/or in exchange for money. Health care workers spend extra time placing emergency orders, redistributing medicines from other facilities or defining the right alternative regimen. In general stockouts cause frustration and loss of confidence in the health system for patients and health care workers. Their societal costs are high.

While multiple innovations with new software systems and mobile technology are emerging and may look promising for the future, one should keep in mind that most countries in sub-Saharan Africa do not have visibility of existing stock levels across the supply chain. There is also limited capacity to react to existing or predicted stockouts, putting at risk the health of patients coming to collect their medicines. In this report different methodologies are presented that actively benchmark and monitor stockouts with the intention of providing a patient-centred measure for supply chain efficacy and critical information needed to respond and solve stockouts (country case studies).



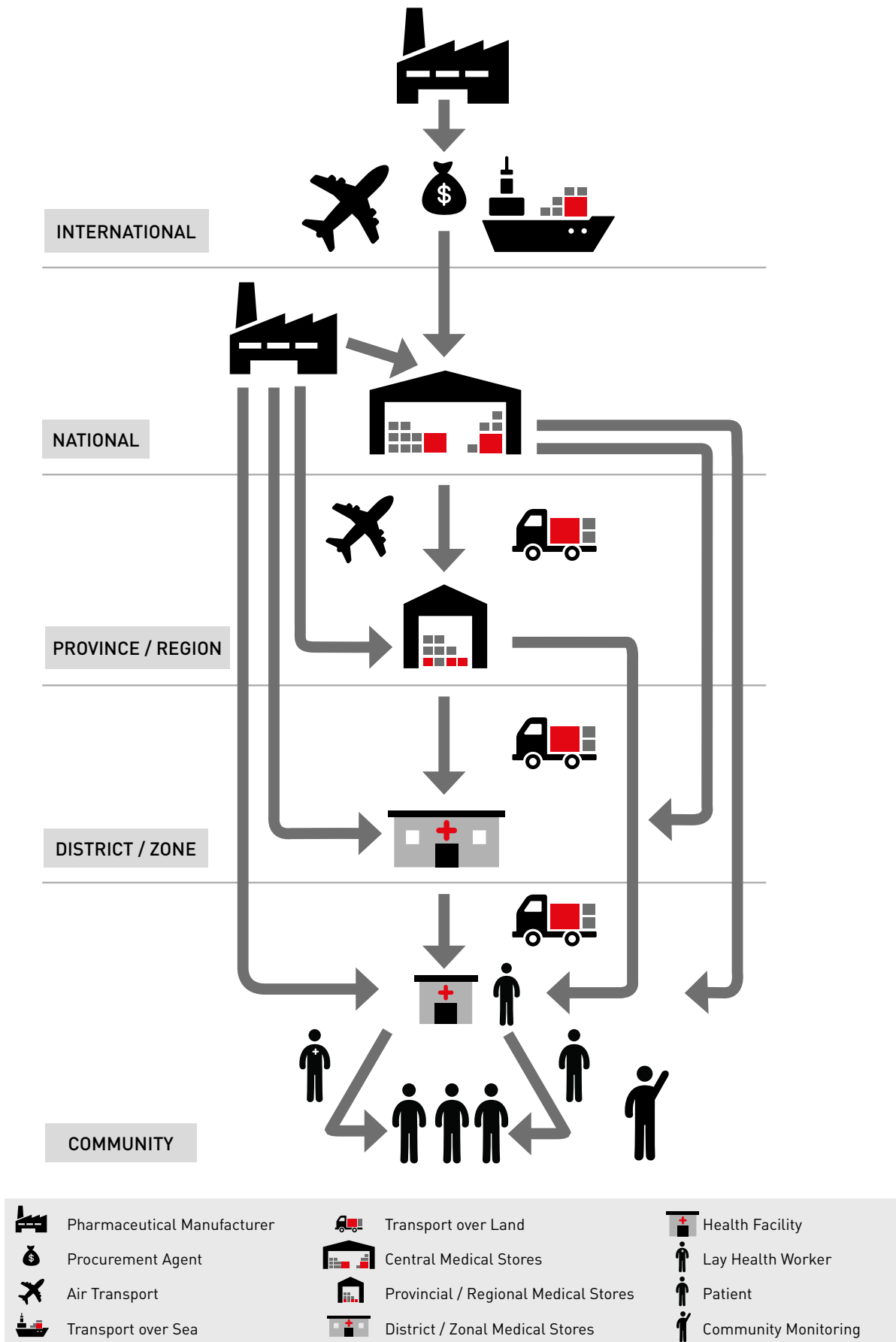
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Frank Pancha Chisel, 38, carries empty boxes of antiretrovirals from the group of residents of a village three hours walk away from the Mikolongwe health center in Malawi, where he will go for a monthly refill on November 27, 2014

“We sometimes run out of HIV tests at hospital level, in which case we need to send people back home even when we suspect they are HIV positive. Considering the high levels of stigma in the DRC many will be too afraid to hear a possible positive result and will never come back. They are lost to follow up even before having a chance to know their status”

Pierre Bilabi Butabambe, director of nursing, in Mbankana hospital, Kinshasa

Figure 1:
THE ROAD OF MEDICINES : SUPPLY CHAINS IN DEVELOPING COUNTRIES





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In most sub-Saharan African countries, governments are responsible for procurement and distribution of health products and manage central medical stores (CMS), as well as the fleet for distribution to the health facilities. In many cases though distribution networks are inefficient, ill maintained, underfunded and incapable of reaching the last mile.

CMS status varies from completely government-owned to semi-independent and increasingly autonomous organisations^{20,21}. Public procurement entities often have insufficient capacity to design efficient and flexible procurement and importation methods, causing procurement to be slow and cumbersome with no room for emergency response.

Warehousing and distribution can be controlled and executed by a variety of public, non-governmental and outsourced private organisations. Warehousing space and storage conditions can be substandard, usually worsening towards the peripheral levels of the chain. If initially kept separate and vertical, often managed by donors, the ART supply chain is being increasingly integrated into the routine medicines supply chain, in order to increase efficiency²². Most countries have implemented pull systems for ARV distribution, thereby putting a higher level of responsibility for ensuring timely and correct ordering at health facility level, where resources are often most deficient^{23,24}. Systems are often too rigid for effective early warning mechanisms to identify shortages, and do not have mitigation and response mechanisms, both essential to avoid stockouts and ART resistance in patients.

SUMMARY OF COUNTRY STUDIES

For four different countries in sub-Saharan Africa -- DRC, Malawi, Mozambique and South Africa -- data were collected on the current state of the HIV response, critical indicators characterising the ART supply chain system and indicators of supply chain flexibility to respond to a patient reality (Table 1). Sources used were mainly country documents and presentations and discussions and consultation with supply chain stakeholders in country. More details per country, including innovative models for

supply chain improvement, are provided in the country cases.

In these four countries MSF and other actors have performed active monitoring of medicines availability in facilities as the primary indicator of supply chain success. The impact of stockouts has also been quantified in order to guide priority areas for supply chain interventions. A summary of the different methods and key results is presented in table 2. More details on methodology and additional results are elaborated in the country cases.

Table 1: Summary of country ART supply chain indicators

| | Indicator | DRC | Malawi | Mozambique | South Africa |
|-----------------------------------|---|---|---|--|--|
| HIV response | PLHIV (million) | 0.45 | 1.0 | 1.6 | 6.4 |
| | Adult HIV prevalence | 1.0% | 10.3% | 11.5% | 19.1% |
| | ART coverage under WHO 2013 guidelines | 24,3% (2015) | 57% (2015) | 45% (of all HIV positive patient, 2015) | 48% (2015) |
| | Scale-up assumptions | 50% (232067) by 2017 | 81% of coverage by 2020 | 81% coverage by 2017 | 81% coverage by 2020 |
| | Adult retention at 12 months | 78% | 79% | 67% | 72% |
| ART Supply chain | ARV funding | GFATM/PEPFAR | GFATM/PEPFAR | GFATM/PEPFAR | NDoH/GFATM (10%) |
| | Procurement body | GFATM PPM/PEPFAR PFSCM | GFATM PPM/PEPFAR PFSCM | CMAM through GFATM PPM /PEPFAR PFSCM | NDoH subcontracting private suppliers |
| | Distribution model | Mixed system | Informed push system | Informed push system | Mainly pull systems, but also direct delivery, CDU, CCMD in specific sites |
| | Number of levels in the chain (incl. CMS and health facilities) | 4/2 | 2 | 4 | Variable |
| | Delivery frequency | Monthly | Bi-monthly | Monthly | Variable |
| | Nationwide facility consumption data collection system in place | Monthly reports in GFATM supported sites, PEPFAR supported sites variable | Yes, quarterly collected data | Yes, monthly MMIA | Site dependent |
| | Theoretical buffer stock at facility | 1 month | 3 months | 1 month | Variable |
| | Private sector involvement in supply chain | Distribution, Warehousing | Distribution, Warehousing | Distribution | Procurement, Production, Warehousing, Dispensing, Distribution |
| | Regular organised distribution to facilities (last mile delivery) | Yes in PEPFAR supported facilities, no in GFATM supported facilities | Yes | No | Variable |
| | External observers of supply chain | Yes, community observatory in GOMA | Yes, NAPHAM | Yes CIP, JAM in Tete Province | Yes, Stop StockOut project |
| Supply chain flexibilities | Refill frequency | 1 month, exceptionally 3 months in PODI and some facilities | 3 months for stable and adherent patients, 6 -12 months for exceptional cases | 3 months in national guidelines, not yet implemented November 2015 | 3 months not opposed by NdoH circular in 2010, but not widely implemented |
| | Task shifting of distribution and/or refill of ART to lay workers or patients | Patient lead community distribution points in Kinshasa | CAG groups piloted in Thyolo district, not part of national policy ART Fast track in Chiradzulu | CAG groups are part of national strategy, ART fast track | CAGs, community and facility adherence clubs |

* References can be found in the country case studies

Table 2: Summary of in country stockout monitoring methods and key results

| Indicators | DRC | Malawi | Mozambique | South Africa |
|---|--|--|--|---|
| Actor performing survey | Provincial PNLs & MSF | MSF in collaboration with MoH | MSF in collaboration with MISAU | Stop StockOut Project |
| Area covered | Sample of ART facilities in urban Kinshasa (79% of city cohort) | MSF supported rural facilities in Nsanje district | MSF supported facilities in Maputo City (urban) and Tete province(rural) | All facilities providing ART countrywide |
| Survey type | Snapshot survey Kinshasa | Continuous monitoring + MSF intervention | Continuous monitoring + MSF intervention | National snapshot survey |
| Period of data collection | April –May 2015 | May –September 2015 | January-June 2015 | October–November 2013, 2014 |
| Number of health facilities | 94 | 14 | 17 | 2139 in 2013, 2454 in 2014 |
| Medicines monitored | 15 ARVs | 12 ARVs | 10 ARVs | All ARVs and TB medicines (open question) |
| Method | Once off physical visits | Weekly telephone contact and monthly physical visits | Weekly telephone contact and monthly physical visits | Yearly telephone contact |
| Period of data coverage | Time of visit + between January and March 2015 | Between May and September 2015 | Between January and June 2015 | Time of contact + The three months prior to survey |
| Data sources | Physical inventory + stock cards | Physical inventory + stock cards | Physical inventory + stock cards | Health care worker reporting |
| Percentage of facilities with at least one ARV or TB stockout over 3 months period | 77% between January and March 2015 | 43% between June and August 2015 0% in May and September 2015 | 41% between January and March 2015 and 41% between April and June 2015 | 21% (2014), 25% (2015) In three months prior to the survey |
| Representation of data for country situation | Kinshasa city has a logistical advantage compared to the rest of DRC in terms of geographical proximity to health facilities | Active monitoring and preventive intervention by MSF is likely to reduce the occurrence of stockouts | Active monitoring and preventive intervention by MSF is likely to reduce the occurrence of stockouts | Health care workers are more likely to under report than over report stockouts to avoid negative evaluation |



“From August 2014 to February 2015, I had been receiving two months’ HIV treatment instead of three. The nurse kept on telling me that the problem is with the supplier. It is a problem for me, because I work a part time job and I have to use my second child’s grant money for transport to get to the clinic.”.

Patient from South Africa.

DISCUSSION AND RECOMMENDATIONS

The results from the in country surveys have been used as a basis to analyse frequent challenges faced in drug supply chains in sub-Saharan African settings. In the following paragraphs these challenges are presented and discussed, and plausible suggestions for improvement are made.

We differentiated supply chain issues specific to ART and those affecting the entire public health supply chain. What makes ART special is the fact that it concerns a lifelong treatment, which does not allow for irregularities in its uptake by the patients, if one does not want to decrease adherence and create wide-spread resistance which would gradually burn the existing treatment lines. For those reasons a stronger focus is put on the ART-specific challenges and a patient-centred approach in the supply design is recommended.

GENERAL CHALLENGES AND RECOMMENDATIONS TO MAINTAIN OR BUILD ROBUST SUPPLY CHAINS IN COUNTRY

Lack of data for quality control and weak data management systems

To feed national program quantification, there is a need for timely transfer of correct data from the health facility where medicines are consumed, to warehouses where they are stocked and ordered, and central pharmacy departments where drug needs are estimated, budgeted for and purchased. While countries have nationally developed tools to manage commodity specific information, they are often not available at facility level, not updated, or not adapted to the capacity of the workers to use them correctly. At the peripheral level, health workers still use paper based tools and complicated order systems, which do not reach in a timely fashion the responsible managers, leaving them without the critical stock information needed to inform suppliers. Feedback to inform facilities or patients on which medicines will not be delivered and when they will be available is lacking in most settings.

Although data on access to medicines for patients and patient outcomes are real indicators to measure supply chain performance, they are not regularly measured to challenge supply chain functioning and monitor improvement and no standard indicators exist.

Insufficient efforts are put on monitoring and timely mitigation of stockouts, despite their frequent recurrence and severe impact on patients outcomes, like resistance. Although most countries monitor national stock levels, data on stockouts at facility level and patient impact are rarely collected by national systems.

National data on medicine availability, when collected, usually covers a limited list of medicines, reported post factum by health care workers who do not wish to expose flaws in their own stock management. Some countries, like Lesotho, have performed snap shot surveys on availability of tracer medicines and use of reporting tools. Although these data can be valuable for program evaluation, and should be collected on a regular basis, they cannot replace build-in monitoring systems necessary for supply chain planning and immediate stockout mitigation.

Recommendations:

Ensure robust and reliable data monitoring systems to ensure full visibility of stock levels along the supply chain, including early warning for anticipated stockouts. Emerging electronic and mobile solutions can increase speed of data transfer needed for regular supply planning and reactivity. For facilities in rural areas with limited connectivity or insufficient ordering capacity, regular collection of information by roving supply chain teams can provide a solution. For ARV supply management, a link is needed between the number of patients per regimen and stock levels for forecasting. Pharmacy-based systems, linking stock levels and medicines dispensed with individual patients, can offer this necessary link.

Active stockout monitoring and reaction to alleviate problems is needed in the interim while robust monitoring systems for continuous and rapid data transfer are being implemented. Indicators should be defined for successful supply chain performance taking into account patient level access and patient outcomes.

Supply chain systems not engaging with their beneficiaries

In each optimised system quality control mechanisms should rely not only on internal but also external assessment, if one wants quality control to work objectively. By ignoring end-user perspectives on supply chain functioning, one risks to inherit sub-optimal quality controls and lose the necessary drive for continuous improvement.

Donors and governments acknowledge the need for community and civil society support and consultation; the GFATM defines community and civil society engagement in stockout monitoring as one out of six core principles in a draft document to strengthen in-country supply chains²⁵. Currently governments do not regularly engage with communities, and most civil society organisations are struggling to access funding, are not invited to supply chain consultations, and find themselves being openly opposed or even side-lined. Patients, civil society and community-based organisations have taken a watchdog role in several countries to hold system managers accountable for medicines access^{26,27,28,29}. Networks uniting patients, health care workers and members of civil society put pressure on policy makers and civil servants, demanding transparency and accountability to reduce drug stockouts. In addition, patients have actively participated in faster and more targeted stockouts resolutions. With access to reporting tools, these groups can provide the much desired last level visibility data missing in most supply chain system.

Recommendations:

Patients and health care workers as the most important supply chain stakeholders, should have access to key forums to know their rights to access, discuss their findings, understand supply chain systems and recommend improvements that respond to their realities. They should be empowered and listened for optimal transparency along the chain. Data gathered through stockout monitoring, reporting and resolution should be used to hold the system accountable, monitor quality through parallel data collection and even provide data on the blind spots where supply chain manager do not have end level visibility.

Civil society, CBOs and other grass roots organisations should be empowered, supported and funded to continue or initiate this role and have representation at local, national and international level.

