AFROCAB

ZIMBABWE WORKSHOP ON TREATMENT OPTIMISATION

JUNE 30, 2016

UNAIDS BOARDROOM, MT PLEASANT, HARARE

Meeting report: **Grace Nyaradzo Pfumbidzayi**

Tapiwanashe Kujinga

Contents

Background

Recent scientific developments in the field of HIV treatment have yielded antiretroviral (ARV) drugs that, among other benefits, are more tolerable and contain fewer side effects than most of the ARV drugs in current treatment regimens. Drug tolerability has a direct effect on adherence which, in turn, has a direct impact on treatment outcomes. Over the past few years, the movement towards initiating all people living with HIV onto antiretroviral therapy (ART), regardless of CD4 count, has gained momentum with the adoption of the 90/90/90 target as well as the Fast Track Strategy. This will entail initiating asymptomatic people living with HIV onto ART, hence the need for ARVs with less side effects becomes paramount, as non-adherence is likely to occur should healthy people fall sick from medication. Further, the anticipated significant scale-up of ART to reach an estimated 34 million people globally will require more tolerable drugs to lessen the default rate which will, in turn, result in some drug resistance.

Civil society has been at the forefront of advocating for affordable, accessible and more tolerable ARV regimens as a strategy for ensuring better quality of life for people living with HIV. Consequently, this sector advocated for the removal of Stavudine (d4T) from the list of WHO recommended drugs due to its serious side effects such as lipodystrophy, peripheral neuropathy and lactic acidosis.

With the advent of more tolerable ARVs, civil society finds itself at the forefront of advocating for the adoption for their inclusion in the treatment regimens in order to ensure that people living with HIV receive the most optimal treatment regimens available. In order for civil society to be able to launch an effective advocacy campaign, it is essential that activists be capacity-strengthened through training so that they are able to comprehend the issues.

The AfroCAB is a small group of African activists whose goal is to ensure that people living with HIV an affected individuals continue policy dialogue by empowering African activists, advocates and expert patients to become effective actors. This is achieved through raising strong community voices that provide valued, significant and independent contribution in issues around HIV, TB and other co-morbidities. The AfroCAB rolled out country training on treatment optimisation in countries where its members are resident, including Zimbabwe.

The Zimbabwe workshop was held on the 30th June 2016 and it brought together a number of representatives from civil society organisations which are involved in treatment advocacy, service delivery and policy analysis.

Opening Remarks

Caroline Mubaira, who is one of the AfroCAB co-Chairs, welcomed the participants to the workshop and gave a background to the AfroCAB, its objectives and activities.

The African Community Advisory Board, AfroCAB in short, advocates for scientific research which includes members of the Community who are not necessarily scientifically trained but can influence policy.

The AfroCAB is a community-driven advisory board that engages with scientific researchers and drug developers to ensure that Africans in need of HIV treatment get the best, the most efficacious, safe and affordable treatment available. It represents the whole of Africa except the Middle East and North Africa (MENA). AfroCAB members participated in the 2015 dialogue on WHO HIV treatment and prevention guidelines, and has participated in treatment advocacy at country level. While there is a dire need for HIV medicines, the side effects cannot be ignored. First line ARVs are causing a lot of side effects, and the AfroCAB has engaged at regional and local levels with the ministries of health to ensure that more tolerable treatment regimens are put in place.

Presentations

Dr Joseph Murungu – Science of HIV infection

For treatment activists and members of civil society to gain a deeper understanding on the new HIV treatment regimens, it is important to revert back to the science of HIV infection to appreciate how ARV drugs work in the human body.

