A hospital-based tuberculosis focal point to improve tuberculosis care provision in a very high burden setting

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Setting: A hospital-based tuberculosis focal point (TBFP) at a tertiary hospital in Johannesburg, South Africa.

Objective: To describe the possible tasks and impact of a hospital-based TBFP as well as staffing and infrastructure requirements for setting up a hospital-based TBFP.

Activities: A TBFP can centralize the notification and referral of new TB cases, perform human immunodeficiency virus counseling and testing, assessment of difficult to diagnose TB suspects and management of complicated TB cases, and it can provide an ideal setting for research and health care worker training.

Results: The number of TB suspects assessed by sputum initially increased, followed by a decrease starting in 2010, which correlates with the globally decreasing TB incidence. The proportion of TB cases who failed to link to TB care decreased from 23% to 14% between 2009 and 2012. Almost 40% of cases with hepatotoxicity required an adjusted treatment regimen. Roll-out of Xpert® MTB/RIF testing and decentralized drug-resistant TB treatment increased the number of rifampicin monoresistant and sputum smear-negative multidrug-resistant TB cases treated on an out-patient basis.

Conclusion: A hospital-based TBFP complements care at primary care level by coordinating TB care for a vulnerable population of patients diagnosed in a hospital setting, and by coordinating the diagnosis and treatment of complex TB cases.

Tuberculosis (TB) remains an important public health problem, with a global TB incidence of 8.7 million in 2011.¹ The human immunodeficiency virus (HIV) epidemic and the emergence of anti-tuberculosis drug resistance represent serious threats for achieving the Stop TB Partnership's goal of eliminating TB as a public health problem by 2050.² South Africa has the third highest TB burden in the world, with an incidence of 993 cases per 100 000 population and an estimated 60–80% HIV co-infection rate, much higher than the estimated global 13% HIV infection rate among all TB patients.^{1,3} South Africa also has the fourth highest rate of multidrug-resistant (MDR) TB.⁴ High rates of HIV-associated TB and MDR-TB result in diagnostic challenges, higher rates of adverse drug reactions (ADR), and a need for individualized treatment regimens in patients with non-tuberculous mycobacterial (NTM) infection and drug-resistant (DR) TB.^{5–7}

Failed linkage to care from a hospital setting to a primary care (PHC) clinic can lead to patients defaulting from the continuation phase of their TB treatment.⁸ To overcome the problem of high attrition rates, Edgin-

ton et al. suggested the creation of a hospital-based TB Care Centre to perform TB education and to provide an essential link between the hospital, PHC clinics and other facilities.⁸

At Helen Joseph Hospital, a tertiary hospital in Johannesburg, South Africa, we embraced the concept of a TB Care Centre, and created a TB Focal Point (TBFP) that started operating in August 2008. We subsequently explored the feasibility of expanding services, including integrated TB-HIV care, induced sputum collection, and support for the management of complicated cases in need of individualized treatment, including patients experiencing ADR, treatment of patients with NTM disease, and ambulatory treatment of DR-TB cases.

We describe the possible tasks and impact of a hospital-based TBFP, the gaps it fills and the staffing and infrastructure requirements for setting up a hospital-based TBFP.

SETTING

The TBFP was established at Helen Joseph Hospital, a tertiary hospital, next to the Themba Lethu Clinic (TLC), the largest antiretroviral therapy (ART) site in South Africa, with over 30 000 HIV-infected patients in HIV care and over 21 000 on ART.⁹ The TBFP notifies over 2000 new TB cases each year. The vast majority of all new cases (76.6%) are diagnosed and initiated on TB treatment during hospitalization, 17.2% are diagnosed in out-patient or emergency clinics, and 6.2% are referred from PHC clinics for diagnosis and initiation of treatment. In 2009, most (68.5%) had smear-negative TB, a large proportion (86.9%) were HIV-infected, 8.9% were HIV-negative and 4.2% had unknown HIV status. The median CD4 cell count at TB diagnosis was 78 cells/mm³ (interquartile range [IQR] 30–178), and only 21% of HIV-infected patients were receiving ART at the time of TB diagnosis.¹⁰