Unclear responsibilities and transparency along the chain

Fragmented responsibilities shared between the CMS, the department of health and the health workers at all levels, lead to situations where each actor can blame another for underperformance of the supply chain. Health system managers are uncomfortable admitting poor performance under their responsibility. Performance of supply chain staff is often not clearly measured and minimal quality criteria are poorly defined or understood. Less confronted with patients, unlike their clinical counterparts, they may be satisfied with suboptimal performance, lacking the understanding of what impact this has on the patients. Finally, as health commodities are valuable resources, fragmented responsibility makes the supply system vulnerable to corruption and theft in every step and renders its management more complex and possibly less transparent.

Recommendations:

Clear objectives, responsibilities and key tasks should be defined for supply chain workers. Performance should be measured based on the clear result of consistent access to medicines for patients. Transparency and pro-active communication between supply chain workers and with all stakeholders on supply chain successes, changes and challenges (like stockouts) is necessary to improve accountability at all levels. Patients with an inherent motivation to take care of the health of their peers should be engaged in the supply chain to improve efficiency.

Private actors, rewarded based on delivered results, could be engaged in key aspects of the supply chain to increase efficiency. Outsourcing aspects of drug warehousing and drug delivery to third party service providers can lead to better supply chain performance. Contract management, the correct and timely payment of private actors, enforcement of contract performance and quality stay in the hands of government officials, who should be well trained to do this.

Lack of funding

Existing funding gaps force ministries to keep suboptimal buffer stock levels, creating just-in-time systems unable to cope with inevitable emergency situations. National procurement actors depend on disbursements from Ministries of Finance, international donors or treasuries to purchase medicines. The disbursements are often delayed with uncertain timelines, leading to changes in supply planning and national stockouts. In-country operating costs to deliver the medicines from central to patient level (fuel, vehicle maintenance, driver salaries, etc.) are often not regularly estimated and budgeted for. However, these costs are essential expenditures and add a significant amount to the drug cost.

An independent audit of the GFATM ³⁰ looking at the adequacy and effectiveness of the GFATM's procurement and supply chain management

assurance mechanisms found that the GFATM “does not yet have in place a supply chain management function or strategy that covers in-country processes such as quantification and forecasting, logistics management and distribution.” Further, insufficient resources are allocated to guarantee some of these activities. Despite an estimated 67% of grant disbursements spent on procurement of health and non-health products, only 5% were allocated to guarantee procurement and supply. It is anticipated that the GFATMs forthcoming “In-Country Supply chain investment strategy will define GFATM's scope of responsibility, oversight and initiative with respect to in-country supply chain challenges.

Recommendations:

Funding of medicines by donors and governments should always be accompanied by all necessary operational costs including but not limited to last mile delivery, security measures (buffer stocks) and mitigation mechanisms allowing reaction to shortages at national level and in country. In most occasions, countries require technical assistance in order to generate realistic and well-defined in-country plans that include all necessary expenses.

Complexity and rigidity

Classical supply chains in developing countries are built up along the administrative lines of the government structure with overly complex and bureaucratic decision making processes, multiple levels and irregular or poor quality information flowing between these supply chain levels. Delay in data transfer makes it impossible for the supply chain managers at higher levels to react and solve stockout problem quickly. Amplification of errors at every step of the chain results in large variation of data when they arrive at central level and ultimately more stockouts. When information flow between different levels of the supply chain is weak, reduction of these levels will improve coordination, increase information flow and improve supply planning. Increasingly countries move away from supply chains that follow administrative structure lines, granting more autonomy to supply units for increased flexibility. The more autonomy the

CMS gets, the more flexibility it acquires to hire staff, implement performance based payment and manage contracts with external suppliers of products and services. Autonomy also allows supply chains to be adapted to distances and population density rather than administrative boundaries. Supply chain decision makers are moving towards integration of existing vertical supply chain for different health programs as a first step to reduce complexity. This should be approached with caution as the nature of the commodities or the program can require a different approach³¹.

Recommendations:

Level jumping and direct delivery to health facilities or community distribution points have been shown to improve product availability by decreasing the number of errors inherent to each level of management and decision making^{32,33}. While attempts to grant supply chain systems more independence and flexibility are welcome, managers should be cautious not to dilute the performance of better supply lines in an integration process. Analysis of performance based on patient level indicators should inform decision making on which aspect of the supply chain to integrate and which to separate.

Systems not adapted to human resource capacity

The current lengthy replenishment cycle demands a high level of forecasting accuracy which often eludes the health care workers untrained in such forecasting. With growing patient cohorts, larger stocks are already needed and longer delivery intervals means health facilities need more storage space and a higher capacity to perform inventory management. Often already overburdened health care workers with no or insufficient supply management background are regularly dealing with complex calculations for ordering a variety of medicines. This takes away precious time that should be spent with patients to ensure quality consultation and dispensing. Reducing lead times for supplies and increasing delivery frequency allow supply planning to depend on shorter forecasts, closer to the reality

of the current needs at the health service level. It also reduces the need for peripheral storage space. Inevitably, transport costs will increase. Pull systems in which delivery depends on orders placed by facility staff can only work when end level forecasting capacity is ensured.

Recommendations:

Supply chain actors should test models to determine the optimal balance between transport cost and the delivery frequency for optimal commodity availability for patients. A choice should be made between push and pull systems, that considers human resource capacity and challenges for data transfer between supply chain levels. In areas with limited capacity at facility level, responsibility for forecasting and ordering can be moved to higher levels in the chain. Data collection through centrally-directed specifically trained roving teams could be considered to decrease the burden of ordering for facility health care workers. In general countries should acknowledge the need for logistically-skilled personnel in the supply chain and invest in appropriate training. Cost/impact analysis of different approaches should guide decision making.

"I was given alternative treatment because Tenofovir tablets were out of stock, and I reacted badly to the medicine. I could not take it anymore. I phoned the Stop Stockouts Project hotline in February 2015. A week after reporting the incident I received a call from the clinic to let me know that my treatment was available. I am happy to be on my treatment again because that other one was making me feel very depressed."

Patient (46 years old) from South Africa

ART SPECIFIC CHALLENGES AND RECOMMENDATIONS FOR FLEXIBLE SUPPLY CHAINS

Systems-centred supply chains

Supply chain managers in developing countries take a bottom down approach on systems strengthening: they prioritise the central level as a first step in improving the supply chain, and then make their way gradually down to the lowest level of the health pyramid where patients are served. This approach does not prioritise continuous medicines availability at the end-user level as a quality indicator. Further, this approach often omits patient realities and demands on how, when and where medicines should be made accessible, hence omitting the principle end-user perspective in the whole supply chain management. Moreover, systems are neither adapted nor designed to serve increasing numbers of otherwise healthy individuals, productive members of society, in need of easy access to their chronic medication.

Recommendations:

To address this weakness, programs would need to reframe HIV care by putting people at the centre of antiretroviral delivery. Ideally supply chains should allow the choice between a variety of service models, with different options related to (i) service intensity, (ii) service frequency, (iii) health worker cadre, (iv) service location, taking into account the patient reality³⁴. Supply chains would need to be adapted to support this range of options to be relevant, appropriate and responsive to the needs of people living with HIV. Practically this would imply defining alternative delivery models, according to local realities, ensuring maximal decentralisation and task-shifting to make treatment as accessible as possible to patients.

“Stockouts are extremely frustrating. Because of stigma it’s very difficult to convince people to get on ARVs, and once they’re adherent we have to tell them that there are no medicine available! What can they think of this? It angers me”.

Bijou Luboya Mudimba, nurse in charge of pharmacy in Bomoto health center, Kinshasa, DRC.

Rigid systems and legislative framework

Médecins Sans Frontières (MSF) has built extensive experience in the implementation of ‘community models of care’, ranging from health service-driven to client-driven options to optimise long-term ART delivery^{35,36}. Health service driven options include appointment spacing and fast-track medicines refills, and facility ART clubs where patients come together in groups of around thirty to access ARVs delivered by lay health workers. Further decentralised are community ART clubs, where lay health workers distribute to clubs gathering in the community.

Patient participation is most developed in patient-managed community ART refill points and in community ART groups in which patients pick up ARVs and deliver them to members of their community.

In these models, ART delivery is interestingly no longer associated with the time or location of the clinical consultation. The strategies generally target stable patients and aim at reducing the burden on clients and health-care providers when providing medication. Different strategies have been implemented in several countries, mostly demonstrating reduced burden on health system and patients, reduced health system cost and improved retention in care. Those strategies rely on flexible and reliable drug supply chain and they require a framework allowing for task shifting of dispensing, distribution and refill to lay cadres and patients. Community approaches to ART delivery should allow for ART refill frequency for stable patients to be extended and as close as possible to the frequency of clinical encounters needed for follow up. However, in many countries, legislation, supply insecurity or overly controlling central supply systems block opportunities for implementation of community models with patients as supply chain participants. Specific examples are discussed in country case studies.

Recommendations:

Although many community models have been piloted and documented, implementation is still limited and multiple months refill (MMR) is rarely implemented in sub-Saharan Africa. Governments and global actors should enable an environment allowing for the most appropriate solution for ART access for the health service and the patients. Adaptation of national legislation with clear definitions of dispensing, distribution and refill may be essential to allow for this. Supply chains should be flexible enough to meet the needs of the patients to access MMR.

Cumbersome ART regimen changes

Most countries in sub-Saharan Africa have adopted WHO guidelines with similar standard HIV regimens. National regimen switches have been cumbersome and insufficient communication and coordination on who and when to switch and subsequent changes in medicine supplies have led to stockouts and overstocks in facilities. In different settings, problematic in-country implementation has caused national stockouts that have impacted heavily on patient care. To accompany regimen transitions, some Ministries of Health, in collaboration with partners, have published guidance on how to phase in new treatment regimens. In some cases, additional guidance has been distributed on clinical decision making when the optimal treatment choice was not available. Despite these provisions, many patients have been switched without the necessary clinical monitoring, switched to suboptimal regimens, or subjected to multiple switches due to unavailability (examples in country case studies). In-country early warning mechanisms and rapid response is usually non-existent, although it is essential to guide these transitions.

“It’s much better when us patients can group together to access our drugs through community ART groups. I would rather have long refill periods, five months or more, for my ARVs”.

Grace Hotti, ART patient, Nsanje, Malawi.

Recommendations:

National platforms engaging all medical and logistical stakeholders should be the forum to match clinical decision making and guide supply before and during regimen changes. Countries should publish clear medical and supply guidance for health care workers before regimen changes and provide clear alternatives in case of stockouts.

Poorly forecasted scale-up of second line ART

Scale-up of viral load testing in the course of 2014 and 2015 has massively increased the need for second line ARV treatment in sub-Saharan Africa. In a number of countries, including South Africa, Mozambique, Lesotho and several eastern African countries, the increase in demand has outpaced scale-up of medicine supply. In some cases, like Malawi, patients no longer responding to first line medicines have been placed on waiting lists to switch to appropriate treatment. Patients already on second-line therapy have been turned away from facilities without treatment during stockouts. One of the most important second-line treatments is lopinavir/ritonavir (LPV/r), which in many countries is only supplied by the pharmaceutical company, AbbVie. Patent monopolies on LPV/r formulations held by AbbVie in South Africa—the largest national second-line cohort in the world, with over 155,000 patients—together with AbbVie’s artificially low prices, have had a detrimental impact on manufacturing and availability of generic LPV/r formulations worldwide. As global demand for LPV/r has increased, reliance on AbbVie as a single supplier has led to supply insecurity for several countries. While some countries have accessed generic suppliers’ LPV/r stock to fill supply gaps, South Africa has experienced over six months of LPV/r stockouts and shortages, while patent barriers and limitations in national legislation have created difficulties in accessing generics. For years, AbbVie has refused to engage in discussions with generic companies to provide them licences to produce adult and paediatric tablet formulations, under terms that would improve supply security for different

developing countries. As demand for second-line treatment continues to increase, the fate of patients in multiple countries should no longer be dependent on the production capacity of a single supplier.

Recommendations:

Companies holding patents on ARVs, such as AbbVie, should voluntarily negotiate licenses with the Medicines Patent Pool, under terms that improve supply security and affordability for all developing countries. Countries that grant patents on medicines, such as South Africa, should ensure their laws allow them to overcome patent barriers on key medicines in emergency situations, in order to provide access to alternative generic supplies. Global health actors should support countries to improve demand forecasting, and to develop contingency plans that include accessing alternative suppliers and overcoming any patent barriers in the case of acute and persistent stock outs.

Lack of regional collaboration in a reality of patient migration

While patients are mobile and migrate in country and cross-border, with a need to access ARVs in different places, country systems are not adapted to a local and regional migration reality. Regional collaboration and stock exchange to respond to this reality is limited.

When patients are faced with stockouts, they often turn to neighbours or family members to exchange or borrow medicines. Facilities with stockouts typically rely on their colleagues in neighbouring clinics for emergency redistribution of medicines. In-country, the same patients often access medicines in different health facilities, depending on their location at the time a refill is needed. Travelling patients like migrant workers move and need medicines refills across borders. Patients living in border areas might prefer to pick up medicines in a facility nearby but on the other side of the country border. These local and international migration patterns have an impact on forecasting of patient needs for the country

and specific facilities. Often, country forecasting tools and legislation are not adapted to serve patients in transit who are not part of the national cohort or do not have a local address or identity card.

Although most countries have similar standard ART regimens, regional exchange mechanism to respond to overstocks or shortages are not developed. In isolated cases, loans or exchange of stocks between countries have been used to alleviate national stockouts, but cumbersome custom procedures and tendering quota imposed by Ministries of Finance limit speed needed to redistribute stocks between countries. Also, these exchanges remain ad hoc stop-gap measures that serve as a last resort when patients are already experiencing stockouts.

Recommendations:

The reality of internal and cross-border migration of patients with similar disease profiles in need of the same regimens demands a regional approach to ART delivery. Supply chains, data management and legislation should be adapted to a reality of patients crossing borders, resulting in changing patient numbers. Unique patient identifiers and ART passports can be tools to address this. In terms of ART supply, neighbouring countries should take lessons from peripheral facilities exchanging medicines and actively engage in communication on national stock levels to loan or exchange stocks before nationwide stockouts or overstocks occur. Regional and in-country legislation should be flexible enough to ensure medicines access for patients in different countries and regional medicine exchanges for public health reasons. Regional and global actors involved in the support of national HIV programs should play an important role by ensuring enough resources and support to implement such flexibilities.



Lack of international coordination

Few global donors provide medicines for most countries in sub-Saharan Africa and thus should have the best overview of international and regional demand and supply lines. Similar stockout situations have taken place in different countries in critical periods when regimens were changed or second line regimens were scaled-up. Similar supply chain challenges and exacerbated problems during these critical periods are faced by countries needing to reach the '90-90-90' targets and needing to put all people living with HIV on treatment in the near future. A single organisation, the Partnership for Supply Chain Management (PFSCM), is currently supplying ARVs for both PEPFAR and GFATM supported countries. Although PFSCM has regional procurement centres to respond to national emergencies, national stockouts do occur regularly in countries served by the two main actors.

Recommendations:

Global actors should coordinate international collaboration on different levels; through creation of forums for the sharing of information and lessons learned between countries and through actively encouraging and supporting regional and international exchange of medicines and pool procurement. Existing regional and international mitigation mechanism like the regional procurement centres should be used to their maximum capacity to alleviate stockouts. Lastly, global actors should also play a role on informing countries and regions on global market preparedness for global regimen changes or regimen scale-up (example of LVP/r). Pro-active supplier's communication on their supply capacity is a precondition to make this happen. Regional and international platforms should share this information openly and coordinate cross country exchange of medicines when necessary.

CONCLUSION

The fight against HIV has historically been driven by increasingly ambitious global targets that, despite some scepticism, have consistently been achieved. This led to the articulation of the 90-90-90 targets with UNAIDS affirming that if over 70% of all people living with HIV worldwide are on optimal treatment,³⁷ the worldwide HIV pandemic will soon be under control. But HIV cannot be defeated without medicines.

The 90-90-90 targets should be heralding a new era where program quality for individuals takes precedence over the faceless numerical count of new initiations. It is only when all patients can access the correct medicines where and when they need them that they can be adherent enough to stay virally suppressed.

This report indicates that the previously overlooked but systemic problem of medicines access at patient level constitutes a regional obstacle to a quality scale-up.

Although in general ART supply chains function better than the distribution system for other commodities, they remain flawed and overly complex, leaving patients at the end of it suffering the consequences of its dysfunctions and lack of accountability. Chronic facility stockouts occur regularly across the region due to internal supply chain deficiencies; additionally national supply shortages cause acute and wide-spread facility stockouts.

Supply chains should be simplified to deliver medicines without gaps, and should be flexible to cope with unexpected circumstances. Visibility and transparency across the chain is a prerequisite to make this happen. Context-specific in-country supply chains models should be tested and evaluated on their impact to improve access to medicines and patient outcomes.

