



## Characteristics and management of presumptive tuberculosis in public health facilities in Malawi, 2014–2016

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<http://dx.doi.org/10.5588/pha.17.0050>

**Setting:** Public health facilities providing tuberculosis (TB) and human immunodeficiency virus (HIV) services in Malawi.

**Objectives:** Using routinely collected health service delivery data to describe trends in HIV ascertainment and access to the Xpert<sup>®</sup> MTB/RIF assay to diagnose TB among HIV-positive presumptive TB cases.

**Design:** This was an implementation study of presumptive TB cases who sought care from 21 facilities between April 2014 and June 2016. Descriptive statistics were used to summarise patient, facility and service level characteristics.

**Results:** Of 28 567 presumptive TB cases analysed, 23 198 (81%) had known HIV status. The proportion of ascertained HIV status in presumptive TB cases increased over the study period. HIV prevalence was 49%, with 73% of HIV-positive presumptive TB cases on antiretroviral therapy. Access to Xpert ranged between 37% and 63% per quarter among HIV-positive presumptive TB patients with smear-negative sputum results. Of 7829 patients with documented Xpert results, 68% were HIV-positive.

**Conclusion:** After the introduction of registers with HIV-related variables, HIV ascertainment among presumptive TB cases increased over time. Access to Xpert was suboptimal among HIV-positive presumptive TB cases. Further collaboration between national TB and HIV programmes may facilitate increased use of Xpert for HIV-positive patients with presumptive TB who seek care in public health facilities.

Tuberculosis (TB) is a leading preventable cause of death<sup>1</sup> and an AIDS (acquired-immune deficiency syndrome) defining condition among those who live with the human immunodeficiency virus (HIV).<sup>2,3</sup> In March 2012, the World Health Organization (WHO) released an update to its policy on collaborative TB-HIV activities.<sup>4</sup> Similar to the 2004 interim policy,<sup>5</sup> it structured 12 activities under three distinct objectives, but with some important differences. These include 1) recognition of the crucial role of early initiation of antiretroviral therapy (ART) initiation in preventing TB in people living with HIV (PLHIV); 2) expanded use of HIV testing and prevention among presumptive TB cases (patients who present with symptoms or signs suggestive of TB, previously referred to as TB suspects), as well as partners and family members of confirmed TB cases; and 3) more guidance for the integration of HIV and TB services in time and place and with other

health services. In line with this, the national TB and HIV guidelines in Malawi both recommend initiation of ART in HIV-infected TB cases within 2 weeks of the identification of HIV.<sup>1,5,6</sup> These policies aim to reduce mortality in TB-HIV co-infected patients.<sup>2–4,7</sup>

The presentation of presumptive TB cases in health care settings is an opportunity to screen for HIV status and facilitate the subsequent initiation of ART if needed. In Uganda, the provision of HIV testing for presumptive TB cases identified 35% of HIV-positive presumptive TB cases who would have been missed if the HIV testing services had been limited to confirmed TB cases only.<sup>7</sup> To standardise HIV ascertainment and management of patients with presumptive TB in Malawi, the National Tuberculosis Control Programme (NTP) collaborated with the Lighthouse Trust (Lilongwe, Malawi) to revise the national presumptive TB case register. This prompted the assessment and documentation of the HIV and ART status of presumptive TB cases.

The revised register was first piloted at the Martin Preuss Centre clinic in Bwaila Hospital (Lilongwe, Malawi) between February 2012 and April 2013 and then in 10 facilities between May 2013 and March 2014. It was then rolled out for national use as of April 2014. While data on the characteristics and management of confirmed TB cases have been published,<sup>8–10</sup> information on the management of presumptive TB cases in Malawi is limited. The present study aimed to describe the trends in uptake of HIV testing services among presumptive TB cases, services received by them and the proportion of HIV-positive presumptive TB cases who were assessed using Xpert MTB/RIF<sup>®</sup> assay (Cepheid, Sunnyvale, CA, USA) in public health facilities.

### METHODS

This study was framed as implementation science that investigated service delivery to presumptive TB cases registered at 21 facilities in Malawi from April 2014 to June 2016. All individuals with information registered in the presumptive TB case register were included.

