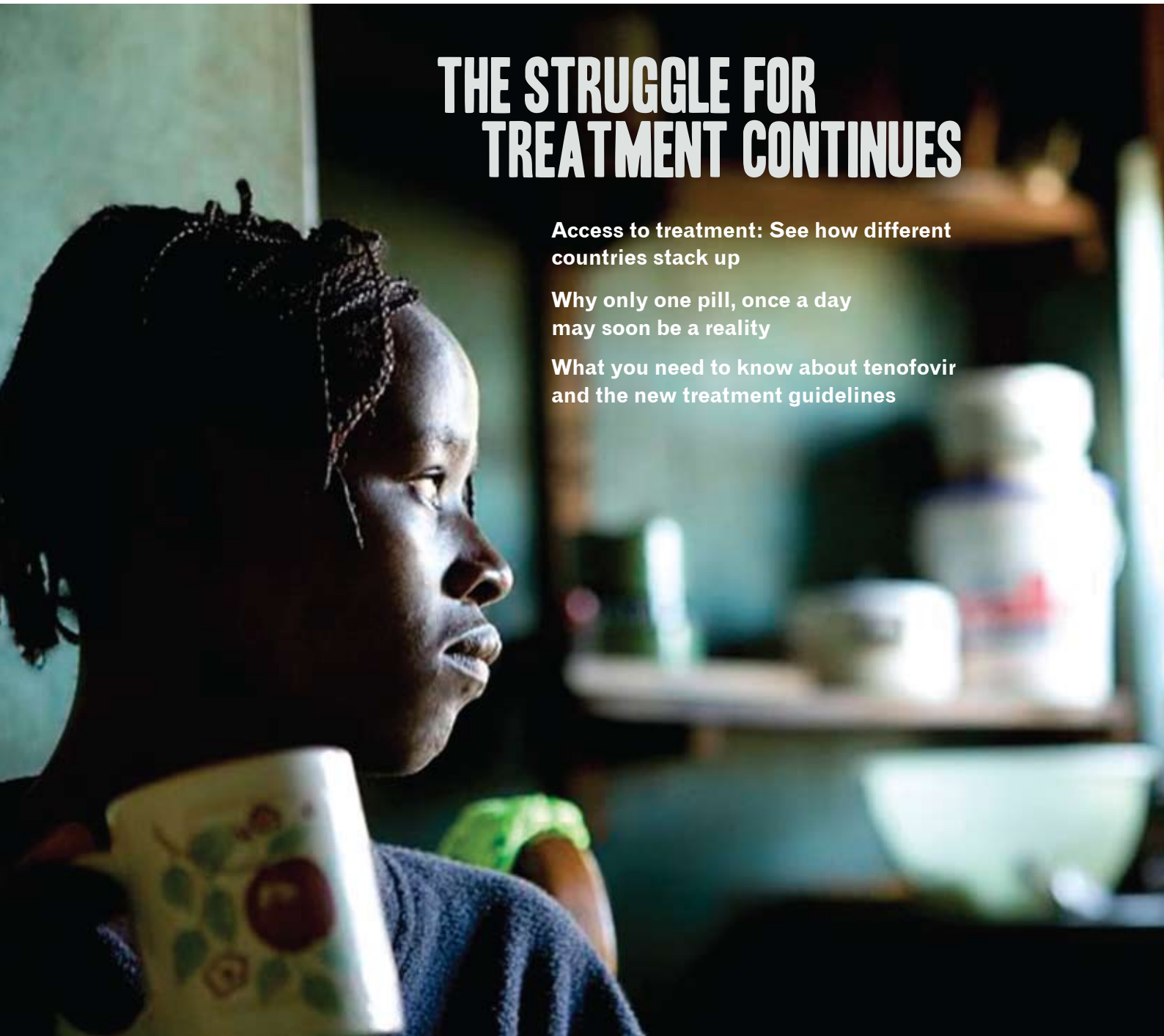
EQUAL treatment

Magazine of the Treatment Action Campaign June 2010



THE STRUGGLE FOR TREATMENT CONTINUES

Access to treatment: See how different countries stack up

Why only one pill, once a day may soon be a reality

What you need to know about tenofovir and the new treatment guidelines

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TAC is committed to providing people with HIV, their families and caregivers accurate information about life-saving medicines and treatment. TAC and its leaders are independent of the pharmaceutical industry as well as of the natural and alternative medicine industries and have no financial interests with them.

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The need for better drugs
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Access: Then and now, here and there
While everyone talks about how the World Cup will turn out, we weigh up how countries compare when it comes to dealing with HIV – and the Brazilians are doing well. We also bring you a timeline showing how access to treatment has changed through the years.

Photo by Mara Kardas-Nelson

Editorial

I was one of the lucky first people to receive antiretroviral treatment (ART) through the Treatment Action Campaign (TAC) Treatment Project in 2003, when my CD4 count was 91. At that time our government was reluctant to provide antiretrovirals (ARVs) to people with HIV because of the denialist views of senior politicians. Many people lost their lives, but nevertheless we continued to fight for access to ART.

When government announced the antiretroviral roll-out towards the end of 2003, our hopes grew. After the PMTCT (prevention of mother-to-child transmission) case, we felt that we had won yet another battle. We campaigned for 200,000 people to be put on ARVs by 2006. We lobbied. We fought for reductions in the prices of drugs, and at times we were wrongly accused of working with pharmaceutical companies. Challenging the stigma associated with HIV, we conducted door-to-door campaigns to educate people on the importance of knowing their HIV status, taking their ARVs and adhering to treatment.

People began visiting their hospitals to get ART. But we still faced many obstacles. Even then, we didn't despair. Instead, we fought harder and continued with our work at community level. Once the ARV roll-out was up and running, there were new challenges: stock-outs, and the need to introduce more effective drugs.

I remember marching to the ASPEN offices in Durban North during our tenofovir campaign. It was a very hot day, but no-one seemed to mind the scorching sun or the long walk up the hill. I remember when we demonstrated outside Mahatma Gandhi Hospital, asking to know why there were more than 1,300 people on the hospital's waiting list. One man asked us if he would still be alive by Christmas if he was not put on ARVs. I remember when my colleagues Promise, Ralph and Sindi were chased away from Westville prison with dogs, because we were advocating for prisoners to receive treatment, too. Those were hard times. But at least we can look back and say that our efforts were not in vain.

The current political leadership has made promising commitments to fighting HIV in South Africa. More than 900,000 people now receive ARVs through the public health system. We have a National Strategic Plan whose targets everyone is working towards. Patients are accessing treatment in their local clinics, and the HIV Counselling and Testing (HTC) Campaign will work towards all primary health clinics becoming accredited as ART sites. Once this happens, fewer people will have to walk long distances for testing and treatment.

We finally have new and improved ARV treatment guidelines and it is estimated that by June 2011 about one million people will have access to ARVs. This is one of the victories that we need to celebrate!

However, many challenges remain. People are still being turned away from clinics because there are no doctors or pharmacists to dispense treatment. Some are being tested very late for HIV, and TB/HIV co-infection is still responsible for a huge number of deaths in South Africa.

The stigma associated with HIV remains, but many people continue to take their ARVs despite the difficulties that they experience. These people are living healthy lives – and I am one of them. We are proof that ARVs do work. We still have a long way to go, but it is a road that we can all walk together. As people with HIV, we must continue supporting each other to adhere to treatment so that we can live longer, fuller lives.

Lihle Dlamini, TAC Deputy General Secretary

The new drug at the clinic

Photo by Mara Kardas-Nelson

By Catherine Tomlinson and Marcus Low

If you are on a regimen containing d4T and you are suffering from lactic acidosis, lipodystrophy, peripheral neuropathy or pancreatitis, then you must ask your doctor as soon as possible about switching to tenofovir. Changing to tenofovir can remove many of the side effects associated with d4T.

The Department of Health is finally starting to replace the drug stavudine (d4T) with tenofovir (TDF). This is a huge step forward for HIV treatment in South Africa. Here is what we need to know.

Why tenofovir is better than d4T

Stavudine (d4T) has been part of the first-line drug regimen in South Africa's public health system for a number of years. If you have been getting antiretrovirals (ARVs) from a public clinic, chances are that one of the three ARVs you have had is d4T. D4T has helped to save millions of lives in the region. However, it has also been responsible for many of the severe side effects experienced by some people on antiretroviral treatment (ART).

For a number of years the Treatment Action Campaign (TAC) has campaigned for d4T to be replaced by tenofovir (TDF). The main reason for this is that tenofovir has far fewer

side effects than d4T. In most rich countries tenofovir replaced d4T several years ago.

Clinical trials have shown the advantages of tenofovir over d4T. A study presented at the International AIDS Society Conference 2009 in Cape Town showed that regimens containing d4T have more serious side effects and require more drug switches than regimens containing tenofovir. The study compared 1000 patients on a regimen containing tenofovir with 1000 patients on an otherwise similar regimen containing d4T. 50.5% of patients taking d4T experienced a d4T-related side effect and 16.2% were switched to a new drug by the end of two years. In the tenofovir group only 2.5% of patients experienced a tenofovir-related side effect.

Some of the serious side effects associated with d4T include lactic acidosis (a condition in which lactic acid builds up in the blood faster than the body can remove it), lipodystrophy (changes in body fat and body shape), peripheral neuropathy (damage to the peripheral nervous system) and pancreatitis (inflammation of the pancreas, an organ that produces essential hormones). In contrast, patients on tenofovir experience far fewer serious side effects. However tenofovir has been associated with kidney damage and patients taking the drug must be monitored for kidney problems.

The new guidelines

The good news is that from 1 April 2010 the Department of Health began to replace d4T with tenofovir as part of first-line treatment in the South African health system.

This does not mean that everyone who is on d4T will immediately be switched to tenofovir. Only people who are starting treatment for the first time after 1 April and people who are experiencing severe side effects on d4T will receive tenofovir. If you are on a treatment regimen containing d4T and you are not experiencing any serious side effects, you will not need to switch to tenofovir.

One reason for not switching all patients to tenofovir at once, is that the government might not be able to get hold of enough tenofovir for everyone. Also, if people are doing well on d4T, there is no reason for them to change their regimen.

Sources: S. Rosen et al., 'Net cost of switching from stavudine to tenofovir in first line antiretroviral therapy in Zambia', IAS 2009. Available at http://www.ias2009.org/abstract.aspx?elementId=200721757.

TAC has called for the roll-out of tenofovir as part of the Resources for Health campaign. Photo by Zethu Mlobeli, courtesy MSF.

TENOFOVIR AND THE 2010 TENDER

The Department of Health buys antiretroviral (ARV) drugs through a special ARV tender. The ARV tender awarded in 2008 comes to an end this year and government will soon award the new tender.

Getting the tender right is crucial to meeting the NSP targets, implementing the new treatment guidelines and reducing drug prices. Throughout the last tender period only one generic version of tenofovir was registered and marketed. This meant that tenofovir remained expensive.

Generic versions of tenofovir pending registration with the Medicines Control Council (MCC) must be registered to increase competition and bring down prices. To improve and simplify drug regimens the MCC must fast track the registration of all tenofovir-based fixed-dose combinations.

