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Declining tuberculosis case notification rates with the scale-up of antiretroviral therapy in Zimbabwe

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Setting: Zimbabwe has a human immunodeficiency virus (HIV) driven tuberculosis (TB) epidemic, with antiretroviral therapy (ART) scaled up in the public sector since 2004.

Objective: To determine whether national ART scale-up was associated with annual national TB case notification rates (CNR), stratified by disease type and category, between 2000 and 2013.

Design: This was a retrospective study using aggregate data from global reports.

Results: The number of people living with HIV and retained on ART from 2004 to 2013 increased from 8400 to 665 299, with ART coverage increasing from <0.5% to 48%. TB CNRs, all types and categories, increased from 2000 to 2003, and declined thereafter from 2004 to 2013. The decreases in annual TB notifications between the highest rates (before 2004) and lowest rates (2013) were all forms of TB (56%), new TB (60%), previously treated TB (53%), new smear-positive pulmonary TB (PTB) (40%), new smear-negative/smear-unknown PTB (58%) and extra-pulmonary TB (58%).

Conclusion: Significant declines in TB CNRs were observed during ART scale-up, especially for smear-negative PTB and extra-pulmonary TB. These encouraging national trends support the continued scale-up of ART for people living with HIV as a way of tackling the twin epidemics of HIV/acquired immune-deficiency syndrome and TB in Zimbabwe.

The human immunodeficiency virus (HIV) is the most important risk factor for developing tuberculosis (TB), a risk that is also dependent on the CD4 cell count of the person with HIV and the amount of transmission of *Mycobacterium tuberculosis* in the community. Antiretroviral therapy (ART) reduces the risk of TB in people living with HIV (PLHIV), with the main risk reduction being in lower CD4 cell counts, although benefit is also seen in those with CD4 cell counts >350 cells/mm^3.[1] Southern Africa is the region most heavily burdened by the TB-HIV epidemic, and TB is largely driven by HIV in affected countries.[2] In this region, however, there has been a tremendous scale-up of ART in the last decade, and one might therefore expect to see a reduction in TB case notification rates (CNRs). In Malawi and Swaziland, the scale-up of ART has been associated with a marked decline in TB case notifications, especially with the types of TB associated with HIV, such as smear-negative pulmonary disease and recurrent TB.[3–5]

Zimbabwe is one of the southern African countries that has a largely HIV-driven TB epidemic, with TB-HIV co-infection rates of nearly 70% among TB patients in 2014.[2] We were therefore interested to see whether there has been any association in Zimbabwe between ART scale-up and annual TB CNRs, stratified by type and category of disease, between 2000 and 2013.

METHODS

Study design

This was an ecological study design using aggregate programme data.

Setting

General

Zimbabwe, a Southern African country with a population of 13 million,[6] has a high HIV prevalence rate of 15%. The total number of adults and children living with HIV was estimated at 1.4 million, according to 2013 national HIV estimates.[7]

The national ART programme in Zimbabwe

ART was first offered in public health facilities in 2004 under the national ART programme at five central level hospitals, and with national scale-up became available in 1459 of 1560 health facilities by December 2014 (source: National ART programme). Since the inception of the ART programme, the initiation criteria for ART in adults has shifted from a CD4 cell count threshold of <200 cells/mm^3 to <350 cells/mm^3 from 2011 to 2013 and eventually to <500 cells/mm^3 from 2014 onwards, in accordance with World Health Organization guidelines.[8–10] During these periods, ART has also been available for those with advanced clinical HIV disease. Towards the end of 2013, there was also a shift in eligibility for lifelong ART in Zimbabwe under Option B+, whereby all HIV-infected pregnant and breastfeeding women, irrespective of their CD4 count or WHO clinical stage, could be initiated on treatment for life. Over this same period, ART regimens have become simpler and less toxic, moving from stavudine+lamivudine+nevirapine in the first 6 years of the ART progamme to tenofovir+lamuvidine+nevirapine, and, as of 2013, to tenofovir+lamuvidine+efavirenz, administered as a single fixed-dose combination pill to be taken once daily.