TUBERCULOSIS FOCAL POINT ACTIVITIES

Notification and referral of new tuberculosis cases

Centralizing the notification of all TB cases diagnosed at the hospital through a TBFP improves the quality of the process and facilitates reporting to regional and provincial programs. At the TBFP, patients are referred for continuation of TB treatment to the most appropriate local PHC clinic based on the patient's home or work address, and are provided with TB medications for 7 days. A standard South African TB Programme

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referral form is given to the patient to deliver to the referral clinic; a copy of this referral letter is kept at the TBFP. To confirm linkage to TB care, the TBFP sends out weekly reports to the regional TB coordinators on all TB cases newly notified and referred to PHC clinics in the region. The TB coordinator provides feedback within a set time period of a few weeks on patients who have arrived at the PHC clinic. TB cases who fail to link to a PHC clinic are reported to a team of tracers of the district City of Johannesburg.

HIV counseling and testing

While the hospital aims to provide HIV counseling and testing to all TB suspects before initiation of TB treatment, and TB education at the time of initiation of treatment, some patients are too ill to absorb this information. Knowledge about TB and HIV is verified in all patients, and additional information is provided as appropriate. All patients with unknown or negative HIV status and tested more than 3 months previously are offered HIV testing. If the patient is HIV co-infected, CD4 cell count and indication for ART initiation, including a time frame, are included in the referral letter. Ideally, HIV-infected TB patients are referred to a PHC clinic that provides integrated HIV and TB care. On the other hand, people living with HIV receiving care at the TLC are routinely screened for symptoms of TB at each visit, and all those suspected of having TB are referred to the TBFP for assessment.

Treatment of tuberculosis cases with adverse drug reactions

ADRs to anti-tuberculosis drugs are common, especially in the HIV-infected population.¹¹ A doubling of the relative risk of adverse events to TB drugs has been reported in HIV-infected individuals compared to non-HIV-infected individuals.^{5,12} TB cases with ADRs require closer monitoring and individualized treatment, which can include second-line drugs that are not available at local clinics. There is a lack of evidence-based guidelines on how to reintroduce drugs suspected of causing the ADR, and it remains unclear what role less effective second-line drugs can play in these patients. Centralizing treatment for TB cases with ADRs in a TBFP guarantees a uniform approach by health care workers experienced in dealing with these complex management issues. Once the clinical condition has improved or stabilized and the drugs in the individualized regimen are available at the PHC clinic, the patient can be down-referred with a clear treatment plan.

Treatment of patients with non-tuberculous mycobacterial disease

NTMs are widely distributed in the environment. *Mycobacterium avium* complex is the most common cause of NTM disease in HIV-infected individuals with advanced immunosuppression, especially those with CD4 counts < 100 cells/mm³. NTM can also cause disease in patients not infected with HIV, usually in individuals with underlying risk factors such as chronic obstructive pulmonary disease, previous TB, bronchiectasis, cystic fibrosis, chest wall abnormalities and smoking.¹³

Clinical presentation of NTM and TB is indistinguishable, the Xpert® MTB/RIF assay (Cepheid, Sunnyvale, CA, USA) does not detect NTM, and both organisms appear as acid-fast bacilli on microscopy. Consequently, a culture is required to confirm NTM disease, but clinical, radiographic, and microbiological criteria are equally important, and all must be met to make a diagnosis of NTM lung disease.¹³ The number of NTM patients initiated on treatment at the TBFP is small (45 in 2009, 27 in 2010 and 29 in 2011). Expert consultation is therefore strongly encouraged when questions arise about the clinical significance of an NTM isolate. The choice of treatment regimen depends on the NTM isolate, co-morbidity and

the co-administration of other medications. Patients also require close monitoring to document culture conversion, as this guides treatment duration. Treatment of patients with NTM infection thus benefits from centralized management by health care workers experienced in treatment of NTM.

