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In this issue:

Integrating TB and HIV services: lessons from the field; *page 2*

- Integrating services for more rapid detection and treatment of TB/HIV coinfection
- Khayelitsha's integrated TB/HIV programme

Integrating TB and HIV services: lessons from the field

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Integrating services for more rapid detection and treatment of TB/HIV coinfection

By Theo Smart

A year and a half ago, investigators of the Starting Antiretroviral Therapy at Three Points in Tuberculosis (SAPIT) trial announced that starting antiretroviral therapy (ART) in people with both tuberculosis (TB) and HIV while they are still taking TB treatment dramatically reduces mortality (see

<http://www.aidsmap.com/en/news/81BF3B62-9197-42D6-9DB3-44A784E2F0B1.asp>). These results, recently published by the *New England Journal of Medicine* – support the integration of TB/HIV services.¹ Other recent data from countries with a high burden of TB suggest that more coinfecting people will receive integrated care in a timely fashion when HIV services, including the initiation of ART, are provided directly within the TB services.

To recap SAPIT's findings: investigators in Durban, South Africa randomly assigned 642 patients with both smear-positive tuberculosis and HIV infection (and less than 500 CD4 cells) to one of three arms, receiving ART:

- 1 within the first two months of starting TB treatment;
- 2 within four weeks of completing the intensive phase of TB treatment; or
- 3 only after the completion of TB treatment (sequential therapy).

Delaying ART was generally the practice at the time, although some observational studies had found improved outcomes with earlier initiation of ART.^{2,3} Everyone in the study was taking the same once-daily regimen: efavirenz plus ddI and 3TC (today, ddI would not be part of the first-line regimen).

The study's data and safety monitoring board recommended discontinuing the sequential therapy arm after a planned interim analysis found that after a median follow-up time of 12 months, mortality rates were 56% lower in the two integrated therapy arms.

Rates of adverse events were similar between the sequential and integrated arms; and although immune reconstitution inflammatory syndrome (IRIS) was three times more common in the two integrated arms, it did not appear to contribute to any of the deaths in the study.

Arms 1 and 2 are ongoing in order to determine the optimal time to initiate ART.

"Our findings provide compelling evidence of the benefit of initiating antiretroviral therapy during tuberculosis therapy in patients with HIV coinfection. The findings also support recommendations by the WHO and others for the integration of tuberculosis and HIV care," Karim et al wrote.

Indeed, the results have already led to a change in WHO policy. The recent guidelines on ART for HIV infection in adults and adolescents recommend: "start TB treatment first, followed by ART as soon as possible after starting TB treatment." This is categorised

as a 'strong recommendation' based on evidence of a 'moderate quality' (the evidence would now have a stronger grading since its publication in a major peer-reviewed medical journal).

Several studies at the 40th Union World Conference on Lung Health held in Cancún, Mexico in December last year lend further support to TB/HIV integration, and the early initiation of ART in people on TB treatment.

Mortality

Globally, a third of the people with HIV are coinfecting with TB, according to a poster from the KNCV Tuberculosis Foundation – and the leading cause of mortality in people with HIV in Africa.⁴ The poster described a KNCV meta-analysis of 15 major cohort studies assessing the impact of TB on mortality in HIV-infected patients. Essentially, the study found that people with HIV who develop TB have twice the risk of death of those people with HIV who do not develop TB.

The effect was less pronounced in people with lower CD4 cell counts – probably because people with more advanced immune suppression are at greater risk of dying from other complications – and was absent in cohorts with access to ART, presumably because ART reduces the risk of TB-related mortality.

Conversely, a study from the International Centre for AIDS Care and Treatment Programmes (ICAP) and the Ministry of Health in Rwanda reported that even though an integrated TB/HIV care programme is scaling up, HIV is associated with a much increased risk of death among TB patients.⁵

TB case detection rates remain low in Rwanda, though the recent efforts to strengthen the TB programme have improved treatment success rates, reaching the goal of 85% treatment success in 2006.