The National TB Programme in Zimbabwe

Zimbabwe has a well-established WHO-recommended DOTS-based[11] national TB programme (NTP) whereby TB treatment services are integrated with general health services at all public health facilities country-

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Zimbabwe; HIV/AIDS; tuberculosis; ART; recurrent TB; operational research

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wide. The DOTS model ensures good structures for the bacteriological detection of TB, mostly through sputum smear microscopy, followed by treatment using WHO standardised TB regimens. These services are provided in conjunction with supervision and patient support, while ensuring an effective drug supply and management system and monitoring and evaluation structures for the routine assessment of treatment outcomes from district to national level.[11] National TB treatment outcomes are defined in line with WHO guidelines and are classified as treatment success (cured plus treatment completed), loss to follow-up (default), died, transferred out or treatment failure.[11]

TB patients are classified as either new or previously treated: new cases are those who have never received anti-tuberculosis treatment or have previously received anti- tuberculosis drugs for <30 days. Previously treated TB cases are those who have previously received anti-tuberculosis drugs for >1 month. New TB cases are divided into smear-positive pulmonary TB (PTB), smear-negative PTB or extra-pulmonary TB (EPTB) cases. As of 2013, new bacteriologically confirmed PTB cases have been added to account for the expansion of GeneXpert® (Cepheid, Sunnyvale, CA, USA) machines in the country. These new bacteriologically confirmed PTB cases include all smear-positive, culture-positive or TB cases diagnosed as positive with molecular techniques such as Xpert® MTB/RIF (Cepheid). As of 2013, this also includes bacteriologically confirmed PTB cases with unknown previous TB treatment history. Previously treated TB patients are categorised as 1) relapse cases, 2) treatment after failure, 3) treatment after default (loss to follow-up), or 4) 'retreatment other'. The NTP also ensures that these TB patients are prescribed a standardised treatment regimen of 6 months for new TB cases or 8 months for previously treated TB cases, observed by a health care worker or community health worker for at least the first 2 months.

Study population

All PLHIV (adults and children) who were recorded as alive and retained on ART at the end of each year and all patients (adults and children) registered nationally each year with TB between 2000 and 2013 in Zimbabwe were included in the study.

Data variables and sources of data

Aggregate numbers of HIV-infected people started on ART were obtained from global reports from the Joint United Nations Programme on HIV/AIDS (UNAIDS). Data on the estimated total population living with HIV were also obtained from the UNAIDS website.[12] These data are generated annually using the Estimation and Projection Package and Spectrum software[13] from UNAIDS based on primary collected data from census reports, antenatal clinic surveillance, population-based surveys and programme data. Data on TB case notifications, stratified by category, type of new TB and HIV status, were obtained from the WHO website.[14] To calculate TB CNRs, national population figures for 2002 and 2012 were obtained from national census reports for the respective years.[6,15] The population figures for the period from 2002 to 2012 were based on the annual average inter-census growth rate for 2002–2012 of 1.1%.[6] The 2013 national population was obtained from official national population projection statistics.[16]

Analysis and statistics

Data were analysed descriptively, mainly by plotting line and bar graphs of the various indicators over time from 2000 to 2013. Due to changing ART eligibility criteria over the years, ART coverage was calculated by dividing the annual total number of HIV-infected persons started and retained on ART by the annual estimated number of PLHIV. Annual TB CNRs were calculated by dividing annual TB case notifications by annual national population figures to obtain case notifications per 100 000 population. Changes in TB notification rates between 2000 and 2013 were determined by comparing the highest and lowest annual TB CNR using tests for proportions in Stata version 13.0 (StataCorp, College Station, TX, USA). Levels of significance were set at 5%.

