ISSUE BRIEF

HIV STATUS? UNDETECTABLE

FOUR ESSENTIAL INTERVENTIONS TO IMPROVE HIV TREATMENT, SAVE LIVES, AND REDUCE TRANSMISSION

Today, nearly ten million people are receiving antiretroviral therapy (ART) in developing countries, but with an estimated additional 18 million people[1] eligible for treatment, the job is far from done. With the release of new ART guidelines in 2013,[2] the World Health Organization (WHO) has laid out a clear benchmark for the quality of care that national treatment programmes, treatment providers and donors should strive to achieve.

The challenge faced today by Médecins Sans Frontières/Doctors Without Borders (MSF) and other treatment providers is therefore two-fold: to scale up treatment at an ever-faster pace, and to ensure that those on treatment are achieving and maintaining 'undetectable' levels of HIV in their blood–an indication that the virus is optimally suppressed and no longer can attack the body's immune system.

To support this goal, the following four interventions should be prioritised: **earlier treatment, viral load monitoring, enhanced adherence support and increased rollout of community-based models of care.** This issue brief will use MSF's experience to illustrate how such interventions can help reach more people with treatment, helping them remain in care and attaining and maintaining undetectable viral load.

THE 2013 WHO ART GUIDELINES INCLUDE THE FOLLOWING RECOMMENDATIONS:

- Starting people on ART earlier in their disease progression (at a CD4 cell count of 500 cells/µl);
- Implementing more effective protocols to prevent mother-to-child transmission of HIV (PMTCT) that better benefit both baby and mother (lifelong ART for all HIV-positive pregnant mothers);
- Providing immediate treatment for all HIV-positive children under five years old;
- Scaling up viral load testing, the gold standard in HIV treatment monitoring; and
- Offering treatment to all HIV-positive people who have HIV-negative partners ('sero-discordant' couples), regardless of the status of their immune system.

To scale-up optimal ART, governments must fulfil their UN-brokered commitment from 2011 to contribute US$22–24 billion annually by 2015.[3] The cost of implementing the new WHO guidelines represents a marginal increase of 10% over this figure.[4]

1. EARLY TREATMENT SAVES LIVES AND HELPS PREVENT THE VIRUS FROM SPREADING

WHO recommends people be offered treatment when their CD4 cell count drops to 500 cells/µl, a change from its previous recommendation to wait until the immune system is further weakened, at a CD4 count of 350 cells/µl. Increasing evidence shows that earlier treatment keeps individuals healthier, while preventing irreversible damage to the immune system.[5, 6, 7] Earlier treatment is not only beneficial to people's own health, but by helping people achieve undetectable levels of HIV in their blood at an earlier point, the chance that the virus will be transmitted to others can also be reduced.

A number of countries are preparing to implement earlier initiation of ART, and these efforts should be supported, particularly in light of the fact that this will involve people being on treatment who may not yet feel ill, and therefore paying close attention to their adherence will be critical. MSF is also beginning to offer treatment to people at CD4 500 in some countries.

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2. VIRAL LOAD MONITORING IS THE BEST WAY TO MAKE SURE TREATMENT IS WORKING

Viral load testing is the gold standard for treatment monitoring and has long been routine in resource-rich settings. Measuring how many copies of virus are in the blood indicates how well the virus is being suppressed by ART. When people are doing well on their treatment, viral load monitoring ideally reveals an 'undetectable' level of virus in the blood (the virus is below the lower limit of test detection)–this is the state where people have the maximum impact of being on ART. Regular viral load monitoring (WHO recommends routine viral load monitoring six months after starting ART and then annually thereafter) can help people stay on track with their treatment, and knowing their status is 'undetectable' is an important motivating factor.

Viral load monitoring is crucial for detecting problems in two ways: First, it helps identify people who may be having trouble adhering to their treatment and need additional support to get back on track. Second, it helps identify people who are indeed failing their treatment and need to be switched to another set of medicines. Viral load monitoring can identify these problems much sooner than CD4 testing, as it tracks the replication of the virus in the blood as opposed to the immune response of the body, where CD4 count drop only happens a while after the virus has begun to replicate.[8] Waiting for the immune response to reveal problems, or for a person to show clinical signs of treatment failure, misses the ideal moment to make course corrections through adherence counselling or to make a necessary switch in treatment. In the worst-case scenario this could be too late altogether to save a person.

