



GLOBAL POLICY, LOCAL DISCONNECTS

A LOOK INTO THE IMPLEMENTATION OF THE 2013 HIV TREATMENT GUIDELINES

July 2014

About ITPC

The **International Treatment Preparedness Coalition (ITPC)** is a worldwide network of community activists unified by our vision of a longer, healthier, more productive life for all people living with HIV. ITPC's mission is to enable communities in need to access HIV treatment. As a grassroots movement based primarily in the Global South, ITPC is the community's voice on HIV treatment and is driven, led by, and committed to the human rights of those most impacted by the pandemic. ITPC is a global coalition that includes nine regional networks in Africa, Asia, the Caribbean, Eastern Europe, Latin America, and the Middle East; and over the past decade ITPC has made over 1,000 grants totaling more than \$10 million to community-based organizations of PLHIV in almost 100 countries.

Additional information about ITPC is available at: www.itpcglobal.org

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Acronyms

- ART** Antiretroviral treatment
- ARV** Antiretroviral
- d4T** Stavudine
- FDC** Fixed-dose combination
- ITPC** International Treatment Preparedness Coalition
- MSM** Men who have sex with men
- NGO** Nongovernmental organization
- PLHIV** People living with HIV
- SW** Sex workers
- UN** United Nations
- WHO** World Health Organization

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Background

The history of the AIDS movement is one of ordinary people uniting to break silences, to force people in power to take action and to achieve

incredible successes in supporting people living with HIV to access treatment. Since the availability of combination antiretroviral therapy (ART) in 1996, the AIDS movement has evolved in communities around the world. In 2014, the movement for HIV treatment remains at a tipping point – more drug regimens are becoming available, yet they remain inaccessible for people in many developing countries; more countries are allocating domestic resources to HIV yet a significant funding gap remains; and laws that criminalize behavior continue to affect access to health services.

Another recent development also shook up the HIV world. In 2011, the groundbreaking HIV Prevention Trials Network (HPTN) 052, a randomized clinical trial study, definitively confirmed what other research had also revealed – that people living with HIV who are taking antiretroviral treatment are extremely unlikely to transmit the virus via sex.¹ Antiretroviral drugs suppress HIV viral load in the blood and genital fluids, preventing onwards transmission.

While people living with HIV and their allies had already been

calling to increase treatment coverage, the new concept of “treatment as prevention” brought more attention to treatment as a way to end AIDS. In response to the HPTN 052 study, the World Health Organization (WHO) issued the revised *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* (the Guidelines) in June 2013, which are used to advise policy makers and clinicians on treatment protocols. The 2013 Guidelines represented a significant shift from previous treatment guidelines, which had until then suggested people living with HIV initiate treatment when their CD4 count drops to a certain level, indicating deteriorating health. In the 2013 update, WHO recommended that, in light of the health and prevention benefits, all people living with HIV be offered the opportunity to start treatment immediately after their diagnosis.

ITPC welcomed the release of the Guidelines, but knew that implementation would not be simple. Many countries would have to commence national processes to develop new treatment policies. The procurement of the optimal drug regimens recommended in the Guidelines depends on complex factors including, but not limited to: national health budgets, supply chain management systems and the availability of generic medicines. Furthermore, many people remain unable to take an HIV test or seek treatment

support due to prejudice and inequity.

In addition, ITPC, the AIDS and Rights Alliance Southern Africa (ARASA) and the Asia Pacific Network of People Living with HIV (APN+), outlined concerns about the Guidelines, including that:

- The Guidelines did not specify how they should be operationalized.
- The Guidelines acknowledged the importance of task shifting, but did not specify the full role community health workers can play in delivering services.
- The Guidelines emphasized offering sero-discordant couples the chance to initiate treatment – but all individuals should have the opportunity, regardless of whether or not they are in a relationship.
- The lack of HIV testing guidance for adolescents and children below 18 years of age.

