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Critical considerations for adopting the HIV 'treat all' approach in Zimbabwe: is the nation poised?

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While the advent of antiretroviral therapy (ART) has increased survival and reduced the number of acquired immune-deficiency syndrome (AIDS) related deaths among people living with the human immunodeficiency virus (HIV) virus (PLHIV), HIV/AIDS remains a global health problem and sub-Saharan Africa continues to bear the greatest burden of disease. There are also major challenges in the HIV response: as of December 2013, only 36% of PLHIV globally were on ART, and for every individual started on ART there were two new PLHIV diagnosed. This has led to considerable debate around adopting an HIV 'treat all' approach aimed at greatly escalating the number of PLHIV initiated and retained on ART, regardless of CD4 cell count or World Health Organization (WHO) clinical stage, with the intended goal of achieving viral suppression which should in turn reduce HIV transmission, morbidity and mortality in affected individuals. This paper examines the issues being discussed in Zimbabwe, a low-income country with a high burden of HIV/AIDS, about the implications and opportunities of adopting an HIV 'treat all' approach, along with pertinent operational research questions that need to be answered to move the agenda forward. These discussions are timely, given the recent WHO recommendations advising ART for all PLHIV, regardless of CD4 cell count.

The human immunodeficiency virus (HIV) and the acquired-immune deficiency syndrome (AIDS) remain a serious global health problem despite a remarkable decline in people newly diagnosed with HIV infection annually, to 2 million (1.9–2.2 million) in 2014 compared to 3.1 million in 2000.[1] The majority of people living with HIV/AIDS (PLHIV) are in sub-Saharan Africa, accounting for 70% of the world total PLHIV in 2014.[1]

The scale-up of antiretroviral therapy (ART) in the last 15 years has been one of the world's greatest public health success stories, with nearly 15.8 million PLHIV globally on ART by mid-2015[1] and 7.8 million (range 6.9–8.4 million) deaths averted globally during 2000–2014 due to ART programmes.[1] Zimbabwe is one of the southern sub-Saharan African countries that has been the hardest hit, with a national HIV prevalence of 17% among those aged 15–49 years,[2] but with a notable decline in HIV incidence from 2.6% in 2000 to 0.9% in 2014.[2]

Prompt initiation of and adherence to ART results in viral load (VL) suppression to undetectable levels, which is good not only for individual health but also for preventing the transmission of HIV infection.[3] The recent START[4] and TEMPRANO[5] studies have stimulated interest and enthusiasm for moving towards an HIV 'treat all' approach, and the World Health Organization (WHO) has recently launched a recommendation that ART be started in all PLHIV, regardless of WHO clinical stage or CD4 cell count.[6]

Modelling of the HIV 'treat all' approach predicts that the early identification of all HIV-infected individuals, followed by immediate initiation on ART regardless of CD4 count or VL, can result in reduced HIV transmission to as low as one incident HIV-infected case per 1000 people within a 10-year period.[7] Other mathematical modelling studies have reached the same conclusion.[8,9] This paper explores the considerations and implications of the HIV 'treat all' approach specific to the Zimbabwean setting in anticipation of the country's adoption and implementation of this strategy. We also outline for each section the important operational research (OR) questions that need to be answered to move the agenda forward.

Identification of people with undiagnosed HIV infection

Despite its heavy HIV/AIDS burden, the most recent Zimbabwe Demographic and Health Survey (ZDHS) of 2010–2011 showed that only 57% of women and 36% of men aged 15–49 years had ever been tested for HIV.[10] The survey also showed that 26% of women and 45% of men diagnosed with HIV infection had never previously been tested for HIV. There are thus still a large number of undiagnosed PLHIV in Zimbabwe who could potentially be identified early in the course of their infection through strategies that promote scale-up of universal voluntary HIV testing.