Similar challenges exist in different countries, and patients move frequently across borders, creating a need for a regional approach to ART delivery. Changes in global demand due to ART regimen changes or scale-up should be anticipated and coordinated to avoid regional and international shortages.

Patients, civil society and community-based organisations, as beneficiaries of the supply chain, should play an important role in its functioning. The patient level data on medicines access they collect through monitoring should be used to evaluate the supply chain alongside the national monitoring system. Civil society should be engaged in forums where supply chain challenges and strategies are discussed. When patients will be enabled to influence supply chain by participating in its functioning, supply chain actors will be accountable to their most important beneficiaries.

We need a system designed for patients and accountable to patients. Supply chains should be adapted to patients' realities, instead of patients to a supply reality.

PART 2.

COUNTRY CASE STUDIES

DEMOCRATIC REPUBLIC OF CONGO

Table 3: Supply chain indicators for DRC

| | | |
|------------------------------------|---|---|
| HIV response | PLHIV (million) | 0.45 ³⁸ |
| | Adult HIV prevalence | 1.0% ³⁹ |
| | ART coverage under WHO 2013 guidelines | 24,3% ⁴⁰ (2015) |
| | Scale-up assumptions | 50% (232067) by 2017 ⁴¹ |
| | Adult retention at 12 months | 78% ⁴² |
| ART Supply chain | ARV funding | GFATM/PEPFAR |
| | Procurement body | GFATM PPM/PEPFAR PFSCM |
| | Distribution model | Mixed system |
| | Number of levels in the chain (incl. CMS and health facilities) | 4/2 |
| | Delivery frequency | Monthly |
| | Nationwide facility consumption data collection system in place | Monthly reports in GFATM supported sites, PEPFAR supported sites variable |
| | Theoretical buffer stock at facility | 1 month |
| | Private sector involvement in supply chain | Distribution, Warehousing |
| | Regular organised distribution to facilities (last mile delivery) | Yes in PEPFAR supported facilities, no in GFATM supported facilities |
| External observers of supply chain | Yes, community observatory in GOMA | |
| Supply chain flexibilities | Refill frequency | 1 month, exceptionally 3 months in PODI and some facilities |
| | Task shifting of distribution and/or refill of ART to lay workers or patients | Patient lead community distribution points in Kinshasa |

SUPPLY CHAIN

In DRC the supply of ARVs is managed through two essentially parallel systems. The GFATM and PEPFAR agencies run separate quantification of ARVs, importation, warehousing, ordering systems and distribution to supply patients in their respective areas of intervention, which in many cases overlap. Parallel data collection systems do not allow for a representative national

estimation of needs, anticipated shortages and appropriate reaction. There are problems with double data collection and confusion in roles and responsibilities, leading to stockouts and over stocks. Since November 2014, significant improvements were noted in collaboration between the main donors as an interagency working group was put in place by the PNLS. Stock information

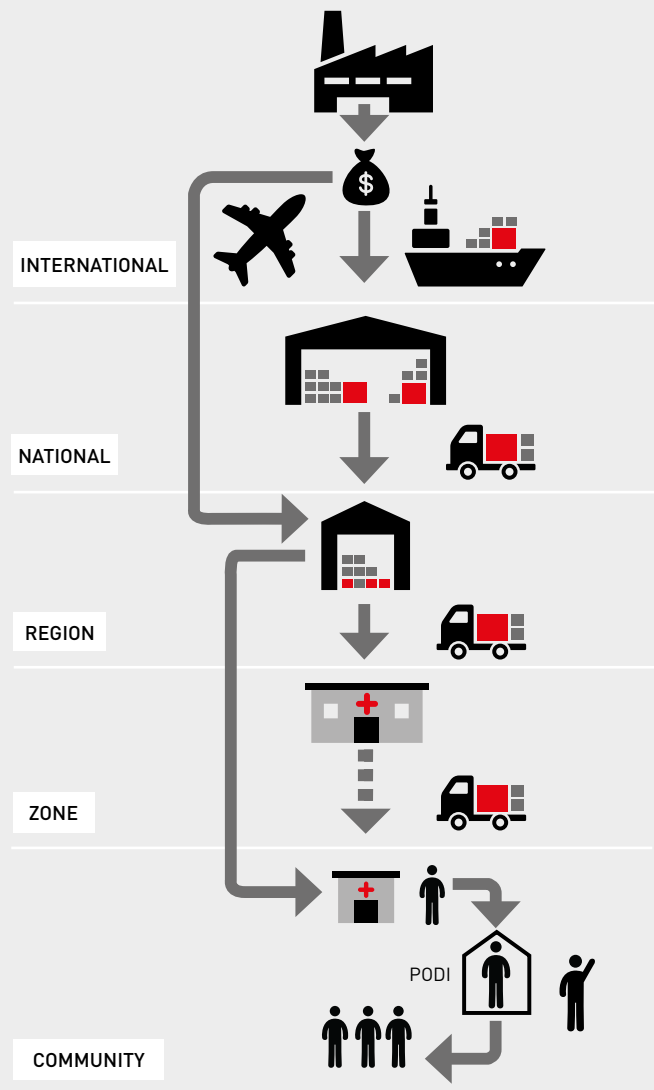
is shared on a monthly basis and an inter-donor loan-system is in place to respond to stockouts. The GFATM primary recipients (PR: CORDAID and SANRU) follow the national administrative structure and pass orders and deliveries via regional and zonal authorisation and warehouses, assisted by sub recipient organisations. Every health facility order needs five different validations to be delivered to the GFATM PR. The GFATM uses three different central stocks: one in Kinshasa (Bolloré, a private actor), one in Lubumbashi (CAMELU, a public-private actor) and one in Goma (ASRAMES, also a public-private actor). Distribution is organised on a quarterly basis to the zonal warehouses. Currently, no regular organised transport between the health zones and the facilities is supported by the GFATM. The medicines cross the last mile through pick-ups by facility staff when they are participating in monthly meetings at health zone level or through the use of zonal vehicles belonging to the health zone, not destined for distribution. The GFATM is planning to provide a monthly financial allowance per health zone and per facility to stimulate medicine pick-ups. However, this sum will not be a guarantee of coordinated and regular distribution. In addition, it is not clear how the impact on medicine availability will be measured or how this will improve the situation for patients.












Previously, PEPFAR-supported health products, imported by Supply Chain Management Systems (SCMS), were stored in different warehouses, depending on the implementing partner (IP). Since September 2015, PEPFAR has started keeping stocks in regional warehouses from where they are transported by the IPs directly to the supported health facilities. PEPFAR ART quantifications are based on a predefined quota of numbers of patients to reach, and not on the needs of the population.

The country is currently facing three critical transitions that will have an impact on the HIV supply chain and increase the risk of stockouts:

The Programme National de la Lutte contre le SIDA (PNLS) has initiated a process of national rationalisation of donor support per province. In the capital Kinshasa, the donor support for HIV-related activities is divided by health zone. PEPFAR is planning full support in 8 'saturation' zones to reach the '90-90-90' objectives (zones

THE ART SUPPLY CHAIN IN DRC



-  Pharmaceutical Manufacturer
-  Procurement Agent
-  Air Transport
-  Transport over Sea
-  Transport over Land
-  Central Medical Stores
-  Regional Medical Stores
-  Zonal Medical Stores
-  Health Facility
-  Patient
-  Community Monitoring

that will be handed over to GFATM in 2016) and 10 'maintenance' zones where the activities will remain the same for the time being. This transition of responsibilities, support and data collection will have major impact on the drug supply, and, if not carefully coordinated, is likely to lead to more stockouts and shortages. At the time of writing, a transitional plan is being discussed and should be presented by the 15th of December by the PNLS.

Secondly, to implement the WHO-recommended first-line ART, the country is preparing the transition from the currently used first line regimen (AZT/3TC/NVP) to the preferred fixed-dose combination (TDF/3TC/EFV). In September, a six month supply of TDF/3TC/EFV arrived at the Bolloré warehouse. The PNLS has stated that it is currently working with the different Provincial Health Departments to develop an adapted transition plan. Pediatric first regimens will change as well from AZT- to ABC- based regimens, impacting heavily on the need for certain formulations. A national transitional plan for this massive treatment switch has not yet been developed.

In early 2015, stockouts of the fixed dose TDF/3TC/EFV formulation were noted when it was introduced for all pregnant women for

PMTCT. As the initiation to the new ARV was not restricted to pregnant women by certain partners, a national stockout of the triple therapy could not be avoided.

Thirdly, the PNLS is working on the roll-out of the WHO-recommended monitoring approach through viral load to diagnose and confirm ART failure. Increasing viral load monitoring leads to better detection of treatment failure and, in general, reveals a higher need for second line treatment. For 2016, a national forecast takes into account the estimated lab material for viral load analyses needed and an extra 5% security stock was added by the PNLS for second line regimens. Although there are five viral load platforms in-country, currently no national data are available on patient numbers who will need alternative second line regimens.

In the light of above discussed crucial regimen changes, national coordination is essential in order to guide clinical- and supply-related decision making at all levels of the chain and ensure the capacity to react swiftly to problems that will present. However, the two donors have done their yearly ART quantification separately and a national plan has not been developed yet.



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Portrait of Bwa Mpana, 37, a patient at the Mbankana General Hospital since 2011. The structure recently had breaks in supply of antiretroviral drugs (ARVs) and inputs. She is currently on cotrimoxazole but can not be initiated on ARVs because the hospital CD4 drive has failed.

STOCKOUT MONITORING

All ART-providing facilities are required to provide monthly activity reports including the number of days key ARVs are out-of-stock. However, reporting rates are low, not allowing for a swift response to an existing stockouts.

MSF staff faces regular stockouts and shortages in MSF-supported facilities in Kinshasa. The teams support the facilities with pharmaceutical mentoring, assist with transport of orders and

supplies from the regional or zonal warehouses, and fill ARV gaps when necessary. In order to establish the scope of stockouts and the impact on care of patients in Kinshasa, MSF and the provincial PNLS undertook a survey on availability of medicines (17 ARVs, 2 formulations of cotrimoxazole and test kits, table 4) and patient impact in 94 facilities and 27 zonal warehouses in Kinshasa in April and May 2015⁴³.

Table 4: ARVs, cotrimoxazole formulations and tests monitored

| Adult ARVs | Pediatric ARVs | Cotrimoxazole |
|--|---|------------------------------------|
| EFAVIRENZ/LAMIVUDINE/TENOFOVIR, EFV/3TC/TDF 600/300/300mg, tabs | LAMIVUDINE/ZIDOVUDINE, 3TC/AZT, 30/60mg, tabs | COTRIMOZAZOLE 480mg, tabs |
| TENOFOVIR/LAMIVUDINE, TDF/3TC, 300/300mg, tab or TENOFOVIR/EMTRICITABINE, TDF/FTC, 300/200mg, tabs | LAMIVUDINE/ZIDOVUDINE/NEVIRAPINE 3TC/AZT/NVP, 30/60/50 mg, tabs | COTRIMOZAZOLE 200/50mg, suspension |
| LAMIVUDINE/ZIDOVUDINE/NEVIRAPINE, 3TC/AZT/NVP, 150/300/200mg, tabs | ABACAVIR/LAMIVUDINE, ABC/3TC, 60/30mg, tabs | |
| LAMIVUDINE/ZIDOVUDINE, 3TC/AZT, 150/300mg, tabs | EFAVIRENZ, EFV, 200mg, tabs | HIV TESTS |
| ABACAVIR, ABC, 300mg, tabs | LOPINAIVIR/RITONAVIR, LPV/R 100/25mg, tabs | HIV 1+2, DETERMINE, test |
| EFAVIRENZ, EFV, 600mg, tabs | LOPINAIVIR/RITONAVIR, LPV/R 80/20mg/ml, 60ml | |
| NEVIRAPINE, NVP, 200mg, tabs | NEVIRAPINE, NVP 50mg, susp tabs or 10mg/ml sirup | |
| LOPINAIVIR/RITONAVIR, LPV/R 200/50mg, comp, tabs | | |

Survey teams composed of MSF and provincial PNLS staff collected data on stockouts of selected items established the duration of the stockouts, and analysed proposed solutions for patients in case of stockouts. Impact was measured with indicators including: the estimated number of patients affected, number of patients send away without medicines or test, and estimated drug days lost, depending on the size of the cohort and the duration of the stockouts (table 5). Stockouts were analysed at the day of the survey through physical stock

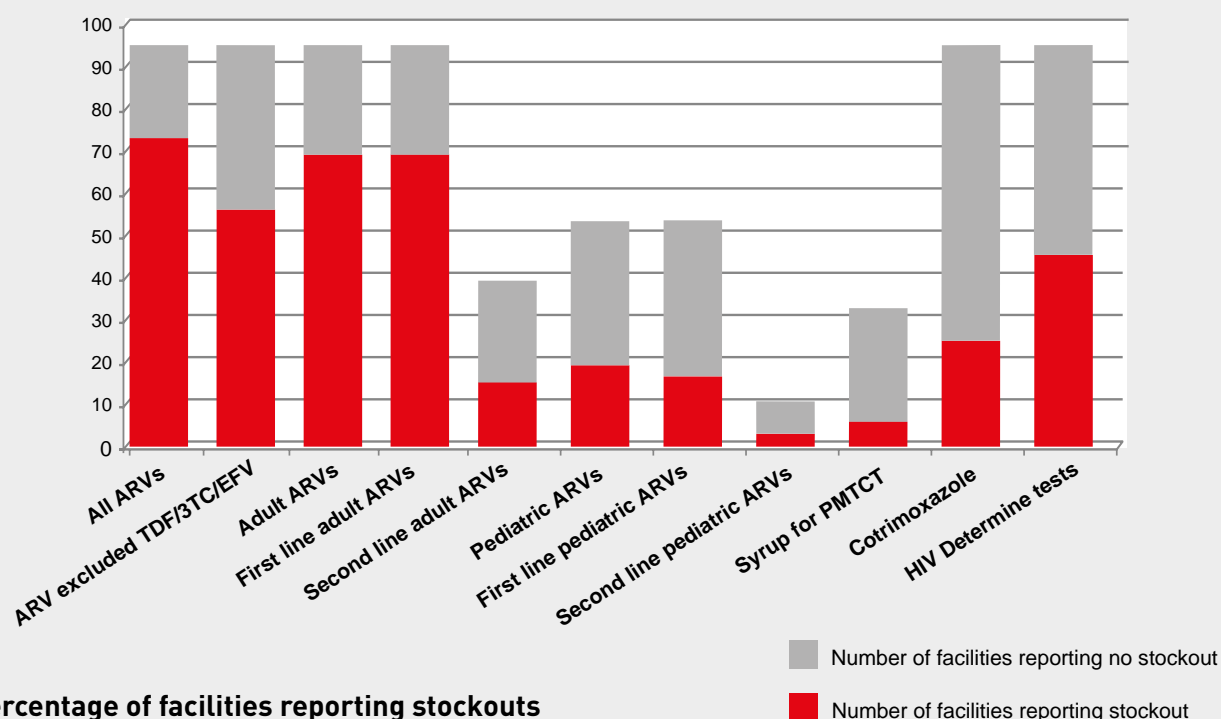
checks and in the period between January and March 2015 through analysis of the stock management tools used. The stockout data collected on the day of the survey can be considered as more exact (as verified physically and not biased by incorrect reporting), while the stockout data collected between January and March 2015 from available reporting tools are more representative for the situation during the rest of the year (as they are covering three months).

Table 5: Impact indicators

| Indicator | Formula |
|---|--|
| Cohort in need (C) | Sum of patients in need of ARV out of stock at the HC |
| Number of patients affected (PA) | Sum of C/30 * Number of days with stockout |
| Number of patients who left without medicines/tests (PL) | Sum of PA of HC where patients left without medicines/test |
| Drug days lost (DDL) | (Number of days with stockout/2)* PL |

Figure 2 shows the number of facilities that experienced a stockout of at least one item at the day of the visit or between January and March 2015. Table x shows the proportion of facilities that experienced a stockout of those facilities with patients in need of those medicines.