One year after the release of the Guidelines, ITPC decided to investigate what the reality was on the ground for people living with HIV. Utilizing ITPC’s nine Regional Networks and ARASA partners in Southern Africa, a cross-section of people living with HIV, service providers and other stakeholders were surveyed across the globe for their experiences, opinions and insights.

1 The study examined sexual transmission among heterosexual couples only.

Methodology

KEY CHANGES IN THE WHO 2013 CONSOLIDATED ARV GUIDELINES

HIV testing: The beginning of a successful implementation of the Guidelines is the scaling up of HIV testing that preferably is community-driven, so that communities can then demand and access HIV treatment.

When to start ART: The Guidelines recommend immediate initiation of ART for anyone with CD4<500. Additional consideration for starting above 500 is made for certain populations – such as sero-discordant couples. But given limited resources, the Guidelines prioritize treating the sickest patients first. So, everyone <500 should be offered and have access to treatment. But greater priority should be to people <200 or <350 and/or who are symptomatic.

Eliminating toxic regimens: Regimens that are not tolerable due to their harsh side effects should no longer be used. d4T is no longer recommended as a first line regimen because of side effects.

Lifelong treatment for pregnant women: Pregnant women should have the opportunity to access life-long HIV treatment under option B+, which ensures prevention of vertical transmission but also their ongoing health.

ITPC set out to understand the status and nature of the implementation of the Guidelines by answering three core questions:

| REGION | COUNTRY |
|------------------------------|---|
| ASIA | China • India • Nepal |
| CENTRAL AFRICA | Cameroon • Democratic Republic of Congo |
| EAST AFRICA | Ethiopia • Kenya |
| EASTERN EUROPE/CENTRAL ASIA | Russia |
| LATIN AMERICA | Guatemala • Honduras |
| MIDDLE EAST AND NORTH AFRICA | Morocco • Tunisia |
| SOUTHERN AFRICA | South Africa • Zambia |
| WEST AFRICA | Cote d'Ivoire • Guinea Conakry |

1. How far are countries in implementing the Guidelines, and what are success factors and challenges?
2. How are communities involved in the implementation of the Guidelines - including in HIV services?
3. What are the remaining challenges for treatment scale-up?

Four surveys were created by community activists and translated into Arabic, French, Russian and Spanish. The four target groups for the surveys were:

- People living with HIV who are currently retained in care
- Service providers (doctors, nurses and others who provide direct HIV services)
- Non-governmental organizations working on HIV
- National-level health policy makers (such as Ministry of Health officials)

ITPC's nine Regional Networks and ARASA administered the surveys in 16 countries, covering a broad range of regions, shown in the table above.

The following responses were received:

- People living with HIV who are currently retained in care: **764 respondents**
- Service providers: **130 respondents**
- Non-governmental organizations (NGOs) working on HIV: **62 respondents**
- National-level health policy makers: **15 respondents**

The data was analyzed both qualitatively and quantitatively. Data sets were analyzed by question for key data points and areas for further country analysis through key word searches, sorting by theme and graphs generated from the survey software. Country analysis was done for several questions to determine variances across regions.

There were several limitations to ITPC's research. Given time and funding constraints, the survey aimed to be a 'quick and dirty' way to gather a broad swath of information – as a result findings are not widely generalizable but instead point to emerging themes and issues that warrant further investigation. While attempts were made to ensure a diverse

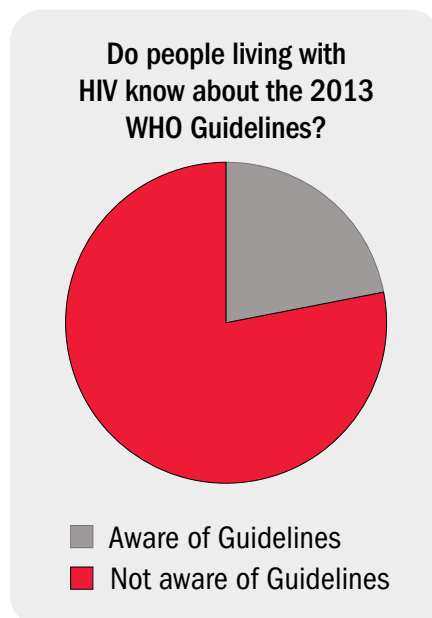
sample of respondents – including by age, gender, class, urban/rural, sexuality and other factors – these were informal efforts. Policy makers working at the national level were also surveyed as a proxy for the government position on treatment issues. We note, however, that responses from the policy makers surveyed do not necessarily represent the official

government position. Finally while findings reveal insights and opportunities for further research, they are not definitive and do not represent the situation in all countries, regions or contexts. Further exploration is needed and suggestions for future research are included in the recommendation section.