See page 12 for more on the 2010 ARV tender and bottlenecks at the MCC.

Eunice's story

Mary-Jane Matsolo interviewed Eunice Lindiso about her experience of changing from stavudine (d4T) to tenofovir (TDF).

Eunice Lindiso is a 33-year-old woman living in Khayelitsha who has a 14-year-old son. Eunice tested HIV-positive in 2007, after finding out that her long-term boyfriend had been unfaithful to her with a woman who was known in the community to be HIV-positive. When Eunice was diagnosed her CD4 count was 192, but at the time she showed no serious symptoms of HIV infection.

In 2007 she started antiretroviral treatment (ART) using stavudine (d4T), lamivudine (3TC) and nevirapine (NVP). About four months into this treatment Eunice began to notice side effects. She suffered extreme nausea and vomited constantly due to a common side effect of d4t known as lactic acidosis (a condition in which lactic acid builds up in the blood faster than the body can remove it). This made it extremely hard for her to look after her son because most of the time she was not well enough to do so.

When she complained about this, her doctor switched Eunice to a regimen consisting of Zidovudine (AZT), 3TC and nevirapine. On this regimen she began to lose weight but at the same time her breasts increased in size from a 32B to a 36D. This combination of fat loss and fat gain is another side effect of d4t known as lipodystrophy.

On 3 February 2010 Eunice's treatment was changed once again. This time she started a regimen of tenofovir (TDF), 3TC and nevirapine. Her doctor explained that this treatment has fewer side effects but that she might experience headaches and nausea. However, this has not happened.

Instead, Eunice has found that the new treatment reversed some of the side effects she had experienced with d4t. Her breast cup size has returned to a 32B and she's living a healthier lifestyle. Thanks to tenofovir she no longer feels sick all the time and has a more hands-on relationship with her son.

Photo by Damien Schumann

New antiretroviral treatment guidelines

In March 2010 South Africa's treatment guidelines – last revised in 2004 – were finally updated after many years of unnecessary delays. The table below shows who will be eligible for which drugs, under the new guidelines that came into effect on 1 April 2010.

Adults and adolescents

First-line	
All new patients needing treatment	TDF + 3TC/FTC +EFV/NVP
Currently on d4T with no side effects	Remain on d4T
Contraindication to TDF: renal disease	AZT+ 3TC +EFV/NVP
Second-line	
Failing on a d4T or AZT-based first-line regimen	TDF + 3TC/FTC + LPV/r
Failing on a TDF-based first-line regimen	AZT + 3TC + LPV/r
Failing second-line – refer to specialist	

Infants and children

First-line	
All infants under 3 years	ABC + 3TC + LPV/r
Children 3 years and over	ABC + 3TC + EFV
Currently on d4T with no side effects	Remain on d4T
Second- line	
Children above 3 years failed ABC + 3TC + EFV	ABC + ddI +LPV/r
Failed on AZT or d4T regimen	ABC + 3TC + LPV/r
Failed LPV/r regimen, infants under 3 years failing first-line or second-line – refer to specialist	

Key: abacavir (ABC), zidovudine (AZT), didanosine (ddI), stavudine (d4T), efavirenz (EFV), emtricitabine (FTC), lopinavir/ritonavir (LPV/r), nevirapine (NVP), tenofovir (TDF), lamivudine (3TC)

One pill, once a day

By Catherine Tomlinson and Marcus Low

Fixed-dose combinations are recommended by health professionals and the Southern African HIV Clinicians Society. The lower pill burden is associated with improved adherence.

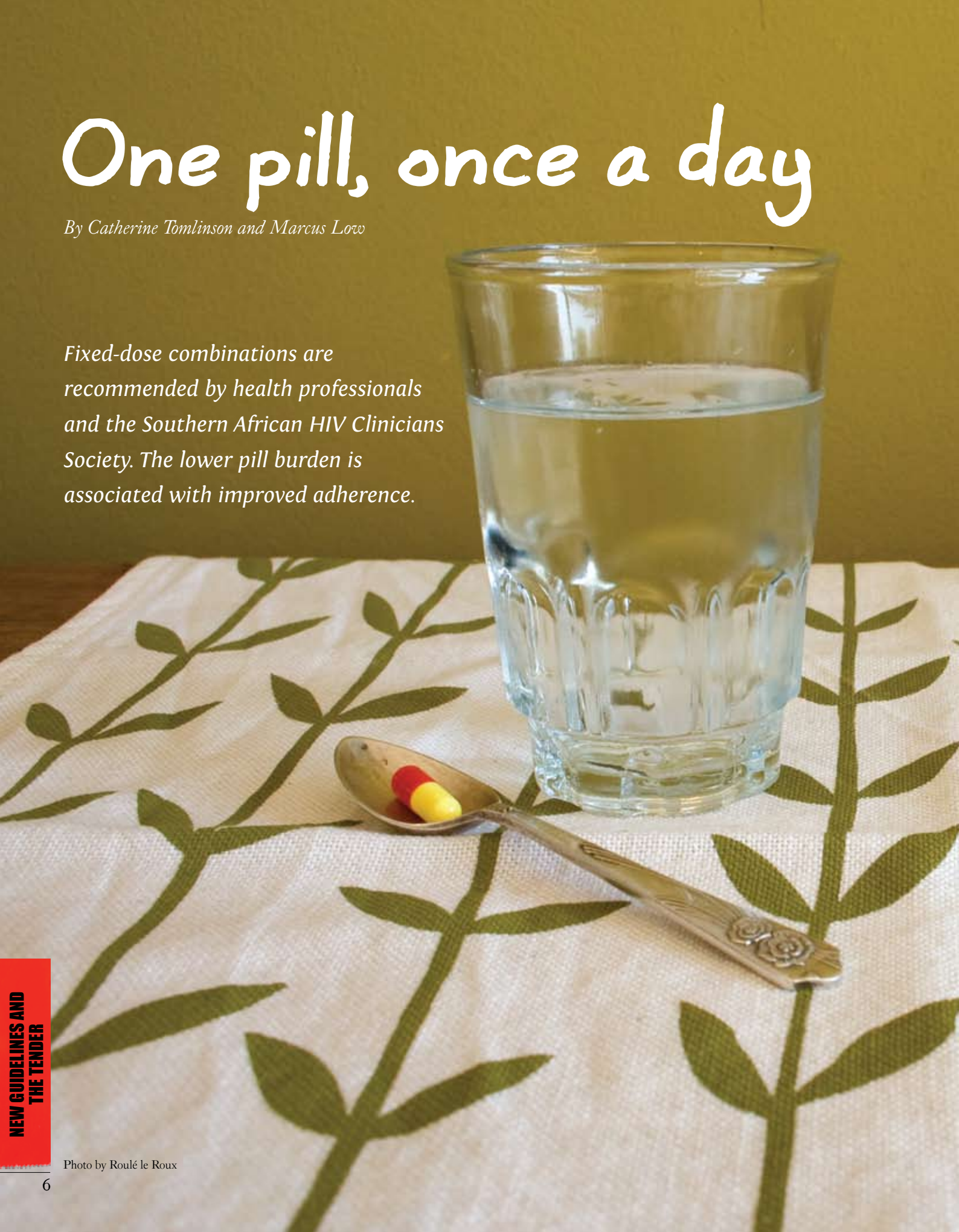


Photo by Roulé le Roux

TAC will continue campaigning to make fixed-dose combinations containing tenofovir a reality in the South African public health system. One pill once a day is affordable, feasible, and in everyone's interest.

Most people in South Africa who are taking antiretroviral therapy (ART) have to take three different drugs every day. Some have to be taken at specific times and others have to be taken before or after meals. Taking so many pills and taking them according to instructions can be hard and requires great discipline. This is one reason why good treatment adherence can be so difficult.

In recent years scientists have managed to combine three different antiretrovirals (ARVs) into one pill that you have to take only once or twice daily. This type of 'three-pills-in-one' combination is called a fixed-dose combination, or FDC. A number of these fixed-dose combinations include tenofovir.

The good news is that fixed-dose combinations containing tenofovir are both affordable and not held back by patent restrictions. There are some obstacles regarding registering these fixed-dose combinations with the Medicines Control Council (see page 12), but if government wants to, they can provide FDCs containing tenofovir on the public health system by late 2010.

The improved treatment adherence associated with having to take fewer pills has been established through a number of studies. An analysis of nine studies tracked the treatment adherence of 20,242 patients – 11,925 patients on fixed-dose combinations and 8,317 patients on free-drug combination regimens – over an average of 8.6 months. The analysis found that the risk of poor treatment adherence is reduced by 26% for patients on FDCs.

Poor treatment adherence leads to increased drug resistance. In turn, greater resistance means that more people have to switch to more expensive second- and third-line treatment. Therefore, introducing fixed-dose combinations could save government money by improving treatment adherence and reducing the need for expensive second- and third-line drugs.

Having to take only one pill once a day also makes it easier to take your medicines in private. This can further contribute to good treatment adherence in situations where it is hard to disclose your status due to stigma or fear of stigma.

Until fixed-dose combinations become readily available, using a medicines blister to sort your medicines will help to ensure that you're taking the right amount each day. Photo by Eric Miller, courtesy MSF.

FDCs AND THE 2010 ARV TENDER

The 2010 ARV tender is a perfect opportunity for government to introduce fixed-dose combinations (FDCs). As the largest global purchaser of antiretroviral treatment, South Africa must use its buying power to demand that regimens be made available in FDCs where possible, or otherwise co-packaged in user-friendly blister packs.

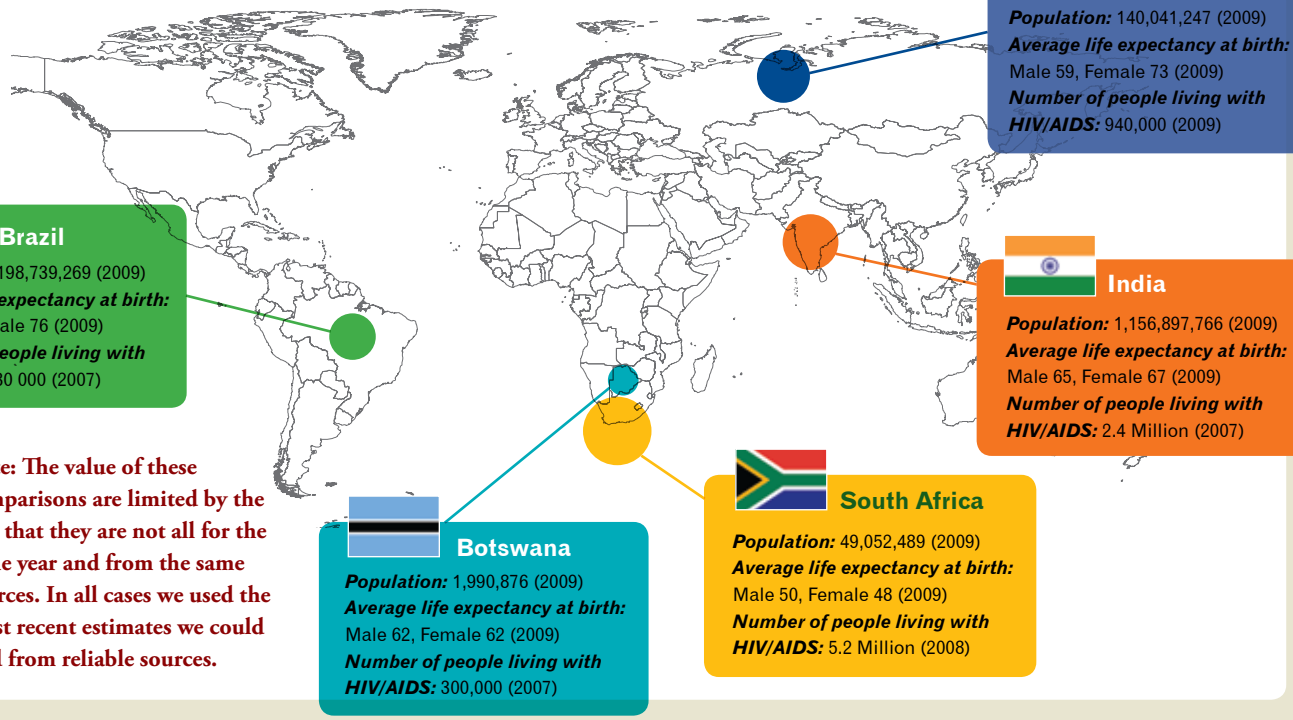
Co-packaging combines all drugs in a regimen into a single blister pack. Regimens should be packaged in adherence-promoting calendar packs, similar to those used for oral contraceptives. This may require generic companies to cooperate with one another on packaging their drugs.