Mortality in people with smear-positive pulmonary TB peaked at 7% in 2002, and in 2006 and 2007 dropped to 5%. When all categories of TB (such as smear-negative and extrapulmonary TB) are included, the rate of mortality is higher: 7.3% in people who are HIV-negative. But in people with HIV it is 19.4%.

The researchers concluded that the strengthened TB programme activities are having a positive impact on mortality, but not enough yet in HIV-infected people. However, the mortality data are only available out to 2007 – and much of the progress getting coinfecting people onto cotrimoxazole and ART has occurred in the last couple of years.

Problems coordinating care for TB/HIV coinfecting patients between TB and HIV services

But the problem may also be that integration hasn't gone quite far enough. Often, TB and HIV service integration means a system of referrals to a co-located clinic rather than full 'one-stop shop' integration. According to another ICAP study, this can lead to disappointing results.

In March, 2008, ICAP supported Mozambique's national TB programme to perform an evaluation of the implementation of TB/HIV collaborative services that had started in the country several years earlier.⁶ Data from a random sample of up to 25 coinfecting patients were extracted from the registers in each of 22 TB facilities in 11 provinces, and then compared to the corresponding files for the same patients at the associated HIV services unit.

Matching files in the HIV services couldn't even be located for 41% (181) of 446 TB/HIV patients selected. Of the remaining 265 files, the HIV registers could not confirm that many of the clients were receiving the services they were reported as receiving in the TB registers. The information on who was receiving cotrimoxazole could only be confirmed in 60%. According to the TB register, 154 of

the subjects were on ART — but this could only be confirmed for 97 clients (63%).

The programme is redoubling training efforts, and a special form for referrals between the two departments has been introduced in an effort to improve communication.

Other studies have similarly reported that people with TB who test HIV-positive often fail to reach the HIV clinic even when it is right next door, indicating the importance of attempting to provide both HIV and TB services in the same clinic.

TB clinics should start providing all the basic HIV services on-site

A study from Durban reported a high rate of HIV among people who presented to the TB clinic — whether or not they were diagnosed with TB.⁷ The study was a cross-sectional survey of 741 clients (many of whom were self-referred) presenting to the clinic; 229 turned out to not have TB, 512 did (407 were cases of pulmonary TB).

Sputum specimens from the patients were screened for HIV using the *OraQuick* HIV1/2 Assay. The HIV prevalence among the suspects without a TB diagnosis was 66.8%; while it was 69.8% among those with pulmonary TB, and 81.6% among extrapulmonary TB cases.

“The high prevalence of HIV among TB suspects suggests that HIV services should be available to ALL individuals who present to the facility. The high prevalence of HIV among individuals who do not have TB, but who present to the facility, provides an opportunity to offer HIV services to a group of self-identified patients at risk... [and] provides further evidence to support the integration of TB and HIV services.”

Full TB/HIV integration at the TB clinic

Increasingly, TB clinics are becoming TB/HIV clinics. In a separate article in this issue, Lesley Odendal of Médecins Sans Frontières (MSF) summarises the experience of the Khayelitsha sub-district in the Cape Town Metro area, which has pioneered full TB/HIV integration in TB clinics.

Two studies from Kenya at the Union Conference this year described successful models where the integration of HIV services into TB clinics dramatically increased HIV screening and access of TB/HIV coinfecting people to ART.

A poster presentation from Mugo et al in Kenya noted that the lack of integration between services results in missed opportunities for diagnosis and care, increases suffering, and increases the cost for patients of seeking out health care.⁸ So in 2008, ICAP working in collaboration with the Kenyan national AIDS and TB programmes established an integrated TB//HIV services site in the TB clinic at the Karatina District Hospital in Central Province, Kenya. Staffing for the site is minimal: a clinical officer and nurse in the TB clinic who have received intensive training in all aspects of TB/HIV management are running the project.

Between June and December 2008, every patient who was registered with TB at the clinic was offered and accepted an HIV test. Thirty-four (21%) tested HIV-positive and were then registered at the comprehensive care clinic (CCC) at the facility.