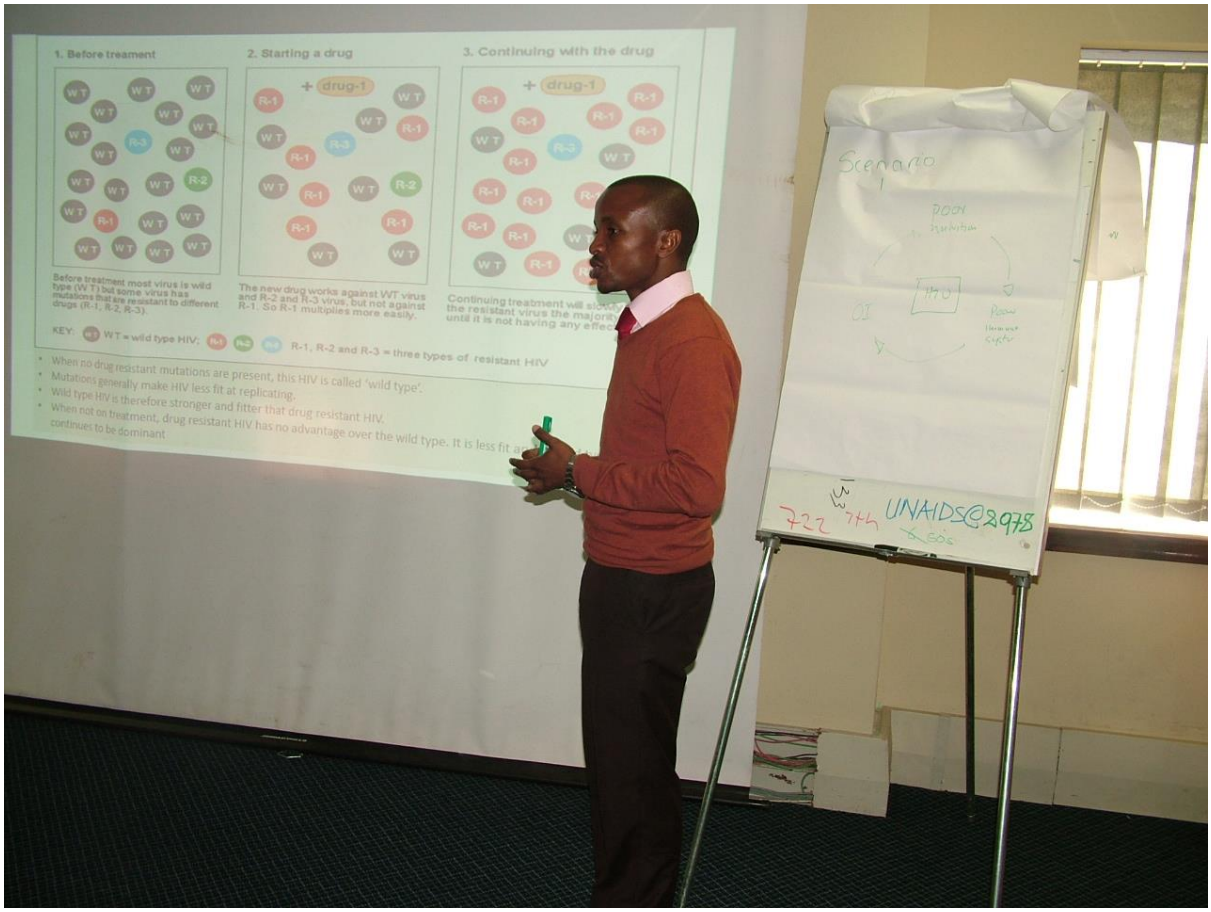
Dr Joseph Murungu is the Deputy National HIV Care & Treatment Program Coordinator in the Ministry of Health & Child Care. His presentation traced the origins of HIV from around 1930 and the first time it was officially reported in 1981. He went on to describe the main types of HIV and the predominant sub-groups. HIV sub-type C is the predominant found in Zimbabwe and is also responsible for more than 90% of the infections in Africa.

The presentation went on to focus on the structure of the virus, its life cycle and the viral reservoirs that are created in the body. Dr Murungu then went on to detail the effects of acute infection, including the common signs and symptoms that manifest at this state. He then pointed out the main opportunistic infections and HIV phases before going on to look at the benefits of antiretroviral therapy.

There are 6 main processes that are targeted by ARV drugs, namely, binding and entry into the human cell, reverse transcription, integration, transcription, assembly and release and protease. Each of the main ARV classes targets these processes, and a combination of ARV classes is necessary to avoid resistance.

Dr Murungu rounded off his presentation by focusing on the current initiatives to find a cure for HIV through activating viral reservoirs. The challenge with an HIV cure is the presence of

latent HIV in the viral reservoirs, and if they can be stimulated to express HIV again, then viral eradication can be achieved.



Dr J. Murungu – WHO 2015 guidelines

Dr Murungu's second presentation focused on the updated World Health Organisation (WHO) guidelines for the treatment and prevention of HIV. The guidelines were updated in 2015 to incorporate new treatment and prevention regimens that had been validated through clinical research. The guiding principles to be considered when implementing the guidelines are:

1. First, do no harm: Seek to maintain the current progress of treatment programs without disrupting the care of those on treatment
2. Accessibility: Ensure that all clinically eligible people infected with HIV are able to enter treatment services.
3. Quality of care: Ensure that care achieves the highest standards possible.
4. Equity of access: Ensure fairness and justice in access to treatment services.
5. Efficiency in resource use: Aim to achieve the greatest health impact with the optimal use of available human and financial resources.