Fragmented progress towards changing treatment policy at the national level

Global and national treatment guidelines do not translate into the lived experiences of people living with HIV. All policy makers surveyed were aware of the Guidelines and all reported that they have developed or initiated a process to develop new national ARV guidelines. Similarly, the majority of service providers and NGOs (though not all) were aware of both the Guidelines and national efforts to adopt them. However, only 22 percent of the people living with HIV who were surveyed (164 out of 739) were aware of the Guidelines. This indication that only a small number of people living with HIV are aware of the Guidelines makes demand creation for implementation extremely challenging.

The few who indicated they were aware of the Guidelines (164 out of 739 people living with HIV) had information because they participated in a workshop or group; were part of an activist process; were told by their physicians or



had accessed some materials online. Quite a few also heard by word of mouth but had no details.

Shockingly, 125 out of 740 respondents indicated that they did not know the government recommended Guidelines for the start of ART, highlighting the issue that many PLHIV are still not receiving the treatment education they need.

While 11 out of 12 policy makers stated that they had support from international organizations for the implementation of the Guidelines in their country, it appears investments have not been made in educating communities.

Lack of funding and political will continue to delay the implementation of the Guidelines.

Among NGO stakeholders who were aware of the new Guidelines, availability of ARVs, frequent stock-outs of essential medicines and diagnostic supplies, lack of funding and low political will were the most common implementation barriers reported. Policy maker respondents highlighted similar barriers but also emphasized the financial burden to meet increased demand for treatment, the re-training of health workers to adopt the new Guidelines and the price of medicines and related treatment commodities.

COUNTRY EXAMPLES OF REVISING NATIONAL GUIDELINES

"Tunisia launched a consultation involving different experts from all medical specialties involved in the treatment of HIV infection to discuss updates [based on] the Guidelines. After [that] there was a national consensus meeting. The guidelines are finalized but not implemented yet - probably it will be done by 2015. The main reason is that we still lack some ARVs that are in the guidelines. Drugs have been ordered but are not yet available."

– policy maker, Tunisia

HAVE YOU NOTICED ANY CHANGES IN THE PAST YEAR?

"Removal of stavudine from the first-line treatment."

– PLHIV respondent, Kenya

"Change in prevention of mother to child transmission - they are using option B+."

– PLHIV respondent, Zambia

On the outside looking in: the neglected role of HIV affected communities

The majority of policy makers surveyed (9 countries out of 15) reported that communities affected by HIV were involved in the development of national treatment guidelines. They indicated that civil society participated in national processes through task forces, consultative meetings and workshops where they can offer input and validate specific recommendations.

However, the mechanism for community involvement in the development of national treatment guidelines remains unclear for people living with HIV. Alarming, only 11 percent of PLHIV surveyed – 78 out of 726 people – indicated they had been involved in or knew about processes to involve communities in national treatment guidelines review or development. Although people living with HIV should be central to guidelines and policies

"Civil society is overshadowed. National treatment guidelines are entrusted to doctors."

– NGO respondent, Guinea Conakry

"We are not allowed to participate in such forums."

– PLHIV respondent, Ethiopia

that affect their lives, communities are under-involved in reviewing national treatment guidelines making them unable to meaningfully contribute to their development. Policy makers that reported no community involvement in the development of national guidelines were from Ethiopia, Honduras, Guatemala, Russia and Tunisia.

