Technical Guidance Note for Global Fund HIV Proposals

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Technical guidance note for HIV proposals for the Global Fund to Fight AIDS, Tuberculosis and Malaria

Rationale for including HIV-associated TB in the proposal

Of the 34 million people living with HIV, an estimated 30% have concomitant (usually latent) infection with *Mycobacterium tuberculosis*; this percentage varies from 14% in Europe to 46% in South-East Asia. The risk of developing tuberculosis (TB) is estimated to be 20–37 times greater among people living with HIV than among people without HIV infection. TB is associated with HIV and immune suppression, and in some African countries 80% of people with TB are living with HIV.

In 2009, there were 9.4 million new cases of TB, of which 1.2 million (13%) were among people living with HIV; of the 1.7 million people who died from TB, 400 000 (24%) had HIV; and of the 1.8 million HIV-related deaths, TB caused 400 000 (22%).

These statistics show that TB is a serious health risk and a leading cause of morbidity and mortality among people living with HIV, particularly in sub-Saharan Africa, where the TB incidence and TB-associated death rates have doubled compared with estimated figures from 1990. Malnutrition and low body mass index (BMI) are associated with an increased risk of mortality after antiretroviral therapy starts of 2–6 times, irrespective of CD4 count. Studies have shown that BMI of less than 17 among people with TB is associated with an increased risk of early death. HIV-associated TB is both preventable and curable by implementing several activities recommended by the World Health Organization (WHO).

Preventing TB requires prevention activities for both HIV infection and TB, including:

- HIV counselling and testing, disclosure and partner testing;
- behaviour modification;
- starting antiretroviral therapy earlier;
- the 'three I's' for HIV-associated TB:
  - isoniazid preventive treatment
  - intensified case-finding
  - infection control for TB.

Progress in implementing the 'three I's' for HIV-associated TB in HIV services has been slow. Of the 34 million people living with HIV, only 85 426 (less than 1%) were enrolled on isoniazid preventive treatment in 2009, although at least 50% of the people living with HIV were eligible for isoniazid preventive treatment. Through the Global TB Surveillance system, TB programmes reported that less than 10% of all people living with HIV were screened for TB in 2009. There are no reports regarding isoniazid preventive treatment from HIV programmes providing care and treatment for people living with HIV. Although many TB programmes reported having an infection control policy, so far none has reported data on the WHO-recommended infection control indicators 'number of health care facilities with demonstrable infection control practices that include TB control' and 'number of health care workers employed in HIV care facilities who develop TB'.

In 2009 WHO updated its policy recommendations on TB infection control in health-care facilities, congregate settings and households, and in January 2010 WHO conducted a global policy meeting to review the evidence on intensified case-finding and isoniazid preventive treatment to revise and reconceptualize the 1998 WHO/UNAIDS policy on preventing TB. The resulting new set of guidelines on the 'three I's' for HIV-associated TB now provides a more comprehensive policy platform for improving the implementation of these potentially

life-saving activities. Managers of HIV programmes should work with their colleagues in the TB field and the community to ensure that people living with HIV have access to these activities, including the 'three I's' for HIV-associated TB, as part of universal access to high-quality comprehensive prevention, care and treatment of HIV infection and TB.

Elements to be considered in the situation analysis

The situation analysis should consider the following:

- the prevalence of HIV infection among people aged 15–49 years;
- the annual incidence of TB among people living with HIV: this should at least include the TB incidence among people living with HIV who are registered as receiving antiretroviral therapy, but ideally it should also include TB incidence among people registered as being in HIV care;
- the prevalence of HIV infection among people diagnosed with TB;
- case detection and treatment outcomes of TB by the national TB programme (treatment outcomes should be reported by HIV status); and
- progress in implementing the 12 WHO-recommended HIV-associated TB collaborative activities and especially access to antiretroviral therapy and the 'three I's' for HIV-associated TB for people living with HIV.