Fixed-dose combination and co-packaging regimens will reduce the burden on health care workers. They will simplify the management of supply and procurement chains for the Department of Health, too. Co-packaging can also reduce bottlenecks, particularly in rural facilities, caused by a shortage of pharmacists. The Pharmacy Act and Regulations allow a post-basic pharmacist's assistant in a state primary care facility or any other facility approved by the Pharmacy Council, to dispense medicines under indirect supervision. This can occur provided the medicines are in patient-ready packs or re-packaged for this purpose at the hospital or provincial depot.

See page 10 for more on the 2010 ARV tender.

Source: SANAC Technical Task Team on Treatment, Care and Support, 'Building the Capacity of the Primary Health Care System for HIV/AIDS Diagnosis, Care and Treatment in South Africa', May 2009; S. Bangalore et al., 'Fixed-Dose Combinations Improve Medication Compliance: A Meta-Analysis', The American Journal of Medicine (2007) 120, 713-719

HOW DO WE COMPARE WITH THE REST OF THE WORLD?



Russia
Population: 140,041,247 (2009)
Average life expectancy at birth: Male 59, Female 73 (2009)
Number of people living with HIV/AIDS: 940,000 (2009)

Brazil
Population: 198,739,269 (2009)
Average life expectancy at birth: Male 68, Female 76 (2009)
Number of people living with HIV/AIDS: 730 000 (2007)

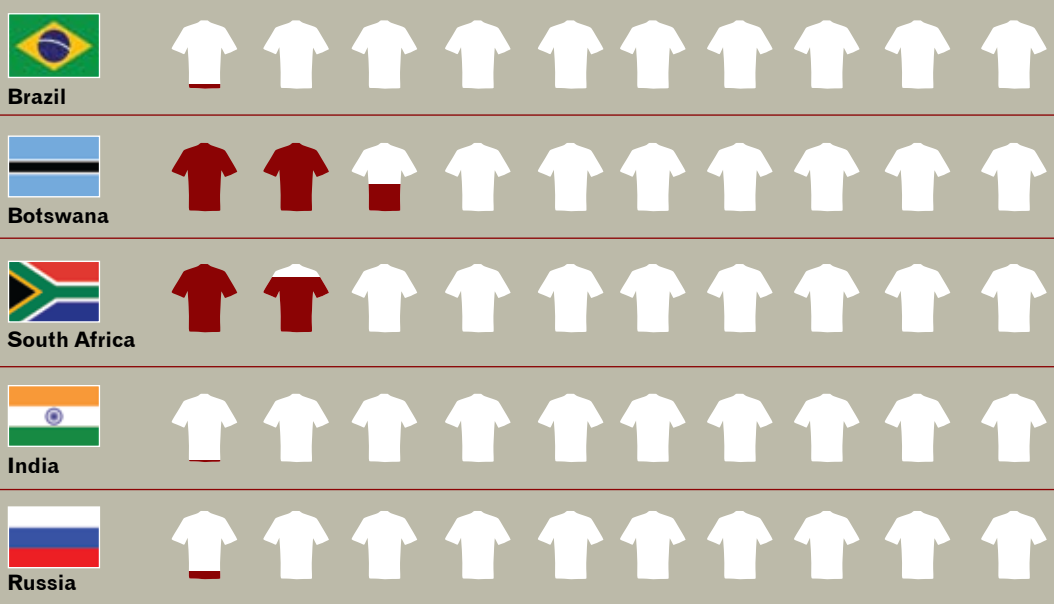
India
Population: 1,156,897,766 (2009)
Average life expectancy at birth: Male 65, Female 67 (2009)
Number of people living with HIV/AIDS: 2.4 Million (2007)

South Africa
Population: 49,052,489 (2009)
Average life expectancy at birth: Male 50, Female 48 (2009)
Number of people living with HIV/AIDS: 5.2 Million (2008)

Botswana
Population: 1,990,876 (2009)
Average life expectancy at birth: Male 62, Female 62 (2009)
Number of people living with HIV/AIDS: 300,000 (2007)

Note: The value of these comparisons are limited by the fact that they are not all for the same year and from the same sources. In all cases we used the most recent estimates we could find from reliable sources.

Estimated adult HIV prevalence:



ART coverage (percent of those who need ART and are receiving it):

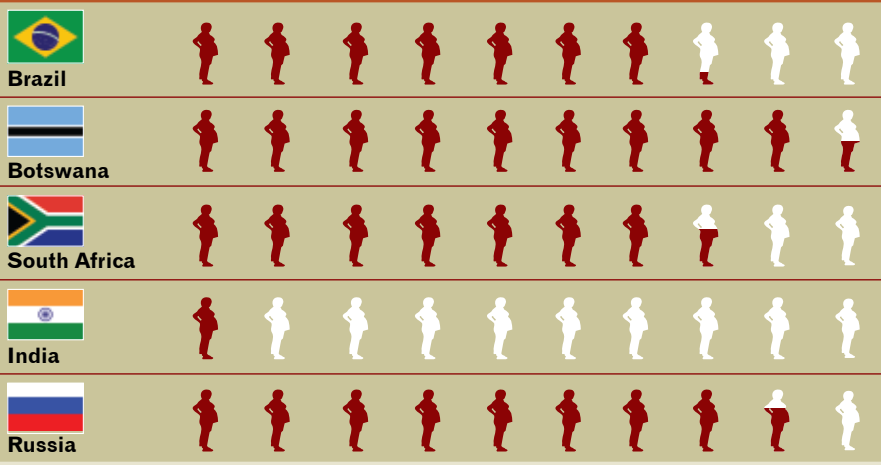
Number of people who need ART:

Brazil	230,000 (2007)
Botswana	120,000 (2007)
South Africa	1.7 million (2007)
India	Insufficient data
Russia	190,000 (2007)

Number of people with access to ART:

Brazil	181,000 (2007)
Botswana	93,000 (2007)
South Africa	460,000 (2007)
India	158,000 (2007)
Russia	31,000 (2007)

PMTCT (prevention of mother-to-child transmission) coverage:



Where we are now

South Africa has the largest public sector ART programme in the world yet it currently only covers half of the people that are in need of treatment. There are currently about 900,000 people on ART which government aims to increase to 1 million by the end of June. It is estimated that around 2 million people are currently in need of treatment. Government aims to double the number of people receiving treatment over the next year through the implementation of the updated treatment guidelines and the HIV Counselling and Testing Campaign.

Sources: UNAIDS/WHO Global HIV/AIDS online database – Country Epidemiological Fact Sheets on HIV/AIDS and Sexually Transmitted Infections; World Health Statistics 2009 report; avert.org; World Bank. Statistics compiled by Catherine Karlsson.

Photo by Oupa Nkosi/*Mail & Guardian*

WILL WE GET THE MEDICINES WE NEED?

THE TENDER:

The barriers between you and better treatment

By Catherine Tomlinson

South Africa has over five million people living with HIV and it is estimated that two million people are currently in need of treatment.

The country has the biggest antiretroviral (ARV) programme in the world – around 900 000 people are receiving treatment through the public sector. This figure needs to double to meet the 80% treatment target in the HIV & AIDS and STI Strategic Plan for South Africa (2007-2011).

Given the scale of the treatment programme, as well as the urgent need to increase the number of people on treatment, South Africa must do everything it can to secure access to affordable drugs. We also need to improve the quality of our drugs to reduce side effects and the need for treatment switches. As the largest global purchaser of antiretroviral therapy (ART), South Africa must use its buying power to secure lower prices as well as improve regimens and procure user-friendly combination and co-packaged regimens.

The current tender for antiretroviral therapy was awarded in 2008 and will expire in May 2010. The previous tender process was criticised for its lack of

openness and participation. Civil society has been engaging with the upcoming tender through the Budget and Expenditure Monitoring Forum (BEMF) which brings together stake holders including legal experts, clinicians, economists, epidemiologists and trade union and civil society activists. Documents from BEMF are available at http://www.tac.org.za/community/BEMF

The National Department of Health is developing the upcoming antiretroviral tender in consultation with the Clinton Foundation HIV/AIDS Initiative (CHAI). CHAI works with governments and with pharmaceutical and generic companies globally to negotiate lower prices for ART.

CHAI has made a number of recommendations to the National Department of Health on ways to improve treatment regimens and control costs in the upcoming tender. The antiretroviral tender must be submitted to and approved by the National Treasury before it is made public for bids.

A point of disagreement is whether bids from South African drug companies should be favoured in the tender. It is recommended that South African companies be favoured only if their bids are competitive. Given the sophistication of local production plants and their sizeable market share, these companies should be able to compete globally.

While the vast majority of antiretroviral drugs purchased through government tender are produced locally, the cost of generic drugs is largely due to the price of their active pharmaceutical ingredients (APIs), which are generally produced abroad. To ensure that South Africa can take advantage of globally competitive prices throughout the tender period, the tender must require companies marketing finished products to lower their prices in response to market shifts that drive down the cost of APIs.

Following President Jacob Zuma's 2009 World AIDS Day announcements, the National Department of Health has updated its treatment guidelines for HIV/AIDS. This was necessary to secure new and better regimens through the upcoming tender. A number of obstacles to securing these regimens however still remain (see box to the right).

KEY TENDER ISSUES

Fixed-dose combinations (FDCs) and co-packages

Government must use the upcoming tender to improve and simplify treatment regimens. To do this it is vital that government purchases FDCs whenever available. When FDCs are not available government must purchase co-packages that combine all of the drugs of a regimen into a single user friendly blister. (See page 7 for more.)