Treatment of drug-resistant tuberculosis cases

South Africa has the fourth highest burden of MDR-TB in the world. Mortality rates are high and associated with a greater degree of immunosuppression and drug resistance.¹⁴ In individuals receiving DR-TB treatment, a high rate of side effects is observed, with an 11 times greater odds of anti-tuberculosis ADRs in a case-control study in Peru.¹⁵

In 2000, the South African National Department of Health (NDOH) implemented a DR-TB management program that requires that all MDR-TB patients be hospitalized for at least 6 months. A hospital-centered DR-TB program faces many challenges, including delayed initiation of treatment, inadequate bed capacity, poor infection control in hospitals, and patients' loss of work and home responsibilities. Based on growing evidence that implementation of a decentralized care model can improve the efficiency and effectiveness of DR-TB treatment, the NDOH changed its policy in August 2011 to embrace decentralization of DR-TB treatment.^{6,16,17} In the decentralized model, there are four levels of care: a centralized DR-TB unit or 'Provincial Centre of Excellence', a decentralized DR-TB unit, a satellite MDR-TB unit, and community support. A hospital-based TBFP could function either as a decentralized DR-TB unit, responsible for initiating and monitoring treatment in MDR-TB, polyresistant and monoresistant patients, or as a satellite DR-TB unit to monitor adherence and side effects for patients initiated in a centralized unit before referral to or in complement with community-based care.

Referral of complicated cases

The majority of TB suspects can be diagnosed and monitored by PHC clinics according to the national guidelines.¹⁸ PHC clinics might refer symptomatic patients with a negative sputum diagnostic work-up for further assessment and advice on treatment initiation. Another common reason for referral to TBFP is for treatment advice on patients who remain sputum smear- and/or culture-positive after completion of the intensive phase of TB treatment.

Sputum induction facility

Sputum induction can be useful in TB suspects who are unable to expectorate spontaneously or who are TB culture-negative on a spot sputum sample. In HIV-infected individuals, the incremental yield of induced sputum ranges from 5.3% to 14.9%.¹⁹ To reduce the risk of nosocomial infection, sputum induction needs to be performed in a well-ventilated room or outside, in the open air. However, because sputum induction needs to be performed in a safe and controlled manner, this procedure is not always feasible at PHC clinics.

The TBFP at Helen Joseph Hospital has access to a negative pressure sputum induction room within the unit with an air ventilation system with high efficiency particulate air (HEPA) filters to guarantee constant clean airflow and maintenance of adequate pressures. Regular maintenance of the airflow and the exhaust system is required.

TUBERCULOSIS FOCAL POINT INFRASTRUCTURE

Physical infrastructure

All patients visiting the TBFP report to a reception area for registration. The well-ventilated waiting area has designated areas for

different patient groups such as TB suspects and patients collecting medication. This approach improves efficiency and infection control, and reduces waiting times. All individuals waiting or working in the waiting area should wear airway protection.

In addition to the waiting room and sputum induction room, one or more consulting and counseling rooms that are equipped to ensure optimal infection control are vital for quality TB care and the privacy needed for integrated TB-HIV care. A small pharmacy stocking anti-tuberculosis drugs and some other commonly used supportive drugs can be integrated into a TBFP, or the TBFP can use the hospital's pharmacy.

The TBFP also benefits from an administrative unit to check the disease notification and patient referral forms, compile the statistical reports for the hospital and relevant authorities at district, provincial and national level, and assist with tracing of new TB cases identified by culture and patients who have missed appointments at the TBFP.

Human resources

Every TBFP should have a dedicated team of health care professionals and support staff, including nurses, a medical officer or physician, counselors, a data capturer and an administration clerk. All staff should attend TB and HIV training courses at an appropriate level. A summary of the TBFP tasks and staff requirements is shown in the Table. A TBFP could be set up as a nurse-driven unit, but availability of a medical doctor is highly recommended, especially if the TBFP engages in treatment of cases with ADRs, NTM, or DR-TB. While the availability of a medical doctor in the unit is recommended, one could also consider a physician or infectious diseases specialist on a consultant basis. The human resource requirements vary depending on whether the TBFP is based at primary, secondary or tertiary care level. At primary or secondary hospitals, a TBFP can be nurse-driven if a medical officer is not available.

CLINICAL RESEARCH

A TBFP provides an ideal setting for clinical and epidemiological research. Appropriate patient recording systems, preferably electronic, can facilitate research.

