

Inextricably linked: but how can we harmonise the monitoring of HIV/TB collaborative activities?

Accurate measuring of progress is difficult when there is no standardisation of indicators at all levels

Background

African Health professionals are likely to be dealing with HIV-related tuberculosis (TB) far more frequently than elsewhere in the world. Tuberculosis is the cause of death of upwards of one-quarter of people living with HIV.¹ Indeed in some postmortem studies from Southern Africa over 40% of deaths in people living with HIV have had underlying disseminated tuberculosis disease.² From the early 1990s onwards tuberculosis programmes in sub-Saharan Africa have had to adjust to a tripling of tuberculosis incidence and have had to deal with the highest rates of tuberculosis disease in the world, fuelled by the HIV epidemic. In some countries in Africa up to 80% of people diagnosed with TB have underlying HIV. In order to address this, the policy on TB/HIV collaborative activities published by WHO in 2004³ is designed to make the national TB and HIV programmes collaborate in two essential ways.

Why monitor TB/HIV collaborative activities?

Firstly to lessen the burden of TB among people living with HIV; all HIV care settings must apply the interventions which are branded as Three Is for HIV/TB: ensure Intensified TB case finding through regular screening for and treating of TB early, prevention of TB by providing people living with HIV with Isoniazid preventive therapy and implementing Infection control measures in healthcare and other congregate facilities that people living with HIV frequent.

Secondly, to lessen the burden of HIV among people living with HIV (PLHIV) diagnosed with TB, the guidelines recommend that all TB patients be tested for HIV and those found to be positive should be provided with co-trimoxazole preventive therapy and HAART and enrolled for HIV treatment and care.

In order to facilitate the standardised monitoring of these activities, the World Health Organization (WHO) also developed indicators for monitoring and evaluating these collaborative TB/HIV activities in 2004.¹ Since that time, national programmes to control HIV and TB have faced the following challenges in implementation of this monitoring.

What are the challenges of monitoring programme indicators?

An initial challenge has been the slow acceptance at country level of TB/HIV indicators as a result of lack of previous experience with their use, inadequate collaboration between stakeholders of HIV and TB control programmes at all levels, and limited technical expertise and resources. An additional obstacle to harmonised indicator use has been the presence of

multiple stake-holders working to address the HIV-related TB, particularly in HIV-prevalent countries. The increasing availability of resources and the burgeoning problem of TB allowed these stakeholders to monitor activities using their own systems and a variety of indicators. This has contributed to a lack of alignment of, and standardised systems for, monitoring and evaluation indicators at all levels including nationally, and globally. This non standardisation of indicators has generated a diversity of reporting systems, with countries unable to simplify and streamline their reporting requirements nationally, as well as internationally to WHO, UNAIDS and donors such as PEPFAR and the Global Fund. Difficulties in comparing performance data and trends from various partners both locally and globally have therefore



Monitoring and evaluation of the ART registers in the Malawi programme

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Table 1 Indicator summary

Summary of indicators measured in HIV care settings by the HIV control programme	
Indicator B.1.1	Number of adults and children enrolled in HIV care whose TB status was assessed and recorded during their last visit during the reporting period, expressed as a proportion of all adults and children enrolled in HIV care and seen for care in the reporting period.
Indicator B.1.2.1	Number of adults and children enrolled in HIV care who started TB treatment, expressed as a proportion of adults and children enrolled in HIV care during the reporting period.
Indicator B.1.2.2	Percentage of estimated HIV-positive incident TB cases that received treatment for TB and HIV.
Indicator B.2.1	Number of adults and children newly enrolled in HIV care, who are started on treatment for latent TB infection, isoniazid preventive therapy, expressed as a proportion of the total number of adults and children newly enrolled in HIV care during the reporting period.
Indicator B.3.1	Number of healthcare facilities providing services for people living with HIV with demonstrable infection control practices that include TB control, expressed as a proportion of the total number of healthcare facilities evaluated.
Indicator B.3.2	Number of healthcare workers employed in facilities providing care for people living with HIV who develop TB in 1 year expressed as a proportion of the total number of healthcare workers employed in facilities providing care for people living with HIV during that same year.
Summary of indicators measured in TB care settings by the TB control programme	
Indicator C.1.1	Percentage of TB patients who had an HIV test result recorded in the TB register.
Indicator C.1.2.1	Number of TB patients registered with documented HIV status on TB register who are HIV-positive, expressed as a proportion of the total number of all registered TB patients with documented HIV status over the reporting period.
Indicator C.1.2.2	Number of TB patients registered with documented HIV status on TB register who are HIV-positive, expressed as a proportion of HIV-positive TB patients estimated to occur countrywide each year.
Indicator C.2.1	Number of TB facilities where free condom distribution is practiced and condoms are available, expressed as a proportion of all TB facilities.
Indicator C.3.1	Number of HIV-positive TB patients who are started on or continue previously initiated co-trimoxazole preventive therapy, during TB treatment, expressed as a proportion of all HIV-positive TB patients registered over the reporting period.
Indicator C.4.1	Number of HIV-positive TB patients referred to HIV care and support services (as defined in local or national HIV/AIDS policy) during TB treatment, expressed as a proportion of the total number of HIV-positive TB patients.
Indicator C.5.1	Number of HIV-positive TB patients who are started on or continue previously initiated ART, during TB treatment, expressed as a proportion of all HIV-positive TB patients registered over the reporting period.