Health facilities were selected based on 1) TB case-load, 2) type of facility (health centre or tertiary and/or district hospital), and 3) the management of facilities. We included central or district hospitals managed by the Ministry of Health (MOH) if they reported >30 smear-positive cases, and other health facilities managed by faith-based institutions if they reported ≥70 smear-positive TB cases during the period between 1 July and 30 September 2013. This resulted in 21/361

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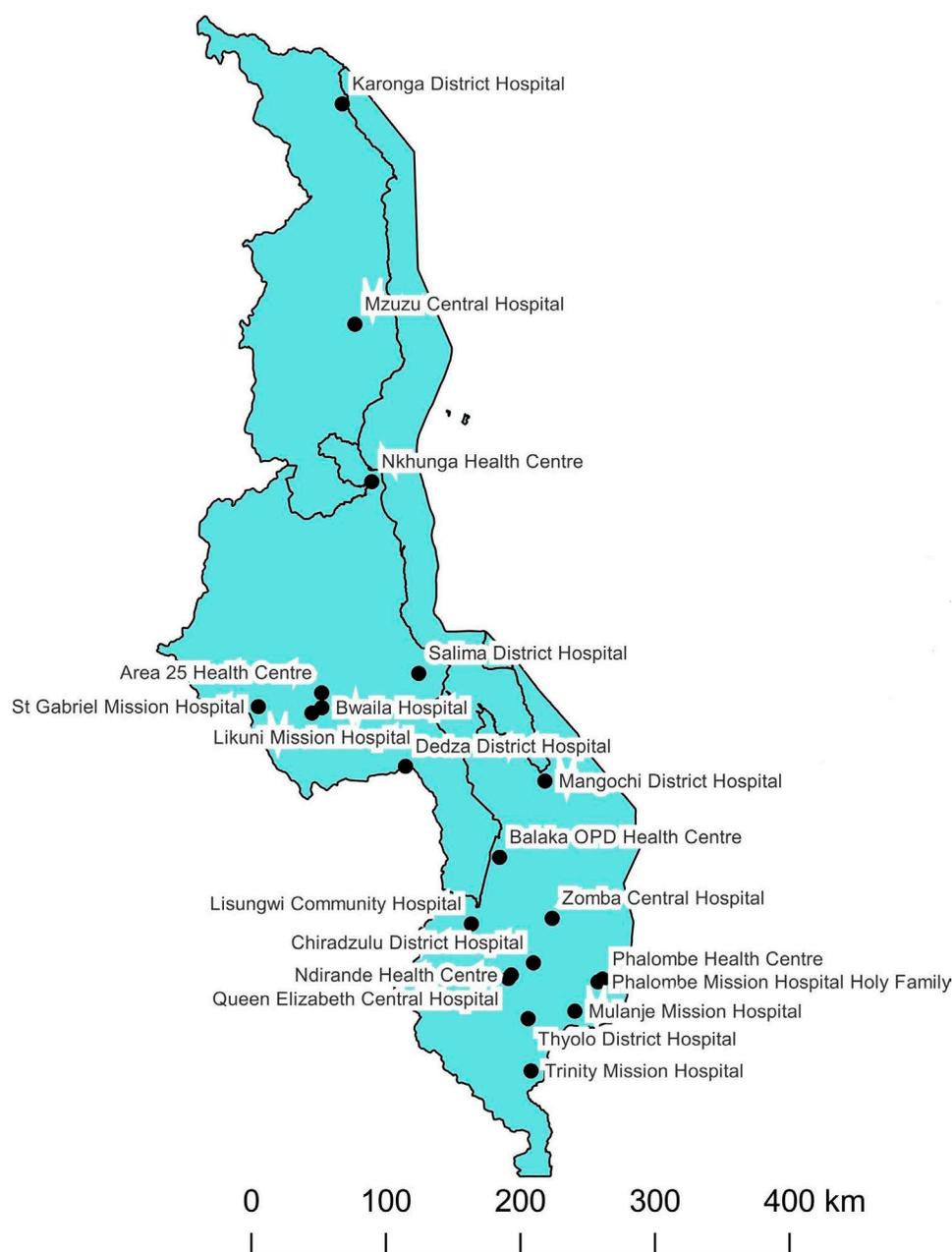
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### KEY WORDS

TB-HIV service integration;  
HIV; TB; Malawi

Received 5 June 2017  
Accepted 29 August 2017

PHA 2017; 7(4): 1–7  
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**FIGURE 1** Integrated tuberculosis and HIV facilities that participated in this study in Malawi, 1 April 2014–30 June 2016. Data source: Malawi Master Health Facility List for Quarter 3, 2016. Accessed May 2017.

(6%) health facilities from all three regions of Malawi being included in the programme evaluation (Figure 1): 4% (2/51), 5% (7/130) and 7% (12/180), respectively, from the northern, central and southern regions.