Community health-care workers remain under-appreciated in the delivery of HIV services. Of the 14 policy-maker respondents surveyed, only five identified community health care workers as being allowed to perform HIV testing under the national HIV guidelines of their country. None identified national guidelines that allowed community health-care workers to perform CD4 testing or treatment initiation services.

Task shifting has not occurred in many contexts. The survey revealed a heavy reliance on doctors and highly skilled professionals to conduct services that can be task shifted to trained staff. Sixty-eight out of 122 service providers reported that nurses performed HIV tests but only 44 identified community health workers. Regarding viral load testing, 69 out of 126 service providers identified doctor-driven

viral load testing in their country; in contrast only eight out of 126 service providers indicated community worker involvement in viral load testing. When asked about treatment initiation, an overwhelming 101 out of 123

service provider respondents identified doctors as the main providers of treatment initiation for patients. Data suggests that communities and community health care workers are mainly involved in the treatment

adherence-related aspects of service delivery – and while critical, this leaves major gaps in how community health workers are being utilized.

Persistent challenges remain for achieving treatment for all

HIV diagnostics remain unavailable and unaffordable in many communities. Receiving a CD4 test is still challenging for a significant number of PLHIV – 39.7 percent of respondents (292 people out of 736) indicated that a CD4 test was “hard” or “very hard” to access.

With regards to viral load testing, 43.9 percent of PLHIV (316 people out of 720 people) did not have routine access. The cost of viral load also remains a barrier for poor people and people without health insurance – countries surveyed that require patients to pay for viral load tests include Cameroon, Côte d'Ivoire, Democratic Republic of Congo, Guinea Conakry, Honduras, India, Nepal, Tunisia and Zambia.

Country level treatment initiation criteria do not match the Guidelines. Among service providers surveyed, despite knowledge that the Guidelines recommend beginning treatment at CD4 <500, only 34.6 percent (44 out of 127) reported initiating treatment at CD4 <500. Fifty-four percent (68 out of 127) reported

COUNTRY EXAMPLES

In Guangzhou, China, patients without local residency are required to pay for viral load testing, while patients with local residency status can get reimbursed by the local Chinese Center for Disease Control and Prevention.

“Access to viral load testing has been restricted to State AIDS Clinical Expert Panel (SACEP) centers, in a centralized manner for each state - thus effectively delaying access to second-line treatment for many.”

–NGO respondent, India

initiating treatment at CD4 <350; 7.1 percent (9 out of 127) initiated treatment for persons with any CD4 count; and only 28 percent (36 out of 127) initiated treatment based on the fact that couples were sero-discordant.

Among PLHIV, the majority of respondents (394 and 369 of 740, respectively) reported that their national government recommended initiation of ART for CD4 <350 and pregnant or breastfeeding women.

National guidance on option B+ and availability of option B+ for women living with HIV remains unclear in many countries. The survey revealed that while 73.3 percent of policy makers (11 out of 15) indicated that their current national guidelines included option B+, the majority (57.1 percent, 32 out of 56) of NGO stakeholders reported that option B+ was not incorporated. Furthermore, 79 out of 120 service provider respondents noted that option B+ was available in their healthcare centers, but did not indicate whether or not it was being actively distributed to pregnant women receiving care.

Fixed-dose combinations are available for some – but not all – ARV regimens. The majority of all respondents (393 out of 702 people living with HIV; 49 of 55

NGOs; 103 of 112 service providers; and 14 out of 15 policy makers) indicated that fixed-dose combinations (FDCs) were available for first-line regimens. However, this was not the case for second- or third-line regimens: 31 of 49 NGO respondents indicated that FDCs were not available for second-line regimens, with an even higher proportion (40 of 41) reporting that they were not available for third-line regimens. Similarly, only 50 of 94 and 2 of 63 service providers reported that second- and third-line regimens had FDC options, respectively. Among PLHIV respondents, 11.4 percent (80 of 702) reported that FDCs were only available for some people.

People living with HIV still lack access to second- and third-line treatment.