The TBFP at Helen Joseph Hospital has performed epidemio-

logical studies on TB and HIV co-infection rates,⁷ on challenges of linkage to TB and HIV care and treatment among newly diagnosed TB cases,¹⁰ and on the incidence and risk factors of TB among individuals receiving ART.²⁰ In collaboration with the Clinical HIV Research Unit of the University of the Witwatersrand, the unit participates in Phase II and III drug trials, including the REMoxTB trial, a controlled comparison of two moxifloxacin-containing treatment shortening regimens in pulmonary TB.²¹ Finally, our TBFP is also actively involved in TB diagnostics research, including the evaluation of the accuracy of Xpert MTB/RIF for the diagnosis of HIV-associated lymph node TB²² and assessment of the sensitivity and specificity of the urine lipoarabinomannan assay in disseminated and extra-pulmonary TB (EPTB).

TRAINING

As a specialized TB unit, a TBFP should reach out and provide training to other health care workers, both hospital-based and at PHC clinic level. The close collaboration of TBFP and TLC, the ART site, has been mentioned earlier. TBFP provides systematic training on TB diagnosis and treatment to new interns and medical officers working in TLC.

IMPACT ASSESSMENT

Although a systematic impact assessment had not been planned, we analyzed available data to assess changes over time. The number of TB suspects assessed by sputum initially increased, followed by a decrease starting in 2010, which correlates with the global trend of decreasing TB incidence (Figure 1).

While we have no continuous surveillance data on linkage to care, data from sentinel surveys show improvement over time. In 2009, 23% (593) of TB patients failed linkage to TB care compared to only 14% in 2012.

Data on HIV testing have been systematically recorded only since 2009; these show an increase followed by a decrease (Figure 2). This is likely due to an increase in the number of people aware of their HIV status before the diagnosis of TB.

Management of patients with toxicity of TB drugs was integrated into the TBFP in 2010, after the TBFP gained access to ofloxacin and more recently to moxifloxacin. The total number of patients with ADRs cared for at the TBFP was 104 in 2010 and 134 in 2011. About 40% of all TB cases with hepatotoxicity completed an adjusted treatment regimen at TBFP, 30% were transferred to a PHC clinic after successful reintroduction of isoniazid (INH) and rifampicin (RMP) and completion of the intensive phase, 20% died, and 10% were lost to follow-up.

TABLE Summary of TB focal point tasks and staff requirements*

TB focal point task	Required staff
Notification and referral of new TB cases	Nurse
HIV counseling and testing	Counselor
Treatment of TB cases with adverse drug reactions	Experienced nurse, medical doctor
Treatment of TB cases with non-tuberculous mycobacterial infection	Experienced nurse, medical doctor
Treatment of drug-resistant TB cases	Experienced nurse, medical doctor
Assessment of complicated TB suspects referred by primary care clinics	Experienced nurse, medical doctor
Sputum induction	Nurse
Administration/data capturing unit	Administration clerk, data capturer
Clinical research	Medical doctor, research nurse
Training	Nurse, medical doctor

*Note: the human resource requirements specified in the table are applicable to a TBFP at tertiary care level.

TB = tuberculosis; HIV = human immunodeficiency virus; TBFP = tuberculosis focal point.

FIGURE 1 Number of TB suspects, TB cases and pulmonary TB cases, 2007–2011. TB = tuberculosis; PTB = pulmonary TB.

FIGURE 2 Number of individuals with unknown or negative HIV status counseled and tested for HIV. HIV = human immunodeficiency virus.

Roll-out of Xpert MTB/RIF testing has resulted in increased numbers of patients diagnosed with RMP monoresistance. Decentralization of MDR-TB treatment increased the number of sputum smear-negative and extra-pulmonary MDR-TB cases. Furthermore, a policy to treat INH-monoresistant cases at PHC level explains the changes in DR-TB cases at the TBFP (Figure 3).