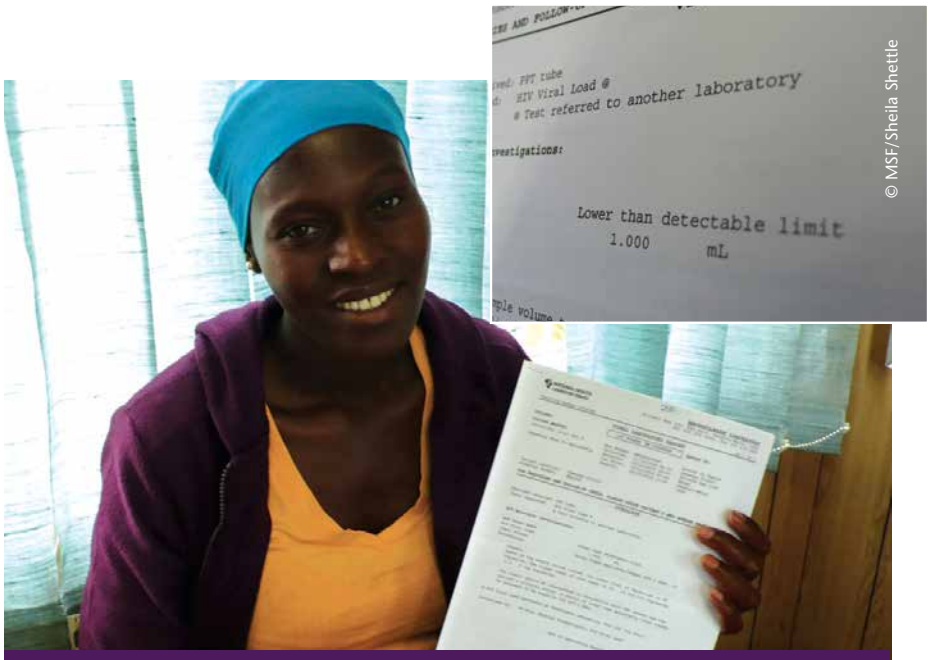
When viral load monitoring reveals that a person's HIV is at significantly detectable levels (above 1000 copies/ml), this sends an important signal to treatment providers to follow up with targeted adherence support. Viral load monitoring should be repeated three months after adherence interventions, in order to determine whether the intervention has helped get the person back on track, and ideally to undetectable levels, or whether it is in fact time to switch to alternative treatment because resistance to the medicines has developed. Treatment failure is under-diagnosed in low- and middle-income countries, with WHO estimating only 3% of people on ART receive second-line treatment. The estimated number of patients with virological failure worldwide in 2012 is however estimated to be one million people.[9]

Because viral load can more accurately detect whether a switch in treatment is necessary or not, it also helps prevent unnecessary switching to more expensive alternative treatment regimens. This is crucial, considering that in most resource-limited settings, only first- and second-line medicines are available, with limited or no treatment options if people fail second-line treatment. Salvage therapy for those failing second-line treatment, when available, costs nearly 15 times as much as first-line therapy in the poorest countries, with prices much higher in 'middle-income' developing countries.[10]

Due to cost and complexity, viral load monitoring to date has only been implemented in few places in resource-limited settings. A survey of 23 countries by MSF in 2012 revealed that while viral load was included in national treatment protocols in nearly all the countries, it was only actually available in four countries.[11] But with a growing number of viral load technologies being developed–including 'point-of-care' tests that can be used outside of laboratory settings–the price and complexity barriers can and must be overcome (see box). Additionally, innovative sample technologies and techniques, like dried blood spots and pooling of viral load samples to make sample transport easier and reduce the number of tests that need to be performed, respectively, make testing less costly and more feasible in rural areas (see infographic).

"My latest viral load count is undetectable. Antiretroviral treatment is life-long so it's encouraging to be told that the treatment is working well for me. It helps to know that whatever the difficulties, I am controlling the virus. I am proud that my viral load is undetectable, and I tell others about it. It helps me plan for tomorrow and I am confident I will live a normal life."

– **Fanelwa Gwashu,** 42, lives with her two children in Khayelitsha, South Africa, where she runs a treatment adherence club. She has been on antiretroviral treatment for nine years.