Tenofovir (TDF)

A number of generic versions of tenofovir, including tenofovir-based fixed-dose combinations are pending registration at the Medicines Control Council (MCC). The MCC must fast track the registration of these drugs. (See page 2 for more.)

Abacavir (ABC)

Generic versions of abacavir, including ABC/lamivudine paediatric combinations, are pending registration at the MCC. The MCC must fast track the registration of these drugs.

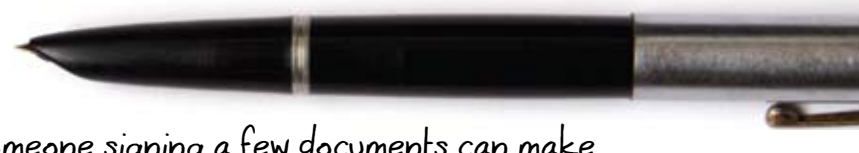
Lopinovir/Ritonavir (LPV/r)

Heat stable paediatric LPV/r tablets are pending registration with the MCC. Availability of the drug is necessary to implementing the updated treatment guidelines. The MCC must fast track registration of this drug. (See page 20 for more on ABC and LPV/r.)

Over the past year we have seen increased political commitment to promoting evidence-based treatment, prevention and care for HIV. Government has recommitted to meeting the National Strategic Plan (NSP) targets, expanded budgets for HIV and is updating and improving the treatment guidelines. Getting the ARV tender right is essential if these changes are to be properly implemented. Government must use this opportunity to improve facilities and simplify treatment and care for patients and health care workers.

Photo by David Harrison

Photo by Delwyn Verasamy/ *Mail & Guardian*



Someone signing a few documents can make the difference to whether you have to keep struggling with some side effect or not, whether you take three pills a day or one. x please sign

The MCC bottleneck

South Africa faces a major barrier to improving treatment regimens – the slow registration of drugs by the Medicines Control Council (MCC). Many essential drugs in the new treatment guidelines have not yet been approved by the MCC, particularly fixed-dose combinations (FDCs) and paediatric formulas.

The HIV Clinicians Society of Southern Africa has called on the MCC to fast-track the registration of a number of antiretroviral drugs before the tender is finalised, particularly tenofovir (TDF)-based fixed-dose combinations as well as abacavir/lamivudine (ABC/3TC) combinations and lopinavir/ritonavir (LPV/r) paediatric formulas.

If the MCC bottlenecks are not resolved in time, the tender must allow for the purchase of drugs not yet registered by the MCC. These drugs must have already been registered by international regulatory bodies such as the Food and Drug Administration (FDA) in the United States. These drugs must also be fast-tracked for registration in South Africa.

Illustration by Brice Reignier

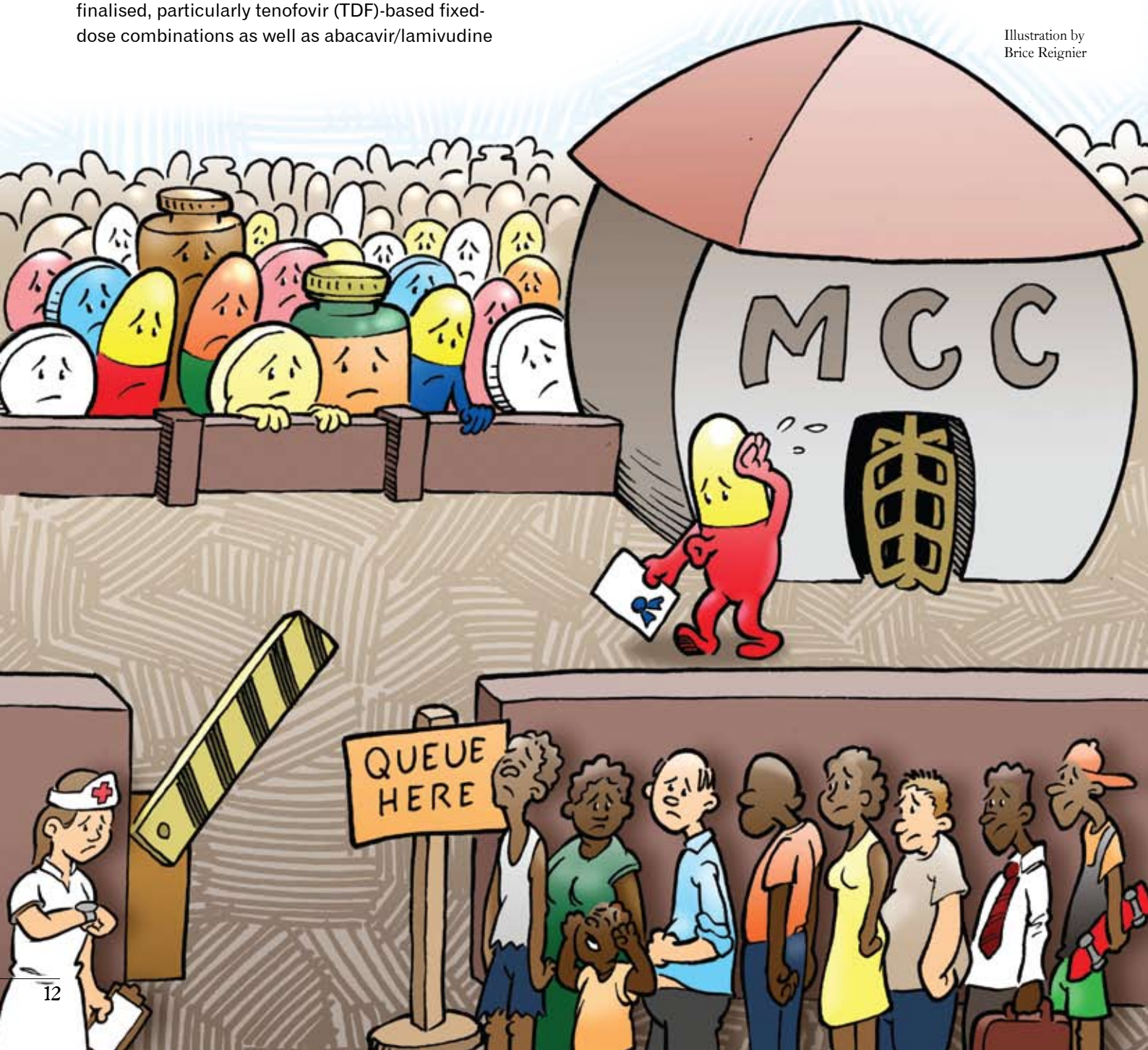


Photo by Ntombizonke Ndlovu

The Edendale tragedy

By Ntombizonke Ndlovu

In May 2009 Edendale hospital in uMgungundlovu stopped initiating new HIV-positive patients onto antiretroviral treatment. By July there were as many as 2,000 people on the waiting list for treatment. Doctors and nurses told the media that patients were dying every week.

One reason for not initiating more patients onto treatment was the lack of doctors and pharmacists at the hospital. Doctors told the media that they had alerted district health officials to the problems as far back as November 2008.

On 16 July 2009 TAC uMgungundlovu and partner organisations arranged a march attended by more than 700 people. The slogan for the march was 'WAITING LIST = DEATH'. The focus was the situation at Edendale Hospital, the shortage of space to run the ARV programme effectively and the shortage of human resources at public facilities. The march took place one day after a vigil held for those who had died due to the lack of treatment. We don't know exactly how many people died due to the shortages at Edendale.


Photo by Ntombizonke Ndlovu

Eventually, due to the work of TAC, various other organisations and the media, the situation was resolved. In July 2009 Kwazulu-Natal MEC for Health, Dr Sibongiseni Dhlomo, removed District Medical Manager, May Zuma-Mkhonza for failing to manage the ARV roll-out at Edendale hospital. It also emerged that Zuma-Mkhonza had turned down an offer from international donors to help pay for extra doctors and pharmacists at the hospital.

"Did it have to come to that? Who should be accountable for all the deaths of our brothers and sisters, our mothers and fathers and our children who died?" – TAC uMgungundlovu newsletter from 2009.

Access to essential medici

the story starts here

1959
Democratic Republic of Congo
The first known case of HIV occurs.

1986
Worldwide
The retrovirus previously identified as the cause of AIDS is officially named HIV.

1987
United States
Zidovudine (AZT) becomes the first drug approved for HIV treatment at a cost of R30,000 per person per year. AZT will not be available in South Africa until 1999.

1987
United States
The AIDS Coalition to Unleash Power (ACT UP) is founded to advocate for better treatment and policies for people living with HIV.

Photo from blog.dragonballyee.com

1989
Worldwide
The price of AZT decreases by 20%, following two years of protest by ACT UP. Treatment costs R24,000 per person per year — still too expensive for the majority of those living with HIV.

2001
Qatar
The Doha Declaration is introduced. This new agreement on TRIPS clarifies how and when member states may disregard patents. Parallel importing (importing generic drugs from other countries) gives low- income countries greater control of treatment measures for their citizens. South African Minister of Health, Manto Tshabalala-Msimang, refuses to use Doha to obtain more affordable treatment.

2001
South Africa
Court rules in favour of the Treatment Action Campaign in TAC vs State, ordering the government to make nevirapine available to pregnant HIV positive women as part of a prevention of mother-to-child transmission (PMTCT) programme.

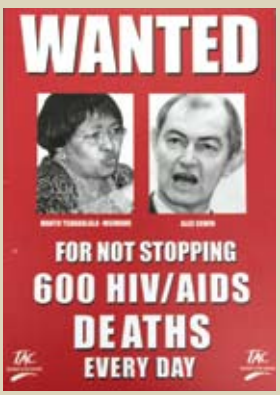
Photo by Eric M

2002
Botswana
Africa's first national HIV treatment programme is launched.

2002
South Africa
TAC and MSF announce that they are importing generic drugs from Brazil for their ARV programmes. This defiance of patents enables an ARV pilot project in Khayelitsha.


Photo by Eric Miller, courtesy MSF

2002
South Africa
Activists charge Health Minister Manto Tshabalala-Msimang and Minister for Trade and Industry Alec Erwin with culpable homicide for the 600 South Africans who die daily because of lack of accessible treatment. This forms part of TAC's 'Dying for Treatment' campaign.



2002
South Africa
As a result of public and international pressure, government unveils their ARV treatment programme under the Operational Plan for Comprehensive Treatment and Care for HIV/AIDS.

2004
India
The National AIDS Control Organization (NACO), in partnership with government, begins to provide free ARVs.


Photo by the International Federation of the Red Cross

ines in the age of HIV

1994
Uruguay

The international agreement called Trade Related Aspects of Intellectual Property Rights (TRIPS) is created, affecting all World Trade Organization member states. This agreement requires countries to comply with patent law—limiting the number of competing drugs on the market, and thus keeping prices high. Since most first- and second-line treatments are still covered by patents, they remain expensive and are mostly available in high-income countries. Low- and middle-income countries are forced to wait for patents to expire, or for branded drugs to decrease in price over time.

1994
United States

AZT used by pregnant women is discovered to reduce mother-to-child transmission by 70%.

Photo by Talia Frenkel/American Red Cross

1994
United States

Highly Active Antiretroviral Therapy (HAART), which consists of a combination of several ARVs, is created. This effective treatment option costs R36,000-R55,000 per person per year. HAART will not be available in South Africa until 2004.