Their initial HIV care is provided by the TB clinic until they complete their TB treatment. Seventeen (half of the HIV-positive clients) qualified for ART (using the eligibility criteria at the time — TB and a CD4 cell count below 350) — and each one began ART while on TB treatment. The proportion of coinfecting people enrolled onto ART increased by 45% after TB/HIV integration. Once TB treatment was concluded, participants were referred to the CCC for continuity of care.

Dr Helena Hueriga from Médecins Sans Frontières (MSF) described the experience implementing a similar ‘one stop shop’ comprehensive TB/HIV care site in a rural district hospital in Homa Bay, Kenya.⁹

Kenya is a high-burden TB country, with an incidence of 353 new cases per 100,000 people per year. Although the HIV prevalence in Kenya was only 7.4% in 2007, the distribution varies markedly throughout the country — the Homa Bay District, situated on Lake Victoria in Nyanza Province, has the highest HIV prevalence in the country at around 24%.

So in July 2005, MSF in partnership with Kenya’s National TB and Leprosy Programme established a one-stop integrated TB/HIV care service in Homa Bay District Hospital.

Some of the first actions that were taken were to improve infection control precautions in the clinic “because these HIV-positive patients are currently seen in the TB clinic (and this is including TB suspects),” said Dr Hueriga. These measures included the construction of an outside waiting area, and the addition of a few more windows and doors to the facility which are kept open to maximise natural ventilation, while nurses are supplied with N95 masks to wear in the unit.

“In terms of human resources, this was a mixed team of MSF and MoH staff. MSF is also working in the HIV clinic of the hospital, so we brought someone from the HIV clinic who was already trained on HIV to the TB clinic to start,” said Dr Hueriga. “Now there are people who are rotating between the HIV and TB clinic, both clinic officers and nurses were trained and can do six months in the TB clinic and then six months in the HIV clinic, and then some other staff will come in. The MoH has a different system, but they also rotate everyone in the hospital — but they rotate them to more places. But this helps foster understanding between one programme and the other.”

The patient file system, reporting and recording system were also improved for better programme monitoring.

Dr Hueriga described a retrospective analysis that was performed to determine the impact of the one stop care site on HIV testing for TB patients, management of HIV-positive TB patients, and TB programme outcomes, using data collected from the TB register book and patient’s files. To measure the impact, the investigators looked at three periods of time: 1) before implementation from January to June 2005, 2) shortly after implementation, from January to June in 2006, and 3) a ‘medium term’ after implementation, January to December 2007.

Prior to integration, around 30% of the TB clients were tested for HIV. Shortly after implementation, close to 80% were tested, while a year later, roughly 90% were tested. After implementation, cotrimoxazole and ART initiation also increased significantly from ~45% and 10% respectively to 85-95% and 40-50% afterwards. (The differences between the short-term and middle-term were non-significant).

As for TB diagnoses, “we expected to see an increase in smear-negative TB diagnosed (~40%) but this proportion remained stable, but on the other hand, we did see an increase in extrapulmonary TB from 22% before integration, to 29-30% afterwards ($p < 0.05$).

Of note, by the medium term follow-up period, TB programme outcomes improved — with a significant increase in success rates ($p < 0.01$), and a drop in mortality ($p < 0.01$), though the rate of default was fairly constant.

“We were surprised by this. We would have expected an impact on the defaulter rate since there was more counselling and more patient education, so we need further investigation to understand why,” she said.

The investigators also looked at TB outcomes based upon the HIV status of the TB subject (HIV-negative, HIV-positive on ART, HIV-positive not yet on ART and HIV status undetermined). Although the HIV-negative patients had the best TB outcomes (with an 82% treatment success rate), the difference between their outcomes and the outcomes of HIV-positive clients who started ART was insignificant. "This probably means that these patients are properly managed for both their TB and their HIV status," said Dr Huerga.