Current models of HIV testing services (HTS) in the country are well established, and include 1) standalone voluntary counselling and testing, 2) provider-initiated testing and counselling (PITC) for patients admitted to hospital or attending out-patient clinics, and 3) PITC in antenatal care (ANC), tuberculosis (TB) and sexually transmitted infection (STI) clinics. Within these models, there is room for scale-up of HTS at all health facility entry points through the training of health workers, to limit referrals of patients to the primary care counsellors who usually perform HIV testing and may be overwhelmed in large, busy hospitals. Potential OR questions include conducting hospital exit interviews or audits of records about whether the numbers of patients seen in various hospital entry points per given period tally with the numbers tested for HIV, and whether patients diagnosed as HIV-positive have been linked to HIV care. In addi-

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tion, a yield analysis of HIV positivity rates at each of the entry points could be conducted to support context-specific decisions on where best to target HTS. An evaluation of the role of lay providers for HTS will be important as part of a task-shifting strategy, to improve service access and alleviate the burden on the already constrained workforce.

Deoxyribonucleic acid polymerase chain reaction (DNA-PCR) testing for early infant diagnosis (EID) of HIV infection is an important testing intervention, with 1442 (92%) of all health facilities collecting dry-blood spot samples for this test by December 2013.[11] In 2014, 86% of HIV-exposed infants had DNA-PCR samples collected ⩽2 months after birth, of whom 74% had a result returned to their carers (source: 2014 Zimbabwe National AIDS Programme data). OR is needed to further increase coverage and to identify and test infants whose mothers are lost to follow-up in the prevention of mother-to-child transmission (PMTCT) programme or who seroconvert during pregnancy. The national PMTCT programme is also setting up an electronic system for tracking mother-baby pairs, with the intention of strengthening the identification of undiagnosed PLHIV and improving retention.

Turnaround times of EID results and linkage to ART initiation for those who are HIV-infected also need to be improved, and this would be another good topic for routine prospective action-orientated OR. DNA-PCR testing is currently centralised, with only three laboratories processing dry-blood spot specimens countrywide, resulting in long turnaround times for results averaging 15.9 weeks.[11] Expansion of laboratory testing services and improving transport to and from these laboratories and peripheral health facilities is a priority. OR around innovative models for sample transportation, such as the utilisation of established supply chain services, such as the postal service network, or more cutting-edge technology such as unmanned aerial vehicles, as is being planned in Malawi, or SMS transmission of central laboratory results to peripheral health centres, might improve timely feedback of HIV results for immediate ART initiation. The age of legal consent is 16 years in Zimbabwe, and there are challenges with testing of older children by health workers in the absence of their guardians,[12] and innovative models in this area, such as routine opt-out HIV testing, need piloting.[13]

National HTS campaigns may also contribute to wider testing coverage and early diagnosis of PLHIV, particularly men in Zimbabwe, who usually present late for treatment,[14] and those living in remote settings without easy access to health services. Campaigns in Zimbabwe have been conducted annually since 2011. Up to 2014, 796 307 people were tested for HIV during these campaigns, the equivalent of 5% of the national population, with 59 296 (7%) diagnosed as HIV-positive (source: National AIDS Programme, Zimbabwe). While diagnosed PLHIV in these campaigns were issued with referral slips to their nearest HIV treatment and care centres, no tracing mechanisms were set up to monitor and evaluate whether the individuals referred are eventually started on ART. Going forward, an HIV 'treat all' approach might reduce the current leakages in the HIV care cascade by removing the barriers that require PLHIV to be referred and assessed for ART eligibility.[15] There is also a need for OR to assess whether routine community-based index client testing or community-based integrated health screening yields higher HIV positivity rates compared with one-off campaigns.