Celiwe Masuku receives HIV treatment through MSF's programme in KwaZulu Natal province, South Africa. She started treatment in June 2012 and was 'undetectable' at her first viral load test, after six months on treatment.

According to publicly available information, the lowest price of reagents is $11 and based on MSF's experience, additional associated costs (such as human resources, equipment, etc.) can be as low as $7 per test. Reagents and consumables represent the bulk of the costs of viral load testing, with prices varying across countries. Higher volumes and pooled procurement across countries by the Global Fund and PEPFAR, would help reduce prices through greater economies of scale.

MSF is currently undertaking a project in seven countries, with support from UNITAID, to roll out various different viral load technologies (both laboratory-based and point-of-care) to determine the best way to implement viral load testing in different contexts in resource-limited settings.

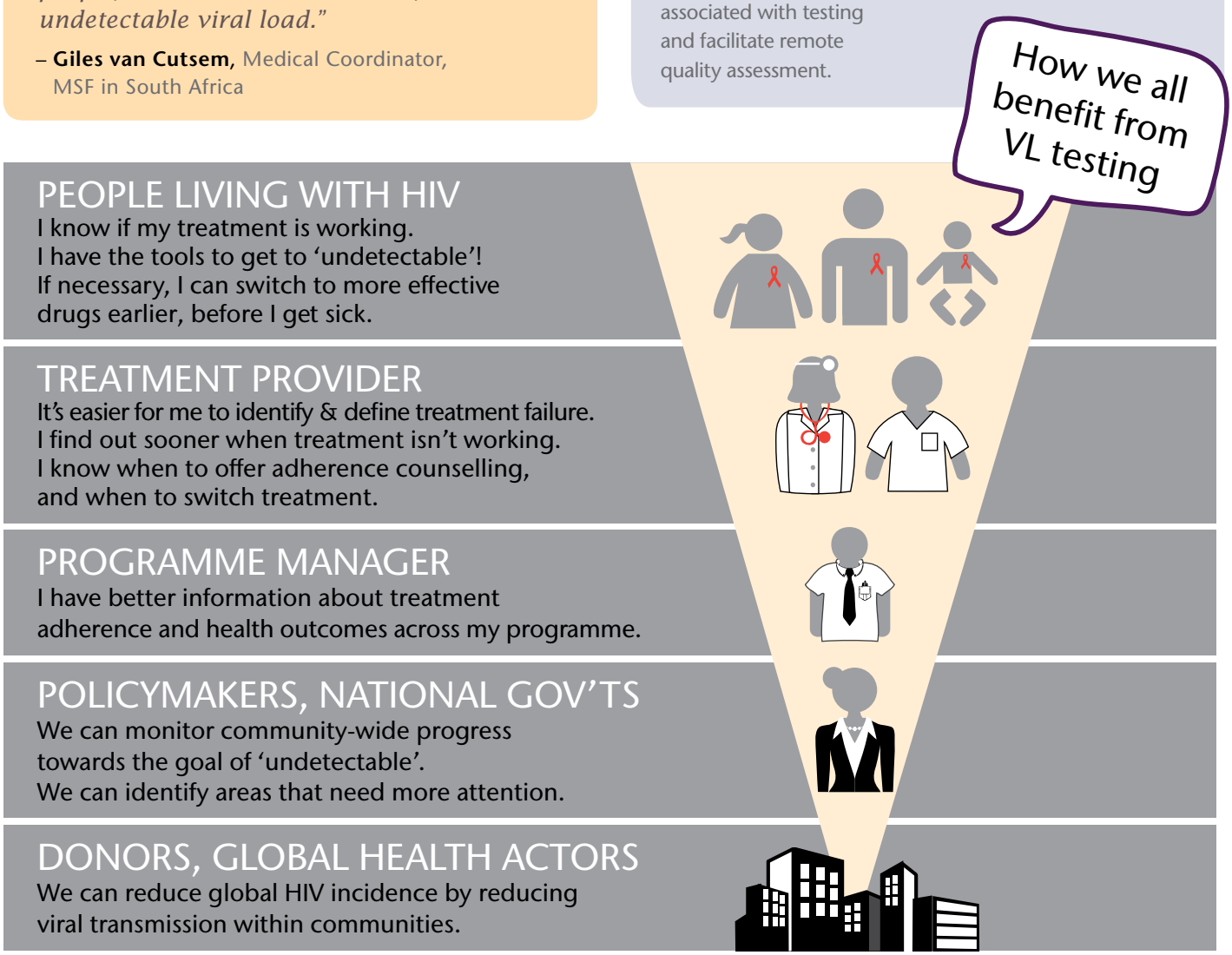
"There's no greater motivating factor for people to stick to their HIV treatment than knowing the virus is 'undetectable' in their blood. Viral load testing is the optimal way of maintaining people on first-line treatment and knowing when to switch them to second-line drugs, so it's high time it's made available in countries with a heavy burden of disease. With new WHO guidelines, our collective goal should now be to scale up without messing up: to reach more people, retain them on treatment, and with an undetectable viral load."