Focus populations

Focus populations for HIV-associated TB collaborative activities are based on the national policy on HIV-associated TB. They include people living with HIV, people with TB infection and people with both TB and HIV. Additional groups may include marginalized populations vulnerable to TB and HIV, such as people who inject drugs, miners and people in congregate settings such as prisons and camps.

Suggested activities

Establish mechanisms for collaboration between TB and HIV programmes

Create a TB and HIV coordinating body functional at the national, intermediate and local level. Ensure adequate representation of the two programmes, partners, and TB and HIV patient support groups. The joint coordinating body should coordinate all actors involved, plan and guide the implementation of activities, and monitor and evaluate it. Important areas of responsibility for the joint coordinating body are capacity-building, including training, ensuring coherence of communication about HIV-associated TB, ensuring the participation of the community in joint TB and HIV activities and ensuring the coordination of TB and HIV operational research.

Conduct surveillance of HIV prevalence among people with TB. HIV testing and counselling for all people with TB should form the basis of surveillance in countries with a generalized epidemic state. In countries with a concentrated epidemic state, HIV testing and counselling for all people with TB should form the basis of surveillance in the administrative areas where groups at high risk for HIV are located. In countries with a low-level epidemic state and in countries with unknown HIV prevalence rates, seroprevalence (periodic or sentinel) surveys are recommended.

Carry out joint TB and HIV planning. TB and HIV programmes should carry out joint strategic planning, resource mobilization for joint TB and HIV activities, TB and HIV capacity-building including training, TB and

HIV advocacy programme communication and social mobilization, enhancing community involvement in collaborative TB and HIV activities and operational research.

Conduct monitoring and evaluation. HIV and TB programmes should agree on a core set of indicators and data collection tools and should collect data for monitoring and evaluating collaborative TB and HIV activities using the WHO guidelines. The monitoring and evaluation system should be mainstreamed into the existing HIV, TB and general health systems, rather than creating a new system.[1] The following two important documents should be used:

- for HIV registers: *Three interlinked patient monitoring systems for HIV care/ART, MCH/PMTCT and TB/HIV: standardized minimum data set and illustrative tools*;[2] and
- for TB registers: revised TB recording and reporting forms and registers – 2006 version; HIV and antiretroviral therapy services providing TB diagnosis, prevention and treatment services need to use the TB registers, as it will help to monitor the outcome of TB treatment among people living with HIV receiving both treatments.

Reduce the burden of TB among people living with HIV

Implement intensified TB case-finding. Evidence has shown that intensified case-finding and treatment of TB among people living with HIV interrupts disease transmission, reduces mortality, reduces the risk of nosocomial TB transmission and offers the opportunity to provide preventive TB treatment to people living with HIV. It has also been established that intensified TB case-finding is feasible and can be done at limited additional cost in existing health services.

Scale up the use of isoniazid preventive treatment. Although isoniazid treatment has been shown to reduce the prevalence of TB among people living with HIV, only a few countries provide this as part of the national HIV package. WHO recommends that HIV programmes provide isoniazid preventive treatment as part of the package of care for people living with HIV when active TB is excluded.

With respect to the above recommendations to intensify TB case-finding and scale up isoniazid preventive treatment, two new WHO guidelines should be noted and implemented.

- The new 2011 WHO guideline on TB screening and providing isoniazid preventive therapy[3] recommend that in settings with high HIV prevalence, a brief questionnaire inquiring about the presence of four symptoms (cough of any duration, fever, weight loss and night sweats) be used to identify people living with HIV who should be assessed for the presence of active TB. But even if all four symptoms are absent, they should start isoniazid preventive treatment.
- In settings with high HIV prevalence in which the new automated DNA test for TB (Xpert® MTB/RIF) is available, WHO recommends that people living with HIV and with presumptive TB should be tested with it as the primary diagnostic test for TB. For those who are found to be rifampicin resistant, culture and drug sensitivity testing should be planned.[4]

Ensure TB infection control in health care and congregate settings. With the roll-out of HIV care and treatment with antiretroviral drugs, people living with HIV and their families frequently congregate in health

1 *A guide to monitoring and evaluation for collaborative TB/HIV activities*. Geneva, World Health Organization, 2009 (http://whqlibdoc.who.int/publications/2009/9789241598194_eng.pdf, accessed 26 September 2011).