1996
Brazil

The first free national ARV programme is launched by a low-income government.

1996
United States

Post-exposure prophylaxis (PEP), a short course of ARV drugs, is recommended to reduce the risk of HIV infection after high-risk exposure in healthcare settings, reducing infection by 79%. PEP will not be available in South Africa until 2002.

1997
Brazil

Brazil implements compulsory drug licensing, which allows local manufacturers to produce generic versions of patented drugs. By disregarding the patent, prices are drastically decreased and access to treatment increased. South Africa has never enforced a compulsory license.

1998
South Africa

The Treatment Action Campaign (TAC) is formed to lobby for greater access to HIV treatment for all people in South Africa.

Miller, courtesy MSF

Photo by Malusi Mbatha

2005
Worldwide

AZT's patent expires, allowing the approval of several generic versions. The drug becomes available for R670 per person per year, 20% cheaper than the patented version and 87% cheaper than original cost.

2006
United States

Atripla, the first one pill, once a day fixed dose combination using triple-drug combination treatment, is approved.

2007
Thailand

The Thai government issues licenses suspending patents on expensive and essential medications, allowing imports of generic ARVs.

2007
South Africa

The National Strategic Plan for HIV/AIDS and STIs (NSP) is launched, aiming to put 80% of people who require treatment on ARVs by 2011.

2010
South Africa

Despite substantial progress made in the last 20 years, less than half of those living with HIV who require treatment have access to it.

the struggle continues...

Drug resistance *and you*

By Marcus Low

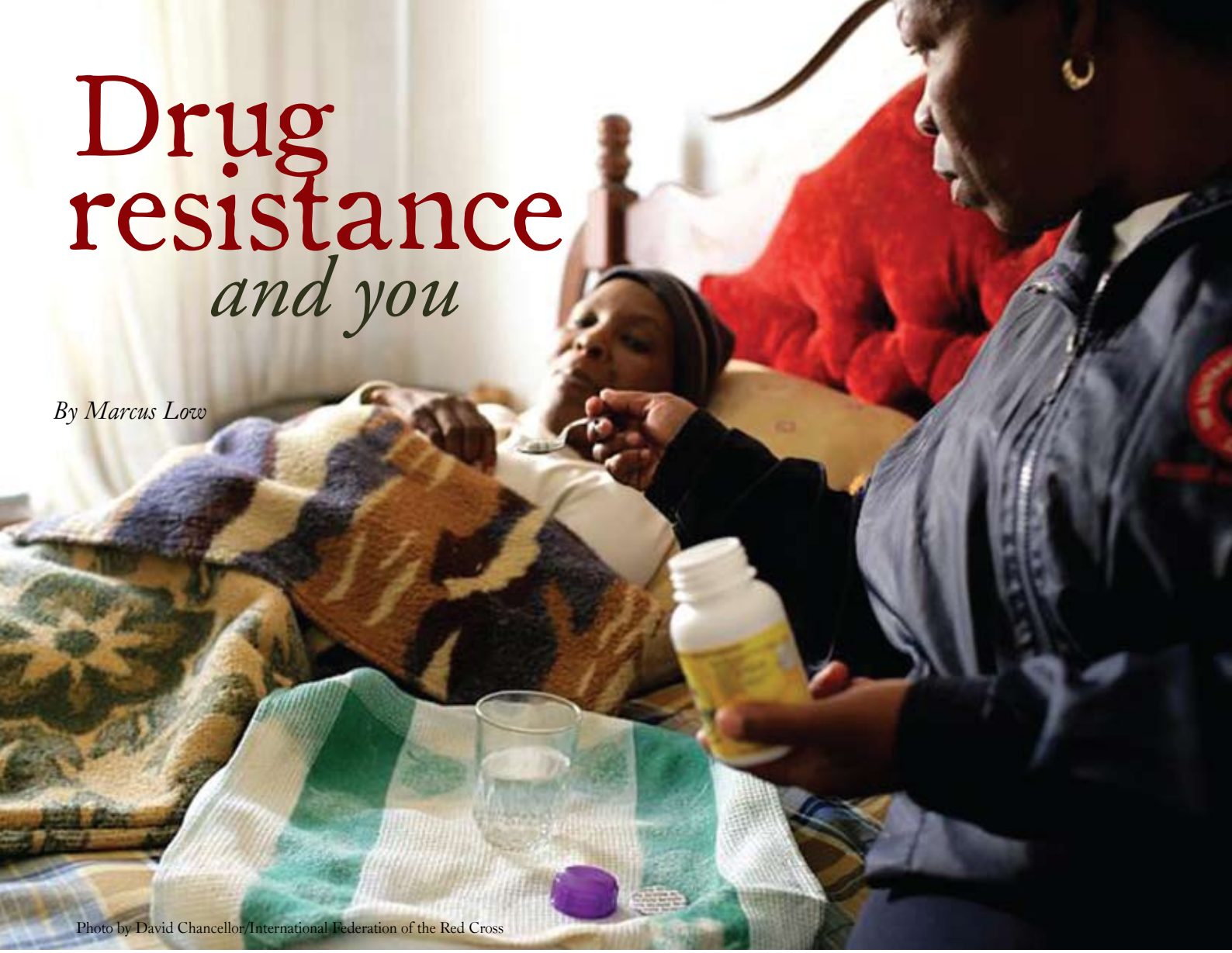


Photo by David Chancellor/International Federation of the Red Cross

What is resistance?

Drug resistance occurs when a specific medicine, or combination of medicines, can no longer suppress or cure a disease. It means the disease has changed in your body in such a way that the medication has stopped working. This is what happens when HIV-positive people have to switch from first-line antiretroviral therapy (ART) to second line ART because the first-line treatment is no longer effective.

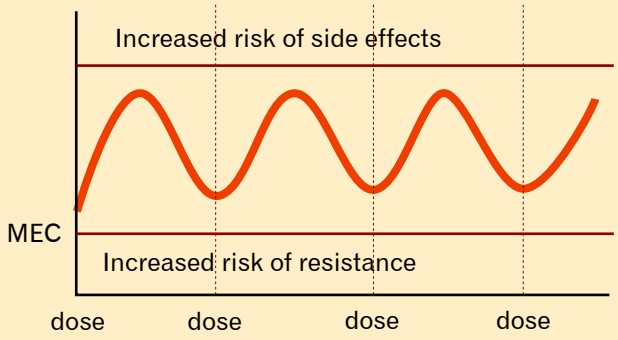
As HIV infects new cells and reproduces in our bodies, it constantly mutates (changes). HIV mutates quickly because it has a very high replication rate (it makes copies of itself rapidly) and it has no 'proof reader' mechanism – this means that when new copies of HIV are made in your body, there is no check that the new HIV is exactly the same as the previous ones. Because of this, mutations occur completely by chance - some are good, some bad, and some make no difference.

If, by chance, one of the mutations has some resistance to your medicines, that resistant form of HIV will multiply because it is better at beating treatment than the other strains of HIV in your body without that mutation. As more and more of these mutations develop, the specific medicines you are taking become less effective.

This is why we have to take a combination of three different antiretrovirals to keep the virus under control. If the virus mutates to beat one of the drugs, the other two can still prevent it from mutating and multiplying.

Graph A: Drug levels and resistance

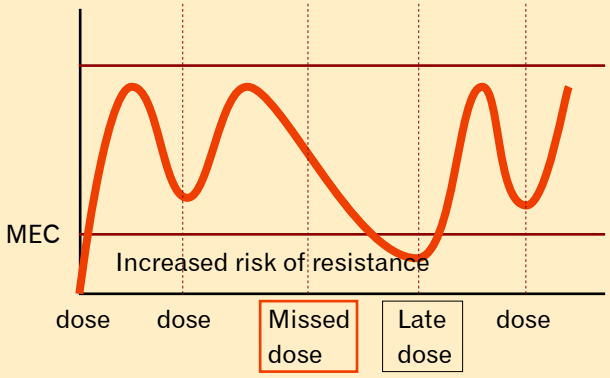
The target drug level needs to be above the MEC to avoid resistance and not so high as to cause side effects



MEC = Minimum Effective Concentration

Graph B: Drug levels and resistance

If you miss a dose or are late drug levels can drop to a level where resistance can occur



Illustrations based on graphs from iBase

How resistance develops

In order to suppress HIV, the amount of antiretrovirals in your body has to be kept at the right level. If the levels are too high, you experience side effects. If the levels are too low, the door is left open for resistance to develop.

Graph A shows the drug levels in your body if you take a specific medicine every 24 hours. Note how the drug level remains in the correct area.

Graph B shows what happens if you skip one dose of a drug that you are supposed to take every 24 hours. Note how the drug level drops down into the area where you are at risk of developing resistance.

The social causes of resistance

When a clinic runs out of medicines and HIV-positive people are turned away, all those people are at risk of developing resistance. Therefore, a reliable supply of medicines is very important for keeping resistance down in our communities.

However, controlling resistance is not only about drugs being available at the clinic. It is also about HIV-positive people taking ART as and when they should. When it comes to successful treatment programmes, access to treatment is only half the story – good treatment adherence is the other.

How drug-resistant TB develops

Drug resistance is a particularly serious problem when it comes to TB. Extreme forms of drug-resistant TB are very hard to treat.

As with HIV treatment, resistance to TB treatment tends to develop as a result of treatment interruptions. With TB drugs this often happens because people stop taking their medicines when they feel better. Even though they feel better, the TB mycobacterium might still be active in their bodies and mutate into a resistant form.

There are two ways to get drug-resistant TB: 1. If you catch it from someone else and 2. If it develops in your own body. The first kind we can attempt to manage using infection control measures such as making sure we have good ventilation wherever we are. The second kind we can avoid by taking our TB medicines as prescribed, even if we already feel better.

You can think of HIV as a snake. You need three heavy stones to hold this snake down. As resistance develops it is like having only two stones and then only one stone and the snake can wriggle free. If you are late in taking your antiretrovirals it is like lifting the stones a little. Resistance is like the snake learning how to wriggle free.

The problem with second- and third-line treatment

As more people spend more time on antiretroviral treatment, we can anticipate that the need for second- and third-line treatment will increase in the coming years. Since second- and third-line treatments are more expensive than first-line treatment, this is likely to lead to serious funding problems. It is therefore important that we proactively campaign to make sure that quality second, third and subsequent lines treatments are affordable and available in the public health system.

Alpha Mlondobozi

Photo by Adam Malapa

Living in fear

Adam Malapa interviewed Alpha Mlondobozi who is resistant to first-line antiretroviral treatment and is currently on a second-line regimen.

Alpha Mlondobozi is 43 years of age. She lives in Bridgeway, just outside the town of Tzaneen in Limpopo Province. She has a 24-year-old son and has been HIV-positive since 2000.

When Alpha discovered her HIV status she was very scared. All she knew about HIV was that it could not be cured and she thought that a person would die soon after learning his or her status. Through the private sector she immediately started antiretroviral treatment (ART). Alpha received no advice on how antiretrovirals (ARVs) work, nor any adherence counselling. Sometimes she was late taking treatment by a few hours and then panicked about this as the doctor had said she needed to take her medicines on time.