6 Sustainability: Understand the long-term consequences of changes with the vision to provide continued, life-long access to ART for those in need

There is also need to look at the strength of the health systems, a phased approach in the implementation of the guidelines might be required, and it was necessary to understand the perspectives of HIV.

The 2015 guidelines contain HIV testing recommendations with some emphasis on the use of lay counsellors in the use of rapid diagnostic tests.

For the first time, ART initiation does not depend on CD4 count but can now be done upon a positive HIV diagnosis. However, CD4 count is still recommended at baseline. This applies for all ages – adults, adolescents and infants. Meanwhile, Option B+ is now the preferred regimen for pregnant women.

The preferred first line ART regimens remain TDF+XTC+EFV600 but the guidelines add DTG and EFV400 as alternatives.

Viral load monitoring is now recommended at 6 months and 12 months after ART initiation, and thereafter every 12 months. However, CD4 count can be used in the event that viral load monitoring is not available.

The Treat All approach means that an estimated 36.9 million people living with HIV are now eligible for ART globally. This, in turn, means that HIV testing services need to be scaled up, supply chain management systems have to be strengthened to ensure continuous supply of ARVs and access to diagnostics, especially viral load monitoring have to be scaled up.

For the first time, the guidelines also recommend the provision of PrEP to populations at substantial risk of HIV infection.

Following the issuing of the guidelines, the Zimbabwe Adaptation Committee commenced work on adapting the recommendations to the domestic guidelines. The objectives of the committee are:

- To review and understand the recommendations from WHO
- To conduct a 'Situational Analysis' to assess the strengths and weaknesses of the health system, availability of resources from both domestic and external funding sources in preparation of the adaptation process and implementation of the guidelines
- To support national programme in development of appropriate phased approaches in the implementation processes of the new recommendations considering country context and existing resources
- To advocate for, and mobilize additional resources to support the implementation of the revised guidelines
- To support the development of a dissemination plan and the dissemination of the revised national guidelines
- To track progress and evaluate the implementation of the new HIV and AIDS guidelines

The committee had 5 thematic groups for HIV testing, ART, elimination of mother-to-child transmission, PrEP and opportunistic infections. The key activities of the thematic groups are:

- Monthly Adaptation Committee meetings
- Sub group meetings
- Stakeholders consultative meetings
- Consolidation of recommendations from the stakeholders and the subgroups
- Printing of the updated guidelines
- Dissemination of the guidelines
- Documentation of the adaptation and implementation of the guidelines

The process is still under way and should be finalised before the end of the year.

Tendai Mharadze – 90/90/90 target

Tendai Mharadze is the Community Mobilisation & Networking Advisor at UNAIDS Zimbabwe office. Her presentation was on the 90/90/90 target which is an ambitious drive to end AIDS globally.

The target was the culmination of a number of recent developments. The first one was the 2011 Political Declaration on HIV and AIDS which ends in 2015. The other one is the new evidence around treatment which shows the preventive value of ART. Data shows that the HIV transmission rates are falling which is evidence of a positive trajectory. Finally, there is need to adopt a fast track approach as opposed to a business-as-usual attitude.

Basically, the WHO and its member states are aiming to have 90% of all people living with HIV know their HIV status by 2020, 90% of all people with diagnosed with HIV infection will receive sustained antiretroviral therapy by 2020, and 90% of all people receiving ART will have viral suppression by 2020.

This is an ambitious plan which requires scaling up at all levels. The first 90 will require targeting various populations, implementing community-based testing models as well as finding ways to reach men. The second 90 will require strengthening of the supply side, stronger linkages between the health systems and communities, and uninterrupted drug supply. The third 9o entails dealing with current challenges such as faith healing which result in people defaulting on treatment, scaling up community delivery systems and addressing the needs of particular populations such as migrants, children and adolescents.

The country has a viral load plan step up plan as well as promised support from PEPFAR for viral load machines.

Tapiwanashe Kujinga – updated Zimbabwe treatment guidelines

Tapiwanashe is a member of the AfroCAB and is also a member of the Adaptation Committee. Part of his presentation had been dealt with by Dr Murungu, hence he focused on the progress made by the Adaptation Committee which held a national consensus building workshop on the updated guidelines from the 21st to the 23rd June 2016. The National Medicines and Therapeutics Advisory Committee will deliberate over the recommendations before formally issuing the new national guidelines.