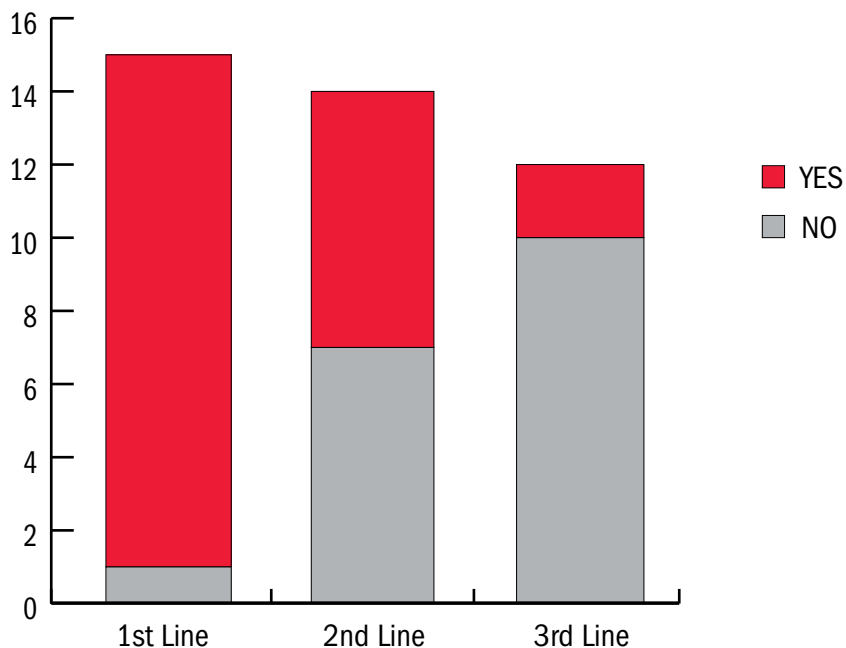
Of 697 PLHIV respondents, only 128 (24.1 percent) indicated that the recommended second-line treatment was widely available for those who need it. Additionally, 169 people out of 697 PLHIV (24.2 percent) indicated that it was available, but only for some.

The gap for access to third-line regimens is even starker – 73.2 percent

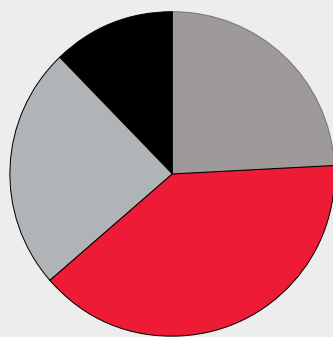
(477 out of 652 PLHIV) reported that third-line treatment was not available in their country. Similarly, 73.3 percent of service providers (88 out of 120) said they had no third-line regimens available at their health centers. This is particularly alarming given the potential adherence issues as people living with HIV initiate treatment earlier in their lives as a result of the Guidelines and then possibly develop resistance to their first and potentially second-

Are fixed-dose combinations (a combination of two or more active drugs in a single pill) available for all ARV regimens?

AS REPORTED BY POLICY MAKER RESPONDENTS



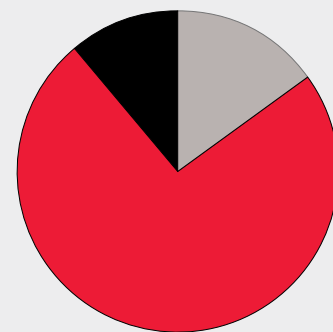
Is the recommended 2nd line regimen for adults and adolescents widely available for those who need it?



■ YES ■ ONLY FOR SOME
 ■ NO ■ I DO NOT KNOW

line regimens as they age. It also highlights the importance of patients not just starting, but also

Are 3rd line regimens available in your country?



■ YES ■ ONLY FOR SOME
 ■ NO

staying on treatment. Respondents also reported a lack of clear national level guidance around third-line treatment regimens.

The full discontinuation of stavudine (d4t) has yet to occur.