There is a need for key population size estimation surveys, particularly for prisoners and sex workers in Zimbabwe, among whom HIV prevalence rates are 27% for male inmates, 39% for female inmates[16] and 60% for sex workers.[17] HIV prevalence and population numbers of men who have sex with men (MSM) are also important, as these data are currently lacking in Zimbabwe. Adapted routine service provision targeting these populations, peer education mobilising these communities for testing and specific strategies to ensure these populations are retested at a higher frequency are necessary. Targeted testing campaigns or routine service provision in high HIV prevalence settings such as farming and mining areas and growth points, according to a recent in-country 'HIV hotspot' analysis, would also be beneficial.[18] Zimbabwe will be participating in a UNITAID multi-country HIV self-testing study aimed at evaluating the acceptability, feasibility and cost-effectiveness of this approach to inform global and country-level policy about whether HIV self-testing can lead to expanded testing uptake and encourage retesting among those most at risk. Encouraging findings from Malawi have shown high acceptability and accuracy of HIV self-testing results at community level.[19]

Increased cohort size of PLHIV on ART

The 'treat all' approach implies that all diagnosed PLHIV would be eligible for ART, and thus the country might witness a large increase in the number of clients receiving ART. The elevation of CD4 count thresholds over the years from <200 cells/μl to <350 cells/μl, and currently <500 cells/μl, has meant that the pool of ART-eligible clients has gradually increased. By the end of 2014, an estimated 1 168 451 adults were eligible for ART in Zimbabwe, based on a CD4 cell count of <500 cells/μl, of an estimated 1 403 426 PLHIV aged ⩾15 years.[2] As this estimate represents 83% of PLHIV, shifting to a universal 'treat all' policy would not constitute a significant increase beyond current targets. However, in practice, 732 919 clients (52% of estimated HIV-infected adults) are receiving ART in Zimbabwe. If the 'treat all' approach was adopted and rapidly implemented, this would mean starting almost 700 000 additional patients on ART in addition to those PLHIV who are newly diagnosed each year. How health facilities might cope with this additional, fairly sudden increase in eligible PLHIV will need to be well documented and shared nationally so that a culture of 'learning by doing', which is so integral to OR, is developed. Buy-in from all external bilateral and multilateral funding mechanisms, which constituted 86% of Zimbabwe's HIV expenditure in 2012, will also be essential[20] to ensure adequate availability and efficient supply chain management of antiretroviral (ARV) medicines.

While annual HIV incidence has declined from a peak of 6% in 1994 to the current level of 0.9%, in Zimbabwe there are still approximately two people initiating ART for each new HIV infection. The 'treat all' approach should reduce the number of persons newly acquiring HIV infection over time, further endorsing the use of this approach.

Retention in antiretroviral therapy care: decentralisation and monitoring

Challenges with follow-up and retention in care are inevitable as the size of ART patient cohorts increase. Initiations onto ART in Zimbabwe were mostly centralised at central, provincial and district hospitals when the ART programme started, due to the availability of medical doctors authorised to initiate ART. This has resulted in hospitals having large ART clinics, with high patient-to-clinician ratios ranging from as high as 551:1 to 2665:1.[21] This system causes difficulties in the active follow-up of patients who miss scheduled review visits, and there are increasing numbers of patients lost to follow-up. Local data on ART initi-

ations between 2007 and 2009 showed that patient retention decreased with longer duration on ART, from 91% at 6 months to 64% at 36 months, and that this reduction in retention was associated with accessing health care from higher level health care facilities compared to primary care facilities, among other factors.[22]

Adoption of the HIV 'treat all' approach will therefore require further decentralisation, which has led to increases in the number and percentage of public health facilities nationwide providing ART services, from 150 (9.6%) in 2007 to 1459 (94%) as of December 2014. Of these, 1056 (72%) were ART initiating sites, 963 (91%) of which are fourth-level health facilities consisting of rural/urban clinics and rural hospitals where there are no medical doctors, and ART is initiated by clinical officers and nurses (source: National AIDS Programme, Zimbabwe). As cumulative numbers increase with a 'treat all' approach, OR will be needed to determine, for example, whether less frequent clinic attendances and less frequent medication pick up will decongest the clinics while at the same time maintaining good retention in care. In addition, OR on strategies for enhancing retention among a fairly asymptomatic population with early ART initiation, and especially among adolescents, is needed as the new WHO ART guidelines are adopted and rolled out.