resulted and cast a shadow on the accurate measurement of programme performance.

Developing 'harmonised' indicators

Since the first publication of the TB/HIV indicators there has been an increasing experience with and awareness of the importance of addressing these challenges through an inclusive and broad-based approach and this has led to the initiation of a harmonisation process of TB/HIV indicators among the WHO Stop TB and HIV departments, UNAIDS, PEPFAR, and the Global Fund. This culminated in the WHO revision of the TB/HIV monitoring and evaluation guidelines in 2009,² through a broad-based consultative and participatory process. An email-based consultation among HIV and TB

stakeholders including national programme managers, implementers, and policy-makers was carried out before finalising the guidelines. Core TB/HIV indicators were agreed among these different stakeholders. The Global Fund incorporated the revised indicators into the 2009 revision of their monitoring and evaluation toolkit.

The main changes in the revised guidelines are as follows:

1. The number of indicators was reduced from 20 to 13.
2. Two new indicators included: (B.3.2) concerns the monitoring of TB in healthcare workers and the second (C.1.2.2) measures the detection of HIV-positive TB patients as a percentage of estimated HIV-related TB cases in a country.

The full list of revised indicators to be measured in HIV

care settings by the HIV control programme, and measured in TB care settings by the TB control programme are given in Table 1 above.

Next steps and conclusion

These indicators are consistent with the revisions of the WHO TB and HIV recording and reporting guidelines. On the TB side these are the revised TB recording and reporting forms and registers⁶ which have been incorporated in most countries revised national TB recording and reporting systems. On the HIV side this is the three interlinked patient monitoring systems for HIV care/ART, MCH/PMTCT and TB/HIV⁷

This provides guidance for the first time on how the TB screening and treatment, as well as IPT provision indicators should be tallied in quarterly cross sectional reports from primary health care facilities and reported to national level. This is crucial for programmes to monitor and manage the progress of the Three I's (Intensified TB case finding through screening, provision of Isoniazid Preventive therapy, and Infection control) in HIV care settings.

1. Clinicians working in primary healthcare facilities need to ensure HIV testing is provided to all TB patients and to patients who presented with signs and symptoms of TB. HIV testing is a gateway for comprehensive HIV care and treatment services and also for effective monitoring and evaluation of TB/HIV activities. Patients with HIV need to be screened for TB and those without TB should be offered Isoniazid therapy.
2. All stakeholders at all levels should ensure the implementation of these indicators in their clinics and monitoring and evaluation systems to measure and manage the TB/HIV collaborative components of their services.
3. All TB and HIV stakeholders and in country partners should collaborate and work together with Ministries of Health to develop one effective national system to document and report their activities and to improve the performance of this system.
4. All TB and HIV stakeholders should ensure that resources and technical expertise are made available for implementing these harmonised indicators and to establish effective national TB/HIV monitoring and evaluation systems, used by all stakeholders.

It is only through activity monitoring that we can



The filing system for individual treatment cards: a need for computers?

effectively manage it, and only by managing it can we ensure that the additional unnecessary mortality and morbidity caused by HIV-related TB is brought under control.

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TB: what's in the news?