Figure 2: Number of facilities reporting stockouts



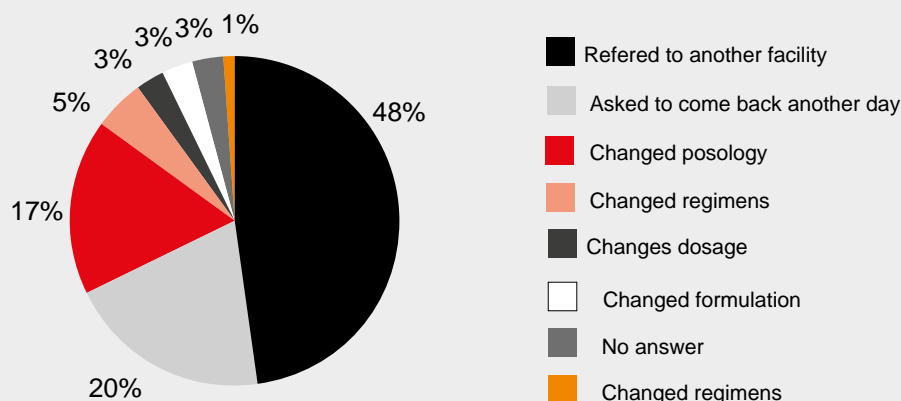
Percentage of facilities reporting stockouts

| | |
|----------------------------|-----|
| All ARVs | 77% |
| ARV excluded TDF/3TC/EFV | 60% |
| Adult ARVs | 74% |
| First line adult ARVs | 74% |
| Second line adult ARVs | 39% |
| Pediatric ARVs | 32% |
| First line pediatric ARVs | 27% |
| Second line pediatric ARVs | 33% |
| Syrup for PMTCT | 21% |
| Cotrimoxazole | 27% |
| HIV Determine tests | 48% |

More than three out of four facilities had a stockout of at least one ARV, and 60% of facilities had a stockout of ARVs that were available elsewhere in Kinshasa (taking into account a national stockout of TDF/3TC/EFV at the time of the survey). Adult ARVs were out-of-stock more often than pediatric ARVs. Cotrimoxazole formulations were found out-of-stock in 27% of facilities and HIV tests in almost half of facilities.

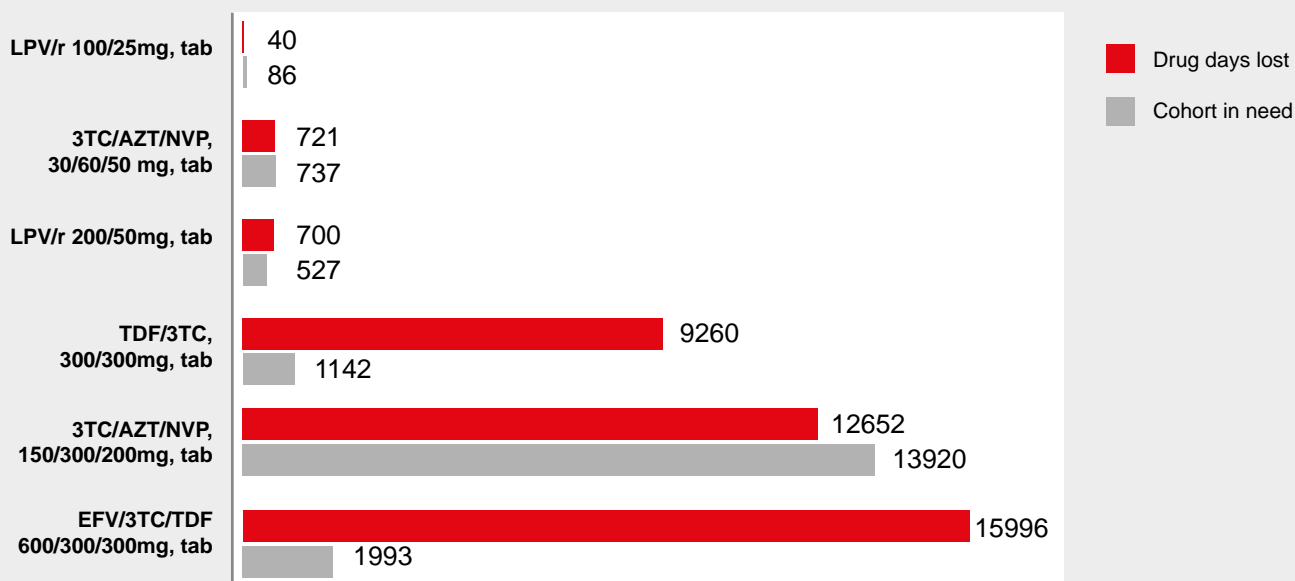
Figure 3 presents the solutions that health care workers proposed to those patients who were in need of the ARVs in stockout at the day of the survey. In 48% of cases of ARV stockouts, patients were referred to another facility and in 20% they came back on a later day, meaning in 68% of cases patients left the facility without ARVs. In all other cases patients were switched to less appropriate regimens, other dosages, other formulations or another way to take the medicines. Similar results were found for stockouts from January until March 2015.

Figure 3: Solutions proposed to patients in case of ARV stockout at day of visit



For the specific case of the TDF/3TC/EFV formulation for which there was a national stockout but separate tablets of TDF/3TC and EFV were available, still half of the structures send patients home without medicines and only 1 in 3 offered the separate tablets. Figure 4 presents the estimated impact of stockouts of key ARVs between January and March 2015 on patients. The formulation of which the stockouts had the highest impact on patients was TDF/3TC/EFV.

Figure 4: Cohort in need and Drug Days Lost for key ARVs



Although only 8% of facilities reported stockouts of AZT/3TC/NVP, widely used as first line option, the stockouts that occurred had a high impact due to high patient numbers. Similar impact was seen for pediatric AZT/3TC/NVP, used by most children on ART. The formulation TDF/3TC, used by limited patient number but reported out of stock in 41% of facilities, also contributed strongly to the patient impact. An estimated 1300 patients left facilities without ARVs due to stockouts between January and March. Due to stockouts in the same period, an estimated 870 patients left facilities without cotrimoxazole and more than 4300 patients did not have access to an HIV test when they presented at the facility.

For all those stockouts encountered the day of the survey at the health centre, the availability in the zonal warehouses was checked. In 45% of stockouts, the same item was available in the zonal warehouse while out-of-stock at the health centre.

In Kinshasa there is a maximum of two hours distance to travel between a facility and the zonal and central warehouses; yet the stockouts encountered lasted over a month on average. As the last mile is not clearly organised, most medicines do not arrive at the facility where patients should have access. A clear mechanism to alert supply chain managers and solve stockouts with available medicines or valuable alternatives would be necessary to avoid lengthy stockouts and loss of access to medicines for patients. Only a few stockouts in a limited number of health centres constituted over 50% of the estimated impact; this negative impact could be largely reduced in the short term with minimal interventions.

Following the release of these survey results in October 2015, the PNLs undertook action by calling a meeting with all stakeholders involved in the ARV supply chain. The main recommendations that were adopted include ensuring last mile distribution while picking up the necessary data on-site, installing a system of alert and response to stockouts, coordinating national transitional periods and quantification and supporting patient organisations to monitor supply chain performance. The PNLs is elaborating a roadmap to improve the situation.

This plan should address the urgency of the situation as planned transitions in the HIV program will give rise to high risk of stockouts and negative impact on patients in the near future.

INNOVATIVE SOLUTIONS FOR SUPPLY CHAIN IMPROVEMENT

Since 2011 MSF has supported the creation of community distribution points (PODI) in Kinshasa, through peer support from the Réseau National des Organisations des Assises Communautaires (National Network of community based organisations: RNOAC). The PODI strategy aims at decentralising treatment for stable patients in order to decongest health facilities and give patients easier and faster options to access medicines in their community. Patients are attended to by fellow patients, reducing stigmatisation. ARV ordering, managing and dispensing is effectively task-shifted to these trained patients. More than 2600 patients currently receive a three monthly ARV refill in three existing PODIs in Kinshasa. Results have shown 94% retention at 12 months⁴⁴.

The PODI strategy has been recognised by the PNLs and both the Global Fund and PEPFAR have expressed interest and made available a budget for scale-up of the PODI model. The proposed model for the absorption of the PODI current health system is the 'integrated PODI', in which the ARVs are supplied directly to the PODIs by the zonal warehouses. By bypassing health facilities and thus decreasing the levels in the supply chain, the delay and errors in ordering and reporting are reduced. In Kinshasa, where geography is not an issue, direct delivery from the national warehouse to the PODIs could be tried to reduce delays and improve availability of ARVs.

ROLE OF PATIENTS AND CIVIL SOCIETY

In February 2015, PLWHA representatives grouped in an 'Observatoire Communautaire' (Community observers) analysed access and quality of services in the province of North-Kivu. 34 health facilities in 13 health zones were visited, and health care workers and patients were interviewed for data collection on service satisfaction and the availability of ARVs, tests

and medicines for prevention and treatment of opportunistic infections. Findings showed that one in ten patients interviewed was not satisfied with the services, mainly due to the need to pay for or non-availability of essential medicines, or irregular access to lab tests. 35% (12/34) of facilities had between 2 and 5 ARVs out of stock in February 2015. 44% (15/34) facilities in 10 different zones had stockouts of opportunistic infection prophylaxis or treatment⁴⁵. 17% (6/34) facilities reported stockouts of one or several HIV tests.

Aside from regular monitoring visits, through the observatoire communautaire, patients report ad hoc access issues regularly and have pushed for fast resolution through communication relayed to the national level. Médecins du Monde and MSF are supporting the start-up of an observatoire communautaire in Kinshasa, in collaboration with organisations representing patients; UCOP+, FOSI, AMOCONGO and RNOAC. In addition to measuring availability of services, this group will also measure impact on patients from limited access to services.

KEY RECOMMENDATIONS

- Monitor and evaluate supply chain efficiency using robust data collection systems measuring access to ART treatment at patient level and make causal links to ART scale-up and adherence.
- Ensure visibility on facility stock levels, including early warning mechanism for stockouts, and capacity to alert and react to impending and existing stockouts, particularly in critical times of regimen transitions.
- Ensure effective, organised and funded last mile delivery with patient availability as the main performance indicator in the scale-up plan to reach the '90-90-90' targets.
- Increase national collaboration of government and donors to ensure national facility level data collection to guide national quantification based on patient needs.
- Simplify the supply chain to fit a robust supply chain logic, rather than further integration into existing administrative structures that might add complexity.
- Enable patients, civil society and community-based organisations, like the observatory, to actively understand, contribute, develop solutions, and flag issues relating to their access to critical medication. The reported data should be used a parallel source of information to complement internal monitoring mechanisms.



Table 6: Supply chain indicators for Malawi

| | | |
|-----------------------------------|---|--|
| HIV response | PLHIV (million) | 1.0 ⁴⁶ |
| | Adult HIV prevalence | 10.3% ⁴⁷ |
| | ART coverage under WHO 2013 guidelines | 57% ⁴⁸ (2015 ¹) |
| | Scale-up assumptions | 81% of coverage by 2020 ⁴⁹ |
| | Adult retention at 12 months | 79% ⁵⁰ |
| ART Supply chain | ARV funding | GFATM/PEPFAR ⁵¹ |
| | Procurement body | GFATM PPM/PEPFAR PFSCM ⁵² |
| | Distribution model | Informed push system |
| | Number of levels in the chain (incl. CMS and health facilities) | 2 |
| | Delivery frequency | Bi-monthly |
| | Nationwide facility consumption data collection system in place | Yes, quarterly collected data |
| | Theoretical buffer stock at facility | 3 months |
| | Private sector involvement in supply chain | Distribution, Warehousing |
| | Regular organised distribution to facilities (last mile delivery) | Yes |
| | External observers of supply chain | Yes, NAPHAM |
| Supply chain flexibilities | Refill frequency | 3 months for stable and adherent patients, 6 -12 months for exceptional cases ⁵³ |
| | Task shifting of distribution and/or refill of ART to lay workers or patients | Community ART groups piloted in Thyolo district, not part of national policy ART Fast track in Chiradzulu |

SUPPLY CHAIN

Since decentralisation of Malawi's treatment program in 2004, efforts have been made to ensure availability of ARVs at all ART treatment points. 'Adequate supply of HIV test kits and ARV drugs' was considered a main prerequisite for a rapid scale-up, with a zero tolerance of stockouts of ARVs and test kits⁵⁴.

Today, Malawi has one of the best ART coverage rates in the region, with ART available in 711 public ART sites country wide. Out of a total of 19,062 viral load results produced at 8 labs in the national program between January and March 2015, 16,116 (85%) were undetectable (VL < 1000 copies/ml)⁵⁵.

This has been partly possible due to the initial set-up of the ART supply chain vertical to the general CMS system in 2004. Generally, vertical supply chain systems are more adapted to the specific nature of the commodities and largely donor supported, increasing the quality but also the cost. Following the recommendations of a 2008 report on supply chain integration, the CMS has been transformed into a CMS-Trust (CMS-T), increasing its autonomy and flexibility. The CMS-T currently manages warehousing and distribution for TB medicines, family planning commodities and other essential medicines, and warehousing for ARVs⁵⁶. The willingness of donors to capacitate the CMS-T for management of commodities for vertical donor supported

programs may have been tempered by reports of commodity leakage at CMS-T⁵⁷. Among investigated commodities, ARVs were best accounted for, despite 16% leakage at health facility level.

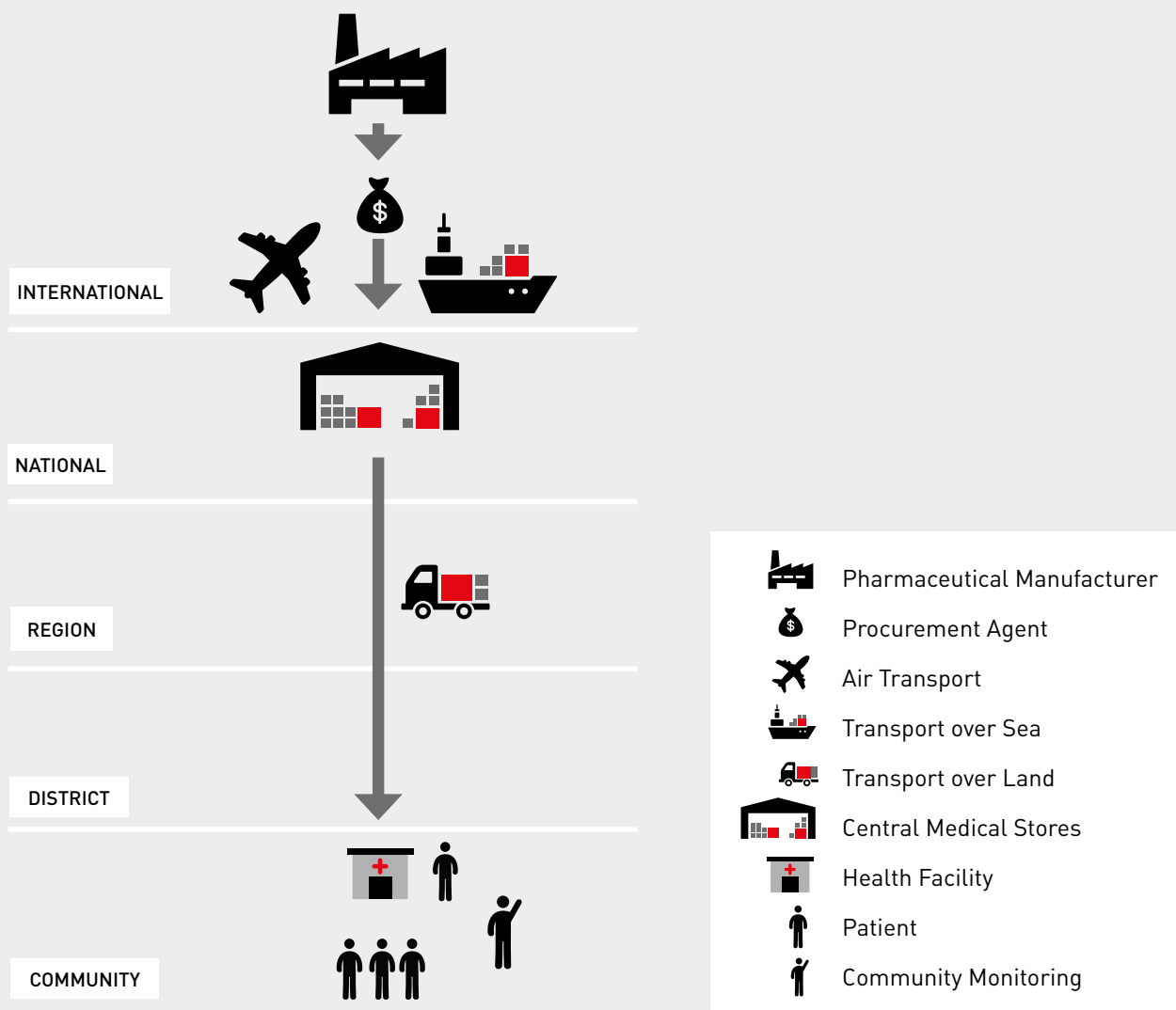
The department for HIV and AIDS manages data collection, forecasting, quantification and distribution planning of HIV commodities. Through a bimonthly push system, ARVs are distributed from the central stores directly to health facilities including a security stock of three months. The distribution plan is shared with all treatment facilities before distribution for verification and discrepancies with current needs. Supportive supervision teams rotate through the different districts on a quarterly basis. Their role includes inventory control to

provide data to the national HIV unit, which forms the basis of the ART distribution planning and national ART needs quantification.