As monitoring of patients is mostly undertaken at the facility level using paper-based treatment cards and registers, increased sizes of ART cohorts can affect data quality and reporting accuracy. There is therefore a need for more data quality audits. In June 2013, an electronic patient monitoring system (ePMS) for electronic capture of individual patient data was introduced. This is operational at 243 health facilities (consisting of all central, provincial, district and major mission hospitals and including some urban/rural clinics and rural/mission hospitals) and monitors over 92 000 patients on ART (source: National AIDS Programme, Zimbabwe). The ePMS can be used to assist with real-time tracing of patients who delay or miss scheduled review visits, a task more difficult to perform when using the numerous conventional paper-based registers. It will therefore be interesting to compare whether retention and data quality are better at ePMS-supported sites than at sites with paper-based registers.

Potential OR to improve retention in care with the increasing size of ART patient cohorts will include the piloting of community ART groups (CAGs) where stable patients are grouped and members take it in rotation to collect ARV drugs for the whole group and report on the group's progress. CAGs have been shown to decongest busy clinics by reducing the number of individual patient visits and improving long-term retention in Mozambique.[23] How these differentiated care strategies improve the quality of the service for the patient (shorter waiting times, less money spent on travel, peer support) and encourage self-management is also worth evaluating.

Adherence to antiretroviral treatment

While ART regimens have become more potent, less complex and better tolerated over time since the advent of the first ARTs,[24] there is still the potential for poor adherence, especially in PLHIV who have high CD4 counts and are asymptomatic when initiated on ART. ART-induced side effects may result in treatment interruptions and imperfect levels of adherence, which are then associated with the development of drug-resistant HIV,[25,26] which is more costly to treat with second- and third-line ARV drugs. Anecdotal reports in Zimbabwe have indicated that some patients are experiencing side effects from current ART regimens. It is paramount to conduct OR to determine the prevalence and management of adverse events among PLHIV receiving ART to quantify the burden of the problem and assess the appropriateness of clinical practices in managing adverse events. The ART pharmacovigilance system also needs to be reviewed and strengthened for early identification of drug-induced adverse events and action.

OR aimed at determining whether early presentation for ART initiation affects ART adherence is needed to inform appropriate interventions. While a systematic review and meta-analysis of drug adherence showed better results in sub-Saharan Africa compared with North America,[27] in one local study in Zimbabwe, only 49% of patients had ART adherence rates >95%.[28] Local data from sentinel surveillance sites for HIV drug resistance (HIV-DR) monitoring also showed HIV-DR and possible HIV-DR (according to WHO definitions)[29] at 12 months after ART initiation of respectively 4.3% and 25.4%.[21] The issue of treatment adherence and drug resistance in Zimbabwe requires more attention.

Viral load suppression/monitoring

Ultimately, the intended goal of the HIV 'treat all' approach is to achieve VL suppression that can lead to a decrease in HIV transmission in the community. There is therefore a need for routine VL monitoring among patients on ART to identify those who have high VL and may be at risk for treatment failure. Clinicians can first offer enhanced adherence counselling (EAC) to those with high VL to try and counteract any possible suboptimal adherence, and for those who then fail to achieve VL suppression, clinicians can switch to second- or third-line treatment as necessary. Currently, only 5% of patients in ART care have undergone VL monitoring in the public sector in Zimbabwe. There are plans, however, to make VL testing available for more than 90% of eligible patients by 2017.[30] Reports from the 12 HIV drug resistance sentinel survey sites (2009–2011) have indicated VL suppression rates of 90% among PLHIV receiving ART at 12 months and 70% of all patients, including those who died and were lost to follow-up.[21] These figures fall short of the target of 90% viral suppression by 2020 among those receiving ART. As VL testing is currently based on conventional high throughput platforms stationed at higher level health facilities and high volume laboratories, there needs to be a better system of efficient and timely referral of dry-blood spot specimens from lower level ART sites if the scale-up of VL testing is to become a reality. Investment is also needed in clinical training and patient awareness if scale-up of VL is going to occur.