The revised presumptive TB case register was designed to reinforce provider-initiated HIV testing and counselling (PITC). During the observation period, HIV-positive presumptive TB cases, all presumptive multidrug-resistant (MDR) TB cases (regardless of HIV status), and hospitalised patients were eligible for assessment using Xpert, while patients with smear-positive microscopy results were not.<sup>6</sup>

In July 2014, staff from the NTP and the Lighthouse Trust visited 21 facilities to capture digital images of the pages of the chronic cough register. All digital images were encrypted, and the data were abstracted and entered in a customised Microsoft Access 2007 database (Microsoft Corp, Redmond, WA, USA). Variables included the facility name, serial number, date of service, sex, age, source of referral, smear result (positive, negative, not documented), Xpert result (detected, not detected, not documented), HIV test and ART status (previous HIV-positive on ART, previous HIV-positive not on ART, new HIV-negative, new HIV-positive, not done, not documented) and referral (TB registration

#### ACKNOWLEDGEMENTS

The authors would like to thank L. Sithole, C. Kang'ombe and J-B Mwafilaso for their contribution in the conceptualisation, data collection and data cleaning stages of this project. The authors would also like to thank the staff at the 21 health facilities who facilitated the data abstraction stage of this project. Funding for this project was provided to the Lighthouse Trust by the US Centers for Disease Control and Prevention (CDC, Atlanta, GA, USA). During the study period, WN, SG, HT, BG, YB and SP worked for a CDC-funded project. The funder had no role in the study design, data collection and analysis, decision to publish or the presentation of the manuscript. Conflicts of interest: none declared.

**TABLE 1** Characteristics of presumptive TB cases who visited selected TB-HIV facilities in Malawi, 1 April 2014–30 June 2016

Patient characteristics ( <i>n</i> = 28 567)	<i>n</i> (%)
Total	28 567 (100)
Sex	
Female	13 006 (46)
Male	15 541 (54)
Missing	20 (<1)
Age, completed calendar years	
0–4	40 (<1)
5–14	893 (3)
15–24	3 211 (11)
25–34	7 427 (26)
35–44	7 254 (25)
45–54	4 023 (14)
55–64	2 459 (9)
≥65	2 329 (8)
Missing	931 (3)
Health facility, rural/urban area	
Rural	1 797 (6)
Urban	26 770 (94)
Year of registration	
2014	11 040 (39)
2015	11 441 (40)
2016	6 086 (21)
HIV/ART status	
New HIV-negative	11 907 (42)
New HIV-positive	2 710 (9)
HIV testing not done	3 284 (12)
HIV-positive and on ART	8 166 (29)
HIV-positive but not on ART	426 (1)
Missing	2 074 (7)
Source of referral	
Walk-in	5 872 (21)
SCP	917 (3)
HTC	676 (2)
ART/PMTCT	2 447 (9)
PP	95 (<1)
OPD	17 004 (60)
Wards	34 (<1)
Missing	1 522 (5)
Facility type	
Central hospital	4 181 (15)
District hospital	17 020 (60)
Health centre	3 448 (12)
Faith-based institution	3 918 (14)

TB = tuberculosis; HIV = human immunodeficiency virus; ART = antiretroviral therapy; SCP = *check*; HTC = *check*; ART/PMTCT = antiretroviral therapy/Prevention of Mother to Child Transmission; PP = private practitioner; OPD = out-patient department.

number, referred to clinical officer, name of referred facility, other, not documented). STATA v. 13.1 (Stata Corp, College Station, TX, USA) was used for data analysis. Descriptive statistics were used to summarise trends in age, sex, source of referral, smear result, Xpert results and the HIV and ART status of all presumptive TB cases. Trends were assessed using the  $\chi^2$  test. Statistical significance was set at  $P < 0.05$ .

The study protocol received ethical approval from the National Health Science Research Committee (NHSRC, Lilongwe, Malawi).

As the study used only routine programme data, patient consent was not required.

## RESULTS

### Characteristics of presumptive TB cases

A total of 28 567 presumptive TB cases were registered in the health facilities between 1 April 2014 and 30 June 2016. Of these, 15 541 (54%) were males. The median age at registration was 37 years (interquartile range [IQR] 29–49). The highest proportion (42%) of presumptive TB cases were HIV-negative, while the smallest proportion (1%) were HIV-positive but not yet on ART (Table 1). Nearly two thirds of the presumptive TB cases were referred for TB screening from the out-patient department; <1% were referred from the wards or private medical practitioners. Nearly two thirds of the presumptive TB cases were registered in the district hospitals, and 14% were registered in facilities managed by faith-based institutions (Table 1).