– **Giles van Cutsem**, Medical Coordinator, MSF in South Africa

WHAT'S COMING OUT OF THE VIRAL LOAD PIPLELINE?

A number of point-of-care technologies that are fully automated, easy to operate, and do not need cold chain storage are in the pipeline. Not only could they help to provide services to patients at the point of care (especially in remote areas where sample networks are not set up for lab-based testing), but also may make testing more feasible. The virtually hands-off automation of some of the existing lab-based platforms have already made testing much more viable. As such, a complement of both point-of-care and lab-based systems, placed appropriately, will maximize access, equity and cost efficiencies. Furthermore, manufacturers offering a range of kits or cartridges will allow for different diseases to be diagnosed and monitored using the same instrument.

In addition, improved connectivity and data management systems are taking advantage of availability of mobile phones and networks to feed lab results more quickly back to the clinic and to the patient and relay point-of-care results back to the centralised database, drastically improving turn-around time, loss of results and loss to follow-up. A further advantage is that connectivity will allow for monitoring of errors associated with testing and facilitate remote quality assessment.



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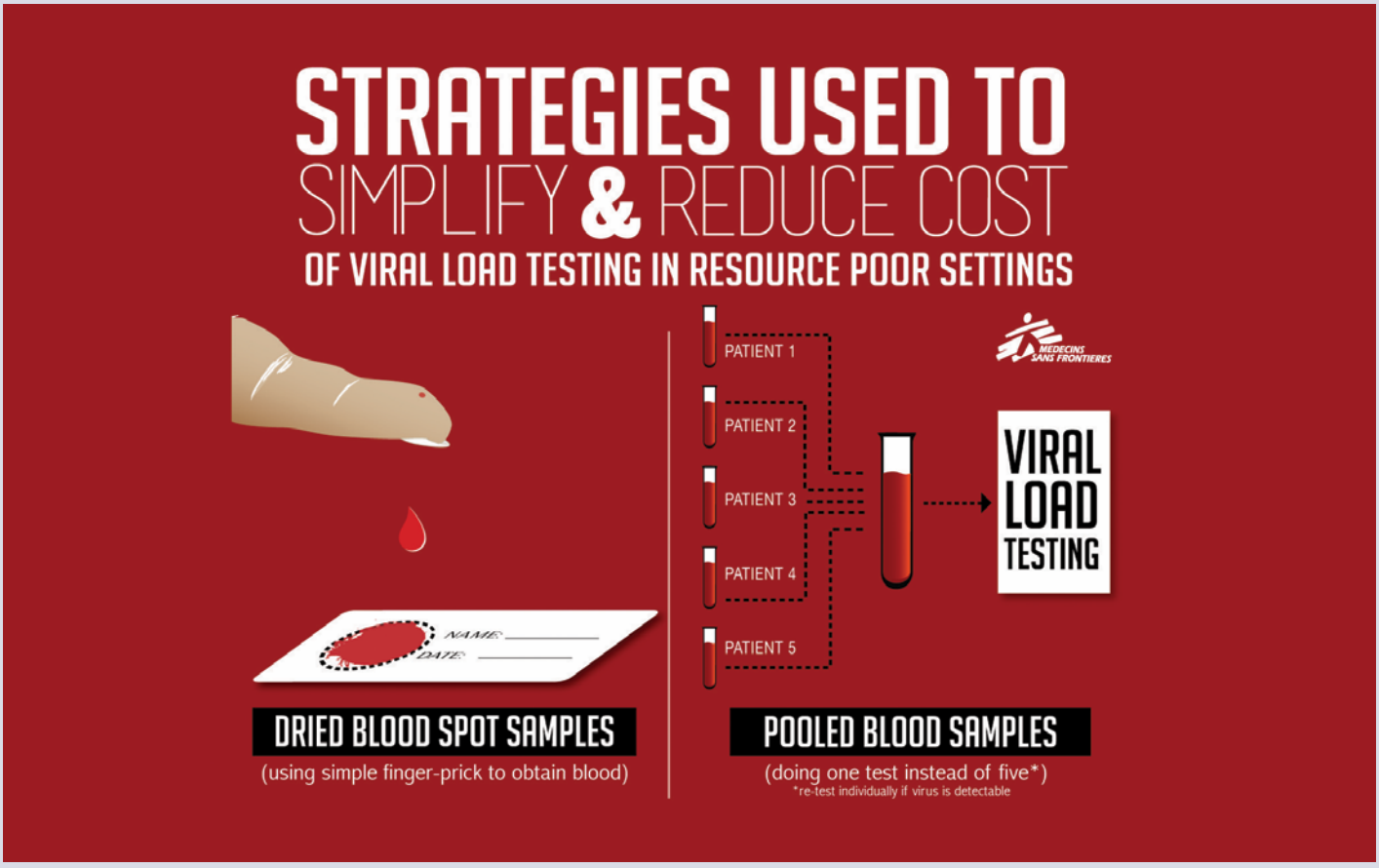
WHAT THE DATA SAYS