The ART subcommittee decided on the following regimens:

- Preferred first line regimen is TDF+3TC/FTC+EFV400
- For pregnant women and TB co-infected patients TDF+3TC/FTC+EFV600
- For patients with anaemia or renal failure ABC+3TC+NVP
- Alternative first line regimens TDF+3TC/FTC+DTG
- AZT + 3TC + EFV (or NVP)

At the end of his presentation, he posed the following issues for the participants:

1. What role can civil society play in ensuring the preferred ARV regimens are made available to people living with HIV?

2. What role can civil society play in ensuring that PrEP is made available to the identified groups?
3. How can civil society groups work together to achieve the identified goals?
4. Which other organisations are useful for the process/who has been left out?
5. What sort of capacity building is needed for the process to succeed?

Kenly Sikwese – Treatment Optimisation

Kenly is the AfroCAB Coordinator. His presentation focused on the concept of treatment optimisation. HIV treatment optimization was defined by the Conference on Antiretroviral Drug Optimization (CADO) as "a process intended to enhance the long-term efficacy, adherence, tolerability, safety, convenience, and affordability of combination ART". Treatment optimisation focuses on one or more of the following:

i. Better therapies and how to make them accessible to a broader population of people living with HIV.
ii. More efficient process chemistry for antiretroviral drugs
iii. Reduction of Antiretroviral dose
iv. Identifying highly effective and affordable nontoxic, once-daily fixed-dose combination regimen for first-line

The broader objective of treatment optimization includes cost effectiveness, drug optimisation, diagnostics and delivery mechanisms. The primary ultimate goal of treatment optimization is to expand access to well-tolerated and effective lifetime treatment to all those in need.

Treatment optimisation came out of a number of realities, which include the current HIV funding gap, the need to ensure value for money on existing resources, as well as the need to utilise scientific evidence in HIV programming.

The concept focuses on three main ARV classes, namely the nucleoside analogues, the protease inhibitors and the integrase inhibitors. On the last class, the new preferred drug Dolutegravir has demonstrated improved efficacy compared to existing drugs, which include less toxicity and less time to viral suppression. The drug is under a voluntary licence in many countries including Zimbabwe, hence its cost is likely to go down.

The dose-reduced Efavirenz which has a compound of 400mg has been proved to be non-inferior to the 600mg dose, but with less central nervous system side effects. Efavirenz remains the drug of choice for pregnant women and TB-coinfected patients.

The other drugs are tenofovir alafenamide which has a smaller compound at 25mg compared to TDF, and darunavir which has been proved to be the most robust protease inhibitor and has now been recommended for second line in the 2015 treatment guidelines.

There is need to raise awareness about treatment optimisation to people living with HIV, caregivers and policymakers.

Tendai Mbengeranwa – How can we advocate for treatment optimisation in Zimbabwe?

Tendai Mbengeranwa is a member of the AfroCAB, and she led discussions on how civil society can advocate for treatment optimisation.

She encouraged young people to know their status so that they can receive timely treatment.

She also encouraged the documentation of personal experiences so that these can be shared in support groups and other fora. This would help immensely with picking up trends of side effects as well as helping the treatment advocates when they engage the authorities on issues of HIV treatment.

She went on to encourage the incorporation of ICT tools to enhance of support group members in the event that they are unable to meet physically as a support group, but can still share and support each other online. ICT tools would also make collation of information required to influence the next level of response easier.

There are ARVs that are being phased out but, unfortunately, some communities and company clinics continue to dispense these to exhaust the stocks that they avoid “wastage”. There is need to monitor company clinics and other subsidiary health providers to ensure that cost cutting is not done at the expense of community health.

Tendai added that 70% of people living with HIV are in sub-Saharan Africa so the respective governments must lead the research in HIV. There is also need for CSOs to lobby for joint procurement of drugs by states for economies of scale

Participants were advised that if the 2020 and 2030 targets are not met, the country will not continue to get external support at the current levels. It was agreed that PrEP should be made available to all the populations that need it and that capacity-building is required across the board

She rounded off her presentation by encouraging people living with HIV to take self-management of the condition seriously so they can become expert patients. It has been found that expert patients are best placed to speak on HIV and its treatment as they speak from experience.

Group work

After the presentation by Tendai Mbengeranwa, the participants broke into two groups to discuss the questions posed by Tapiwanashe Kujinga.