Although the verticalised and centralised ARV supply chain is costly and donor driven, it has surely contributed to the success of the ART program in Malawi by limiting the levels in the supply chain and emphasising a well-coordinated national quantification system.

Through central coordination and push distribution, the Malawi department for HIV and AIDS has successfully made three months' worth of ARVs available for all stable patients in country and up to 12 months for exceptional cases since 2011⁵⁸. This makes them one of the first countries in the region to include these provisions in the national HIV guidelines⁵⁹.

THE ART SUPPLY CHAIN IN MALAWI



STOCKOUT MONITORING

Although quarterly physical checks allow confirmation of ARV stock and consumption in every health facility in the country, there is no regular documentation of stockouts. The stockout risk is considered minimal due to the well-stocked central stores and a direct delivery model. However, as facility health care workers are not involved in quantification and ordering of ARVs, there is limited ownership on ARV management at the last level.

Table 7: ARVs monitored

| ARVs monitored |
|---|
| Adult ARVs |
| TDF 300 mg / 3TC 300 mg / EFV 600 mg, tab. |
| 3TC 150 mg / AZT 300 mg / NVP 200 mg tab |
| TDF 300 mg / 3TC 300 mg, tab |
| 3TC 150 mg / AZT 300 mg, tab. |
| NEVIRAPINE (NVP), 200 mg, tab. |
| LPV 200 mg / r 50 mg, tab. |
| ATV 300 mg / r 100 mg, tab |
| Pediatric ARVs |
| 3TC 30 mg / AZT 60 mg / NVP 50 mg tab. |
| ABC 60 mg / 3TC 30 mg, tab. |
| NEVIRAPINE (NVP), 50mg/5ml, oral suspension |
| NEVIRAPINE (NVP), 50 mg, disp. tab |
| LPV 100 mg / r 25 mg coated tab. |

In the MSF supported district of Nsanje, Malawi's southern-most district, MSF pharmacy teams are monitoring the availability of 12 key ARVs through weekly visits in 14 health facilities since May 2015 (table 7). Stockouts are defined as absence of the medicines at health facility level. For those items out of stock, the duration of the stockout in days was determined by consulting the stock cards.

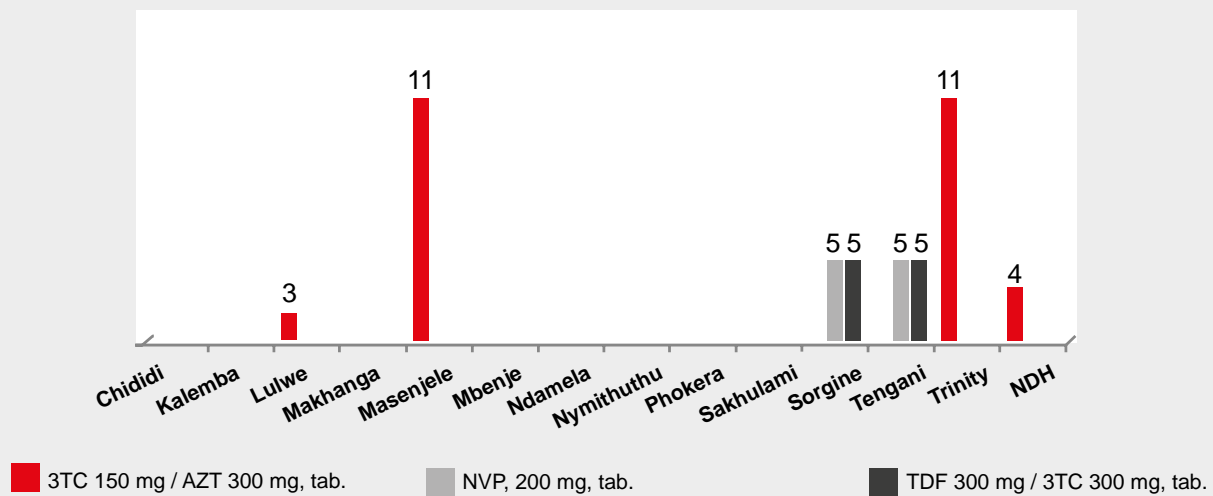
Impact on patients from ARV stockouts is quantified as follows: We assume there are 30 days in a month and patient visits are regularly distributed over a period of one month. The number of patients on each regimen is divided by 30 to estimate how many patients visited the health centre each day and multiplied by the days of stockout to estimate the number of patients affected. Of those patients, it is assumed that they show up to the health centre on average in the middle of the stockout and don't have access to their ARVs until the end of the stockout. So depending on the size of the cohort affected and the duration of the stockout, the drug days lost (DDL), or the estimated total number of days the concerned patients did not have access to ARVs, is calculated (table 8). Although most stable patients receive refill for three months, as some do not, we consider that patients return each month. In a situation where there is a stockout and patients receive MMR, the stockout is likely to have a smaller impact on patients than the same stockout in a situation where patients receive only one month refill.

Table 8: Impact indicators

| Indicator | Formula |
|---|--|
| Cohort in need (C) | Sum of patients per HC in need of ARV out of stock |
| Number of patients affected (PA) | Sum of C/30 * Number of days with stockout |
| Drug days lost (DDL) | (Number of days with stockout/2)* PA |

In May 2015 no ARVs were reported out of stock. Between the beginning of June and the end of August 2015, out of twelve ARV monitored, three items were reported out of stock at least once, while the other nine items were never reported. After this period, in September no ARVs were reported out of stock.

Figure 5: Number of days reported out of stock per formulation and per health centre from June until end of August 2015 in Nsanje



Out of 14 facilities, 6 (43%) reported a stockout over the three month period. 4 facilities reported a stockout of AZT/3TC for an average of 7.25 days. 2 facilities reported stockouts of TDF/3TC and NVP for 5 days (figure 5).

Figure 6: Cohort in need, number of patients affected and Drug Days Lost per health centre with stockouts from June until end of August 2015 in Nsanje.

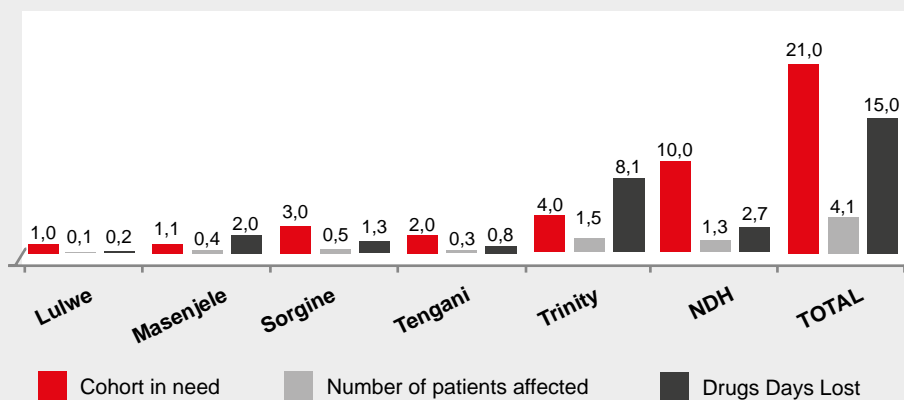


Figure 6 shows that over three months, an estimated four patients were affected by stockouts and did not have access to the appropriate ARVs when presenting at the health centre, resulting in a total of fifteen days without access to medicines (DDL). 86% (12.9/15.0) of the impact was due to the AZT/3TC shortages. According to the health centre staff, those patients were requested to come back later but only one patient from Masenjele interrupted treatment for three days. Considering that stable patients receive three month refill, the stockouts of first line medicines in Sorgine and Tengani

are likely to have had less negative impact, as patients present only once per quarter. The patients on second line (including AZT/3TC) receive a one month refill.

The most reported ARV is AZT/3TC, mainly used in the treatment of second line patients. As MSF supports roll-out of viral load (VL) testing in Thyolo and Nsanje districts, the rise in numbers of patients in need of second line medicines increased rapidly. In Nsanje district, the number of patients switched to second line went from 10 patients in February to 67 in September

2015. In Thyolo district, the need increased from 307 patients in March 2015 to 328 in August 2015. When larger numbers of patients change regimens, consumption of specific medicines increases accordingly and a higher level of alertness and response is needed to avoid stockouts. With the use of VL testing, insufficient attention was given to the quantification and reporting of patients in need of second line, to ensure enough second line ARV regimens. As consumption reporting is done only once per quarter, patient numbers increased substantially in that period and there was a delay in reporting higher stock consumptions.

In Thyolo district, more than 130 patients with high VL remained on a waiting list for over 2 months because second line medicines were not available.

The ARV supply chain in Malawi is considered to function well. Other medicines are stored and distributed through a network of parallel supply chains⁶⁰. Monitoring of other essential medicines in Nsanje district showed regular and long lasting stockouts of antimalarial medicines in all facilities between July and September 2015 and stockouts of the first line adult TB medicines in ten facilities in July. Lessons should be taken from the ARV supply chain in order to improve availability of other medicines and reduce patient impact of other stockouts.

Although stockouts of ARVs are not frequently reported in Malawi, when occasional stockouts occur they might not be noticed immediately through the quarterly reporting system. When many patients switch to another treatment line, there is need for increased levels of alertness, increased frequency of reporting and timely delivery reactivity at critical moments to ensure uninterrupted access to appropriate ARVs. Government, donors and implementing partners all have a role to play in ensuring optimal coordination and faster data transfer to reduce patient impact in times of treatment changes. As there is currently no ongoing monitoring of stock availability outside MSF supported areas, MSF and MoH will conduct a broader study on availability of ART and other medicines and impact of stockouts in the course of 2016.

INNOVATIVE SOLUTIONS FOR SUPPLY CHAIN IMPROVEMENT

In Thyolo district, stable patients from the same community have formed community ART groups (CAG) and between them take turns for clinic visits and drugs refills. 14% of the patients ever initiated are part of these groups and 97% of the members were retained in care until June 2015. In Chiradzulu district, patients benefit from a fast-track service in which lay cadres provide 3-monthly ART refills and check the adherence of the patients. These models effectively task-shift the refilling of ART to patients and lay workers, reducing patient contact points and waiting times and decreasing the patient burden on the health facility⁶¹. Despite the flexibility to allow multiple month refill and positive experiences with CAG groups in Thyolo and increasingly in other districts, current policy does not allow a national roll out of the handling of medicines by lay cadres.

Community health care workers in Malawi are involved in the distribution of essential medical supplies into the community and are equipped with a simple mobile phone for re-ordering of supplies. The data on remaining stock levels are sent up to health centres and a central supervision database. Low stock levels are flagged and permit timely refill. Introduction of this 'c-stock' has allowed reduction of stockouts at patient level and has reduced delivery times^{62,63}. Already existing tools like C-stock could assist in bringing ARVs closer to patients, by fellow patients or lay workers, without losing control of supply levels and consumption, hence preventing potential stockouts.

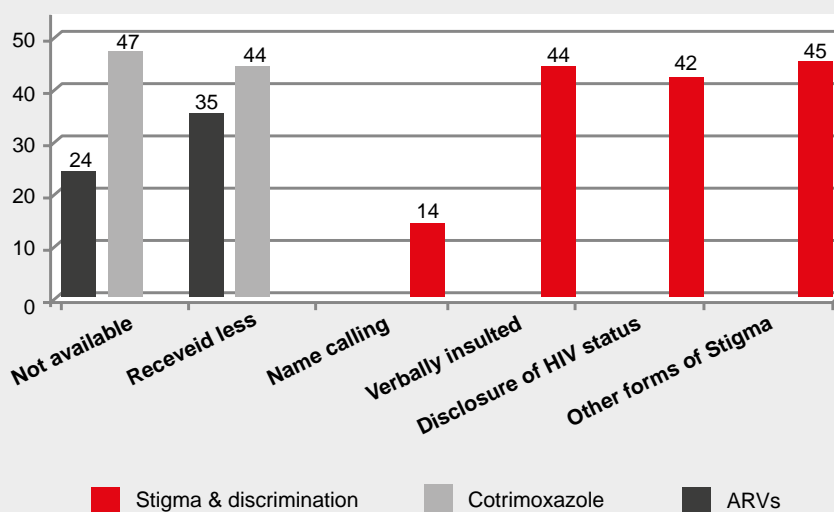
Although the supply chain in Malawi has shown to be robust in providing ART to facilities, it has shown insufficient flexibility in allowing implementation of community distribution of ART by patients. Models of community ART delivery are central to addressing increasing numbers of patients in chronic care and sustaining a successful quality ART program.

ROLE OF PATIENTS AND CIVIL SOCIETY

In July 2014, the Malawi Network of People Living with HIV/AIDS (MANET+) reported stockouts affecting patients in Phalombe district for several days. Initially the findings were not acknowledged by MoH. In reaction MANET + performed an on-site investigation, confirming that patients were being sent home with insufficient supplies and health centres workers were redistributing ARVs to cope with the shortages. Reasons given were increasing patient numbers due to earlier initiation and increased influx of Mozambican patients, combined with late delivery of supplies and inadequate reaction by health facility staff. After MANET + published a position paper, action was taken by the MoH and the stockouts were resolved⁶⁴.

Since April 2015, the National Association for People living with HIV/AIDS in Malawi (NAPHAM), a member organisation of MANET +, has started monitoring and reporting on access to ARVs and cotrimoxazole in health facilities across the country. Building on an established network of people living with HIV, representatives in different districts have been equipped with mobile phones to report stockouts, shortages and cases related to discrimination and stigma of people living with HIV. Reported cases are being followed up and verified by network members. Figure x shows cases as reported per category in April and May 2015.

Figure 7: Reports received between 9 April and 20 May 2015



Most cases have not yet been verified. Preliminary verification results show that 'less ARVs' often means a one month refill instead of three months for patients who need adherence counseling. Real ARV shortages were confirmed in four health centres. Cotrimoxazole shortages and stockouts were confirmed in seven different health centres, where health care workers rationed tablets because insufficient supplies had been received. All confirmed cases of shortages have meanwhile been solved. With already high rates of reporting and problems solved in the first month of the project, these monitoring activities by engaging patients at health facility levels promise to have a significant impact in improving services for people living with HIV in Malawi. Improvement is needed for verification of the cases and active advocacy through mobilisation of district and national representatives. Donor support to this initiative has stopped in June 2015 and NAPHAM is currently looking for funding to continue to fulfil this patient watchdog role.



KEY RECOMMENDATIONS

- Allow task-shifting of dispensing and distribution of medicines to lay workers and patients to ensure implementation of community models of care.
- Monitor and evaluate supply chain efficiency using robust data collection systems measuring access to ART treatment at patient level and make causal links to ART scale-up and adherence.
- Ensure increased and timely visibility on facility stock levels, coordination and reaction to shortages in critical periods of regimen transitions.
- Apply lessons learned from the vertical ART supply chain to other supply chains, to bring them up to the same level of efficiency, rather than focusing on complete supply chain integration.
- Continue support to NAPHAM and other patient-, civil society- and community-based organisations to actively understand, monitor, contribute to and flag issues relating to their access to critical medication. The reporting data should be used as a parallel source of information to complement internal monitoring mechanisms.

Table 9: Supply chain indicators for Mozambique

| | | |
|-----------------------------------|---|---|
| HIV response | PLHIV (million) | 1.6 ⁶⁵ |
| | Adult HIV prevalence | 11.5% ⁶⁶ |
| | ART coverage under WHO 2015 guidelines | 45% ⁶⁷ (of all HIV positive patient, 2015 ¹) |
| | Scale-up assumptions | 81% coverage by 2017 ⁶⁸ |
| | Adult retention at 12 months | 67% ⁶⁹ |
| ART Supply chain | ARV funding | GFATM/PEPFAR |
| | Procurement body | CMAM through GFATM PPM /PEPFAR PFSCM |
| | Distribution model | Informed push system |
| | Number of levels in the chain (incl. CMS and health facilities) | 4 |
| | Delivery frequency | Monthly |
| | Nationwide facility consumption data collection system in place | Yes, monthly MMIA |
| | Theoretical buffer stock at facility | 1 month |
| | Private sector involvement in supply chain | Distribution |
| | Regular organised distribution to facilities (last mile delivery) | No |
| | External observers of supply chain | Yes CIP, JAM in Tete Province |
| Supply chain flexibilities | Refill frequency | 3 months in national guidelines, not yet implemented November 2015 |
| | Task shifting of distribution and/or refill of ART to lay workers or patients | CAGs are part of national strategy ⁷⁰ , ART fast-track |

SUPPLY CHAIN

The Mozambican system for ordering and supply of ARVs is based on a monthly report on ARV consumption and patients per regimen (Mapa Mensal de Informação ARV; MMIA) made by the pharmacy responsible at health facility level. These reports physically travel up the chain through district and provincial compilation before being sent electronically to the Central de Medicamentos e Artigos Medicos (Central store for medicines and medical items; CMAM). ARVs are delivered monthly to the provincial depots, destined for specific facilities. From there, transport is organised to the district. However, the last part of the distribution line is not systematic and relies on availability of district vehicles or health facility staff travelling to pick

the ARVs up at the district warehouse. In addition, amplification of delays and errors in orders at every intermediate level make it difficult to ensure a timely supply of the quantities needed for growing and changing patient numbers.