Alpha started a regimen of stavudine (d4t), lamivudine (3TC) and efivarenz (EFV). She often suffered severe diarrhoea and vomiting. The only way to control these side effects was to be admitted to hospital for a few days. She was frequently nauseous and always felt weak.

After seeing no improvement on this treatment she switched to a second-line regimen. This time Alpha enrolled at a public health facility. She attended treatment literacy and adherence sessions at Letaba Hospital where she gained more knowledge about HIV and about how important it is to take your treatment. After a few months on second-line treatment there were major changes in her health. She started to regain stamina and joined support groups at the hospital, where she shared her experiences with other HIV patients.

For Alpha, second-line treatment is her last hope in the public health sector. Although the treatment is helping, she can't get used to the bitterness of some of the drugs, for example didanosine (ddI), which is taken once a day on an empty stomach. It is a difficult pill to take as it is so large. You have to either melt it or chew it so that it can be swallowed. "I can't explain its taste but it doesn't taste good," Alpha says. "The other challenge for me is lopinavir/ritonavir (LPV/r). I have to take four 100mg [pills] to make 400mg which [is the right amount for] my weight. For me [that] is just too many pills at once," she comments. "Previously it was better because I was taking them as capsules, but now I'm taking them as pills which I have to taste, which is not good for me at all."

Alpha is also afraid of what will happen in future if she develops resistance to the regimen that she now uses. "I really don't know what will happen. I guess a person will just be waiting for death."

children
and antiretrovirals

By Catherine Karlsson

Photo by David Chancellor/International Federation of the Red Cross

The most effective way to prevent HIV infection in children is PMTCT (prevention of mother- to-child transmission) treatment, but in cases where children are infected despite these efforts there is a critical need to provide them with ART. As HIV-positive infants usually show clinical symptoms within their first year of life the World Health Organization recommends putting such infants on treatment immediately after birth. On World AIDS Day last year, president Jacob Zuma announced that South Africa will follow these recommendations starting in April 2010.

Mark Cotton, director of the Children's Infectious Disease Clinical Research Unit at the University of Stellenbosch, says that he is pleased with the new guidelines as this is what South Africa's experts have been advocating for the last three years. The president's announcement was a step in the right direction, but challenges remain when it comes to providing ART for infants and children.

Cotton says that the lack of special drug combinations for children remains a major obstacle.

Without antiretroviral treatment (ART), more than 30% of HIV-infected children will die before their first birthday and about 50% before the age of two. With treatment however, about 75% of these infants can be saved.

Like adults, infants and children need to be treated with at least three different drugs to limit the risk of developing resistance. However, the drugs need to be given in smaller doses. Furthermore, the portions and combinations of these doses have to be changed regularly as the child grows. In order to portion doses correctly, careful calculations must be made, applying a complicated formula based on the child's length and weight.

These calculations are often impossible to do at health clinics in rural areas as they often lack the necessary equipment, such as calculators. Instead, health workers have to do simplified calculations and divide adult antiretrovirals (ARVs) up for kids. This approach increases the risk of over- or underdosing. (See page 17 for more on how underdosing can lead to resistance.)

Photo by Emily Chastain

Simplifying dosing can have serious consequences for the child. Overdosing can increase side effects, while underdosing can lead to drug resistance.

Dosing is further complicated by the fact that infants are not capable of swallowing tablets. They therefore have to take the drugs in the form of syrups or powders. This causes problems since it is not possible for all parents to store the syrup in a refrigerator or to get drinking water to mix the powder in. Also, the unpleasant taste can make a child reluctant to swallow.

So-called fixed-dose combinations (FDCs) that combine multiple ARVs in a single tablet for children have recently been developed. In countries where these tablets are available medicines are now easier to store, transport and administer. The risks associated with clinicians having to divide up adult tablets for children have been eliminated in these places. However, paediatric formulations are more expensive than adult treatments. They are often unaffordable in the areas where they are most needed.

Earlier this year, in an article for Plus News, Dr. Eric Goemaere, medical coordinator for South Africa for the volunteer doctors organisation Médicins Sans Frontières, expressed concern about people not treating children because they are scared of wrongly calculating doses and making them even more ill. He called for paediatric treatment to be made nurse-friendly at a primary care level so that treating children will be as easy as treating adults.

It is clear that further development of cheap, fixed-dose combinations for children is greatly needed.

Sources: Newell, M. et al, *'Mortality of infected and uninfected infants born to HIV-infected mothers in Africa: a pooled analysis'*, The Lancet 364:9441 (2004).

The 2010 ARV Tender and Paediatric Regimens

As South Africa scales up ART for infants and children, it must ensure access to a consistent supply of safe, high-quality paediatric drugs.

Abacavir (ABC)

The World Health Organization has recommended the use of ABC in paediatric 1st line regimens. Studies have shown that it can be used effectively in resource limited settings.

Following a competition commission complaint of TAC and partners, a number of generic producers can now market ABC. Access to affordable ABC is hindered by slow registration of new ABC products by the Medicines Control Council (MCC).

The HIV Clinicians Society has called on the MCC to fast-track all ABC products and particularly paediatric ABC/lamivudine combinations.

Lopinovir/Ritonavir (LPV/r)

Under the new guidelines LPV/r is used in 1st line treatment for all infants under 3. LPV/r is also used in 2nd line regimens for children over 3, adolescents and adults failing 1st line treatment.

LPV/r is under patent in South Africa and solely marketed by Abbott Laboratories. If lower prices for generic LPV/r become available then the Minister is empowered by the Patents Act to require Abbott to issue licenses to generic manufacturers on reasonable terms.

Heat stable paediatric lopinovir 100mg/ritonavor 25mg tablets are pending registration with the MCC. These tablets are necessary to implementing the new guidelines and the MCC must fast track their registration.

Sources: www.who.org; www.avert.org; www.newsplus.org; P. Nahirya-Ntege et al, 'Successful management of suspected abacavir hypersensitivity reactions among African children in the ARROW', IAS (2009); Violari, A. et al, 'Early antiretroviral therapy and mortality among HIV-infected infants', N Engl J Med. 359, 2233-44, 20 November 2008 (http://www.ncbi.nlm.nih.gov/ pubmed/19020325).

Sphelele Yende is four-years-old and has been on ART since September 2007.

Photo by Malusi Mbatha

SPHELELE'S story

Sphelele Yende is a four-year-old boy from Iswepe village in Gert Sibande, Mpumalanga Province. He is an energetic child living happily with HIV. Sphelele has been on antiretroviral treatment (ART) since September 2007 when his mother first found out that he was HIV-positive. Malusi Mbatha spoke to Sphelele's mother Nomsa Nhlengethwa, a Treatment Action Campaign (TAC) member and volunteer at Iswepe clinic. Nomsa gave a heartfelt account of her child's experiences since he was diagnosed HIV-positive.

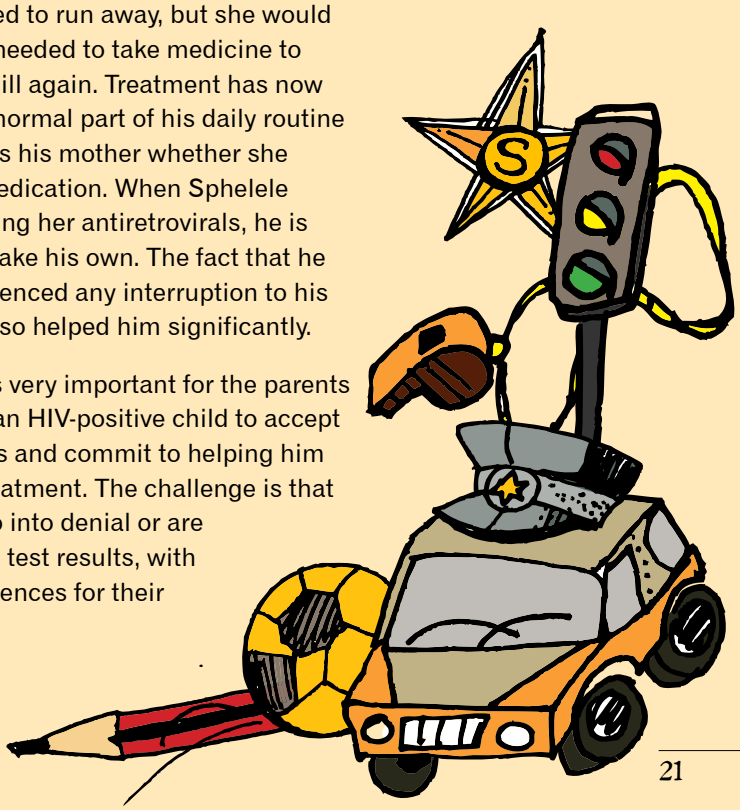
Around September 2007, when Sphelele was two years old, he fell ill and his mother took him for an HIV test. She had discovered her own HIV status the previous year.

After being diagnosed HIV-positive, Sphelele immediately began treatment on regimen 1a at Piet Retief Hospital. Nomsa had to adjust quickly to the HIV status of her son, and help him to take ART so that he could live a normal life. The first treatment regimen that Sphelele tried did not work well for him. He continued to be very ill – vomiting, suffering regular headaches, struggling to eat and losing a lot of weight. During this time Sphelele also developed psycho-social withdrawal symptoms. He no longer enjoyed being with other children, often preferring to stay at home with his mother. After six months, he went for a check-up. The doctor found that his viral load was 45,000, and immediately switched him to zidovudine, didanosine and lopinovir/ritonavir.

Sphelele responded well, and is no longer ill or losing weight. Nomsa reports that he is now a very active and playful child. He enjoys all the games that other boys in his locality play, such as soccer, fighting games, playing with cars and so on. He is looking forward to pre-school next year, and wants to be a policeman when he grows up so that he can arrest all bad people.

When asked how her child reacts to taking medication everyday, Nomsa says that initially Sphelele would resist. Laughing, she describes how he often tried to run away, but she would tell him that he needed to take medicine to avoid becoming ill again. Treatment has now become such a normal part of his daily routine that he even asks his mother whether she has taken her medication. When Sphelele sees Nomsa taking her antiretrovirals, he is more willing to take his own. The fact that he has never experienced any interruption to his treatment has also helped him significantly.

Nomsa feels it is very important for the parents or guardians of an HIV-positive child to accept the child's status and commit to helping him or her to take treatment. The challenge is that some parents go into denial or are scared to collect test results, with serious consequences for their child's health.



PATENTS

What you need to know

By Lamya Moosa and Catherine Karlsson

What is a patent?

A patent is an exclusive right that is given to an inventor by law. It means that the inventor alone gets to decide how his or her invention can be used.

For example, if you invent a completely new kind of oven that uses a clever new way to heat food, then you can apply to get a patent for your oven. If you are awarded the patent, then other people are forbidden to sell ovens that use your clever new way of heating food – unless they have your permission. The same patent system is in place for new medicines and many other kinds of inventions.

Patents only last for a specific number of years – with medicine it usually ranges from 10 to 20 years. The idea is that, for a limited period, the patent rewards the inventor for his work in developing the new oven or medicine. If you alone have the right to sell your wonderful new product, you can ask very high prices and quickly make a lot of money from your invention.