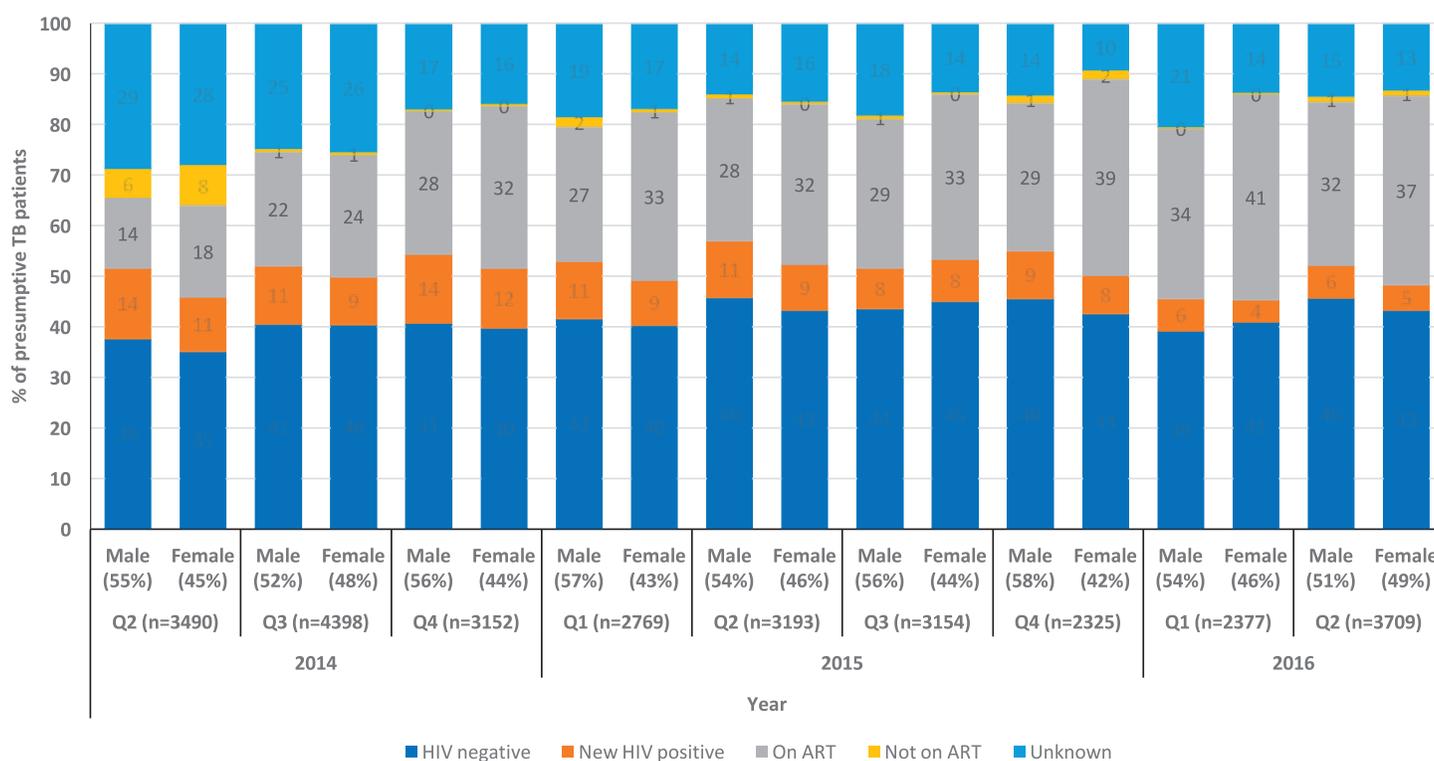
### HIV-related services received by presumptive TB cases

Overall, 81% (23 207/28 567) of the presumptive TB cases had known HIV status, with similar proportions among males and females (81% males, 82% females). There was an increasing trend in the proportion of patients with known HIV status, from 71% in Q2, 2014 to 86% in Q2 2016. The overall prevalence of HIV among presumptive TB cases was 49%: 48% among males and 50% among females. HIV prevalence among persons newly tested for HIV was 19% (2718/14 615): 20% (1613/8165) among males and 17% (1104/6445) among females ( $P < 0.01$ ); the sex of five of the newly HIV-tested presumptive TB patients was undocumented. Decreasing trends were observed among presumptive TB patients with unknown HIV status (from 29% in Q2 2014 to 14% in Q2 2016), those not on ART (from 7% in Q2, 2014 to 1% in Q2 2016) and newly diagnosed HIV-positive patients (from 13% in Q2, 2014 to 6% in Q2 2016). The proportion of HIV-negative patients increased from 36% in Q2 2014 to 40% in Q3 2014, then remained almost stable from Q3 2014 onwards. The proportion of presumptive TB patients receiving ART on presenting to the TB clinic increased from 16% in Q2, 2014 to 35% in Q2 2016. Overall, males had a higher proportion of unknown and new HIV-positive status, while a higher proportion of females were already on ART (Figure 2). There was a strong association between documented HIV and ART status and using the revised presumptive case register in the later quarters ( $P < 0.001$ ) (Figure 2).