- An MSF study looking at the first-ever viral load test among adults on ART in three African countries starting to implement viral load (Kenya, Malawi, and Zimbabwe) showed that a substantial proportion (10%) of patients had high viral loads, despite the vast majority showing no evidence of clinical or immunological treatment failure–this points to the need to scale up routine viral load testing in developing countries in order to detect adherence problems or treatment failure as early as possible.[12]
- An MSF study in KwaZulu Natal province, South Africa, showed how scaling up viral load testing, combined with improving adherence counselling services, can have a positive impact. Among people who had started treatment between 2005 and 2013, 37% had detectable viral load, suggesting high rates of adherence problems and/or drug resistance. After MSF's intervention to increase viral load testing and improve adherence counselling services, it was shown that people who started treatment in 2012 had lower rates of detectable viral load than those who started in 2011.[13]
- An MSF study looking at viral load monitoring in rural districts in Malawi and Zimbabwe showed that certain strategies could reduce costs and facilitate viral load scale-up in resource-limited settings with human resource constraints. Strategies included using 'dried blood spot' samples (gathered either through a blood draw or from a simple finger-prick method), and pooling of samples, whereby one test is performed on five patient samples. If the pool is detectable, individual testing is carried out to identify the patient/s with high viral loads (see infographic). Sample pooling using dried-blood spots reduced the number of tests required in a rural district with over 30,000 patients on ART in Malawi by 30%, and resulted in district-wide savings of US $207,000 per year. In Zimbabwe, by the end of the first full year of viral load implementation, 70% of patients on ART had received viral load testing.[14] This method is undergoing further evaluation.
- In a three country study, MSF found that of patients with suspected treatment failure based on clinical or immunological criteria, only 30% had an elevated viral load. This means that 70% of patients could have been switched to second-line treatment unnecessarily if viral load was not used to confirm treatment failure.[15]
- According to an MSF three-country study of people on ART receiving their first viral load, viral load was more likely to be elevated in children five to nine years of age (27%) and adolescents aged 10 to 19 years (35%) than in adults over 25 (9%). MSF found similar results at its programme in Swaziland: the odds of having a detectable viral load were four times higher in patients under 20 years of age.[16, 17]



3. PROVIDING ENHANCED SUPPORT TO HELP PEOPLE ADHERE TO THEIR TREATMENT

To be most effective, viral load monitoring roll out in developing countries should be inextricably coupled with the capacity to provide enhanced adherence counselling for those people who are identified with detectable viral load. In MSF programmes, counselling often involves a monthly adherence counselling session over three months after an adherence problem is detected. A second viral load test is then administered after three months to determine whether the intervention has had the desired effect of getting the person back on track with their treatment, and back to an undetectable level of HIV.