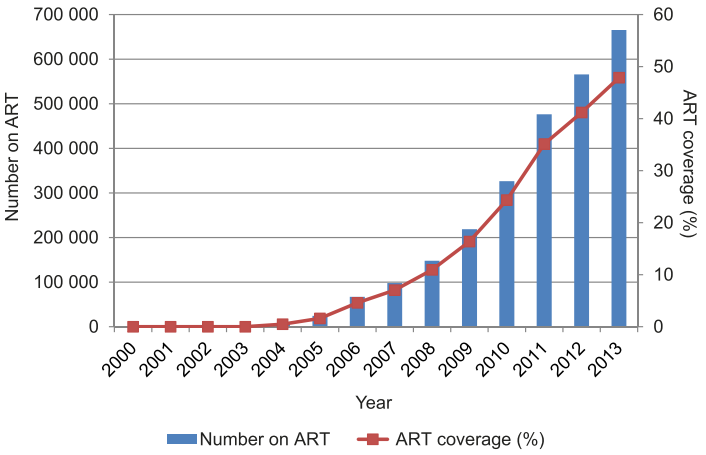

FIGURE 1 Numbers and coverage of PLHIV alive and retained on ART in Zimbabwe, 2000–2013. ART coverage was calculated using the estimated HIV-infected population as the denominator from national projections obtained from the Joint United Nations Programme for HIV/AIDS Estimation and Projection Package and Spectrum software.[13] ART = antiretroviral therapy; PLHIV = people living with human immunodeficiency virus.

Ethics approval

Ethics approval was sought and obtained from the Ministry of Health and Child Care, Harare, Zimbabwe, and the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease, Paris, France.

RESULTS

Figure 1 shows the number and coverage of PLHIV alive and retained on ART in Zimbabwe from 2000 to 2013. There was a rapid, exponential increase in the number of HIV-infected patients receiving ART, from 8400 in 2004 to 665 299 in 2013. This is equivalent to an increase in ART coverage of the estimated HIV-infected population from <0.5% in 2004 to 48% in 2013.

Figure 2A shows the TB CNRs for all patients, stratified by new and previously treated TB, from 2000 to 2013. For all TB cases, there was a sharp increase in CNRs, from 450/100 000 in 2000 to 600/100 000 in 2003, after which there was a steep decline to approximately 300/100 000 in 2008. From 2009 to 2010, there was a slight increase in CNR, followed by a steady decline to an all-time low over the 13-year period, of approximately 250/100 000 in 2013. New cases, constituting the majority of all TB cases, followed the same trend as for all TB cases. The CNRs for previously treated TB increased slightly, from zero in 2000 to 58/100 000 in 2004, before decreasing slowly over time to 27/100 000 in 2013.

Figure 2B shows declines observed in the CNRs for all types of new TB from 2000 to 2013, although these were more pronounced for EPTB and smear-negative/smear-unknown PTB cases combined. Smear-negative PTB cases alone declined between 2000 and 2008 before increasing up to 2010 and eventually declining to 110/100 000 in 2012. The Table shows that TB CNRs declined significantly among those with new TB compared with

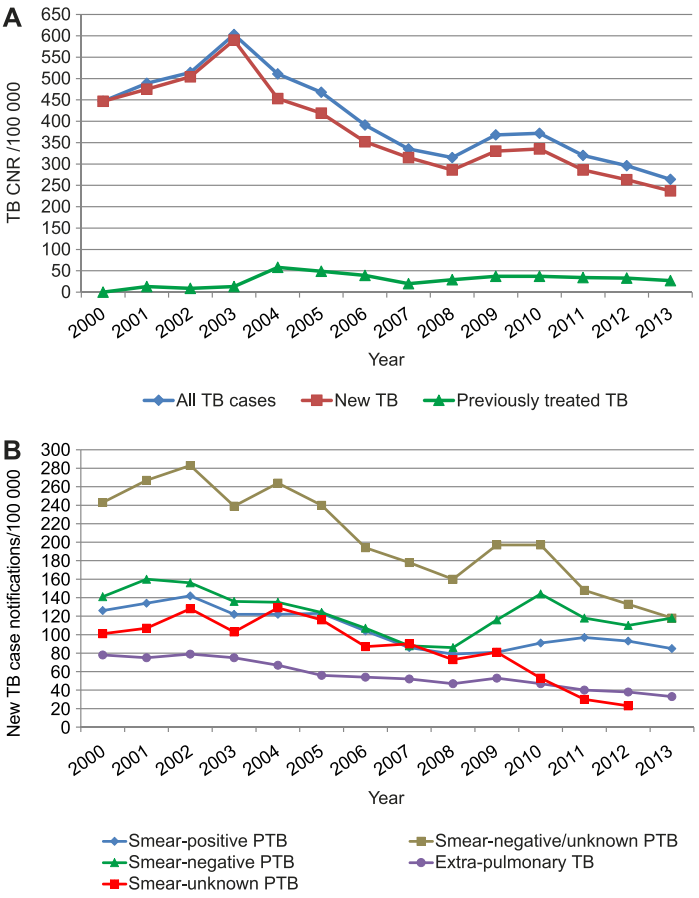

FIGURE 2 **A)** Notification rates of all TB cases in Zimbabwe stratified by TB category, 2000–2013. **B)** Notification rates of new TB cases in Zimbabwe stratified by type of TB, 2000–2013. PTB = pulmonary TB; TB = tuberculosis.