The services received by HIV-positive presumptive TB cases are shown in Table 2. Among the HIV-positive presumptive TB cases ( $n = 11 302$ ), 72% were already on ART at the time of registration for TB screening. Of those presumptive TB cases assessed as smear-positive, HIV-positive ( $n = 1 297$ ), 49% (638) were registered for TB treatment. Further clinical review was documented for 6% of the HIV-positive presumptive cases, and 1% underwent chest X-ray examination (Table 2).

### Use of Xpert

The use of Xpert is summarised in Figure 3. Overall, Xpert was used to assess 7958 (28%) of the 28 567 presumptive TB cases, of whom 5399 (68%) were HIV-positive. Xpert was more likely to be used for HIV-positive (48% of 11 310) than HIV-negative patients (13% of 11 897,  $P < 0.001$ ). Xpert was used in clinical assessments in 6% of the HIV-positive patients despite smear-positive sputum results. Among the HIV-positive patients, 82% had smear-negative results, and 12% did not undergo sputum smear examination (Figure 3). Xpert was used to detect *Mycobacterium tuberculosis* in



**FIGURE 2** Trends in HIV status by quarter and sex of patients with presumptive TB registered in selected TB-HIV facilities in Malawi, 1 April 2014–30 June 2016.  $P < 0.001$ ,  $\chi^2$  test for trend. TB = tuberculosis; Q = quarter; HIV = human immunodeficiency virus; ART = antiretroviral therapy.

8% of the smear-negative and 21% of smear result unknown cases. *M. tuberculosis* was detected in 83% of the with smear-positive cases.

The trend in coverage of Xpert among HIV-positive presumptive TB patients with smear-negative results is shown in Figure 4. Between Q2 2014 and Q3 2014, the use of Xpert for smear-negative cases increased from 45% to 63%, and then dropped steadily to 37% in Q3 2015, after which it again increased (Figure 4). The proportion of sub-groups of patients who had neither Xpert nor sputum smear examination results documented were: 794/11907 (7%) HIV-negative cases, 223/2710 (8%) newly diagnosed HIV-positive cases, 727/8164 (9%) cases who knew their HIV status and were already on ART, 47/426 (11%) cases who knew their HIV status but were not yet on ART at the time of TB screening and 645/5358 (12%) cases with undocumented HIV status.

**TABLE 2** Services received by HIV-positive presumptive TB cases in selected TB-HIV facilities in Malawi, 1 April 2014–30 June 2016

Service received (n = 11 311)	n (%)
Chest X-ray	87 (1)
ART	8 216 (73)
Started TB treatment*	1 297 (11)
Xpert	5 399 (48)
Clinical review	705 (6)

\*Derived from TB numbers indicated for patients with a sputum smear-positive result; documentation of starting TB treatment based on presumptive TB register was observed in 638/1 297 cases.

