



# Community and activists demand for tenofovir/emtricitabine or lamivudine/dolutegravir and routine viral load testing

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## Purpose of review

Since the beginning of the HIV epidemic, informed communities have demanded and fought for access to life-saving treatment. The last several years have seen interesting developments in this area – particularly with respect to the switch to dolutegravir (DTG)-based regimens and scale-up of routine viral load testing (RVLT), and how these directly and indirectly impact issues of treatment optimization, HIV drug resistance, and sexual and reproductive health. In this review, we present recent advances in antiretroviral treatment and monitoring in the context of how treatment education and community demand for them.

## Recent findings

The latest developments with DTG and RVLT highlight underlying issues for global health systems that need to be addressed – including drug surveillance, supply chain management, and comprehensive care linkages – and the importance of community engagement in such issues.

## Summary

Decisions about treatment must be grounded in informed community demand, and should exist in the context of optimal care and treatment across the entire HIV cascade. Informed advocacy is essential for people living with HIV and their communities, so that they benefit from existing and future therapeutic advances. Research is needed on the importance of community demand across the HIV treatment cascade.

## Keywords

community-led advocacy, demand creation, dolutegravir, HIV treatment, routine viral load testing

## INTRODUCTION

The last several years have seen huge strides and exciting developments in HIV treatment, and the way in which community demand has responded to the introduction of new innovations. In particular, dolutegravir (DTG), an HIV integrase strand transfer inhibitor, and the transition to DTG-based regimens have received increasing attention over the past year. In 2015, WHO recommended DTG as an alternative first-line antiretroviral (ARV) [1]. It was upgraded to a preferred ARV in 2018 because of its effectiveness, tolerability, and high genetic barrier to HIV resistance – and its affordability in low-income and some middle-income countries [2,3]. DTG access is increasing, and countries like Botswana, Kenya, and Brazil have already rolled out DTG in first-line treatment [4,5]. However, questions still remain about the transition to dolutegravir – particularly in light of the recent report from a birth outcomes surveillance study in Botswana, which led to subsequent drug safety alerts [6<sup>a</sup>,7].

The resulting WHO guidelines update – launched at the 2018 International AIDS Conference in Amsterdam – recommend that DTG be used for women who have access to consistent and effective contraception, which is in turn driving additional demand for access to sexual and reproductive health (SRH) services [2].

Attention and momentum have also grown significantly around the ‘zero risk’ of sexual transmission for people living with HIV (PLHIV) who have an

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## KEY POINTS

- Community demand for DTG and RVLT is high – with ongoing community-led campaigns calling for access, and denouncing the practices and policies that keep them unavailable and unaffordable in select countries and communities – but treatment education is critical to ensure informed demand is sustained.
- There is an inextricable link between access to DTG and RVLT. Increasing access to RVLT results to monitor effectiveness of DTG-based regimens remains crucial, particularly as people living with HIV choose to start or switch their treatment.
- The latest developments with DTG and RVLT highlight underlying issues for global health systems that need to be addressed – including drug surveillance, supply chain management, and comprehensive care linkages – and the importance of community engagement in such issues.
- Decisions about treatment must be grounded in informed community demand and should exist in the context of optimal treatment across the entire HIV cascade.
- Communities and recipients of care need – and have the right to demand – access to information and research that is relevant to their circumstances, choices they make about their health, and their outcomes.

undetectable viral load. Campaigns like ‘Undetectable=Untransmittable (U=U) and Can’t Pass It On’ are amplifying the conclusions drawn from accumulating evidence, like that provided by the recent PARTNER and PARTNER 2 studies, where HIV was not transmitted from PLHIV with undetectable viral load to their sexual partners [8]. The possibility of eliminating risk for sexual transmission, along with the individual health benefits of viral suppression underscore the importance of access to routine viral load testing (RVLT), which has been WHO-recommended since 2013 [9]. RVLT is essential for monitoring the global response to HIV, as a mainstay of the third UNAIDS 90-90-90 target, achieving and maintaining viral suppression on antiretroviral therapy (ART).

As has been previously discussed [10<sup>□</sup>], the introduction of treatment guidelines and scientific evidence alone do not instantaneously translate into widespread implementation at country-level or sufficient access for people living with HIV. It is often the demand from civil society and communities that drives action – either in support of or in opposition to these new policies and developments, and their intended or unintended consequences, to ensure they respond to the lived realities and needs of people living with HIV.

In this review, we present recent advances in HIV treatment and monitoring, in the context of treatment education and community demand for them.

## REVIEW

### Methods

A literature review was conducted to identify publications describing the current community demand for dolutegravir-based regimens for HIV treatment and routine viral load testing (RVLT). The search was conducted in Medline (PubMed) for articles published in English and published between 1 January 2017 to 31 July 2018. A mix of free text and MeSH search terms were used around the themes of ‘dolutegravir,’ ‘ARV treatment,’ ‘HIV viral load,’ ‘community,’ ‘HIV treatment monitoring.’ Conference abstracts and presentations from the International AIDS Conference and annual Conference on Retroviruses and Opportunistic Infections were also searched. The reference list of select articles was reviewed and additional publications were identified to supplement any late-breaking developments (i.e. those not yet published in the scientific literature). The titles and abstracts of the articles and publications identified in the search were reviewed; articles were included if they discussed the prospects of dolutegravir-based regimens, opportunities and challenges of viral load scale-up and demand creation for access to DTG-based treatment and RVLT.