Among the policy maker respondents surveyed, 58 percent (7 out of 12) categorically reported that d4t was no longer used, while a third indicated that it is still a part of some regimens (e.g. for pediatric patients). Countries that indicated the continued use of d4t in some regimens included Russia, China, Nepal, Guatemala and India. Among PLHIV, 58.2 percent (417 out of 717) reported that d4t was not part of their ART regimen or used by someone else in their community. However, 19.0 percent (136 out of 717) reported that they knew someone in their community that continues to use it.

The majority of service providers (78.8 percent; 93 out of 118) also indicated that d4t was no longer a part of any regimen, but a small proportion (21 percent; 25 out of 118) reported it was still a part of some. This included providers from Cameroon, China, DRC, Ethiopia, Guatemala, India and Kenya. Interestingly, among the 88 out of 124 (71 percent) of service providers who changed their practice based on the Guidelines, many reported the discontinuation of d4t among the top changes, along with ensuring option B+ for all pregnant women and the earlier initiation of treatment.

Drug resistance testing is rare.

Diagnosing treatment failure is critical to indicate a person needs to switch ARV regimens. Yet drug resistance testing appears unavailable in many communities - 74.1 percent of PLHIV (512 out of 691 people) said genotype testing was not available. Fifty-five percent (65 out of 118) of

COUNTRY EXAMPLES

In Guinea Conakry, regular CD4 and viral load testing are often unavailable for patients due to frequent stock-out of lab reagents. Waiting times to end stock-outs also varies unpredictably, from a few days to months.

In Morocco, a respondent reported that a stock-out of testing kits that occurred recently (within the last 12 months) lasted for one month before supplies were replenished.

In Nepal, a respondent reported that some of the opportunistic infection medicines were out of stock at the district center. They believed that negligence and ineffective coordination of the government staff at the district and central level were key issues.

"We sometimes have shortage of essential medicines as we have challenges with supply chain from depot to health facilities."

– policy maker, South Africa

service providers also reported that genotyping testing is not available at their health center.

"As a government, we are trying hard to make services available to contain the epidemic, but the laws that criminalize key populations and stigma in communities are still a hindrance to access to health services."

– policy maker, South Africa

Weak procurement and health systems result in frequent drug stock-outs that affect the health of people living with HIV. A total of 379 out of 650 people living with HIV reported they had experienced or heard about stock-outs of essential medicines during the past 12 months. Frequent stock-outs have direct

implications on treatment monitoring and adherence. Two hundred and forty-five out of 565 PLHIV respondents indicated that they simply interrupt their treatment regimen when stock-outs occur and are forced to wait until supplies are replenished.

NGOs reported that poor planning, forecasting and budgeting; delivery delays; and corruption were the most common reasons for stock-outs. Of the 79 service provider respondents, 62 percent reported stock-outs of CD4 test kits over the last 12 months; 35.4 percent reported stock-outs of viral load tests. Regarding essential medicines, 60 percent (75 out of 124) of the service provider respondents reported stock-outs explaining this was due to procurement plans that could not keep pace with the rapid increase of medicines needed for new patients; drug supply issues; logistics and lack of funding.

Services for key populations, adolescents and other marginalized groups vary wildly in terms of being accessible, appropriate and stigma-free.

With respect to treatment services for sex workers, people who use drugs, men who have sex with men, transgender people, adolescents aged 10-19 and migrants, the survey revealed that the ability to access services differed across groups.

Interestingly, the majority of NGO stakeholders reported that ART centers do not have specific services for these populations, while the vast majority of policy maker respondents indicated that

they do. Fifty-percent of service provider respondents indicated that they had no training to work with key populations, raising troubling questions about their ability to provide appropriate and human rights-based services.

At the community level, service providers stressed that testing, linkage to treatment and adherence were key areas needing increased attention for key populations. Additionally, ease of testing and treatment initiation were also areas of concern among recipients, with many reporting that it was 'very difficult' or 'more difficult than for the general public' for people

from key populations to get tested and access treatment.

Despite widespread attention to the use of mobile and new technologies for health, use of these outlets remains surprisingly low.