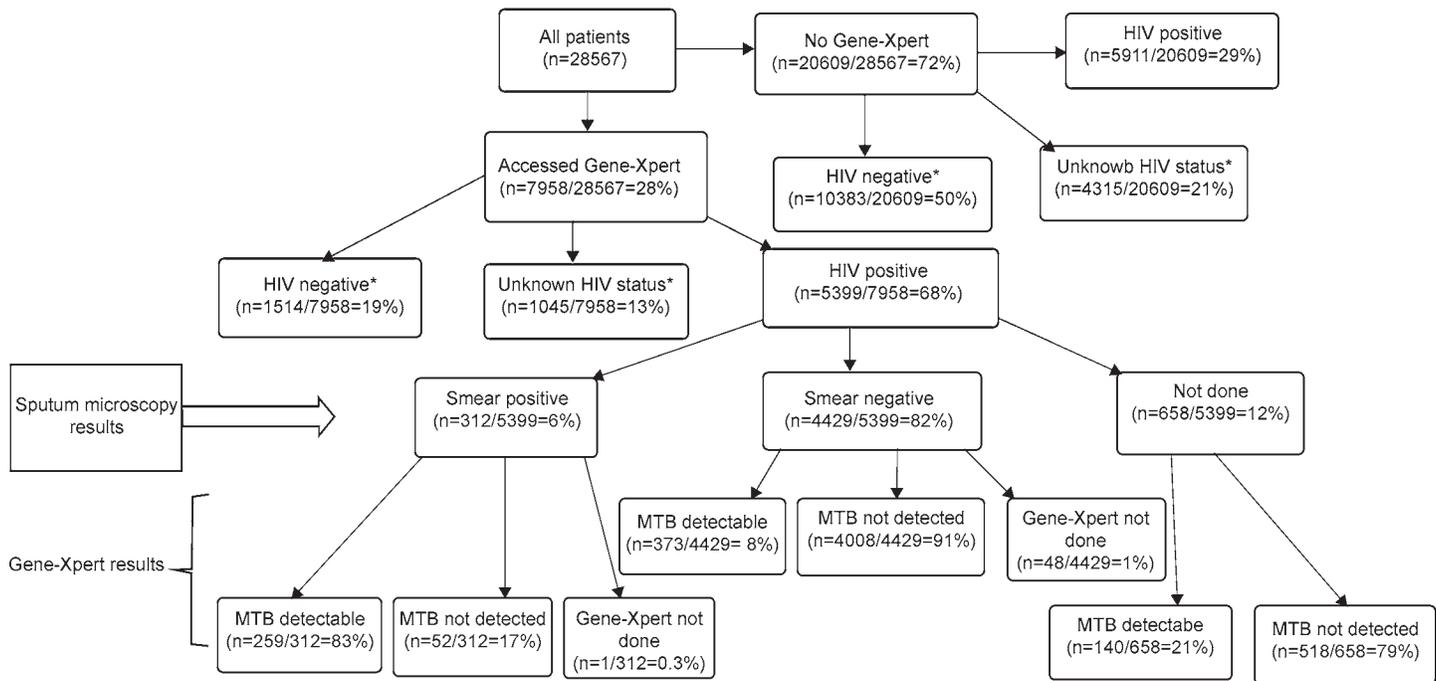
HIV = human immunodeficiency virus; TB = tuberculosis; ART = antiretroviral therapy.

## DISCUSSION

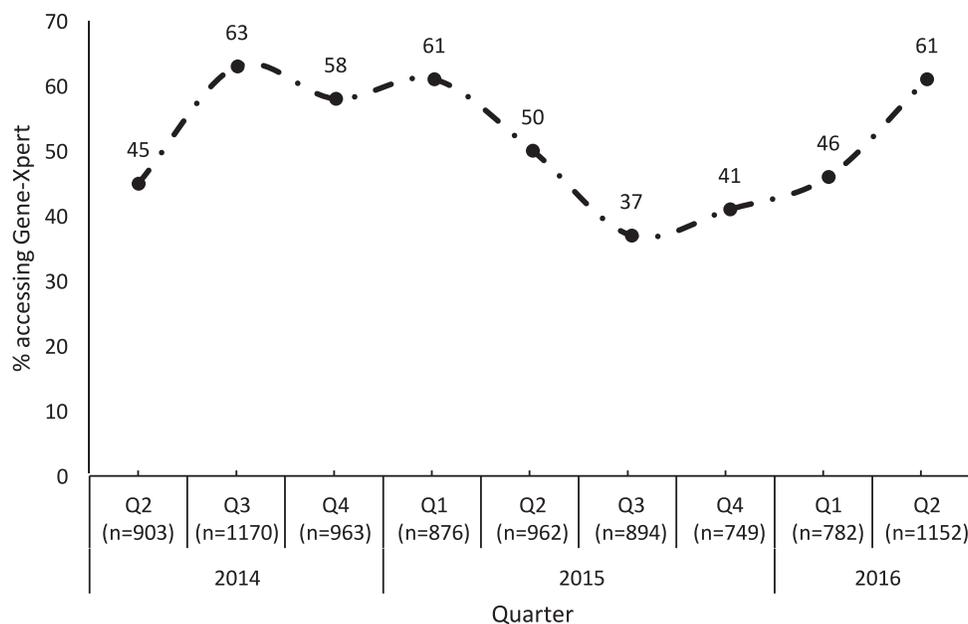
This analysis of the characteristics of presumptive TB cases included facilities from all regions in Malawi. Introduction of a register that prompted the screening and capture of the HIV and ART status of presumptive TB cases allowed us to evaluate the proportion of presumptive TB cases who needed HIV treatment and provide them with the necessary services. The fact that 81% of presumptive TB cases knew their HIV status is encouraging. This is an opportunity that can be maximised as it identifies the HIV status of a sub-population who is seeking care and likely to be infected with HIV. Of the presumptive TB cases who already knew their HIV status, approximately half were HIV-positive. Of those who knew their HIV status, 72% were already on ART.