those with previously treated TB, while declines in CNRs among new smear-unknown PTB, EPTB and smear-unknown/smear-negative PTB cases were significantly greater than among new smear-positive PTB cases.

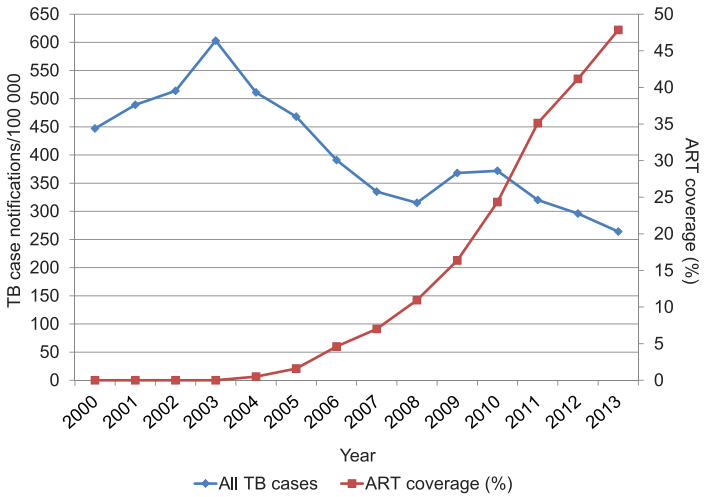

FIGURE 3 Trends in notification rates of all TB cases vs. ART coverage, 2000–2013. ART coverage was calculated using the estimated HIV-infected population as the denominator from national projections obtained from the Joint United Nations Programme for HIV/AIDS Estimation and Projection Package and Spectrum software. TB = tuberculosis; ART = antiretroviral therapy; HIV = human immunodeficiency.

In Figure 3, there was an observed inverse trend in the declining total TB CNRs with increasing coverage of ART from 2000 to 2013.

DISCUSSION

This study shows the respective rise and fall of TB in the pre-ART and ART scale-up periods in Zimbabwe. First, there was a sharp increase in the TB CNRs in the pre-ART scale-up era, which was more pronounced for new TB cases, particularly for new EPTB cases and smear-negative and smear-unknown PTB cases combined. The resurgence of TB in much of sub-Saharan Africa in the last two decades before the advent of ART was largely attributed to the HIV/acquired immune deficiency syndrome (AIDS) epidemic.[17] There was a particular increase in cases of smear-negative

TABLE Comparisons of TB case notification rates, stratified by type and category, before 2004 (at start of ART scale-up) and after ART roll-out in Zimbabwe

Type of TB	Highest notification rate per 100 000 *n*	Year	Lowest notification rate per 100 000 *n*	Year	Decrease between highest and lowest %	*P* value*
All TB	603	2003	264	2013	56.2	–
New TB	590	2003	237	2013	59.8	
Previously treated TB	58	2004	27	2013	53.4	<0.001†
New smear-positive PTB	142	2002	85	2013	40.1	–
New smear-negative PTB	160	2001	86	2008	46.3	0.278‡
New EPTB	79	2002	33	2013	58.2	0.01§
Smear-unknown PTB	129	2004	23	2012	82.1	<0.001¶
New smear-negative and smear-unknown PTB combined	283	2002	118	2013	58.3	<0.001#

*Test of proportions.
†Comparison of percentage decreases between new TB and previously treated TB cases.
‡Comparison of percentage decreases between smear-positive and smear-negative PTB cases.
§Comparison of percentage decreases between smear-positive and EPTB cases.
¶Comparison of percentage decreases between smear-positive and smear-unknown PTB cases.
#Comparison of percentage decreases between smear-positive and smear-negative and smear-unknown PTB cases combined.
TB = tuberculosis; ART = antiretroviral therapy; PTB = pulmonary tuberculosis; EPTB = extra-pulmonary TB.