Good documentation of existing practices and the testing of innovative ways to make these systems work are important OR priorities. As the programme rolls out the VL testing services, further studies are needed to fully operationalise the 'differentiated care' approaches to HIV management using VL testing algorithms.

Experiences from the implementation of Option B+

In line with the HIV 'treat all' approach, in April 2012 the WHO released a programmatic update on the use of ARV drugs regardless of CD4 count for treating pregnant women and preventing HIV infection in infants, termed Option B+.[31] The PMTCT Option B+ approach was first introduced by Malawi in July 2011, with the WHO officially recommending the approach in its 2013 consolidated HIV guidelines.[32] Zimbabwe adopted the Option B+ approach in September 2013; by September 2015 it was being offered in 1495 of the 1560 health facilities providing PMTCT services, and 46 391 women were on Option B+. Nationwide data on retention in care with Option B+ are lacking, although a recent study in two rural districts of the country showed 6-month retention of 83%.

There were many useful lessons to be learnt with the roll-out of Option B+, starting with the development of a costed, operational plan along with monitoring and evaluation tools and commodity distribution systems. Consultation with implementing partners was critical in providing technical and financial support in policy dissemination, planning and actual implementation of Option B+. Second, there was intense advocacy, training of health workers and community sensitisation. Provincial and district health executives ensured coordination of implementing partners and easy entry into districts and provinces, while PMTCT focal persons at national, provincial and district levels provided critical leadership. Third, Option B+ was delivered at sites already initiating ART, followed by accreditation and delivery at non-ART-initiating sites. Village health workers were an important resource for tracking defaulting patients in rural facilities. These steps all need consideration when moving towards a 'treat all' approach.

Findings from surveys of women on Option A who registered for ANC in 2012 showed poor retention in care.[32,33] It is hoped that better results will be found with Option B+. OR will be needed to determine the optimal health service models of care for pregnant and breast-feeding women. It is also important to conduct studies to determine the optimal timing for referring mother-baby pairs from ANC settings to the mainstream ART clinics. Strategies for enhancing 'male involvement' in HIV care for the mother and baby are also needed to support disclosure, adherence and long-term retention of the mother-baby pairs in care.

CONCLUSION

The HIV 'treat all' approach is a novel intervention that presents opportunities to expand the uptake of HIV testing and the coverage of ART among PLHIV with the goal of mitigating the HIV epidemic and bringing it to an end. Adopting this approach will first require innovative strategies for increasing HIV testing coverage and identifying areas of high HIV prevalence within the country to improve the incremental yield of diagnosing PLHIV. This means expanding PITC to all health facility entry points, especially TB and STI clinics, nutrition and in-patient wards, targeting high-risk settings such as prisons, and focusing on vulnerable populations such as sex workers. Routine community-based index client testing or community-based integrated health screening may also be innovative, effective strategies for targeting PLHIV who do not reach the health facilities. The success of the 'treat all' approach secondly depends on the country's ability to provide an uninterrupted supply of ARV drugs to the anticipated burgeoning population of PLHIV while simultaneously ensuring that treatment is decentralised and easily accessible at lower-level health facilities and, where feasible, in the community. Third, there is a need to ensure that routine monitoring and active tracing of all patients initiated on ART is strengthened to limit suboptimal adherence to ART, reduce attrition from care and avert possible increases in HIV drug resistance.