With essential medicines like antiretrovirals it becomes more complicated than with ovens. Companies are awarded patents and these patents allow them to keep prices high. To do this while people are dying because they cannot afford a certain medicine can be seen as unethical. For this reason, we have arrangements like patent pools, compulsory licenses and parallel importing (explained elsewhere in this article). A patent protection in a given country does not extend to other countries.

Patent pools

An HIV drug patent pool permits drug companies to voluntarily submit their patents to an independent organisation like UNITAID, which is hosted by the World Health Organization and whose primary goal is to increase access to drugs for global diseases. UNITAID then distributes the patents of HIV drugs to generic drug companies and researchers in return for fair royalty payments to the original inventors or patent holders.

The patent pool is therefore like a one-stop shop where companies can go to get licenses to manufacture specific drugs. Rather than negotiating with other companies, manufacturers will ideally only have to deal with the patent pool.

In circulating these patents, the patent pool permits greater competition between drug companies and allows for the production of drugs by generic companies. These companies can produce exact copies of the drugs that will be more affordable to those in need.

An HIV patent pool also allows for easier development of fixed-dose combinations, because all the patents will potentially be available for researchers wanting to combine certain antiretrovirals into one pill.

The most effective way to increase the distribution of HIV drugs is through a monitored and working patent pool. This will enable wider distribution of life-saving HIV drugs by breaking down monopolies and reducing unnecessary red tape.

Sources: http://www.msfaccess.org/main/access-patents/make-it-happen-campaign/campaign-updates/february-9-2010/; http://www.unitaid.eu/en/20091215237/News/UNITAID-APPROVES-PATENT-POOL.html

Pharmaceutical companies on average spend twice as much on marketing and administration as they spend on research and development. This suggests that the billions made thanks to patent protection are mostly spent on marketing and not on research.

What is TRIPS?

TRIPS stands for Trade-Related Aspects of Intellectual Property Rights, an international agreement administered by the World Trade Organization (WTO). TRIPS introduced patent laws into the international trading system and placed certain restrictions on WTO member countries in relation to intellectual property rights. Many argue that TRIPS resulted in limited access to essential medicines in developing countries. **The Doha Declaration was an attempt to rehabilitate TRIPS so as to promote access to medicines in the developing world.**

What is the Doha Declaration?

The Doha Declaration on TRIPS was passed by the World Trade Organization in 2001 in Doha, Qatar. It reaffirms and clarifies the right of developing countries to manufacture generic drugs and, in times of national health crises, to overlook patents held by major drug companies. Since HIV is an emergency in South Africa, the Minister of Health could use the Doha Declaration to grant compulsory licenses (see below) for drugs that are too expensive due to patent restrictions. No South African health minister has used this power.

What is a compulsory license?

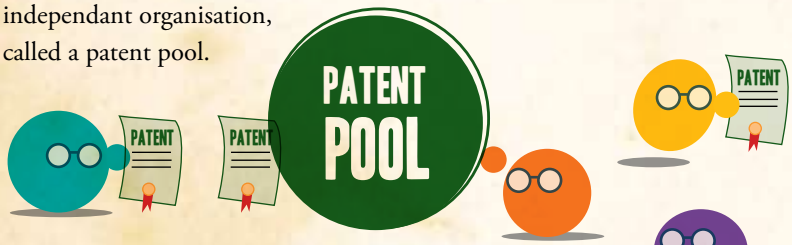
If patented drugs are too expensive and there is a public health crisis, compulsory licenses can be awarded. These give local generic manufacturers the right to produce the patented drug regardless of whether the patent holder agrees to it or not. When generic manufacturers then start to produce the drug, its price comes down drastically due to competition. Despite having the legal power to do so, no South African Minister of health has ever made use of this right.

What is parallel importing?

Parallel importing is when a country imports generic medicines from another country without the consent of the patent holder. This usually takes the form of developing countries importing from other developing countries (like India) that have strong generic medicine manufacturers. Parallel importing can save governments a lot of money because there are substantial price differences between the same pharmaceutical products sold in different countries.

HOW A PATENT POOL MIGHT WORK...

1.
Companies give HIV patents they invented to an independant organisation, called a patent pool.



2.
Drug companies and researchers can now access and buy the patents from the patent pool. The inventer receives royalties from the sales.

3.
Lots of drug companies can make and sell the same drugs. This makes the price of the drug come down.

4.
Researchers can use the patents to develop child-friendly drugs and essential new combined pills.

MAKE IT HAPPEN! PUSH FOR THE POOL!

CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

These illustrations are based on an MSF patent pool video, which is available on www.youtube.com. Read more about the MSF Access campaign at MSFAccess.org.

Photo courtesy of Gallo Images/Getty Images

WHERE MEDICINES COME FROM

1. Tropical rain forests like those found in the Amazon region of South America are home to 50% of all plant species, and so are essential to drug research. However, many medicines, including antiretrovirals, contain no plant products.

Photo by Roger Segelken, Cornell University News Service, copyright © 1997 Cornell University.

2. Many of the synthetic materials used in medicine are replications of plant materials, but with higher potency or lower toxicity. Many labs prefer testing synthetic materials as plant materials cannot be patented as easily.

Photo by Damien Schumann

3. A tablet comprises a mixture of active and inactive substances, usually in powder form, pressed or compacted into a solid. A tableting machine can make hundreds of thousands of tablets an hour.

4. A highly automated factory machine will bottle between 120 and 240 bottles of pills per minute, and will produce between 2000 and 5000 blister packs per minute.

Photo courtesy of Gallo Images/Getty Images

5. Even though some pills are produced in South Africa, the active pharmaceutical ingredients, or APIs, often still have to be imported from overseas. This means that, even before trucks take pills from big city depots to your local clinic, some of the ingredients in the pills have traveled thousands of kilometres from overseas to get to the South African factory where it is made.

Photo by Paul Bettings

6. The Department of Health buys antiretroviral medicines through a special antiretroviral tender. The 2008 tender was worth more than R3.6 billion. The 2010 ARV tender will be awarded later this year.

Photo by Flickr user Mike Blyth

7. Long queues and medicines stock-outs can result from clinics being under-staffed and without access to essential medicines.

Photo by Oupa Nkosi/*Mail & Guardian*

8. Even after the pill's long journey to reach those who need them, many people don't take their pills as prescribed. Having access to treatment is only half the challenge when it comes to living with HIV - good treatment adherence is the other.

Photo by Oupa Nkosi/*Mail & Guardian*

a Deadly Deal

Photo by Suraj Mishra, courtesy MSF

Within a matter of months, over a million people with HIV in South Africa will be receiving antiretroviral (ARV) treatment. One of the main reasons why this has been possible, is that the prices of ARVs have fallen so much over the last ten years. In the 1990s, ARV treatment cost over R3,000 per month. Now the government buys the standard regimen for R150 per month.

Lower prices have made the HIV treatment programme affordable for the state. Without these massive price reductions, nearly a million additional people would be dead or dying now in South Africa.

How ARVs became affordable

In the early 2000s, because these drugs were patented, only the company with the patent decided who could sell them. This meant that there was no competition on ARVs and so companies could charge very high prices.

However three things helped to lower the prices:

1. Manufacturers based mainly in India (but also in Brazil and elsewhere) produced much cheaper generic versions of ARVs. They could do so because medicines were not patented in India. However, at first these drugs were not available in South Africa because they were patented here.
2. Activists in South Africa, Africa and across the world were able to campaign for licenses to be given to these generic manufacturers to sell their medicines in Africa.
3. Following this pressure the companies manufacturing ARVs under patent either dropped their prices substantially (e.g. fluconazole, efavirenz and tenofovir) or allowed generic competition (e.g. ddI, d4T, AZT, lamivudine and nevirapine).

Many ARVs manufactured in India are now sold in South Africa at affordable prices.

The Indian Patent Act

In 2005, the Indian government passed legislation that allowed medicines to be patented. As a result, medicines developed since 2005 cannot as easily be produced by generic companies operating in India. This means that step one above no longer happens with new drugs. It is therefore harder to campaign successfully for lower medicine prices.

For example, raltegravir is an important new ARV especially for people who are resistant to other ARV regimens. It currently costs R2,396 including VAT. This is far too expensive for the South African public health system. There is no generic version of it in India or anywhere.

At least two new tuberculosis drugs are likely to become available in the next few years. These are urgently needed especially because of the growing drug-resistant TB epidemic. It is worrying that they might not be affordable where they are most needed: in poor countries.

The EU/India negotiations

Now, the prospect of making new ARVs available in South Africa at affordable prices is under threat because of events unfolding in India. In particular, the European Union (EU) is putting pressure on the Indian government to sign a trade agreement that will make competition on essential medicines still under patent even harder.

A leaked draft of the negotiating texts shows that the EU is pushing for a five to nine-year restriction on the information generic companies can use when they apply to register their medicines with the Indian medicines regulation body. This will make it much more difficult to register generic drugs.

The EU is also pushing for the life of the patent (usually 20 years) to be made longer. The EU also wants to be able to seize medicines that are in breach of EU patents at EU borders, even if these medicines are on their way to a country outside the EU, such as an African one.

If these measures are adopted, generic competition on patented ARVs in sub-Saharan Africa will become very difficult. Unless we act, new drugs will be often unaffordable. This will cause avoidable suffering and death.

Lower antiretroviral prices have saved many lives. But now the European Union is trying to force a trade agreement deal that will make it difficult to force lower drug prices in the future.

Photo by Damien Schumann

HOW ACTIVE TB IS DIAGNOSED

By Nathan Geffen

Active tuberculosis (TB) is difficult to diagnose. It takes a long time to get an accurate result and patients often need treatment urgently. Far more money must be invested in researching a quick, accurate and affordable test for active TB.

It is easy for a clinic to test whether you have HIV. A small amount of blood is taken from your fingertip, and the blood is then used in simple tests.

Within 20 to 30 minutes, you can know your HIV status. The tests are fast, cheap and highly accurate. If an HIV test procedure is carried out properly, the chance of a wrong diagnosis is very small.

Unfortunately, this is not the case for TB. At least half of all people in South Africa are infected with TB. But most people infected with TB will not become ill with the disease. Their TB is inactive in their lungs. It does not reproduce and remains under the control of their immune systems. Because so many people have latent (inactive) TB and because it seldom means they will get sick, it is usually not that important to diagnose latent TB. Instead, what we really need to be able to diagnose is people whose TB is reproducing. They will usually be sick or about to become sick from TB. This is called active TB.

Active TB is slow and expensive to diagnose. This is a problem, because people with active TB often need to be treated right away. If doctors cannot be sure what disease a patient has, it is difficult to make the right treatment decisions.

Methods of diagnosing active TB

X-ray

Usually patients with symptoms of TB (e.g. coughing for two weeks, weight loss, night sweats) will have a chest x-ray taken. The x-ray on the right below shows a patient with TB.

Doctors need to be experienced to diagnose TB using x-rays. But even then x-rays often do not provide enough information to make a TB diagnosis. Also, x-rays cannot detect TB that is active outside the lungs (known as extra-pulmonary TB).