When HIV testing was conducted for those with unknown HIV status, 19% (2718/14 615) were newly diagnosed with HIV. Given the high uptake of HIV testing in this population, similar settings may find a higher yield of HIV-positive cases by targeting HIV testing services in clinics that serve presumptive TB cases. We have also demonstrated that approximately two thirds of the presumptive TB cases were referred for TB screening from out-patient departments, indicating that out-patient departments are another high yield area for HIV testing.

Similar HIV ascertainment in presumptive TB cases was observed in Zimbabwe,<sup>7,11,12</sup> while other settings reported a lower HIV testing uptake.<sup>13–16</sup> In Malawi, the high level of HIV ascertainment was attributed to the integrated TB-HIV services:<sup>2</sup> all presumptive TB cases are encouraged to undergo testing for HIV before undergoing testing for TB.<sup>1</sup> The regular availability of rapid HIV test kits in all public health facilities where HIV testing is performed, at no cost to the patient, may have contributed to the



**FIGURE 3** Flow diagram of access to Xpert among patients with presumptive TB in integrated TB-HIV facilities in Malawi, 1 April 2014–30 June 2016. \*Microscopy vs. Xpert disaggregation is more relevant for HIV-positive status and is not shown for HIV-negative or unknown HIV status. HIV = human immunodeficiency virus; TB = tuberculosis.



**FIGURE 4** Trend in Xpert coverage among HIV-positive presumptive TB patients with sputum microscopy smear-negative results in integrated TB-HIV facilities in Malawi, 1 April 2014–30 June 2016. HIV = human immunodeficiency virus; TB = tuberculosis.

high level of HIV ascertainment. Similar to other studies conducted in sub-Saharan Africa, high HIV prevalence was observed among presumptive TB cases.<sup>11,16</sup> New HIV positivity rates were consistently higher in men throughout the observation period. This may be attributed to the custom of men seeking curative care

only when they are sick, rather than preventive care, in comparison to women.

The majority of the HIV-positive patients were referred for ART. ART scale-up has been associated with decreased trends in TB case notification.<sup>17,18</sup> Given that more than a quarter of pre-

sumptive TB cases with known HIV status were not on ART at the time they visited the TB clinic, collaboration between the national TB and HIV programmes should focus on interventions that enhance linkage systems for presumptive TB cases who are not on ART. With the 'test and treat' HIV strategy,<sup>19</sup> HIV treatment initiation has become more straightforward, as the need to confirm TB infection has been eliminated. As linkage to HIV and TB treatment has been demonstrated as an area of challenge, linkage may be supported through the use of registers with line lists of all HIV-positive presumptive TB cases along with their contact information and actively following up whether or not they have been started on ART within the specified 2-week period. For those who do not initiate ART, enhanced counselling and other interventions may be explored by actively following and encouraging their care-seeking behaviour. This is especially true in view of the challenges of reaching men in many HIV programmes in sub-Saharan Africa. Similarly, screening for TB in HIV clinics will need to be reinforced by the use of specific, prompted questions to the patients; TB status should not be assumed by the health care provider based on symptoms observed for a few minutes during a clinic visit.

Regarding the screening and management of TB, our study has demonstrated an area for improvement in assessing smear or Xpert results for HIV-positive persons. In the cases where these were intended to be assessed but were not, providing guidance to document the reasons for the unavailability of the TB diagnosis results may help managers at different levels of the MoH to monitor programme performance and introduce interventions focused on improved patient management.<sup>20</sup> Adequate budgetary support for Xpert services and educating presumptive TB cases on the need for sputum assessment may facilitate adequate TB-related investigations for HIV-positive cases. Xpert services were managed as a project in Malawi, and during the transition from one implementing partner to another, a downward trend was observed due to a lack of continued logistical support during the transition.<sup>21</sup> The Xpert service needs to become a programme with enough human and monetary resources so that all patients who need Xpert testing have access to it.

The large sample size and the use of data from routine health care settings has allowed us to demonstrate operational practices that can inform policy change. Missing data and selection bias may have limited the generalisability of our findings. The facilities included in this study were already reporting relatively high numbers of smear-positive cases using the revised register. However, all facilities in Malawi that reported high caseloads based on the inclusion criteria were included. Furthermore, previous TB history was not documented at assessment and was thus not taken into consideration in our analyses. Having such information may help guide TB screening and referral for appropriate management.