CONCLUSION

A hospital-based TBFP can coordinate TB care for a vulnerable population of TB suspects and cases in a hospital setting. The TBFP complements care provided at PHC level by improving linkage to TB care, integrating HIV and TB services and diagnosing and treating complex TB cases that require intensified diagnostics, modified treatment regimens or closer monitoring. A TBFP with similar principles can be implemented at primary or secondary level hospitals. Human resource requirements will vary depending on the setting.

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FIGURE 3 Total number of drug-resistant TB cases treated at the TBFP. Data for 2012 only reflect the number of cases up to November 2012. INH mono = isoniazid monoresistant; RMP = rifampicin monoresistant; Poly = polyresistant; MDR = multidrug-resistant; TB = tuberculosis; TBFP = tuberculosis focal point.

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Contexte : Un point focal de tuberculose (TBPF) dans un hôpital tertiaire à Johannesburg, Afrique du Sud.

Objectif : Décrire les tâches et l'impact possible d'un TBFP basé sur l'hôpital ainsi que les exigences en matière de ressources humaines et d'infrastructure pour développer un TBFP centré sur l'hôpital.

Activités : Un TBFP peut centraliser la déclaration et l'orientation des nouveaux cas de TB, se charger de l'accompagnement et des tests du virus de l'immunodéficience humaine, évaluer les suspects de TB difficiles à diagnostiquer et la prise en charge des cas de TB ; il constitue un contexte idéal pour la recherche et la formation des travailleurs des soins de santé.

Résultats : Le nombre de suspects de TB évalués par l'examen d'expectoration a augmenté initialement, suivi par une diminution débutant en 2010, ce qui est en corrélation avec l'incidence décroissante

de la TB au niveau mondial. La proportion de cas de TB qui n'ont pas eu accès aux soins de TB a diminué de 23% à 14% entre 2009 et 2012. Près de 40% des cas avec une hépatotoxicité exigent un régime ajusté de traitement. Le lancement des tests Xpert® MTB/RIF et la décentralisation du traitement de la TB résistante aux médicaments ont augmenté le nombre de cas monorésistants à la rifampicine et les cas de TB multirésistants négatifs à l'examen du frottis de crachats traités en ambulatoire.

Conclusion : Un TBFP centré sur l'hôpital complète les soins au niveau des soins primaires en coordonnant les soins TB au profit d'une population vulnérable de patients diagnostiqués dans un contexte hospitalier et en coordonnant le diagnostic et le traitement des cas complexes de TB.

Marco de referencia: Un centro de enlace de tuberculosis (TB) con base en un hospital terciario de Johannesburg en África del Sur.

Objetivo: Describir las eventuales tareas y la incidencia de un punto focal de TB basado en un hospital y evaluar los requisitos en materia de personal e infraestructura que exige su puesta en marcha.

Actividades: Un punto de enlace de TB puede centralizar la notificación y la remisión de los casos nuevos, llevar a cabo el asesoramiento y las pruebas diagnósticas del virus de la inmunodeficiencia humana, proveer orientación en los casos con presunción clínica de TB y diagnóstico difícil y en el tratamiento de los casos complicados; el centro ofrece además un marco ideal para la investigación y la capacitación de los profesionales de la salud.

Resultados: Con la intervención, inicialmente aumentó el número de casos con presunción clínica de TB examinados por baciloscopia, el cual comenzó a disminuir a partir del 2010 de manera simultánea

con la disminución mundial de la incidencia de TB. La proporción de casos de TB que no lograron establecer un vínculo con el sistema de atención de la enfermedad disminuyó de 23% a 14% entre el 2009 y el 2012. Cerca de 40% de los casos que presentaron hepatotoxicidad necesitaron un reajuste del plan terapéutico. La puesta en marcha de la prueba Xpert® MTB/RIF y la descentralización del tratamiento de la TB farmacorresistente aumentó el número de casos monorresistentes a rifampicina y multidrogorresistentes con baciloscopia negativa que recibían tratamiento ambulatorio.

Conclusión: Un centro de enlace de TB en medio hospitalario complementa la atención sanitaria a nivel primario, pues coordina el manejo de la TB en una población de pacientes vulnerables cuyo diagnóstico se ha establecido en medio hospitalario y organiza el diagnóstico y el tratamiento de los casos difíciles.