The collective responses to the five questions are as follows:

What role can civil society play in ensuring that the preferred ARV regimens are made available to people living with HIV?

- Educate people on ARVs on treatment options
- Dialogue with government with regards revival of Pharmaceutical manufacturing in the interests of costs, availability and quality control
- Advocate for the best treatment options, being specific on advantages, disadvantages and side effects
- Research on ARVs and share findings with communities
- Capacitate CSOs so that they can engage authorities from a position of strength founded on the lived experiences of all concerned
- Mapping best practices
- Using advocacy to ensure that we reach the target groups such as policy makers
- Use treatment literacy to educate health personnel and capacitate the support groups
- Use expert patients as mentors at health centres
- Support existing support groups
- Sensitise communities on the importance of the right use of ARVs

What role can civic society play in ensuring prep is made available to the identified groups?

- Advocacy
- Mapping
- Sensitize the community on the importance of PreP
- Share information on PrEP research with communities
- Capacity building of Civic Society Organisations on PrEP
- Education of traditional and church leadership on PrEP
- Education of health practitioners and other personnel on PrEP
- Capacitation of media
- Media campaigns
- Engage with organisations working with target groups
- Advocate for access to PrEP for groups that are not part of the target groups

How can civil society groups work together to achieve identified goals?

- Create Technical Working Groups with representation from the various interest groups. TWGs to meet monthly or more frequently where necessary to discuss developments and assess progress

- Call for dialogue at all levels
- Share resources
- Make use of existing structures and strengthen them
- Improve knowledge and capacity of CSOs
- Utilise communication effectively in working together and implementing activities
- Come up with an MoU on how CSOs can work together

Which other organisations are useful for the process/ who has been left out?

- Faith based organisations
- Sex workers
- Politicians (Parliamentary portfolio committees)
- Health workers
- Ministry of Health
- NAC
- People living with disabilities (including DHAT)
- ZINATHA
- Mentally challenged persons
- Transport operators
- The chronically ill
- SAfAIDS
- The UN family
- Katswe Sisterhood
- The Law Society
- ZNNP+
- Padare
- Family AIDS Caring Trust
- Mighty Women of Hope
- Trans-Smart (organisation for trans people)
- ZiCHIRE)
- ZBCA
- ZAAM

What sort of capacity needed is needed for the process to succeed?

- Financial support
- Technical support
- Training of trainers
- Resource mobilization
- Material support e.g. IEC materials
- Research

Action planning

This session was led by AfroCAB member, Tapiwanashe Kujinga. The participants submitted that the following steps were critical to achieving success in the treatment optimisation agenda:

i. Cascade information to relevant stakeholders, including other CSOs, health workers and people living with HIV
ii. Creating a national dialogue, inclusive communication
iii. Creating a low cost communication platform such as WhatsApp to update and capacitate each other
iv. Making use of radio programs for information dissemination
v. Creation of TWGs on treatment optimisation
vi. Capacitate the Zimbabwe AIDS Network (ZAN) so that it can effectively play its role of coordinating the civil society response to HIV
vii. Develop IEC materials

Participants

	Name	Organisation
1	Tapiwanashe Kujinga	AfroCAB
2	Caroline Mubaira	AfroCAB
3	Tendai Mhaka	AfroCAB
4	Kenly Sikwese	AfroCAB
5	Emmanuel Gasa	The AIDS and Arts Foundation
6	Grace Pfumbidzayi	PATAM
7	Eunice Goremusandu	Dreams HIV/AIDS Youth Network
8	Sylvester Nyamatendedza	GALZ
9	Imelda Mahaka	PANGAEA Global
10	Alina Kandawasvika	ZHAAU
11	Olive Mutabeni	Life Empowerment Support Organisation
12	Tafadwanashe Nkrumah	Community Working Group on Health
13	Tanyaradzwa Munouya	Community Working Group on Health
14	Alice Shayahama	Mabvuku Health Promoters
15	Vincent Tavarwisa	INERELA
16	Rev Zvidzayi Chiponda	ZINERELA
17	Nicola Willis	AFRICAID
18	Tendai Mharadze	UNAIDS
19	Joseph Murungu	Ministry of Health
20	Addmore Chadambuka	EGPAF
21	Funmi Adesanya	PEPFAR

22	Shaw Nyakandi	Zimbabwe Health Network
23	Annah Chapeyama	Zimbabwe Health Network
24	Ernest Fukuwo	The AIDS and Arts Foundation
25	Janet Bhila	ICW