An estimated 68% of the Mozambican population lives in rural areas, relying on ARVs from facilities that are located at long distances from district storage facilities, only accessible via hours of driving on unpaved roads⁷¹. There are chronic shortages of vehicles at the district level and insufficient logistic capacity to ensure the needed/requested distribution planning, leading to an ad hoc distribution and leaving no flexibility for delivery of emergency supplies. Challenges

intensify during the yearly rainy season, when roads may get flooded, cutting off access to some facilities and the patients they serve. While there are many factors causing delays in ordering and distribution, creating thus regular stockouts of critical supplies, the lack of the last-mile transport is a significant contributor. With Mozambique's vast geography, reliable and regular distribution of essential medicines until the last mile is crucial for rural health facilities to avoid stockouts affecting patients⁷².

The Strategic Plan for Pharmaceutical Logistics (PELF) approved in 2013, aims at improving the national supply chain to ensure uninterrupted supplies of essential medicines for patients over a ten year plan. The status of the CMAM has changed to a full department within the Ministry of health, providing it more autonomy and financial and managerial flexibility. This new department will assume the responsibility to ensure availability of medicines at the last level. The PELF also aims at moving away from administrative networks by reducing the number of warehouses in the country from 154 provincial and district warehouses to 30 regional warehouses. The PELF foresees an electronic medicines order systems and transport of all health products to all levels of the chain in the most cost-effective way^{73,74}. These interventions are likely to have an important impact on the improvement of medicines availability, when implemented. However, the budget provisions for its implementation amounts to 120 million dollars over 11 years. At this moment it is unclear how the PELF will be funded.

Progress has been made by CMAM and supporting partners to ensure national availability of ARVs. Regular coordination meetings take place to analyse pipelines and shortages and coordinate response when necessary. Still, unanticipated national ARVs stockouts occur.

Although viral load scale-up is still limited, it has resulted in increasing patient numbers in need of second line regimens. In the middle of 2014, standard second line treatment experienced a national shortage, preventing new initiation for patients failing under the first line regimen.

When second line syrup for children was out of stock nationally early 2015, MSF managed through coordination with CMAM to exceptionally

import the syrup from a private supplier in South Africa.

When Mozambique implemented the WHO-recommended first line regimens for adults (TDF/3TC/EFV), the previously used regimen (AZT/3TC/NVP) ran out of stock nationally. Exceptionally ARVs were borrowed from the MoH in Zimbabwe to cope with the national shortage.

While these ad hoc measures are welcome to deal with specific situations, there is still presently no clear emergency mechanism for emergency orders when there is a public health need. The successful example of regional redistribution from Zimbabwe should not remain only an exceptional stop-gap measure. Ongoing communication on national stock levels and exchange of medicines between countries could, when well-coordinated, alleviate unavoidable emergency situations.



Counselor Raja Simone Reis meets with five Community ART Group members and their children under a baobab tree in Changara, Tete, Mozambique. Poor infrastructure in rural Mozambique plays a role in stock outs.

The Mozambican government has made notable progress in the fight against HIV/AIDS in the past years, in large part by increasing access to ART. Implementation of the National Acceleration Plan increased access to care, support, and ART to over 700,000 people by June 2015, compared with 497,000 by end of 2013. Despite these efforts, only 45% of all adults living with HIV were on ART by the June 2015 according to the National AIDS report⁷⁵. Patient outcomes are of important concern, with results of viral load testing in Manhica district hospital showing that 35% of patients had a detectable viral load. Of those, 89% showed HIV drug resistance⁷⁶. Preliminary data from Tete Province show that 40.9% of patients with a result available in Changara district had a viral load above 1000 copies/ml. Of a sample of 30 of those patients, 93% indicated drug resistance. Although the provision of three month refills for stable patients is part of the national strategy⁷⁷, national supply insecurity has not yet allowed its roll-out.



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STOCKOUT MONITORING

On a monthly basis, the MMIA reports show ARV stock levels in the health facility at the moment the report is written. These 'snapshot' data are used at national level for ARV stockouts reporting. Although they provide an indication of historical stockouts, they do not allow real time stockout reporting and the necessary response. In 2014, a study conducted in Sofala province on availability of essential medicines revealed that only one out of 26 HCs visited had all the 15 items in stock⁷⁸. In the same year, a study performed by Village Reach in 15 facilities in Cabo Delgado Province revealed substantial levels of stockouts of rapid tests to diagnose malaria⁷⁹. Both studies were performed in collaboration with MoH.

MSF teams, in close collaboration with the respective provincial authorities, have been regularly monitoring availability of key medicines since November 2013 in 17 health centres in Maputo City (7) and Tete (10) province. MSF is present in these areas with supportive pharmacy staff, means of transport and a buffer stock for key medicines to react to problems encountered. Stockouts are defined as the absence of the medicines at health facility level. MSF pharmacy support staff collected information on the availability of a tracer check list of 10 ARVs and some other medicines used primarily for treatment of HIV and TB patients from January to June 2015 (table 10).

Table 10: Monitored ARVs

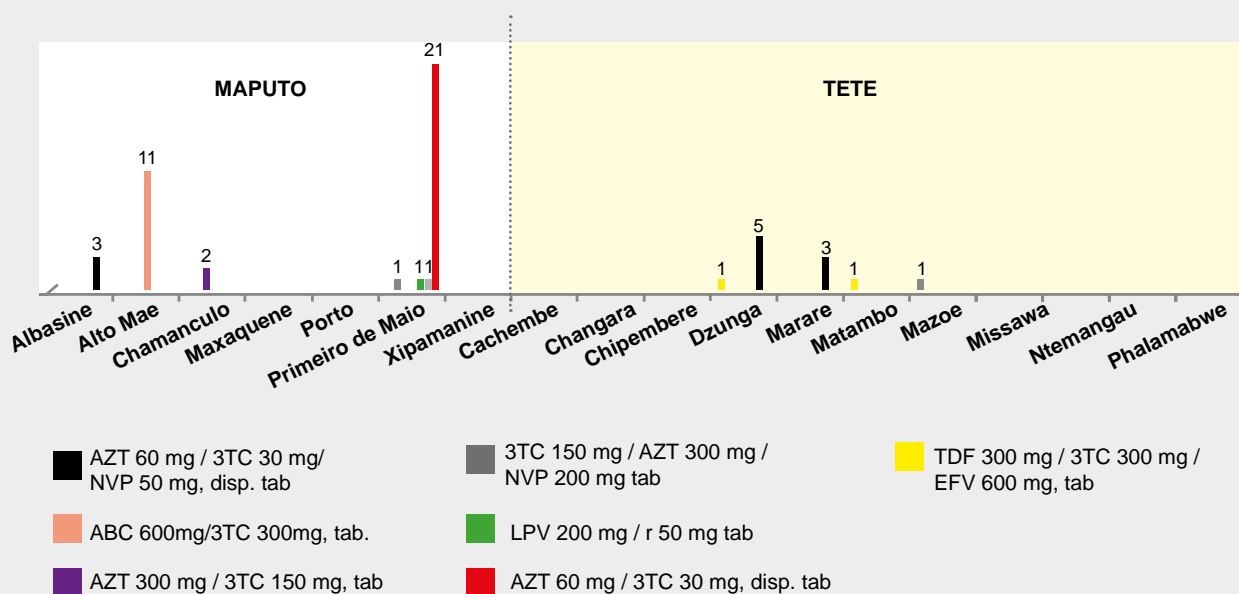
| |
|--|
| Adult ARVs |
| TDF 300 mg / 3TC 300 mg / EFV 600 mg, tab |
| 3TC 150 mg / AZT 300 mg / NVP 200 mg tab |
| AZT 300 mg / 3TC 150 mg, tab |
| TDF 300 mg / 3TC 300 mg, tab. |
| ABC 300 mg / 3TC 300 mg, tab. |
| EFAVIRENZ (EFV or EFZ), 600 mg, tab |
| LPV 200 mg / r 50 mg tab |
| Pediatric ARVs |
| AZT 60 mg / 3TC 30 mg/ NVP 50 mg, disp. Tab |
| AZT 60 mg / 3TC 30 mg, disp. Tab |
| LPV / r 80/20mg/ml, oral solution, 60ml |

Data were collected from physical stock counts, stock cards and MMIA order forms. When a stockout or shortage interruption or was encountered, MSF teams tried to accelerate the distribution by following up on supplies at different levels of the chain. MSF reacted with donations or loans of medicines, or transport or support with in the ordering process. Impact of ARV stockouts on patients is quantified as follows: We assume 30 days in a month and monthly ART visits for those patients on the regimens affected by stockouts. The number of patients on each regimen is divided by 30 to estimate how many patients visited the health centre each day and multiplied by the days of stockout to estimate the number of patients affected. Of those patients, it is assumed that they show up to the health centre on average in the middle of the stockout and do not have access to their ARVs until the end of the stockout. Depending on the size of the cohort affected and the duration of the stockout, the DDL, or the estimated total number of days the concerned patients did not have access to ARVs, is calculated (table 11). When a stockout risk was identified and the stockout was avoided through redistribution of medicines in between health facilities, this was not included in the impact analysis.

Table 11: Impact indicators

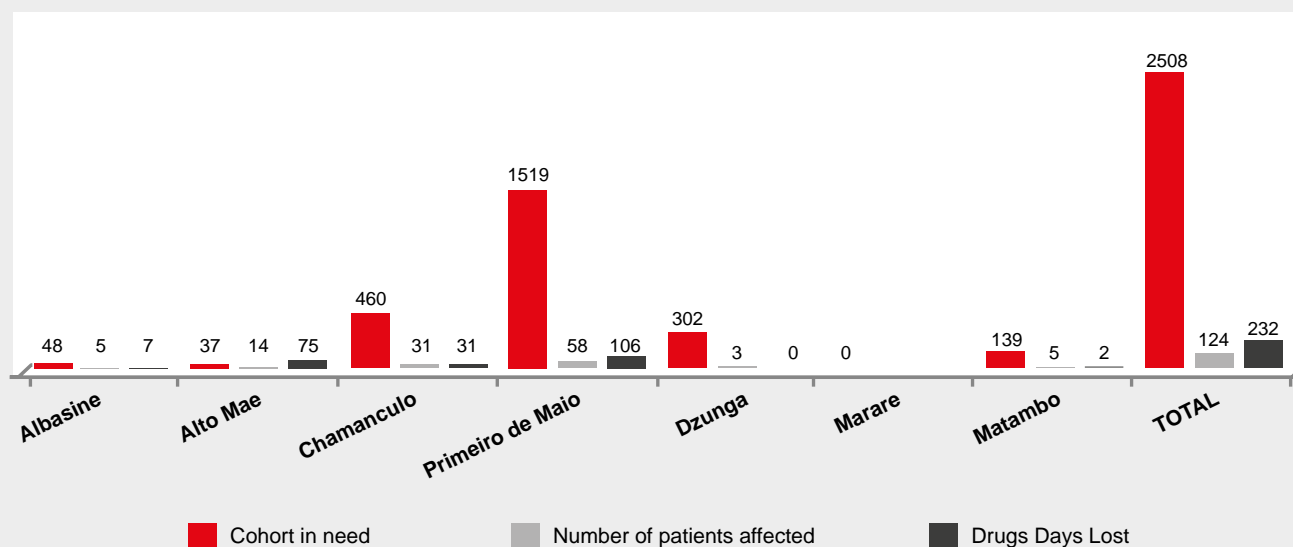
| Indicator | Formula |
|---|--|
| Cohort in need (C) | Sum of patients per HC in need of ARV out of stock |
| Number of patients affected (PA) | Sum of C/30 * Number of days with stockout |
| Drug days lost (DDL) | (Number of days with stockout/2)* PA |

Figure 8: Number of days reported Out of Stock per Formulation and per Health Centre from January until end of March 2015



From 17 monitored facilities, 7 (41%) reported at least one stockout of the monitored ARVs in both Q1 and Q2 of 2015. The average duration was 4.25 and 6.4 days in Q1 and Q2 respectively. 7 different ARVs were reported in Q1 and 6 in Q2. Only one out of all reported ARVs, the pediatric AZT/3TC, was out of stock nationally at the time of the monitoring. The data for Q1 are presented in figure 8.

Figure 9: Cohort in need, number of patients affected and Drug Days Lost per health centre with stockouts from January until March 2015.



Stockouts in health facilities over Q1 2015 are estimated to have impacted 124 patients. Cumulatively, the patients did not have access to the appropriate ARV for 232 days. The relative impact of the stockouts was mainly caused by the stockout of pediatric AZT/3TC in Primeiro di Maio (35% = 81/232 DDL) and adult ABC/3TC in Alto Mae (32% or 75/232 DDL). Pediatric AZT/3TC was out of stock at national level and MSF did not have buffer stock to fill the gap. The fixed dose combination ABC/3TC has recently been made available in Mozambique and is not yet included on the MMIA reports, causing errors in reporting and delay in delivery. In Q2 2015, stockouts in the monitored health facilities are estimated to have impacted on 60 patients. Cumulatively, the patients lacked access to the appropriate ARV for 626 days. The largest part of impact (89% or 555/626) was due to a stockout of adult ABC/3T in Alto Mae; the formulation that was not yet available on the MMIA form. The data for Q1 are presented in figure 9.

The data from six months of monitoring show that ARV stockouts happen regularly in different health facilities. When monitored and reacted to, as MSF did in Tete and Maputo, duration and impact can be limited. All but one formulation were available in country at the time of the stockout. In case of national stockouts or changing formulations, impact is higher and extra coordination, reporting and reaction to offer a valid clinical alternative is needed to limit the impact on patients. The findings suggest that ARV stockouts occur both

in rural and urban Mozambique. Despite active monitoring and reaction by MSF with transport and redistributions to prevent stockouts and limit their impact, they still take place. It is likely that impact of stockouts is higher in areas where MSF is not present.

Aside from ARVs, MSF teams also monitored 9 medicines for treatment and care of TB patients and 5 essential medicines for prevention and treatment of opportunistic infection and sexually transmittable illnesses (STI) in the same facilities. Results show that 18% of health facilities had at least one stockout of first or second line TB medicines for an average duration of 12 days (Q1 and Q2). TB medicines reported varied between first line, drug resistant TB medicines and medicines for side effect management like pyridoxine. In Q1 and Q2 respectively 6 and 31 DR-TB patients in the 17 health facilities are estimated to have been affected by stockouts. 59%-71% (Q1-Q2) of health facilities had at least one stockout of other selected essential antibiotics, of an average duration from 22 to 66 days. Although this report focuses mainly on the ARV supply chain, it is clear that stockouts are wide-spread over different supply lines. Long lasting stockouts of antibiotics for TB or STI treatment negatively impact the health of patients and the spread of antibiotic resistance.

MSF is currently in discussion with CMAM for a wider analysis of the availability of essential medicines and impact of stockouts on patients in all ART-providing facilities of Tete Province and Maputo City.

INNOVATIVE SOLUTIONS FOR SUPPLY CHAIN IMPROVEMENT

The concept of Community ART groups (CAGs) was born in rural Mozambique, where ART patients decided to form groups from the same community in order to take turns for medicines pick-ups. These patients share transport costs and discuss the challenges they face with their groups members when the medicines are distributed in the community. The Ministry of Health has included the CAG model as part of the national strategy,⁸⁰ thereby effectively delegating distribution and ART refill to patients. A qualitative study in Tete revealed that a robust supply system is a critical enabler to the sustainability of the CAGs⁸¹.

A pharmacy software system for ART dispensing is functional in three MSF supported health centres, of which two are in Maputo City and one in Beira City. The system allows patient identification with a unique barcode, rapid

dispensing by scanning the barcode and an electronic follow up of existing stock levels. The system has been improved to produce monthly MMAs and automatic alerts to show low stock levels and suggested order quantities. Use of the system has reduced the time spent on stock management, order preparation and dispensing, thereby helping to reduce patient waiting times and health worker workload. In addition, by identifying directly the medicines dispensed to a specific patient, the systems allows for a follow up of the ART cohort and a monitoring of patient adherence profiles.