In conclusion, the use of presumptive TB registers with HIV-related variables has enabled Malawi to standardise the recording of the HIV status of presumptive TB cases, thereby simplifying the estimation of HIV prevalence in presumptive TB cases. The observed increasing trend in the proportion of HIV status ascertain-

ment demonstrates the feasibility of this initiative in routine health care in resource-limited settings, once the right tools are provided. Access to Xpert among HIV-positive patients was sub-optimal, missing a key opportunity to reach the End TB goal by 2035 in the context of the generalised HIV epidemic.

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**Contexte :** Structures de santé publiques offrant des services de la tuberculose (TB) et du virus de l'immunodéficience humaine (VIH) au Malawi.

**Objectifs :** Utilisant des données recueillies en routine de prestation des services de santé, décrire les tendances de la vérification du VIH et de l'accès au test Xpert® MTB/RIF afin de diagnostiquer la TB parmi les cas présumés de TB qui sont VIH positifs.

**Schéma :** Etude de mise en œuvre des cas présumés de TB qui ont sollicité des soins dans 21 structures entre avril 2014 et juin 2016. Nous avons utilisé des statistiques descriptives pour résumer les caractéristiques des patients, des structures et des services.

**Résultats :** Sur les 28 567 cas présumés de TB qui ont été analysés, 23 198 (81%) connaissaient leur statut VIH. La proportion de statuts VIH vérifiés parmi les cas de TB présumés a augmenté tout au long de

la période d'étude. La prévalence du VIH a été de 49%, avec 73% des patients VIH positifs présumés TB sous ART. L'accès à Xpert est allé de 37% et de 63% par trimestre parmi les patients VIH positifs présumés TB avec des résultats de frottis de crachats négatifs. Sur les 7829 patients ayant des résultats documentés d'Xpert, 68% ont été VIH positifs.

**Conclusion :** Après l'introduction des registres comportant des variables liées au statut VIH, la constatation du VIH parmi les cas présumés de TB a augmenté dans le temps. L'accès au Xpert a été sous-optimal parmi les cas de TB présumés VIH-positifs. Davantage de collaboration entre les programmes nationaux TB et VIH pourrait faciliter une utilisation accrue d'Xpert pour les patients VIH positifs avec une présomption de TB qui sollicitent des soins dans des structures de santé publiques.

**Marco de referencia:** Los establecimientos públicos de atención de salud que prestan servicios relacionados con la tuberculosis (TB) y la infección por el virus de la inmunodeficiencia humana (VIH) en Malawi.

**Objetivos:** A partir de los datos recogidos de manera sistemática sobre la prestación de los servicios de salud, describir la evolución de la determinación de la situación frente al VIH y del acceso a la prueba Xpert® MTB/RIF para el diagnóstico de TB, en los casos positivos frente al VIH con presunción clínica de esta enfermedad.

**Método:** Se llevó a cabo un estudio de implementación de los casos con presunción de TB que buscaron atención en 21 centros, de abril 2014 a junio 2016. Se utilizaron estadísticas descriptivas a fin de resumir las características de los pacientes, los establecimientos y los servicios.

**Resultados:** De los 28 567 casos con presunción de TB analizados, 23 198 conocían su situación frente al VIH (81%). La proporción de determinación de la situación frente al VIH en los casos analizados

aumentó durante el período del estudio. La prevalencia de infección por el VIH fue 49% y el 73% de estos casos recibía tratamiento antirretrovírico. El acceso a la prueba Xpert osciló entre 37% y 63% por trimestre en los pacientes positivos frente al VIH con presunción de TB y resultados negativos de la baciloscopia de esputo. De los 7829 pacientes con resultado de la prueba Xpert, en el 68% la prueba fue positiva.

**Conclusión:** Tras la introducción de los registros que comportan variables relacionadas con el VIH, la determinación de la situación frente al VIH en los casos con presunción de TB ha aumentado en el transcurso del tiempo. El acceso a la prueba Xpert fue deficiente en los pacientes positivos frente al VIH, con presunción clínica de TB. Una mayor colaboración entre los programas nacionales contra la TB y el VIH facilitaría la utilización de la prueba Xpert en los pacientes seropositivos con presunción de TB que buscan atención en los centros públicos de atención de salud.

Author: Reference 21. Please provide more information. Abstract? Article? Published by whom? Presented when and where??" Ed

Author: Table 1: please explain abbreviations EXP and HTC. Ed

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e-ISSN 2220-8372

**Editor-in-Chief:** Dermot Maher, MD, Switzerland

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