Finally, routine monitoring of VL is a component that needs to be rapidly scaled up to identify those patients who need EAC or who are in need of switching to second-line ART to avert possible increases in cases of drug resistance or morbidity and mortality due to unaddressed treatment failure. VL testing may also be an important enabler of differentiated care. At all of these levels, OR will be needed to document the status quo and assess and test innovative strategies to deal with bottlenecks and challenges. Zimbabwe is currently working on the in-country adoption and implications of the 90-90-90 strategy recommended by the Joint United Nations Programme on HIV/AIDS (UNAIDS), which has set new targets for 2020 of 90% of all HIV-infected individuals knowing their HIV status, 90% of those receiving sustained ART, and 90% of those attaining viral suppression.[33] The HIV 'treat all' approach, if accepted and taken to scale, will facilitate the achievement of these ambitious targets by 2020.

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Si l'arrivée de la thérapie antirétrovirale (TAR) a accru la survie et réduit le nombre de décès liés au syndrome d'immunodéficience acquise (SIDA) parmi les personnes infectées par le virus de l'immunodéficience humaine (VIH), le VIH/SIDA reste un problème de santé publique mondial et l'Afrique sub-saharienne continue à supporter la plus lourde part de la maladie. La riposte au VIH/SIDA est également confrontée à de grands défis : en décembre 2013, seulement 36% des personnes infectées par le VIH dans le monde étaient sous TAR, et pour chaque patient mis sous TAR, il y avait deux nouvelles infections à VIH. Ceci a entrainé un débat considérable à propos de l'adoption de l'approche VIH « traitement pour tous » visant à augmenter considérablement le nombre de personnes infectées par le VIH mises et maintenues sous TAR, sans tenir compte du nombre de CD4 ni du stade clinique de l'Organisation mondiale de la santé (OMS), dans le but d'aboutir à une suppression du virus qui, à son tour, réduirait la transmission, la morbidité et la mortalité parmi les personnes affectées. Cet article discute des questions qui sont en cours de débat au Zimbabwe, un pays à faible revenu durement frappé par le VIH/SIDA, à propos des implications et des opportunités de l'adoption d'une approche du VIH de type « traitement pour tous » en parallèle avec des problèmes pertinents de recherche opérationnelle qui nécessitent une réponse pour que les choses avancent. Ces discussions arrivent à point nommé en raison des récentes recommandations de l'OMS relatives au TAR pour toutes les personnes infectées par le VIH, quel que soit le nombre de CD4.

La disponibilidad del tratamiento antirretrovírico (TAR) ha mejorado la supervivencia de los pacientes aquejados de síndrome de inmunodeficiencia adquirida (sida) y disminuido la mortalidad asociada con el sida en las personas infectadas por el virus de la inmunodeficiencia humana (VIH); sin embargo, la infección por el VIH y el sida siguen siendo un problema mundial de salud y África subsahariana soporta aun la más alta carga de morbilidad. Existen además obstáculos mayores en la respuesta al VIH. Hasta diciembre del 2013, solo el 36% de las personas infectadas por el VIH en el mundo recibía TAR, y por cada persona que lo iniciaba, se presentaban dos casos nuevos de infección. Esta situación ha dado lugar a discusiones frecuentes sobre la adopción de la estrategia de 'tratar a todas las personas' infectadas, con el fin de aumentar en gran medida la escala de administración del TAR y la fidelización al mismo, independientemente del recuento de linfocitos CD4 y del estadio clínico de la enfermedad según la escala de la Organización Mundial de la Salud (OMS); la meta prevista es alcanzar la supresión del VIH, reducir la transmisión y disminuir la morbilidad y la mortalidad de las personas afectadas. El presente artículo examina los aspectos que se analizan actualmente en Zimbabwe, un país de bajos ingresos con una alta carga de morbilidad por el VIH/sida, en materia de repercusiones y oportunidades de adopción de la estrategia de 'tratar a todas las personas' afectadas por el VIH, y considera además las problemáticas de investigación operativa que se deben resolver a fin de avanzar con el programa. Estas deliberaciones son muy oportunas, dadas las recientes recomendaciones de l'OMS sobre la administración del TAR a todas las personas infectadas por el VIH, con independencia del recuento de linfocitos CD4.

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