By identifying people who need the most attention in terms of adherence support, viral load monitoring can also help health staff focus their efforts on people who need the most support. In a large MSF-supported programme in Chiradzulu, Malawi, where ART has been available since 2001, community health workers could focus on the less than 10 percent of people with detectable viral load, among the roughly 30,000 people on ART in the district.

While MSF and others have found that adherence counselling is a vital tool to improving people's adherence and also preventing unnecessary switching to other, more expensive, treatment regimens, an alarming trend MSF has been witnessing is that support from national governments and donors for lay or peer counsellors, who are the cornerstone of adherence counselling, is waning. Without these counsellors, it is not possible to adequately and effectively address adherence problems.

"Experience from our programmes shows that when you identify someone who needs help getting back on track with their treatment, quick, targeted action in the form of enhanced adherence counselling can make a real difference. Viral load monitoring, combined with adherence support for those with identified barriers to adherence helps us make sure people are doing the best they can on their treatment and avoid unnecessary switching to more expensive drugs.

– **Dr. Helen Bygrave**, MSF Southern Africa Medical Unit

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An HIV/AIDS counsellor at work in a health clinic in Thyolo District, Malawi.

WHAT THE DATA SAYS

- An MSF study looked at people in three cohorts (in Kenya, Malawi and Zimbabwe), with viral loads greater than 1000 copies/ml at their first-ever test, and who were referred for enhanced adherence counselling, followed by a second viral load test eight to 24 weeks later. Overall, 31% of people had suppressed the virus to less than 1000 copies after the adherence intervention, but those with high viral loads (over 5000 copies) were less likely to suppress (around 15%) than those with viral loads 1000–5000 (53% re-suppressed). In addition, viral re-suppression was more likely among those tested within nine months of starting ART. These findings highlight the importance of identifying viral failure early by routine testing in the first year. The high numbers re-suppressing the virus show the importance of repeating viral load testing before deciding to switch to second-line ART.[18]
- An MSF study in Khayelitsha, South Africa, showed that among patients on first-line ART who had a first-ever detectable viral load, fewer patients had a subsequent elevated viral load following an adherence support intervention.[19]
- In an MSF programme in the Shiselweni region of Swaziland, the introduction of routine viral load monitoring found more than 85% of people on ART to have an undetectable viral load. Specific interventions have had the desired effect of helping 54% of patients with a detectable viral load get back to an undetectable level of HIV. These interventions include baseline adherence and clinical assessment, monthly drug pick-ups, and stepped-up adherence counselling to help identify and address adherence barriers.[20]
- A review of eight studies looking at the link between viral- load-triggered adherence support found that 70% of people who receive adherence support following a detectable viral load result re-suppressed the virus.[21]

4. INCREASING PEOPLE'S AUTONOMY: MOVING TO COMMUNITY-BASED TREATMENT MODELS AND SELF-MANAGED CARE

Over the last decade, MSF and other treatment providers have recognised the importance of ensuring treatment is available as close to where people live as possible. Decentralising care to rural clinics and health posts has been critical to fostering treatment scale-up, and has been enabled by shifting medical tasks, so that lower levels of health staff can perform tasks previously reserved for doctors.

Over the last few years, MSF has been working to get care even closer to where people live, and to further ease the burden on their personal and professional lives, while at the same time easing the burden on the health system. Extending facility-linked health services at the community level has shown to reach more people and improve retention in care. As such, a number of different strategies have been implemented in various contexts to reduce the number of visits to clinics that patients who are stable on treatment must make.

In some contexts, this entails people on ART forming 'adherence clubs' where a group of up to 30 people come together to a clinic or a venue in the community, receive a quick clinical assessment, meet with an adherence counsellor as a group, receive their ARV refill and are in and out of the facility in under two hours. This has helped decongest overburdened health facilities.