Across all groups, the majority of respondents reported that they did not know of any services available to communicate with patients using mobile or Internet technologies. Of the minority who did indicate knowledge of such services (China, East Africa, India, Latin America and Russia), mobile phone services and smart phone applications were the most common technologies utilized.

Change the paradigm moving forward

The data indicates that while progress is slowly occurring at the national level, more can be done to ensure rapid implementation of the Guidelines. The following suggestions are for policy makers, programmers, funders and people living with HIV.

Build grassroots awareness of the Guidelines. It's not enough for policy makers at the national level to know the Guidelines – people living with HIV must be aware of the main recommendations in them in order to generate demand for earlier treatment initiation, option B+, the phase-out of stavudine, and more. Yet, to date, relatively little investment appears to have occurred in building community knowledge about the Guidelines. Some options for increasing awareness of the

Guidelines include:

- Integrate information about the Guidelines into existing treatment literacy curricula and programs.
- Make information about the Guidelines publicly available in local languages at ART centers and clinics.
- Share information about the Guidelines on your

organization's website, Facebook page and other social media sites.

- Host a Q&A session on the Guidelines for people living with HIV in your community, service providers and the government.

Involve communities in the design, delivery and monitoring of HIV services. Health systems do better for more people through shifting tasks from doctors and nurses to community health workers. In addition, people living with HIV and their allies can support HIV testing, linkages to care, treatment initiation, adherence and treatment literacy. Investments in true grassroots involvement need to be increased and maintained to ensure communities can continue

IMPORTANT RESOURCE

Check out ITPC's ACT Toolkit for an easy to use training on the Guidelines:

www.itpcglobal.org

playing a vital role in implementing health services. Monitoring of policy implementation by and with communities, such as described in this briefing, needs to be resourced to ensure national and global accountability.

Fulfill the right of all people living with and affected by HIV to access health services and receive the treatment they need. Health and community systems must be responsive to the needs of the people they are serving. Key populations, adolescents, migrants, prisoners and other groups need to access services that are convenient, confidential, free or affordable, non-discriminatory and appropriately designed to meet their unique desires and circumstances. Service providers should receive training on how to best meet the needs of marginalized populations in their communities, and these trainings should be *led* by these populations.

Fix broken procurement systems that result in stock-outs of essential medicines. People living with HIV should not have to wait for medicines because of weak procurement systems. Unavailability of medicines puts the lives of people at risk. Governments must ensure timely and efficient distribution of medicines.

Act now to make second- and third-line treatment available before it's too late. As people living with HIV, especially adolescents who were perinatally infected, initiate treatment earlier in their lives as a result of the Guidelines, they will potentially

develop resistance to their first- and second-line regimens as they age. The current lack of access to second- and third-line treatment is alarming given the potential adherence and resistance issues on the horizon. Governments, pharmaceutical companies, international actors and people living with HIV must work together to make second- and third-line treatment available and affordable for all people living with HIV – including through the utilization of Trade Related Intellectual Property Rights (TRIPS) flexibilities, compulsory licenses and all means at their disposal to keep people alive. Funding and support also need to reach communities on the ground so that people affected by HIV can fully understand intellectual property issues and available opportunities under TRIPS to demand their governments pursue action on price reductions.

Further research is needed to:

- Gain an in-depth understanding at the national level of causes of slow implementation in the following areas:
 - » Procurement and delivery systems
 - » Costs (medicines, opportunistic infections, diagnostics, service delivery and other treatment related services)
 - » Budgeting
 - » Policy development
 - » Civil society engagement especially with key affected populations

- Suggest possible solutions to barriers and challenges at the national level for the roll-out of the Guidelines, using implementation and operational science.
- Identify the main drivers that perpetuate the disconnect between global policy and national level implementation; and the disconnect between national policies and people affected by HIV.
- Have a deeper understanding of key population-specific treatment needs, key barriers to access and appropriate solutions that increase access to treatment.

All of these recommendations can only be implemented if communities are truly part of the solution. Their involvement needs to be resourced and maintained to ensure **all** people can fully realize their right to health.



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