2 *Three interlinked patient monitoring systems for HIV care/ART, MCH/PMTCT (including malaria prevention during pregnancy) and TB/HIV: standardized minimum data set and illustrative tools*. Geneva, World Health Organization, 2009 (http://www.who.int/hiv/pub/imai/pmg_form_booklet_090907.pdf, accessed 26 September 2011).

3 *Guidelines for intensified tuberculosis case finding and isoniazid preventive therapy for people living with HIV in resource-constrained settings*. Geneva, World Health Organization; 2010 (http://whqlibdoc.who.int/publications/2011/9789241500708_eng.pdf, accessed 26 September 2011).

4 *Roadmap for rolling out Xpert MTB/RIF for rapid diagnosis of TB and MDR-TB*. Geneva, World Health Organization 2010 (http://www.who.int/tb/laboratory/roadmap_xpert_mtb-rif.pdf, accessed 26 September 2011).

care settings. TB, in particular multidrug-resistant TB and extensively drug-resistant TB, are recognized as emergent risks for transmission from patients to patients and patients to health care workers. It is essential that health care and congregate settings have a plan and implement administrative, environmental and personal infection control and protection measures to reduce the transmission of TB.[5]

Ensure implementation of early antiretroviral therapy. WHO recommends early antiretroviral therapy for people living with HIV with a CD4 cell count below 350 per mm^3 and for people with both HIV and TB irrespective of CD4 cell count. Observational studies showed that antiretroviral therapy can prevent 50–90% of TB cases and can serve as a major TB prevention activity.

Reduce the burden of HIV among people with TB

Provide HIV testing and counselling. Provider-initiated HIV testing should be offered to all people with TB in settings with a high prevalence of HIV. In some countries with a high HIV prevalence, up to 80% of people with TB tested for HIV actually have HIV. TB presents an early entry point for detecting and treatment of HIV.

Introduce HIV prevention methods. TB control programmes should adopt and implement comprehensive HIV prevention strategies for people with TB, their partners and their families, focusing on sexual, parenteral and vertical transmission, or should establish a referral linkage with HIV programmes to do so. Early access to antiretroviral therapy is one of the strongest activities for preventing HIV transmission and preventing the development of TB (WHO recommends starting antiretroviral therapy among people living with HIV with a CD4 count below 350 per mm^3 and for all people with both TB and HIV irrespective of CD4 count).

Introduce co-trimoxazole preventive treatment. All people with both HIV and TB should be given co-trimoxazole preventive treatment during their TB treatment and for life thereafter, unless contraindicated or unless they receive antiretroviral therapy and their CD4 cell count rises above 500 per mm^3. To gain maximum benefit, people with TB should start co-trimoxazole preventive treatment as soon as possible after being diagnosed with HIV infection, because mortality is highest early in the course of TB treatment.

Ensure HIV care and support. TB control programmes should establish a referral linkage with HIV programmes to provide the continuum of care and support for people living with HIV who are receiving or who have completed TB treatment.

Introduce antiretroviral therapy. Antiretroviral therapy significantly improves the quality of life, reduces morbidity and enhances the survival of people with advanced HIV infection or AIDS. In addition, antiretroviral therapy reduces HIV transmission and the incidence of TB. People with both HIV and TB comprise one of the largest groups already in contact with the health service who are likely to benefit from antiretroviral therapy, and efforts should be made to identify and treat all eligible people. In general, in the absence of CD4 counts, antiretroviral therapy should be considered for all people with both HIV and TB.[6]

Follow a food and nutrition programme. Enrolment in a food and nutrition programme improves treatment success. Food and nutritional support is time limited (3–6 months), with clearly defined entry and exit criteria following nutritional recovery on antiretroviral therapy. Food and nutrition activities as part of comprehensive treatment, care and support enable HIV treatment success and include:

- nutrition assessment, education and counselling for all people living with HIV and people with TB under directly observed treatment, including infant feeding practices for pregnant and breastfeeding women living with HIV; and

5 *Policy on tuberculosis infection control in health-care facilities, congregate settings and households.* Geneva, World Health Organization, 2009 (http://whqlibdoc.who.int/publications/2009/9789241598323_eng.pdf, accessed 26 September 2011).