### Community demand for tenofovir/lamivudine/dolutegravir

Since the beginning of the HIV epidemic, informed communities have demanded and fought for access to life-saving treatment. As with other advances, informed communities have mobilized around access to dolutegravir. DTG was approved in 2013 and, even before that, was highly anticipated as a game-changing drug because of its potential to simplify ART delivery and optimize HIV treatment [11,12]. Today, DTG is a WHO-preferred first-line ARV for adults, adolescents and children over 6 years old because of its efficacy, improved tolerability, minimal drug interactions, and high genetic barrier to resistance [2,5]. Recent studies also demonstrate the cost-effectiveness of the generic fixed-dose combination of tenofovir (TDF), and emtricitabine or lamivudine (XTC) with DTG – referred to as TLD – and support its efficacy and safety in adolescents, where the lifelong duration of treatment can make adherence challenging [13,14].

Unsurprisingly, community demand for DTG is high. Ongoing, community-led campaigns are calling for access to the drug, and denouncing policies that keep it unavailable and unaffordable in certain countries and communities [15–19].

Most recently, communities of PLHIV – and women, in particular – have mobilized to demand access to DTG following treatment guideline changes in countries like Kenya, Uganda, Malawi and Tanzania that prohibit all women of reproductive age from accessing DTG-based regimens, forcing them to remain on efavirenz (EFV)-based treatment, or make access conditional to long-term contraceptive use [20<sup>1</sup>]. These sweeping and reactive policy changes came in response to the drug safety alert issued by WHO in May 2018, based on data from the ongoing National Institutes of Health (NIH)-funded Tsepamo study in Botswana. The study reported a potential safety signal of increased risk of neural tube defects in infants born to women who were using DTG at conception – and up to 8 weeks afterwards (but not during pregnancy) [6<sup>1</sup>,7,21]. WHO now recommends that women of childbearing potential use consistent and reliable contraception with DTG-based treatment until more information becomes available; it is expected in 2019 [2].

This potential safety signal, the resulting guidelines and the restrictions that have been imposed on women of childbearing potential have reinforced the importance of informed choice and community-led engagement. Community and civil society organizations have been vocal about the need for information and about the rights of people living with HIV to choose their own treatment options, as illustrated by statements from groups like the International Community of Women Living with HIV and the African Community Advisory Board:

The needs and priorities of women living with HIV in relation to contraceptive use, conception and HIV treatment are diverse, therefore we cannot have a one size fits all situation when it comes to issues of contraception and HIV treatment... All women living with HIV irrespective of age should access full information on all antiretroviral treatment including DTG and contraceptives for them to make decisions and choice on what best suits them. [20<sup>1</sup>]

We strongly urge WHO and various stakeholders – especially our governments – to respect the voices of those actually affected. At no point have we, or any actual women living with HIV, been consulted in the guidance offered by Ministries of

Health especially now in light of the potential early NTD signal with DTG. We know women fall pregnant frequently and unexpectedly on ARVs, but we feel it is patronising to not give women the choice in this. We were shocked to learn of the potential harm to babies, but we do think it is critical to not just see the pregnant mother, and indeed all women of childbearing potential, as vessels of babies, but as individuals in their own right, who deserve access to the very best, evidence-based treatment available and the right to choose what they feel is best for them. [22<sup>1</sup>]

These developments also highlight the need for universal access to sexual and reproductive health services for all women in low and middle-income countries (LMICs), as well as the need for surveillance systems to detect safety issues at conception and during pregnancy among women using ART [23–25]. Moreover, reports have called for additional clinical data specific to DTG use – to inform DTG dosing in children who are less than 6 years of age and weigh less than 15 kg, and for people switching from EFV-based treatment to TLD who have an unknown or a detectable viral load [26<sup>1</sup>,27<sup>1</sup>]. Furthermore, ongoing and widespread HIV treatment education is necessary to ensure that all communities know their treatment options and can advocate for improved access to optimized treatment and monitoring. Access to this information empowers people living with HIV – including women of childbearing potential – and their communities to advocate for more effective treatment, SRH services and access to monitoring with RVLT.

### **Viral load testing: the value to communities**

Viral load testing (VLT) provides individual-level, community-level and programmatic-level benefits. It motivates people who are maintaining an undetectable viral load and finds people who may need counseling and adherence support – or a switch to a more effective regimen to prevent drug resistance [28–29] and progression to advanced HIV disease, the appearance of which is of growing concern [30]. Access to VLT also facilitates prevention of sexual HIV transmission, benefitting individuals and their communities [31].