Comprehensive web site on TB diagnosis now live

A new web site, Evidence-Based Tuberculosis Diagnosis, has been developed and launched by the Stop TB Partnership's New Diagnostics Working Group in collaboration with the Foundation for Innovative New Diagnostics, the Special Programme for Research and Training in Tropical Diseases, the Global Laboratory Initiative, and the Public Health Agency of Canada.

The site aims to provide the most comprehensive single source of evidence synthesis, policies, guidelines, and research agendas on TB diagnosis. It offers access to relevant systematic reviews; policies, guidelines and research agendas; and reports, monographs, training modules, and presentations.

It is also a source for complete up-to-date information on the current TB diagnostics pipeline. Standard operating procedures and package inserts for several tests also are available. All information is provided as open access, with no registration or fee requirements.



www.tbevidence.org

Clinton Foundation teams up with Pfizer and Matrix to reduce cost of HIV and TB drugs

The William J Clinton Foundation and the pharmaceutical companies Pfizer and Matrix Laboratories Ltd have announced an agreement that will lower the cost of second-line antiretroviral drugs for drug-resistant forms of HIV and the TB drug rifabutin.

Pfizer will offer the tuberculosis drug rifabutin in 10 countries for US\$1 per dose, or US\$90 for a full course of treatment over 6 months. Rifabutin is the best TB drug for use in people taking second-line ARVs because other medicines have undesirable interactions with protease inhibitors – the class of ARVs that represent the backbone of second-line treatment. To counteract this effect, ARV dosage is often increased, but this leads to greater toxicity, worse treatment outcomes and higher costs. Pfizer's rifabutin does not interfere with protease inhibitors.

Aeras and South Africa's Aurum Institute will test safety of a promising TB vaccine candidate in people living with HIV

The Aeras Global TB Vaccine Foundation has announced a new collaboration with the Aurum Institute on the first study to test the AERAS-402/Crucell Ad35 TB vaccine candidate for safety in people living with HIV. Aurum will conduct this trial in people living with HIV at its clinical trial site near Johannesburg. The Medicines Control Council of South Africa and two Independent Ethics Committees in South Africa have given approval

to test the vaccine in South Africa. AERAS-402/Crucell Ad35 has been previously tested for safety in healthy adults in the United States and HIV-negative adults and infants in South Africa.

In preliminary clinical trials AERAS-402/Crucell Ad35 produced the highest levels of CD8 immune cells ever seen in trials of any TB vaccine. Inducing CD8 cellular immunity is one of the leading strategies experts are pursuing to develop effective vaccines against TB.

Smoking increases risk of developing active TB

Smoking is a risk factor for active tuberculosis disease, according to a new study on TB incidence in Taiwan.

The research analysed data from nearly 17 000 individuals in Taiwan as part of Taiwan's 2001 National Health Interview Survey (NHIS).

While past studies have reported increased mortality among TB patients who smoke, none have been able to specifically examine the direct effect of smoking on active TB incidence using a longitudinal design in a general population. 'In this prospective cohort study we found a two-fold increase in the risk of active TB in current smokers compared with never-smokers,' said lead author, Hsien-Ho Lin, from Brigham and Women's Hospital, in Boston, USA. The results are reported in the *American Journal of Respiratory and Critical Care Medicine*, published by the American Thoracic Society.

Dr Lin and collaborators retrieved information from the individual NHIS records on smoking data and exposure to second-hand smoke at home. They also identified potential confounders, including sex, age, living in a crowded home, household income, marital status, alcohol use, and employment. They then identified all incident cases of TB occurring between 2001 and 2004 by using that National Health Insurance database.

When they compared the likelihood of active TB among ever-, never-, and current smokers, they found that ever-smokers had 2.69 times the risk of developing active TB than never-smokers; current smokers had 2.73 times the risk. After adjusting for potential confounders, the increased risk remained significant for current smokers, who had twice the risk of developing active TB in comparison to never-smokers.

Interestingly, they also found that younger smokers were more likely than smokers older than 65 to develop active TB relative to their non-smoking counterparts.

'The small number of TB cases in this study prevented us from examining the age-gradient of smoking-TB association at a finer age scale, and more studies are needed to confirm these findings,' Dr Lin said. 'Because the baseline risk for active TB is higher in the elderly in many countries, a smaller but still elevated relative risk in this population may yet translate to a greater number of cases of active TB, and our findings should not be interpreted to mean that smoking poses a lower risk in the older population.'