6 *Guidelines on antiretroviral therapy for HIV infection in adults and adolescents.* Geneva, World Health Organization, 2010 (http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf, accessed 26 September 2011).

- specialized food products for the nutritional rehabilitation of people with malnutrition, including people living with HIV and their children attending services for maternal, newborn and child health and for preventing mother-to-child transmission as well as nutrition services.

In settings where injecting drug use is an important mode of HIV transmission, proposals should consider how services for people who use drugs can collaborate with the TB and HIV programmes to reduce the burden of TB and HIV among these people.[7] Access to antiretroviral therapy is critical for people who use drugs, both to reduce morbidity and mortality and to prevent HIV transmission.

Suggested key indicators

Budgeting for monitoring and evaluation is essential. Measuring progress in implementing HIV-associated TB activities should be a core aspect of the budget. Programmes often omit a budget for staff and the resources necessary to conduct and maintain technical support in the field.

Key indicators include the following:

- the percentage of people with HIV and newly diagnosed TB who received treatment for TB and HIV;
- the percentage of newly registered people with TB who are recorded to be living with HIV and who have started or continued receiving antiretroviral therapy;
- the percentage of newly registered people with TB who are recorded to be living with HIV and who have started or continued receiving co-trimoxazole preventive treatment;
- the percentage of people newly enrolled in HIV care starting isoniazid preventive treatment;
- the percentage of people enrolled in HIV care who were screened for TB at their last visit;
- the number of health care facilities with demonstrable infection control practices that include TB control; and
- the number of health care workers employed in HIV care facilities who develop TB.

Approach to costing

The costs for purchasing co-trimoxazole and isoniazid specifically for prophylaxis purposes based on the focus populations described above should be included in the costing exercise. The costs for logistics to ensure the availability of co-trimoxazole and isoniazid at all health facilities may also be considered. In many countries, co-trimoxazole is purchased only for therapeutic use without considering that people living with HIV need to use it for prophylaxis. Many countries struggle with their supply chain management systems, resulting in erratic supply and shortages of drugs. Addressing the supply challenges of the HIV and TB programmes together may be an opportunity to improve health procurement and supply chain management systems more broadly. Infection control plans may entail substantial costs and create significant supply chain demands (such as training, communication, respirators and reconstruction). For more information on costing TB activities, the WHO Stop TB department has a planning and budgeting tool, which can be accessed at http://www.who.int/tb/dots/planning_budgeting_tool/en/index.html.

7 *Policy guidelines for collaborative TB and HIV services for injecting and other drug users.* Geneva, World Health Organization, United Nations Office on Drugs and Crime and United Nations Joint Programme on HIV/AIDS, 2008 (http://whqlibdoc.who.int/publications/2008/9789241596930_eng.pdf, accessed 26 September 2011).

Links with other service delivery areas and programmes

The TB component of the Global Fund proposal also includes TB and HIV collaborative activities. Other related services include testing and counselling, antiretroviral therapy and treatment of opportunistic infections.

Type and sources of technical assistance that may be required during implementation

Areas in which technical assistance may be required include:

- evaluating TB and HIV services;
- developing or updating the national TB and HIV policy;
- developing training programmes for TB and HIV;
- revising TB and HIV care and treatment recording and reporting tools and monitoring and evaluation frameworks; and
- developing and reviewing TB and HIV guidelines.

Further information

The main HIV and TB publications of the WHO Department of HIV/AIDS are available at http://www.who.int/hiv/topics/tb/en and http://www.who.int/hiv/topics/artforprevention/en/index.html.

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