In other contexts, 'community ART groups' (CAGs) are formed with six friends or neighbours teaming up and taking turns getting the medicine refills for the rest of the group. This means that each CAG member goes to the clinic just once or twice a year, at which point they get their medical check-up and monitoring blood tests, pick up the refills for all other group members, and distribute them to the rest of the group in a convenient location. This way, each CAG member gets their monthly refill from the CAG member 'on call' that month. This strategy has shown tremendous success in boosting people's likelihood to remain in care, reducing the time and effort spent to get a monthly ART refill, creating peer support that helps improve adherence, empowering people to deal with stigma, generating interest among others in the community to get tested, and resulting in a feeling of relief and comfort.

In other contexts, fast-track refill systems have been put in place at clinics, separating the need for a clinical assessment versus a simple drug refill, and in other settings medicine refills are provided in the community by community-based organisations, community health workers, and other people on treatment.

Access to viral load monitoring helps clinicians more easily refer stable and adherent people on ART for community-based follow up and dispensing, with only a smaller proportion of patients needing to be referred to health centres in order to be seen by medical staff.

All of these strategies reduce the burden on people's lives by helping them fit ART into their lives rather than forcing them to arrange their life around their treatment.

It also reduces the burden on over-worked staff at health centres, enabling them to have more time to treat people in need of clinical care (for example, better treatment of opportunistic infections and dealing with patients who are failing their treatment). These models are an important step in taking HIV care more in the direction of other chronic disease management models.

> *"Moving treatment down to the community level means the interest of patients and health systems overlap. We're showing that we can take HIV care out of hospitals and keep people healthy, while making life easier for patients and easing the strain on the health system. We're starting to move toward a model of patient care similar to that of chronic disease management in developed countries."*
>
> – **Dr. Tom Decroo**, MSF Operational Center Brussels


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Carmen Jose Panti delivers ARV refills to the other members of her Community ART Group at her home in Tete province, Mozambique.

WHAT THE DATA SAYS

- The Community ART Group 'CAG' model was first implemented in Tete province, Mozambique, where after 12 months in a CAG, retention in care among people was 97.7%; 96% at 24 months and still 91.8% after 48 months in a CAG.[22] This compares favourably with published data. CAGs were also more recently established in Thyolo, Malawi, where after nine months, among 50 CAGs with 299 patients, clinical outcomes were positive, with 90% of patients alive and remaining in care.[23] In Lesotho, out of the 108 members who formed 21 CAGs in one pilot site, all were retained in care after five months.[24]
- A further study on CAGs showed non-existence and lack of financial support of a lay cadre of health workers within Ministries of Health threatens the sustainability of CAGs, while longer drug supplies maximize benefits for patients, e.g. in Zimbabwe, where three-month ARV refills reduce clinic visits substantially.[25]
- In an MSF study assessing the cost-effectiveness of the adherence club model compared to decentralised, clinic-based, nurse-led standard of care in Khayelitsha, South Africa, adherence clubs have shown to better retain people in care (97% compared to 85%), with the cost-per-patient year $58 in the adherence club model compared to $109 in the standard of care. There were fewer barriers to on-going access to care in the adherence club model, with patients perceiving the reduced barriers to be shorter wait times (67 minutes compared to 176 minutes), higher acceptability of services and higher attendance at appointments (19% of club respondents ever reported missing an appointment compared to 37% in the standard of care group). Adherence club participation reduced loss to follow-up by two thirds and nearly halved the proportion of people with virologic rebound or breaks in monitoring compared to those in clinic-based care.[26] MSF has assisted with broad replication of this model, and by September 2013, there were 794 adherence clubs across Cape Town, which covers 18,626 patients. This is 23% of all patients taking ARVs in the Cape Metro area, and adherence clubs are now policy in South Africa's Western Cape province. This study suggests that adherence clubs should be considered as a possible long-term strategy for retention in care in all high-burden settings.[27]
- An MSF study in the Western Cape of South Africa, which has high rates of circular migration, showed that short-term outcomes were good among adherence clubs members with no difference in defaulting or viral suppression between patients receiving two or four months of ARV refills over the holiday period. These findings also suggest that less-frequent visits for stable ART patients should be evaluated as regular practice in order to alleviate an unnecessary burden on patients and clinic resources.[28]
- In the Democratic Republic of Congo, MSF, together with a local NGO, established community ART distribution points in Kinshasa, bringing ARV refills closer to where people live. These points are managed by people living with HIV who are trained to provide ARV refills, adherence support and basic health follow-up. Stable patients are eligible to participate in the programme, whereby they receive three months of ARV refills and report annually for clinical consultation. As of July 2013, 2,162 patients were referred for the programme, and 89% had been retained in care after 12 months.[29]