PTB, mainly due to the effects of severe immune suppression on the development of TB pathology in the lungs.[18] In Zimbabwe, the strong association between HIV and TB was manifested in high co-infection rates, which reached a peak of 79% in 2009 and were still high, at 68%, in 2013.[2]

Second, from 2004 to 2013, there was a decline in all categories and types of TB as ART coverage in the public sector increased, and although causality cannot be proven in an ecological study such as this, the decline in the TB burden is likely due to the protective effects of ART on PLHIV. The impact of ART in reducing TB incidence among PLHIV has been observed in both high-income countries[19] and resource-limited settings with a high HIV burden. In Zimbabwe, as in other African countries, the indicated CD4 cell count threshold for starting ART has increased over the past decade, from <250 cells/mm^3 to the current threshold of <500 cells/mm^3. This has the potential to allow more PLHIV to start ART with less advanced HIV disease, thus further reducing their risk of developing TB. Another plausible explanation for the significant decline in TB CNRs in this period may be the large decline in HIV prevalence in Zimbabwe, from a peak of 29.6% in 1999 to a low of 17% in 2013, according to the 2014 UNAIDS Spectrum HIV estimates.[20] Going forward, the recent international support for a 90-90-90 approach,[21] which could pave the way for an HIV test-and-treat approach, could result in an even sharper decline in TB case notifications and TB incidence.

Despite the overall decline in all forms of TB case notifications, there was a slight increase in notifications of all TB cases and smear-negative PTB cases from 2008 to 2010, before a further decline to a 12-year and 13-year low in 2012 and 2013, respectively. With the exponential increase in ART coverage since the start of the public ART roll-out in 2004, the increase in TB CNRs may be explained by the prevailing socio-economic turmoil in Zimbabwe at that time, when the nation experienced the worst hyperinflation in the twenty-first century, of 2600% between 2007 and 2009, according to the country's Central Statistics Office.[22] This period resulted in declining production and severe food shortages, which may have contributed to immunosuppression among PLHIV and the resurgence of new TB cases, particularly those with smear-negative PTB.[22] The 2008–2010 increase in smear-negative PTB cases can also be attributed to significant declines in smear-unknown PTB cases, along with increasing availability of smear-microscopy laboratory services in the country at this time. These smear-unknown PTB cases are likely to have added to the number of smear-negative cases, given that approximately three in four TB patients in Zimbabwe are TB-HIV co-infected and are likely to have smear-negative PTB.

A significant decline has been observed since 2004 in the number of previously treated TB cases. ART will lead to an increase in the CD4 cell count in TB patients who are already undergoing or have completed treatment, and their enhanced immunity would provide some protection against recurrent TB. This has been observed elsewhere, with two Malawian studies showing a reduction in the incidence of recurrent TB in association with ART.[23,24] The effects of ART in reducing recurrent TB may become more evident as there has been a continued increase in ART initiation among HIV-infected TB patients, from 23% in 2007 to 77% by 2013,[14] and attaining 100% uptake of ART for all HIV-infected TB patients could further reduce TB case notifications.

There are two other considerations: first, ART on its own may not do the job. While ART can greatly reduce the risk of developing TB, an 8-year follow-up study of an ART cohort in a South African community has shown that PLHIV with a CD4 cell count of >700 cells/mm^3 still had incidence rates of TB that were approximately four-fold higher than among persons without HIV-infection in the community.[25] The national ART programme may thus need to scale up isoniazid preventive therapy (IPT), which alone,[26] and in combination with ART,[27,28] has a more profound effect on reducing TB incidence among PLHIV. IPT has been provided to PLHIV in ART clinics in Zimbabwe since 2013, although uptake is still in its infancy, with only 10 926 (<1%) PLHIV having received this prophylactic treatment in 2013.[29] At the population level, IPT is unlikely to have had any additional effect as yet on reducing the rate of TB case notifications.