However, HIV-positive patients who were not on ART had a significantly lower treatment success rate ($p < 0.01$) and higher rate of death ($p < 0.05$). People with an unknown HIV status had the worst outcomes, and were significantly more likely to default treatment as well.

"The implementation of one-stop comprehensive TB/HIV care in the Homa Bay District Hospital was very successful and provides a model which should be implemented in all of our TB clinics," said Dr Huerga. "It is important to note that this improved not only the management of HIV, but outcomes for the TB programme in general."

One audience member asked whether there were any plans to scale the model up.

"Yes, I think the Kenyan authorities are trying to implement `one-stop` services wherever it is possible to do it," she said. "The problem is that in Kenya and many other African countries, the TB programme is much larger and far more decentralised than the HIV programme, so there are many more TB clinics than HIV clinics. To introduce HIV care and treatment to all the TB clinics is going to take some time and effort, but I think it is on the mind of the national programme."

"Nowadays this is the only way of correctly managing TB and HIV – managing them together – there is no other way. 80% of the TB patients in this hospital are coinfecting with HIV so it doesn't make any sense to separate the patients and have 80% of the patients going to the TB clinic and going to the HIV clinic."

Some common themes

There are indeed more TB clinics and units than HIV services, and given the burden of coinfection in many settings – and the need to scale-up to universal access to ART – there will be an increasing emphasis on how to deliver HIV care in these settings

There are some common factors to the successful scale up of TB/HIV integration in these facilities.

One is that TB/HIV services can be successfully provided by trained nurses and clinical officers – who can start and follow-up ART patients.

Another is the importance of TB/HIV training – and the transfer of experienced staff, who can help launch the service and provide ongoing mentoring to less experienced healthcare workers.

It is also essential to implement good infection control – both to protect TB suspects, staff and HIV-infected clients from people with infectious and possibly drug resistant TB.

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Khayelitsha's integrated TB/HIV programme

By Lesley Odendal

Lesley Odendal works for MSF in Khayelitsha

Despite the poverty of the largest township outside Cape Town, South Africa, Khayelitsha's TB/HIV programme has not only demonstrated that full TB/HIV integration is achievable, it can improve patient outcomes significantly. Furthermore, it could help programmes reach goals for universal access.

Khayelitsha (with a population of around 500,000) was the first place in South Africa where antiretroviral therapy (ART) was provided in public sector clinics. Its initial successes can be attributed to the paradigm shift from the former consensus (that providing ART was not feasible in poor settings) to making it a priority. Now, more than 13,500 patients had been started on ART at ten sites in Khayelitsha. New enrolments are increasing despite the scarcity of staff. This was only possible because nurses provide ART and because ART services were decentralised to all clinics – including most of the TB services.

Management of the Khayelitsha sub-district health system is shared between the Western Cape Provincial Department of Health, the City of Cape Town Department of Health, and Médecins Sans Frontières. Together they have delivered a programme that has consistently been in the vanguard of HIV and TB clinical practice, introducing a number of innovations – such as clinics targeting men, adherence clubs and full TB/HIV integration.

It is also one of two pilot projects in South Africa to provide treatment for drug-resistant tuberculosis (DR-TB) in clinics while patients live at home, rather than requiring hospitalisation away from family and friends for at least six months.

Khayelitsha's experiences are proving critical at a time when the direction of South Africa's health policy has completely changed. In fact, doctors working in Khayelitsha hailed the first of December last year as the first "happy" World AIDS Day South Africa had ever seen. President Jacob Zuma's speech that day and the newly approved HIV treatment guidelines included evidence-based HIV and TB policy shifts for which many activists had been fighting for years

These include providing ART to all HIV-infected infants and to pregnant women and people with TB with a CD4 count of less than 350. The President also committed to treating TB and HIV "under one roof" and ensuring that *all* the health institutions in the country are ready to assist patients, not just a few accredited ART centres.

For these objectives to become a national reality, ART will need to be provided in close to 4000 health centres, while currently it is only being provided in 400. A scale-up of this immensity will require the implementation of many of the lessons learnt in Khayelitsha,

including task-shifting to nurse-led initiation of ART, full TB/HIV integration, and adherence clubs for patients on long-term ART.