Experience with mobile technology used to order ARVs in rural Mozambique has proven to reduce the delay in monthly reporting of stock levels and consumption, by eliminating the need for health care workers to travel for the delivery of their ARV orders⁸². Tablets have been introduced to some facilities in Tete province to replace paper stock cards, classically used for consumption follow up. Through real time data



transfer, district and provincial supply managers can determine if there are stockout risks at health facility level and intervene more rapidly. This intervention aims at reducing stockouts by improving the visibility at end-user level, by making order calculations easier and allowing for fast electronic ordering.

The International NGO Village Reach has previously tested a supply model for vaccines in the province of Cabo Delgado. A team drove around monthly to health centres with vaccines, collecting data on the spot and replacing the vaccines used, resulting in a reduction of stockout reported to less than 1% of supported facilities⁸³. In November 2015 Village Reach will start a similar project in Tete province, outsourcing the distribution of vaccines and ARVs to a private distributor for the last-mile delivery to peripheral health facilities. MSF and Village Reach will work together to analyse the impact of this intervention on the availability of ARVs and on the health of patients.



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ROLE OF PATIENTS AND CIVIL SOCIETY

Since 2014, the Mozambican civil society organisation Centro de Integridade Publica (CIP) has made a toll free number and a website available for anyone in Mozambique to report stockouts of all essential medicines. The reports are displayed publicly on the website and fuel regularly-published opinion pieces^{84,85}.

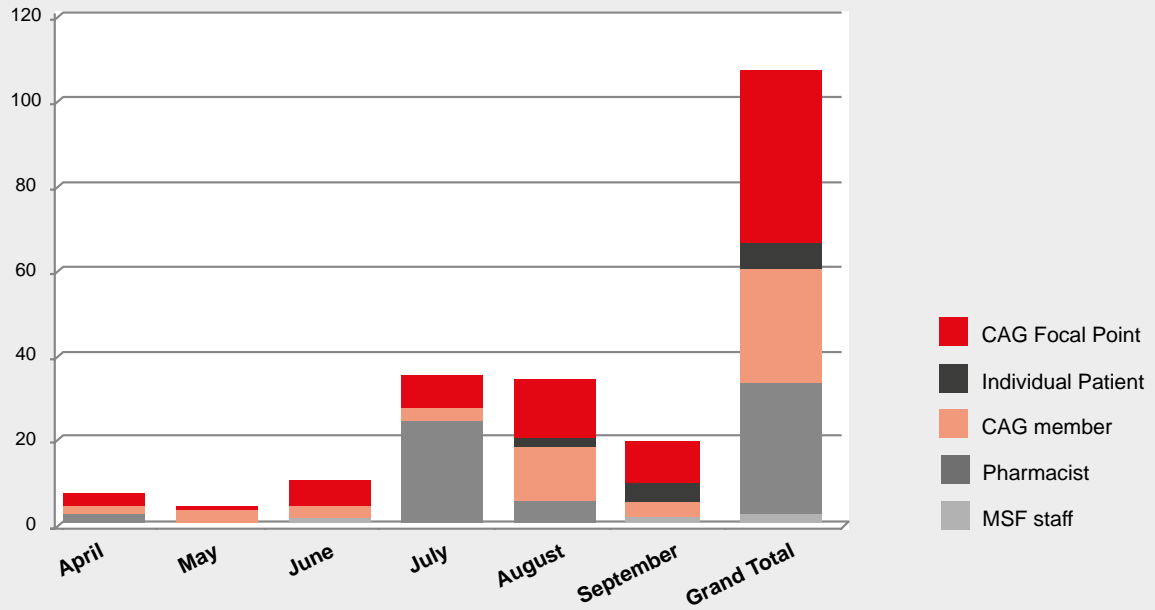
In June 2015, the Forum de Monitoria de Orçamento, a forum of Mozambican CBOs, shared a policy brief to launch a campaign for increased funding for the drug supply system. The document draws attention to multiple concerns, including an expenditure of only 7% of total health budget on supply and of the fact that 81% of all medicines are funded by external donors. The documents highlighted stockouts as major barriers to access to quality health services⁸⁶.

In the rural province of Tete, MSF is working with the Provincial Direction of Health on a project, named “Juntos Pelo Acesso aos Medicamentos” (JAM). The JAM engages people living with HIV, most of who are members of CAGs, to report and solve stockouts and to advocate for improved access to medicines. Patients and health care workers can report by calling a toll free number or by filling in reporting cards. Patient representatives follow the problems along the chain of supply and push for quick resolution. Patients and CAG members are trained on concepts such as the right to health care, the functioning of the supply chain and the importance of uninterrupted access to medicines. Existing community consultation forums are used to address facility- and district-specific problems.

“When the health center was out of stock, the staff told me that they were supposed to have received the medicines but the delivery was late, so I ended up buying them at the private pharmacy. I was very dissatisfied by this lack of information: I knew that without drugs I was running the risk to end up with full blown AIDS. So I reported the incident to the JAM hotline and a few days after they called me to say that the drugs were available for me to pick up”.

Joao Braquinho, Moatize, Mozambique.

Figure 10: Number of reports per month and profile of person reporting



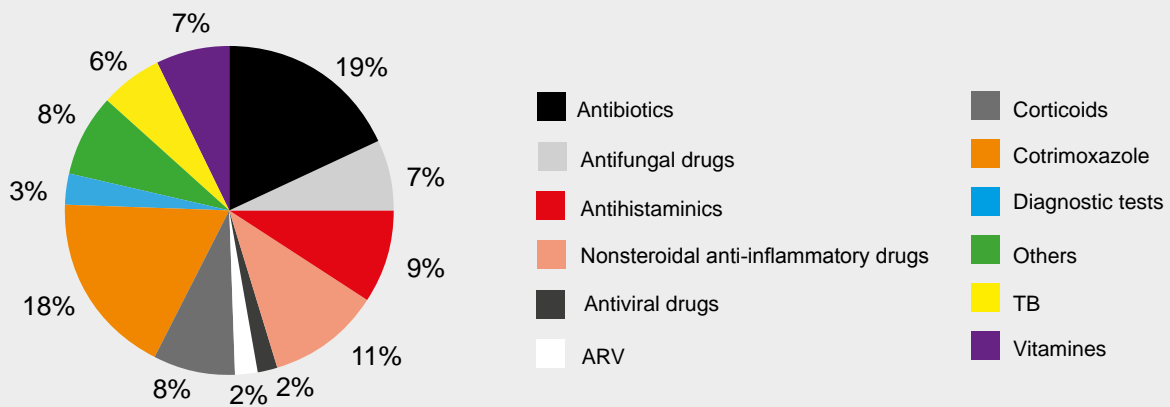
Currently with patients of only five health facilities trained, a total of 109 stockout reports have been received, mainly sent out by CAG members but also by facility pharmacists.

Of the 109 reported cases, 95 have been solved (87%). The average duration was 1 day for ARVs (2 cases), 2 days for TB medicines and 7 days for other medicines.

Antibiotics were most reported out-of-stock, particularly cotrimoxazole, an important antibiotic for the prevention and treatment of opportunistic infections in PLHIV.

Although the patients reporting are mainly people living with HIV, ARVs and TB medicines represent only 8% of the reported stockouts. In several cases, patients arranged their own transport in order to pick up the medicines for the facility in the district warehouses.

Figure 11: Reports per type of medicines reported out of stock



Before the end of 2015, the project will expand further into more rural areas in Tete province.



KEY RECOMMENDATIONS

- Include supply chain in all medicine funding initiatives along with all related operational costs required for drug provision. This includes, but is not limited to, last mile delivery costs and national and buffer stock to respond quickly to local and national shortages and to allow for multiple month refill.
- Ensure timely emergency importations, possibly through an optimised regional coordination and information sharing on overstocks and shortages.
- Monitor and evaluate supply chain efficiency using robust data collection systems measuring access to ART treatment at patient level and make causal links to ART scale-up and adherence.
- Accelerate implementation and ensure funding for the National Strategic Plan on Pharmaceutical Logistics
- Enable and support patients, civil society and community-based organisations to actively understand, monitor, contribute to and flag issues relating to their access to critical medication. The reporting data should be used as a parallel source of information to complement internal monitoring mechanisms.

“Once I was told that there was no cotrimoxazole at the pharmacy. My aunt lent me 14 of her tablets to tie me over. At the time I didn’t report the problem to anyone because I had no idea I could do so. But if that were to happen again I would not hesitate to report it through the JAM hotline. I’m not afraid to do it openly because I know it is my right to receive my medicine. In fact me and my friends from the community ART group have already reported stock outs through the hotline”.

Ana-Bela Fernando Mucuala, from Changara, Tete province

Table 12: Supply chain indicators for South Africa

| | | |
|------------------------------------|---|--|
| HIV response | PLHIV (million) | 6.4 ⁸⁷ |
| | Adult HIV prevalence | 19.1% ⁸⁸ |
| | ART coverage under WHO 2013 guidelines | 48% ⁸⁹ (2015) |
| | Scale-up assumptions | 81% coverage by 2020 |
| | Adult retention at 12 months | 72% ⁹⁰ |
| ART Supply chain | ARV funding | NDoH/GFATM (10%) |
| | Procurement body | NDoH subcontracting private suppliers |
| | Distribution model | Mainly pull systems, but also direct delivery, CDU, CCMDD in specific sites |
| | Number of levels in the chain (incl. CMS and health facilities) | Variable |
| | Delivery frequency | Variable |
| | Nationwide facility consumption data collection system in place | Site dependent |
| | Theoretical buffer stock at facility | Variable |
| | Private sector involvement in supply chain | Procurement, Production, Warehousing, Dispensing, Distribution |
| | Regular organised distribution to facilities (last mile delivery) | Variable |
| External observers of supply chain | Yes, Stop StockOut project | |
| Supply chain flexibilities | Refill frequency | 3 months not opposed by NdoH circular in 2010 ⁹¹ , but not widely implemented |
| | Task shifting of distribution and/or refill of ART to lay workers or patients | CAGs, community and facility adherence CLUBS |

SUPPLY CHAIN

South Africa has the largest HIV treatment program in the world, with 3.1 people on treatment (DHIS, March 2015)⁹². Implementation of WHO's newest guidelines would lead to 6.8 million people being eligible for treatment. Without appropriate investment and support, the task of doubling the number of people maintained on treatment will strain an already stretched system.

The South African supply chain management is decentralised, leading to vertical fragmentation. Each of the nine provinces has its own medicine depot, with the exception of the Eastern Cape which has two depots. The different provincial authorities are responsible for their own supplier contract management, distribution networks, ordering procedures, forecasting, and

software systems. This means that there is no one national system to consolidate consumption figures with patient cohort data. This in turn makes national quantification of ART numbers and national forecasting difficult.

ARVs in South Africa are almost exclusively procured by the National Department of Health (NDoH) from local manufacturers or their local distributors. Recently supplier contract management has changed, and suppliers can be fined for non-compliance. The country is moving further towards direct delivery models, passing the responsibility for supply chain performance to private manufacturers and distributors rather than with government facility personnel. NDoH has agreed to tackle stockouts as a priority including initial supply chain indicators in its annual plans. The NDoH attempted to provide an

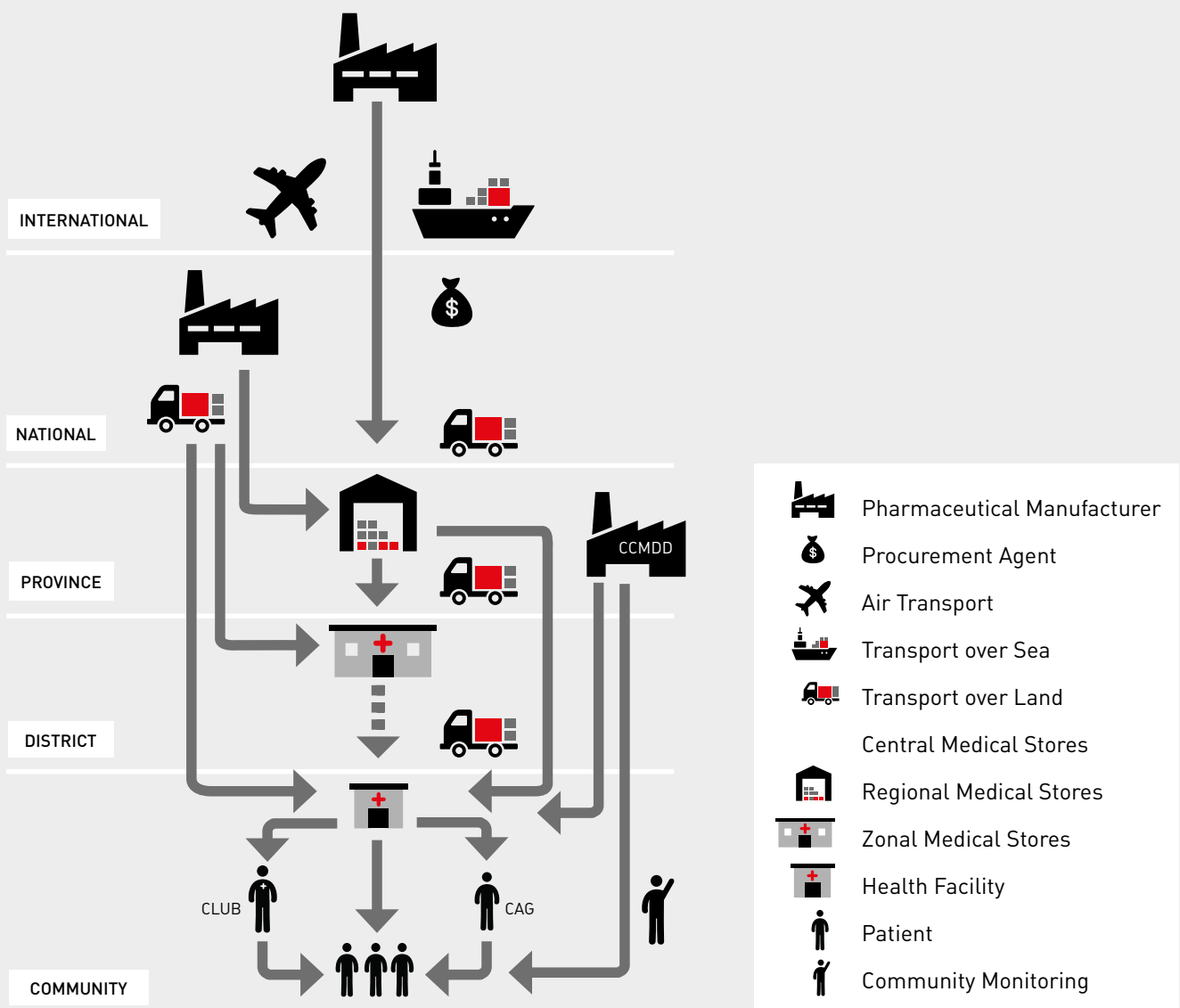
early warning system and published a list with national stockouts and shortages on its website; however this initiative to increase transparency was discontinued.

National stockouts of ARVs have occurred on multiple occasions in the past few years. During the roll-out of a single tablet first line option for adult patients (TDF/3TC/EFV), simultaneously with guideline changes to earlier initiation of patients following WHO 2013 guidelines, massive switches in treatment, including an earlier initiation scale-up, caused national stockouts and shortages for over half a year. In 2014 there were national stockouts of NVP syrup to prevent HIV in children born from HIV positive mothers. These children received AZT syrup instead, a less

optimal ARV with a higher chance of side effects. In May 2015, national stockouts of different ABC formulations for adult and children occurred. Through exceptional importation, the situation stabilised at facilities after several months.

South Africa's current system for granting and protecting patent rights limits the government's ability to respond quickly to medicine stockouts caused by a single supplier's failure to meet demand. Pharmaceutical company AbbVie holds multiple patents on LPV/r formulations in South Africa, which block generic competitors from entering the market. While other countries have rejected LPV/r patents, South Africa does not examine patent applications to ensure patents meet national criteria and are truly deserved.

THE ART SUPPLY CHAIN IN SOUTH AFRICA



Over the course of 2015, AbbVie failed to supply the needed quantities of LPV/r adult tablets, a formulation needed for second line treatment of over 155,000 patients country wide. Although other quality-assured generic manufacturers already have local registration of LPV/r products, AbbVie has refused to grant licenses on its patent rights for these products which could facilitate generic supply to countries like South Africa. Governments can act to override patent barriers and permit generic supply when companies cannot supply adequate quantities of medicines, by issuing compulsory licenses, including licenses for public non-commercial use. In South Africa, however, issuing compulsory licenses is a process that can require a court decision, if the patent holder is not willing to cooperate with the licensing terms. AbbVie has opened new production sites to supply the South African market, and claimed to have alleviated the supply situation in October 2015, after over six months of shortages. However, over 9% of 796 facilities contacted in four provinces in October were still experiencing LPV/r stock outs.