Second, the study is dependent on the accuracy of TB case notifications, and these may be affected by the sensitivity of smear microscopy in peripheral laboratories, resulting in possible underdiagnosis of bacteriologically confirmed PTB and the well-understood difficulties in excluding other HIV-related diseases, with possible over-diagnosis of smear-negative PTB. The use of Xpert technology has been scaled up in Zimbabwe for screening active TB among PLHIV in HIV treatment and care settings, with a total of 108 instruments currently in use countrywide. This is likely to increase the accuracy of detection of some smear-negative TB cases.

In conclusion, this study shows encouraging national trends of decreasing TB case notification rates that support the continued scale-up of ART to PLHIV as a means of tackling the twin epidemics of TB-HIV/AIDS in Zimbabwe.

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Contexte : Le Zimbabwe connaît une épidémie de tuberculose (TB) induite par le virus de l'immunodéficience humaine (VIH) avec le traitement antirétroviral (TAR) en expansion dans le secteur public depuis 2004.
Objectif : Déterminer si cette expansion nationale du TAR a été associée à une diminution des taux annuels de notification nationale des cas de TB, stratifiés par type de maladie et par catégorie, entre 2000 et 2013.
Schéma : Une étude rétrospective a été entreprise grâce à des données agrégées émanant des rapports mondiaux.
Résultats : Le nombre de personnes vivant avec le VIH et mises sous TAR entre 2004 et 2013 a augmenté de 8400 à 665 299, avec une couverture du TAR passant de <0,5% à 48%. Les taux de notification des cas de TB, tous types confondus, a augmenté de 2000 à 2003, puis a décliné de 2004 à 2013. Les diminutions de la notification annuelle de la TB entre le taux le plus élevé (avant 2004) et le plus bas (2013) ont été de 56% pour toutes formes de TB, 60% pour les nouveaux cas de TB, 53% pour la TB déjà traitée, 40% pour les nouveaux cas de TB pulmonaire à frottis positif, 58% pour les nouveaux cas de TB pulmonaire à frottis négatif ou inconnu et 58% pour la TB extrapulmonaire.
Conclusion : Des déclins significatifs des taux de notification des cas de TB ont été observés au cours de l'expansion du TAR, surtout en ce qui concerne la TB pulmonaire à frottis négatif et la TB extrapulmonaire. Ces tendances nationales encourageantes sont en faveur de la poursuite de l'expansion du TAR pour les personnes vivant avec le VIH en tant que stratégie qui combat la double épidémie du VIH/syndrome d'immunodéficience acquise et de la TB au Zimbabwe.

Marco de referencia: En Zimbabwe existe una epidemia de tuberculosis (TB) determinada por la infección por el virus de la inmunodeficiencia humana (VIH); desde el 2004, en el sector público se ha ampliado la escala de administración del tratamiento antirretrovírico (TAR).
Objetivo: Determinar si la ampliación de escala del TAR se correlacionó con las tasas anuales de notificación de casos de TB, en función del tipo y la categoría de la enfermedad, del 2000 al 2013.
Método: Se llevó a cabo un estudio retrospectivo a partir de los datos conjuntos de los informes mundiales.
Resultados: El número de personas con diagnóstico de infección por el VIH que permanecían en TAR del 2004 al 2013 aumentó de 8400 a 665 299 y la cobertura mejoró de menos de 0,5% a 48%. Las tasas de notificación de casos de TB de todos los tipos y categorías aumentaron del 2000 al 2003 y luego declinaron del 2004 al 2013. La disminución anual de las tasas de notificación de TB, tomando como referencia las tasas más altas (antes del 2004) hasta las tasas más bajas (2013) fue de 56% en todas las formas de TB; 60% en los casos nuevos de TB; 53% en los casos tratados previamente; 40% en los casos nuevos de tuberculosis pulmonar (TBP) con baciloscopia positiva; 58% en los casos nuevos de TBP con baciloscopia ya fuese negativa o desconocida; y de 58% en los casos de TB extrapulmonar.
Conclusión: Durante la ampliación de escala del TAR se observaron disminuciones notables de las tasas de notificación de casos de TB, sobre todo en los casos de TBP con baciloscopia negativa y de TB extrapulmonar. Esta evolución de ámbito nacional prometedora respalda la continuación de la ampliación del suministro de TAR a las personas infectadas por el VIH, como una estrategia de lucha contra las epidemias concomitantes de infección por el VIH y sida y la TB en Zimbabwe.

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