Such innovation was born out of necessity. Khayelitsha has an enormous burden of both HIV (with a 31% antenatal HIV prevalence) and TB (case notification rate of close to 1,600 per 100,000 in 2008). Around 70% of all TB patients are HIV-positive. It would have been virtually impossible to effectively manage such a great burden of coinfection, without integration of TB and HIV services.

TB/HIV integration

Integration of TB/HIV was piloted in 2004, at the Ubuntu clinic, site B, and then scaled up to other clinics. The goals were to improve HIV screening and counselling among people with TB, and to improve access to cotrimoxazole, CD4 cell monitoring, and ART among those who were coinfecting.

Another objective was to improve the diagnosis of TB including smear-negative and extrapulmonary TB which are common in people with HIV.

Integration could also improve programme and service efficiency; clients would benefit from an integrated approach to adherence support and defaulter tracing; and monitoring and evaluation could be better coordinated.

Previously, patients were referred from TB clinics to distant ART service points (and vice-versa), resulting in long waiting times and duplication of both clinical and laboratory investigations and medical records. Patients were also seen by different health care staff, which was a waste of resources and a confusion for patients.

"It is a matter of one patient with two diseases. There are different meanings of TB/HIV integration, but we are striving for full integration. It is more than treating a patient for HIV and TB under one roof — it is about one queue, one clerk, one nurse, one doctor for both diseases per patient. This is true integration," says Dr Gilles van Cutsem, Khayelitsha Project Coordinator for Médecins Sans Frontières (MSF), who has been based there for over a decade.

In Khayelitsha, TB treatment is provided in primary healthcare clinics by nurses. While doctors were prescribing ART nationally at centralised sites, the Khayelitsha programme's success hinges on nurses being able to initiate ART at each clinic (in fact, nurse-based care has enabled the ART programme to be decentralised to all the existing primary health clinics in Khayelitsha).

Nurse-led, doctor supported

The Khayelitsha programme developed a nurse-led model supported by a mobile doctor team, which was available to initiate clients on ART (as required by South African regulations at the time). Nurses were also taught to flag difficult-to-manage cases for up-referral, such as people with very low CD4 cell counts, advanced TB/HIV disease, central nervous system disease and immune reconstitution inflammatory syndrome,

Ten essential conditions were identified for successful implementation of the nurse-led model:

- Redefine roles and responsibilities within each facility based on task shifting/sharing
- Appropriate staffing (professional nurses, counsellors, pharmacist assistants and administrative staff)
- Functional physical space, and fully equipped consultation rooms
- Guaranteed supply chain for drugs, laboratory tests and management tools
- Large scale clinical training and clinical mentorship (doctor-supported roving teams)

- Ongoing mechanism for efficient referral and/or telephonic doctor support, and red flags for difficult conditions requiring referral
- TB/HIV integration and universal TB infection control
- Quantitative and qualitative targets /facility based on NSP targets
- Quality control and supportive supervision
- Community involvement in patient support activities

Since 2001, MSF working with the City and Provincial health departments, has organised quarterly training of over 500 nurses on TB and HIV, including ART. Doctors and nurses already working in the township lead the courses, and the methodology involves linking theoretical knowledge with practical cases.

On-the-job training is continuous, with education meetings held every two weeks to discuss cases, review policy and listen to expert presentations. Mentorship is also ongoing — and during the first few months of introducing ART into a facility, an experienced nurse works with the existing facility members to make certain that programme implementation is successful. There are regular audits to monitor and improve the quality of care that is delivered.

This nurse-based scale up of ART has not jeopardised standard of care or patient outcomes. After five years on ART, 70% of people remain alive and in care, with viral load undetectable or low and stable in 85%. Over time, there has also been a decrease in patients presenting with low CD4 counts, and mortality has decreased significantly.

The integration of ART within TB services in Khayelitsha has also improved clinical care for clients, increased programme efficiency and may now be having a population level effect on TB incidence (which has recently stabilised in the township).