VLT is instrumental for WHO-recommended differentiated service delivery (DSD), as it identifies stable clients who do not need frequent clinic visits, saving their time and money while generating cost-savings for healthcare systems and allowing them to focus on clients who need more intensive medical care [32]. VLT can ultimately be used to monitor and inform HIV treatment programs and improve gaps

in the cascade of care, given that low viral load suppression rates among particular sub-groups and geographical areas may highlight the need for tailored program interventions or approaches [31]. In addition, implementation of dried blood spot and point-of-care testing could reduce inequities among PLHIV communities with limited access to health services, including those in rural settings or among key populations, by increasing access to VLT [33]. These strategies could be particularly useful among children and adolescents, where adherence and viral suppression remain challenging, and viral load testing is essential for treatment management [34,35].

Communities that are informed about the benefits of VLT have an important role to play in advocating for access. Improvement of the infrastructure for VLT will not be sufficient without community demand. Treatment education initiatives are crucial for increasing awareness among communities about the benefits of access to routine viral load testing for treatment management and their long-term health outcomes [10<sup>26</sup>,29].

Our review identified several challenges to overcome, particularly in LMICs, before the benefits of viral load can be maximised. Offering viral load testing in places with the infrastructure to support it requires considerable financial investment, given the costs associated with laboratory equipment, personnel, training, maintenance and supplies such as reagents [32,36]. Such equipment is not widely available across primary health facilities, and is underutilized where it is available. Data collected by the International Treatment Preparedness Coalition (ITPC)'s Regional Community Treatment Observatory in West Africa, for example, revealed that Mali had seven machines with the capacity to perform 35 000 viral load tests, but only performed 1455 tests in 2017 [37]. Procedures for collecting and transporting blood samples are often inadequate and poor management of client data and lab tests leads to lost results that never reach recipients of care. Such gaps in access are not restricted to a particular region. Data derived from ITPC's ongoing Global Treatment Survey on treatment access in Honduras, Ukraine, Kyrgyzstan, Vietnam and Zimbabwe, showed that only 34% ( $n=783$ ) of PLHIV had access to a viral load test within 6 months of ART initiation [37]. Lastly, healthcare workers do neither always recognize the importance of viral load testing, nor do they have the capacity to perform viral load testing and correctly interpret the results [33,36].

Notably missing from the literature was the importance of routine viral load testing. It is critical to highlight the need for viral load testing that is done routinely, per the WHO treatment guidelines,

as U=U and similar campaigns reach communities where RVLTL remains unavailable. Some recommendations, emerging from the review, identify avenues by which access to RVLTL can be scaled up. These include establishing strong policy guidance establishing viral load testing as integral part of ART programmes, along with financial investments in equipment and reagents as well as personnel training. Additional recommendations included multi-sectoral partnerships to reduce pricing, use of dried blood samples and point-of-care viral load testing to improve blood sample management [28,32], maximizing use of available resources such as multiplex testing that can also be used for tuberculosis, hepatitis C and early viral load testing in infants and treatment [35] and making use of mobile technologies to increase awareness communities as well as viral load test result management [29]. Ultimately, availability of routine viral load testing is only significant to the extent that the test results reach the healthcare providers and the recipients and are used to inform decisions around treatment.

### **Linking community demand for tenofovir/lamivudine/dolutegravir and routine viral load testing**

There is an inextricable link between access to DTG and RVLTL. DTG-based regimens are promoted as a better alternative to EFV-based regimens for first-line ART because of the promise of fewer side effects, and a higher resistance barrier that could reduce emergence of HIV drug resistance and treatment failure [38]. Therefore, it is paramount that increased access to RVLTL remain a part of ART scale up programmes, to ensure quality treatment monitoring and management [35]. Furthermore, increasing access to RVLTL to monitor effectiveness of DTG-based regimens remains crucial, particularly as PLHIV decide to advocate for starting or switching their treatment [26<sup>26</sup>]. The hope that the switch to TLD (or other DTG-based regimens) could reduce the frequency of treatment monitoring is premature, as resistance testing is largely unavailable, and should be cautioned against until data are available to support such recommendations. In light of current developments, the switch to TLD should be viewed as an opportunity to increase and support adherence and expand access to SRH services – particularly in LMICs.

### **CONCLUSION**

The latest developments with DTG and RVLTL highlight underlying issues of global health systems – including drug surveillance, supply chain

management, and linkages to comprehensive care services – that need to be addressed. They also underscore the importance of community education about, and principal engagement on these issues. Communities and recipients of care need – and have the right to demand – access to information and research that is relevant to their circumstances, to inform choices they make about their health, and treatment outcomes. This cannot be understated as we look at the possibility of up to 15 million people being on DTG-based regimens in the next 5 years [24]. Informed advocacy is essential for PLHIV and their communities, so that they benefit from existing and future therapeutic advances. Research is needed on the importance of community demand across the HIV treatment cascade.

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## Conflicts of interest

There are no conflicts of interest.

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