Sputum microscopy

A better way to try to diagnose TB is to ask the patient to cough up sputum (or gob). Then the sputum can be sent to a simple laboratory. There, a special stain applied to the sputum will show up the TB under a microscope. On the right below is a photo of what TB looks like under a microscope.

But sputum microscopy has problems too. Its accuracy depends on the process being carried out by a skilled laboratory worker. Also, many patients, particularly HIV-positive ones, do not have enough tuberculosis in their sputum for it to show up under the microscope. Like x-rays, sputum microscopy cannot detect TB outside the lungs.

Culture

The most accurate way to diagnose TB currently is to send a sputum sample to a sophisticated laboratory that will put the sputum into a special culture where microbes (germs) like TB can grow. If no TB grows in the culture, then the patient probably does not have TB, at least not in the lungs. If TB does grow, then the patient has TB.

Culture tests can be used to diagnose TB outside the lungs. This is done by taking tissue from the part of the body that is suspected of having TB. For example, if it seems that a person has TB of the spine, spinal fluid can be sent to the laboratory for culture.

But culture tests have problems too. They are slow, usually taking a few weeks to give a result. They are also expensive, and must be done in a sophisticated laboratory. Furthermore, the sputum or other body tissue has to be transported carefully from the clinic to the laboratory.

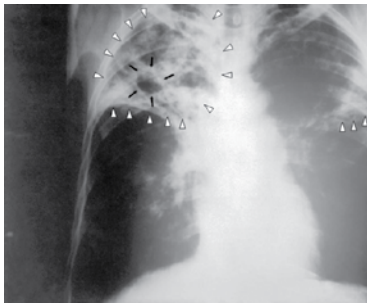
PCR

As with HIV, active TB can be detected using a PCR (polymerase chain reaction) test. But it is expensive, needs a sophisticated laboratory and is not as accurate as culture.

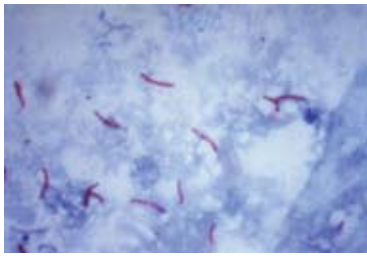
New methods

New TB diagnostic methods are being researched. One interesting new diagnostic is being tested in Khayelitsha, but it is too early to say how practical and affordable it will be.

But there is far too little money being invested in new TB diagnostics. Ultimately we need a test for active TB that works like an HIV rapid test. It should be cheap, accurate, easy to carry out and give a result in minutes. There is a long way to go before we get that. In the meantime, the Treatment Action Campaign (TAC) should pressurise the South African government, the United States-based National Institutes of Health and the World Health Organization to help ensure that much more money is invested in TB research.



The arrows show an abnormality on this lung x-ray which indicates TB. Photo from Wikipedia.



The red tubes are tuberculosis bacteria. Photo from Wikipedia.

HIV rapid tests are fast, cheap and accurate. But unfortunately TB testing is a much longer, more involved process. More money needs to be invested in a more rapid, accurate TB test. Photo by Paymon Ebrahimzedah.

There are two measures of the accuracy of a medical test: sensitivity and specificity.

A test should be SENSITIVE:

If a patient has TB, the test should detect TB.

A test that is 90% sensitive detects TB nine times out of ten when it is there, but one time out of ten it fails to detect TB when it is there.

A test should be SPECIFIC:

When a patient does **not** have TB, the test should **not** detect TB.

If a test is 90% specific, this means that nine out of ten times the diagnostic correctly does **not** detect TB when it is not there, but one time out of ten it detects TB when it is actually not there.

TAC Branch News

Khayelitsha condoms award - 500,000 condoms a month

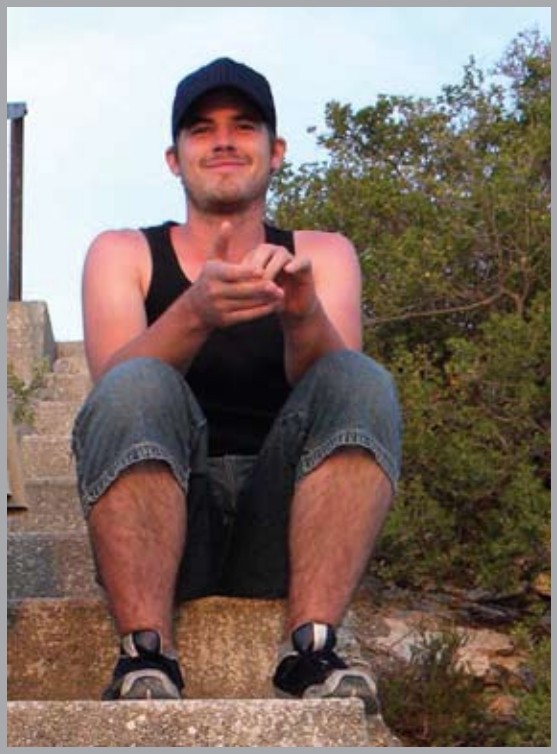
By Mary-Jane Matsolo

Treatment Action Campaign (TAC) Khayelitsha was honoured in March by the Western Cape Department of Health for being the NGO to distribute the most condoms in the Western Cape. TAC was awarded a certificate of excellence by the Department. The award was accepted by TAC Khayelitsha's dedicated condom distributor, coordinator Thobela Vika.

A condom drive known as 'Super Saturday' takes place where TAC comrades cover as many areas as they possibly can. They hand out condoms at schools, shebeens, hair salons and taxi ranks and do all they can to ensure that condoms reach as many people as possible.

TAC Khayelitsha alone distributes 500 000 condoms a month throughout Khayelitsha. This would not have been achievable if it weren't for our hard working comrades in the district.

Photo by Mary-Jane Matsolo



TAC remembers Andrew Warlick

Andrew Warlick passed away tragically on Sunday 11 April 2008. His loss comes as a shock to many, and in particular the many within TAC whose lives he has touched.

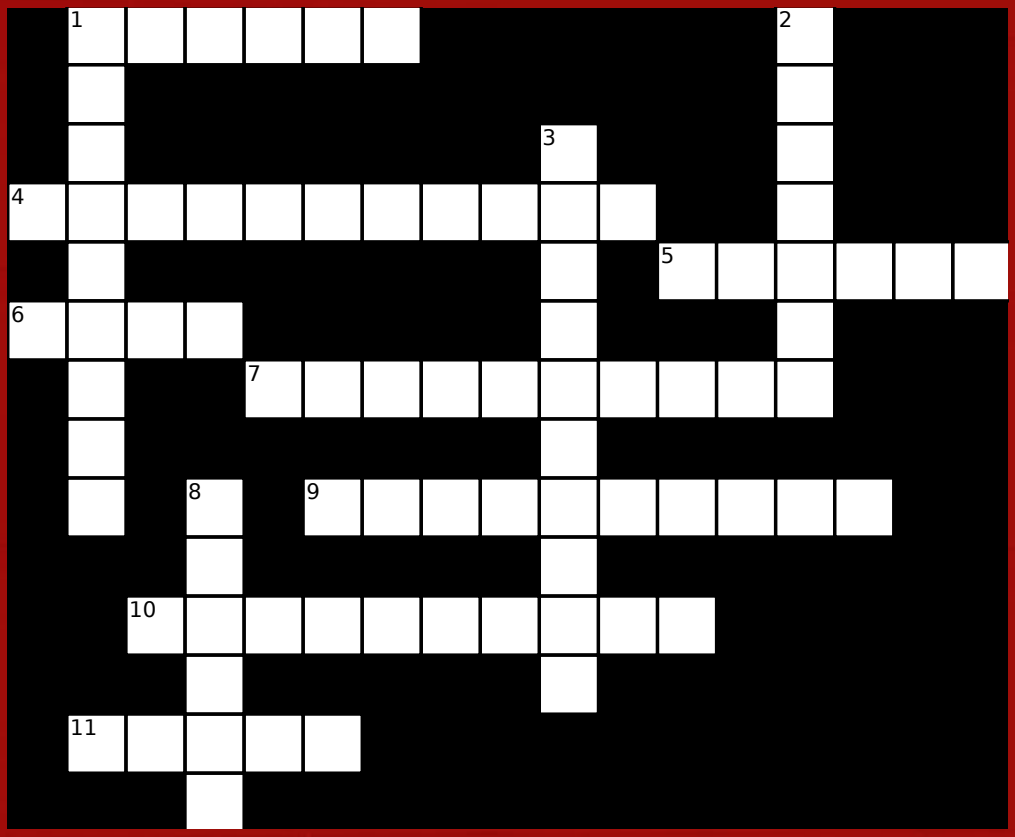
Andrew approached the task of Monitoring and Evaluation (ME) management with enthusiasm and creativity, pulling together our ME system and laying the basis for exciting future development. With every breakthrough, he couldn't contain his excitement - and his enthusiasm was infectious. He was not just a number cruncher, but wanted to see the success of the initiatives that he monitored.

Equal Treatment was a project very close to his heart, and he had a passion for ensuring its maximum impact.

Andrew also had an extraordinary concern for the wellbeing of others – many will miss his interest in their lives.

Hamba kahle, comrade and friend.

Equal Treatment's Crossword Puzzle



We will give a R200 Pick n Pay gift voucher for the first crossword drawn from a hat with all the correct answers. The answers can be found in this issue of *Equal Treatment*.

Last month's winner will be announced in a future issue.

Fax or post your completed crossword, with your name, address and contact number.
Address: Equal Treatment, PO Box 2069, Cape Town 8001
Fax: 021 422 1720

Across

1. The Department of Health buys antiretroviral medicines through an antiretroviral ___.
4. A pill that combines a number of different pills into one pill is called a fixed dose ___.
5. To do a culture test for tuberculosis requires that a ___ sample is sent to a sophisticated laboratory.
6. When patents for medicines are administered and negotiated by one central institution, it is called a patent ___.
7. What was the first drug approved for HIV treatment?
9. When the levels of antiretrovirals in your body drop too low, you are in danger of developing ___.
10. Medicines for children are called ___ medicines.
11. An important international agreement that bound World Trade Organization member countries to uphold patent rights.

Down

1. What drug is starting to replace d4T in first-line treatment?
2. The most accurate way to diagnose tuberculosis at the moment is called a ___ test.
3. When a company is forced to grant licenses allowing generic manufacturers to produce a patented drug, it is called ___ licensing.
8. What country implemented compulsory licensing in 1997 to ensure that its citizens have access to HIV treatment?

CAMPAIGN FOR
ACCESS
TO
ESSENTIAL
MEDICINES

MEDECINS SANS FRONTIERES

Lulama James will turn 40 in April. In addition to being HIV-positive, she has had TB since 2005, progressing to drug-resistant TB and recently to extensively drug-resistant TB. In February of this year, she stopped responding to treatment.

LULAMA NEEDS MORE TREATMENT OPTIONS NOW.

Campaign for Access to Essential Medicines

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NEW DRUGS AND TREATMENT OPTIONS ARE DESPERATELY NEEDED.

THE REASON? WITHOUT IT, PEOPLE'S OPTIONS FOR LIFE-SAVING DRUGS WILL RUN OUT.