KEEPING DRUG PRICES DOWN:

What remains critical in the response to the HIV/AIDS epidemic is the steady supply of affordable drugs. Thanks to competition among producers of generics medicines, primarily in India, the cost of treatment for HIV has come down by 99% over the last decade, from more than $10,000 per person per year in 2000 to around $120 per person per year today. However, increased patenting of newer medicines in key generics-producing countries means that the price of these drugs will remain high unless governments step in to overcome the patent barriers. While the price of second-line medicines has declined thanks to competition, to at best $303 per year, this still involves a more than doubling of the price of a first-line regimen. In addition, for those people failing their second-line combination, switching to a possible salvage regimen involves a major price jump, with the most affordable combination costing nearly 15 times more (over $2,000 per year) than first-line treatment in the poorest countries. The situation is much more dire in 'middle-income' developing countries, where companies negotiate prices on a case-by-case basis with very little transparency, leading to astronomical prices being paid for second-line and salvage combinations.

STOPPING STOCK OUTS TO MAINTAIN UNDETECTABLE VIRAL LOADS

For patients to adhere to treatment and maintain undetectable viral loads, country programmes must ensure a regular, uninterrupted supply of ARVs. In South Africa, which has the world's largest ARV programme with approximately 2.4 million people on treatment, the Stop Stock Outs Project found that between September and October 2013, among 91% of the 2,342 public health facilities contacted, a shocking one in five health facilities reported experiencing a stock out or shortage of ARVs and/or TB medicines within the previous three months. The reported median duration of a stock out/shortage was 30 days, but ranged from one day to one year. Over 420,000 patients rely on those affected facilities for life-saving ARVs. In 20% of facilities affected by stock outs, patients were sent home or referred elsewhere without medicines, putting tens of thousands of patients at risk for treatment interruption. Potential ramifications of such widespread systemic failures include development of drug resistance, the inability of patients to remain adherent to treatment and maintain undetectable levels of viral load, and subsequently, increased risk of HIV transmission in the community. Patients and health care workers should report stock outs in order to hold national and provincial governments accountable for finding solutions to address the problem's root causes.

WHAT NEEDS TO HAPPEN

While the last 13 years of ART in developing countries have brought many important advances, there needs to be a concerted global effort to expand treatment to more people while ensuring the best treatment and monitoring is available. Implementing the new WHO treatment guidelines must be a priority for all national governments as well as donors, with a specific emphasis on ensuring viral load monitoring coupled with enhanced adherence support is made broadly available. Finally, moving to models of care that emphasise increased autonomy for people living with HIV should be prioritised.

At country level:

- The recommendations in WHO's 2013 treatment guidelines should be taken up by national treatment programmes, should be reflected in Ministries of Health applications to the Global Fund, and be supported by the US government's PEPFAR programme, with a focus on rapid scale-up of optimal ART, in keeping with the *PEPFAR Blueprint: Creating an AIDS-Free Generation*.[30]
- Adherence programmes should be strengthened (based on evidence), by supporting lay health workers, community workers, and community organisations to play a larger role in delivering treatment and adherence support.
- National governments should ensure there are no interruptions in supply of ART or essential drugs to treat opportunistic infections, so that people living with HIV are never at risk of treatment interruption.
- National programs and health initiatives should monitor ART programme outcomes not only through retention in care, but by proportion of patients retained with an undetectable viral load.
- National programmes should support community-based strategies and empowerment of people living with HIV.
- National governments should use all available safeguards and flexibilities under international trade rules to ensure patents are not a barrier to affordable prices for ARVs.

At global level:

- The international community should support a global goal of 70% of all people living with HIV/AIDS having undetectable HIV, or at least 90% of those on treatment with a viral load less than 1000 copies.
- Funding should be replenished to meet the ambitions for scaling up ARV treatment and monitoring.
- Global health actors should ensure that newer ARVs that are more robust and easier to take are affordable and available.
- Global health actors should support open and polyvalent diagnostic technologies in order to foster competition (and keep prices low) and address multiple pathologies, including HIV, TB, and hepatitis B and C.

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