In a reaction to civil society and media reports of ongoing, chronic and systematic ARV stockouts in April 2015, the Minister of Health stated that South Africa would find a way to allow for emergency importation of medicines with a WHO prequalification label. Presently, the Medicines Control Council (MCC), the drug regulatory body, does not have a procedure for quicker registration of medicines that have already been recognised by other globally-recognised stringent regulatory authorities, such as the FDA. The MCC registration procedure can take as long as two to three years, and information on registrations in process are not publicly available. There is a need for increased transparency on current processes and increased openness to implement urgent measures and recognise internationally validated sources, especially in emergency situations. The creation of the South African Health Products Regulatory Authority (SAHPRA) to replace the MCC might improve future registration procedures⁹³.

Although the provision of multiple months refill for stable patients is not opposed by legislation, it is currently not widely implemented in South Africa due to reluctance by pharmacy personnel and the Department of Health. Current pharmaceutical legislation also restricts the prescribing of medicines to cover a six month period, blocking the possibility of having fewer clinical visits to coincide with yearly viral load testing guidelines for stable ART patients. In a country where pharmacists and doctors are a scarcity and patient numbers are exploding, there is an urgent need for pharmacists to start proactively promoting and implementing flexibilities to allow task shifting in prescribing, dispensing and distribution of medicines.

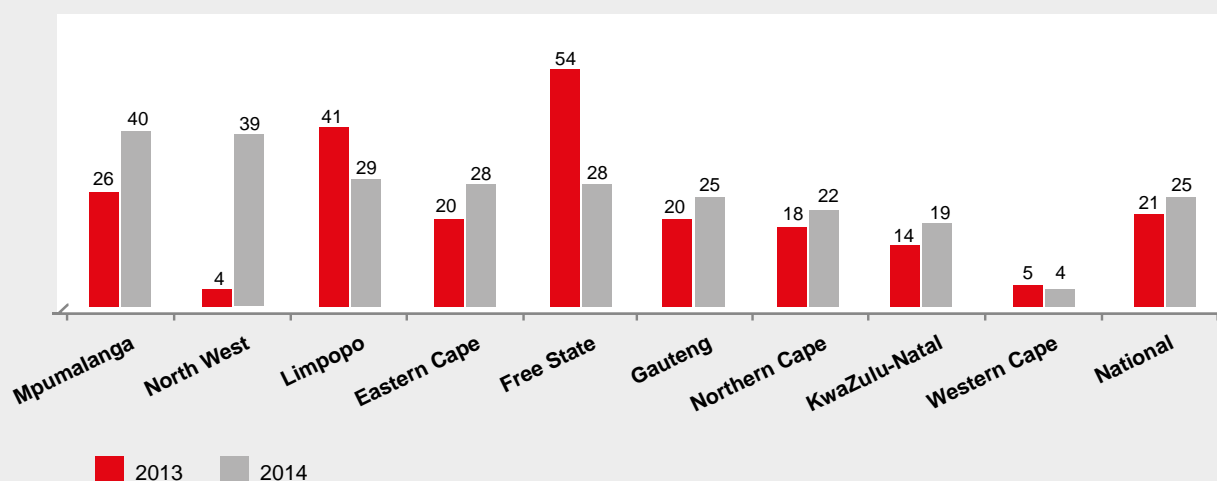
STOCKOUT MONITORING

As there is no common national consumption follow up system, and stockouts are not regularly monitored at facility level. A stock visibility system providing data on the scope of stockouts at facility level is currently being implemented⁹⁴.

The Stop Stockouts Project (SSP), an independent consortium of civil society actors, has undertaken yearly national stockout surveys since 2013. This telephonic survey attempts to reach all health facilities nationwide (3732 identified) and is conducted during the fourth quarter of each year. The survey collects data on the availability of ARVs, TB medicines, vaccines and essential tracer medicines. In 2013 and 2014 respectively 91% and 87% of facilities that were contactable by telephone after four attempts participated in the survey.

In 2013, 21% (449) of the 2139 participating facilities experienced at least one ARV and/or TB medicine stockout during the three month survey period; 19% reported ARV stockouts and 3% TB medicines stockouts. In 20% of affected facilities, patients were turned away without even a small supply or any alternative treatment. In 2014, 25% (614) of the 2454 participating facilities reported at least one ARV and/or TB medicine stockout during the three month survey period.

Table 13: Proportion of facilities by province for 2013 and 2014 reporting at least one ARV/TB stockout in the three months period prior to contact.

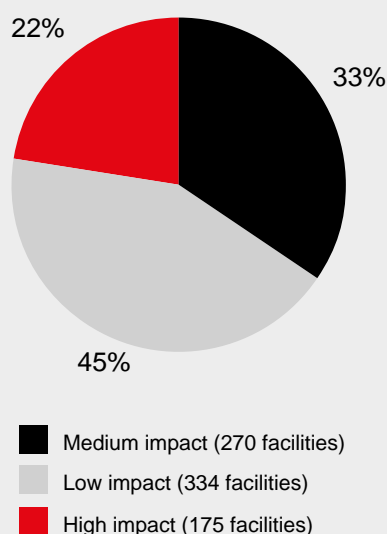


In 2014, the first line adult fixed dose formulation (TDF/3TC/EFV) was available in more facilities as compared to 2013. While 75/614 facilities reported stockouts, only 18 facilities sent patients home with a smaller supply and 9 facilities sent patients home with no supply of this drug. However, there were frequent stockouts of other first line ARVs, second line ARVs, paediatric ARVs, isoniazid preventive treatment (IPT) for TB, and treatment for complicated TB. Specific geographic areas (5 provinces and 7 districts) were more largely affected by stockouts, indicating in-country, downstream management, accountability and supply chain challenges. The provinces which experienced the majority of ARV and/or TB stockouts were: Mpumalanga (40% of facilities experiencing an ARV/TB stockout), North West (39% of facilities experiencing an ARV/TB stockout), Limpopo (29% of facilities experiencing an ARV/TB stockout), Eastern Cape (28% of facilities experiencing an ARV/TB stockout) and Free State (28% of facilities experiencing an ARV/TB stockout). Specifically, seven districts were especially hardly hit with more than 40% of facilities in those districts experiencing stockouts.



A Stop Stockouts (SSP) activist at an activist meeting in Soshanguve, a township outside of Pretoria on April 16, 2015.

Figure 12: Impact of ARV/TB stockouts



Nationwide in 2014, 22% of the cases where an ARV/TB medicine was reported out of stock, the patient was sent home with no medication (high impact), compared to 20% in 2013. In 35% (230/779) of cases the patient was either given a smaller supply, their pill burden was increased or a less than optimal medicine was given (medium impact). In 43% (334/779) of stockouts reported the facility was able to borrow medicine and the patient went home with their full supply of treatment (low impact).

Of all stockouts reported nationwide, 32% lasted longer than one month, 43% lasted between one and four weeks and 25% were resolved within the week. The 2014 survey has shown that less than 30% of all stocks monitored were related to national shortages or stockouts and the majority of medicines out of stock were most likely caused by in-country downstream challenges.

With the release of the data in April 2015, a number of recommendations were made to the NDoH, including: focusing on investigating bottlenecks and reducing impact in the seven worst performing districts; establishment of a standardised national minimum standard metrics for supply chain functioning and stockout resolution time frames for provinces; and the development of provincial action plans with timeframes focusing on four main areas: governance and accountability, increased visibility and surveillance, rapid response mechanisms and supply chain reforms and strengthening. Five provinces engaged in

constructive dialogue with the civil society and submitted action plans to tackle the stockout situation. Besides ARVs and TB medicines, the SSP also monitors vaccines and tracer essential medicines in its 2014 and 2015 survey. In 2014, 12% of facilities reported stockouts of at least one childhood vaccine (measles, rotavirus or pentaxim) on the day they participated in the survey. Stockouts on the day of survey contact of other tracer items include salbutamol inhaler (12% of facilities) and sodium valproate (7% of facilities).

A third national survey is ongoing during the fourth quarter of 2015.

INNOVATIVE SOLUTIONS FOR SUPPLY CHAIN IMPROVEMENT

MSF has started implementation of a model of clubs in South Africa since 2007 in order to provide patients with an alternative, quicker and closer-to-home model of care for screening and medicine pick-up. In this innovative model, pre-packed ARVs are delivered by lay workers to patients who meet every two months in groups of 30, and only have one clinical visit per year with a nurse or doctor. Clubs meet either close to the facility or in community centers.

The GFATM is funding the roll-out of adherence clubs for stable patients on antiretroviral therapy in South Africa. This alternative model of delivery of ART is essential to achieve scale-up whilst minimising the burden on the health system and providing adherence support by peers, yet it necessitates a robust supply chain to ensure minimal risk of treatment interruption.

The government of the Western Cape, one of South Africa's provinces, has outsourced dispensing and distribution of chronic medicines to a private company. Scripts are collected at the health facilities, checked for conformity with national treatment guidelines and the medicines, including ARV, are ordered, pre-packed and delivered back to the health facility in a patient-specific labelled bag. The model has shown to improve disease management, reduce patient waiting times and facility workload, and increased patient satisfaction^{95, 96, 97}.

Taking this model further, private actors have been engaged in other provinces to deliver these prepacks to alternative pick up points in the community that are either easier or more acceptable to access. The pick-up points can vary among private retail pharmacies, supermarkets, community halls, community club meetings and even patients' homes.

For distribution, the NDoH is outsourcing increasingly to private distributors who deliver straight to the facilities, thereby effectively reducing the storage levels in the supply chain. To avoid having a number of companies driving long distances to arrive at the same facility, cross docking stations have been introduced. In these stations medicines from different companies, labelled for specific facilities, are stored in a cage until transport provides the full package for a certain facility. These cross docking stations do not require pharmacists or complicated handling of medicines. A central data control tower has been created, manned with logistical experts to interpret all available country data and move towards a push system, in which decision-making on supplied facility quantities is no longer the responsibility of an overburdened health care worker but is managed centrally⁹⁸.

A new model of Remote Automated Dispensing Units is being piloted, a vendor machine for patients to access their medicines with a unique ID card or a patient barcode. A pharmacist is available through a television screen to provide pharmaceutical advice and monitor the functioning⁹⁹.

Although South Africa is clearly pushing innovation, there is a long way to go to ensure countrywide last mile delivery and full visibility across the supply chain. As stockouts at facility level have been shown to be worse today than they were in 2013, it remains to be seen how the proposed innovations will decrease stockouts at the last level and benefit the patients.

ROLE OF PATIENTS AND CIVIL SOCIETY

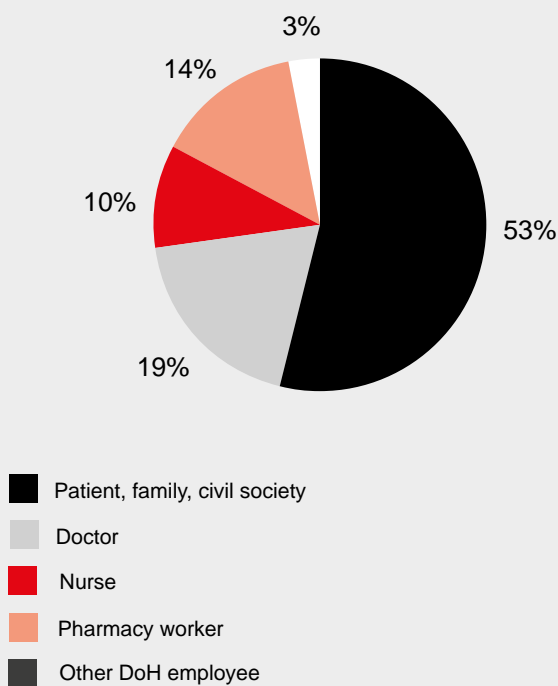
Ongoing problems experienced by the under-resourced depot of Mthatha (located in one of the nine provinces – Eastern Cape) reached crisis point in September 2012 when contract employees embarked on an unprotected strike. The crisis affected over 300 clinics and 100 000 patients on ARV treatment in the area. MSF and the Treatment Action Campaign (TAC) were requested to intervene by the DoH to assist with stock reception, order processing and deliveries to affected health care facilities. Additionally, TAC set up and maintained a stockout monitoring network to help prioritise the distribution of essential medication to those facilities that were most in need. The depot was handed back over to the DoH in January 2013. In a follow-up survey conducted in the area served by this provincial depot in May of 2013, it was found that thousands of HIV and TB patient's lives remained at risk with stockouts and shortages becoming a chronic crisis in the area of the Eastern Cape supplied by the Mthatha depot. 40% of the surveyed facilities had suffered either ARV or TB stockouts in the 3 months preceding the survey and 24% of them reported ongoing stockouts. 64% of the facilities referred patients elsewhere and only 7% of the facilities were able to provide their patients with alternative treatment in the interim.

During this time, in parallel, a consortium of concerned organisations met to co-ordinate efforts and created the Stop Stockouts Project (SSP). This project monitors the availability of essential medicines nationwide and addresses medication stockouts when they occur. All organisations have been actively involved in receiving reports from patients and healthcare workers for decades and working on the ground to investigate and resolve bottlenecks. The consortium includes the Rural Health Advocacy Project, the Southern African HIV Clinicians Society, the Rural Doctors Association of Southern Africa, the TAC, SECTION27 and MSF. These organisations represent health care workers, patients and legal activists whose members or beneficiaries are constantly experiencing the impact of stockouts.



The SSP accepts confidential reports of stockouts on a day-to-day basis through various free communication mechanisms (Please Call Me, web survey, SMS and Whatsapp) from anyone. Reported stockouts are verified with the facility and communicated to the responsible people along the supply line through an escalation protocol, agreed upon with the NDoH to push for a quick resolution and inform those accountable in DoH along the supply chain. Wide-spread and critical stockout cases are analysed more in depth and when not resolved are communicated through media and other advocacy strategies. When stockout cases are resolved, the stockout case manager closes the case and the original person reporting is contacted to confirm the resolution.

**Figure 13:
Breakdown of users of the SSP hotline.**



Between January and September 2015, 414 people reported stockouts, of which 47% were health care workers. 44% of stockouts reported were ART stockouts. The six consortium members use their vast network across the country to engage beneficiaries from all corners of the community to unite their voices to respond to stockouts. The Southern African HIV Clinicians Society has taken a role in issuing clinical guidance for health care workers in order

to provide the necessary alternative in case of stockouts. Through nationwide workshops, conducted by TAC trainers, patients and health care workers are informed on their rights to health care and medicines, basics of how a functioning supply chain should work and ways to report stockouts.

Citizen-based reporting used in parallel with internal government monitoring mechanisms should be considered as a valuable tool in complementing the efforts of public authorities and providing information on if NDoH if services have reached the end user. The availability of end-user data should allow for synergies with NDoH systems to (i) confirm signals of lack of medicine availability in areas where there are supply monitoring systems in place and (ii) provide information from areas where there is no visibility. End user independent data allows for transparent and accessible information to be used both by citizens and decision-makers to assess gaps in service delivery and resource allocation, determine the magnitude of the problem and identify health facilities where the lack of medication threatens the lives of patients. Civil society data provides for independent verification and serves as a check and balance to internal DoH monitoring mechanisms, thus ensuring transparency and accountability in the delivery of medicines.

Partnerships and relationships between activists and enlightened individuals in government have played a critical role in the initial response to HIV in the face of denial, stigma, and lack of funding. The voice of the patient continues to be the key in holding governments accountable. However, as access increases, the perception of urgency and emergency has diminished. Activism around HIV has waned as funding decreases, especially in areas where transparency is lacking and negative reflections on the government can be suppressed.

This project, like other civil society initiatives, effectively pushing for transparency, governance and accountability of the South African health care system, needs the necessary resources and support to continue its groundbreaking work.



KEY RECOMMENDATIONS

- Conduct emergency investigation of causes of stockouts in seven worse performing districts, utilising standardised methods, and set up emergency response for both short- and long-term resolution.
- Work with civil society partners to utilise citizen-based data collected from patients and healthcare workers to complement internal government monitoring mechanisms
- Establish mechanisms that promote active communication and consultation with healthcare workers, patients and civil society. Issue timely communication from suppliers and DoH regarding shortages and recommended guidelines for clinicians to manage patients on a publicly available website.
- Overcome patent barriers on a short term to allow generic LPV/r supplies or alternative second-line treatment into the country and expedite national patent law reform.
- Monitor and evaluate supply chain efficiency using robust data collection systems measuring access to ART treatment at patient level and make causal links to ART scale-up and adherence.
- Accelerate the restructuring of the national drug regulatory for timely registration of key medicines and ensure full transparency on procedures and status of registration dossiers.
- Accelerate efforts to restructure the supply chain, prioritising nationwide visibility of facility stock levels and cohort data to guide quantification.
- Adapt legislation to allow effective task-shifting of dispensing and distribution of medicines and spaced refills aligned with the frequency of clinical visits.
- Evaluate, document and share experiences on innovative supply chain interventions, assessing them on availability of medicines for patients at facility-level.

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