Integration of ART in TB clinics appears to have been an incentive for TB clients to take an HIV test: in 2008, 99% of TB clients received counselling and 95% accepted to be tested due to the opt-out strategy. Among those who tested positive, 99% had at least one CD4 cell count performed and began cotrimoxazole prophylaxis.

Enrolment on ART for TB patients was low prior to integration. In 2007, only 19% of patients enrolled on ART were referred from TB services. The newly integrated Khayelitsha clinics show a radically different picture: a folder review in one clinic reveals that up to 68% of the people on TB treatment, have been enrolled onto ART (about the same percentage (~70%) of coinfecting people one would expect to be in need of ART). TB/HIV integration has shortened the time to initiation of ART in co-infected patients from 42 days before to 26.5 days after integration of services.

Likewise, many TB cases are being detected and treated sooner than they would have been without service integration. The increased use of smear negative TB algorithms and culture has also increased the detection of smear negative and extrapulmonary TB.

Finally, coinfecting people are receiving more patient-centred care. In addition, the Treatment Action Campaign (TAC) has been running a treatment literacy programme in the facilities to empower clients. Along with ART readiness and adherence, TAC emphasises TB/HIV covering the need for screening (particularly in people with HIV), infection control (in both the facility and the community), cough etiquette, TB treatment adherence and TB drug resistance.

"You cannot expect one patient to use two different approaches to managing their TB and HIV. If we had not decentralised our ART in the same manner as the TB treatment, patients would not have adhered to both treatment for HIV and TB. It is a waste of resources for your patient and your programme to do it any other way," says Dr van Cutsem.

While treatment outcomes for drug-sensitive tuberculosis are satisfactory in Khayelitsha, with 82% success rate and 74% cure rate (2007), an increasing number of patients have been diagnosed with drug-resistant TB. Again, the Khayelitsha programme recognised that hospital-based management of large numbers of drug resistant TB (DR TB) cases would simply not be practical – so the programme pioneered a decentralised approach to care for people with DR TB. A future issue of HATIP on community based care for DR TB will describe Khayelitsha's approach to decentralised DR-TB care in more detail.

Infection control

But due to the DR TB programme and full TB/HIV integration, an infection control policy emphasising the three levels of TB infection control (administrative, environmental and personal protection) has been implemented in each health facility in Khayelitsha.

Administrative controls include the establishment of infection control committees in each facility with ongoing staff training, education in cough hygiene and identification of coughing patients, routine screening of health care workers and adjustments to patient flow in order to reduce overcrowding in poorly ventilated corridors.

Environmental controls are centred on improving natural ventilation (opening windows and doors leading outside). `Stop TB, Open Windows` stickers have been placed on all windows.

Wind-driven air extractor turbines (whirlybirds) have been installed in indoor waiting areas, corridors and consultation rooms to increase natural ventilation. Wall or door grates have been installed to increase airflow if windows are closed during the winter months. Outdoor waiting areas are used where feasible and all health facilities have well-ventilated sputum collection booths outdoors.

Measures for personal protection include encouraging the use of N95 respirators by all clinic staff. Paper masks are provided to all clinic attendees in the reception and waiting rooms. These have helped to reduce the stigma around mask wearing.

All of the achievements have been made without a proportional increase in staffing. Non-financial incentives such as ongoing training, clinical on-site coaching and ongoing supervision are essential.

These required a dedicated district management team open to regular meetings with community organisations; constant programme adjustments informed by a rigorous monitoring and

evaluation system, and streamlined decision-lines to allow for quick decisions and additional resource-allocation where justified.

This also required the persistent combined efforts of Khayelitsha residents, the Treatment Action Campaign, Medecins Sans Frontières, the Provincial Government of the Western Cape, the City of Cape Town, the Universities of Cape Town and Stellenbosch, and many others.

The greatest challenge for the ARV scale-up now is how to retain patients in care over the long-term, while at the same time increasing enrolment on ARVs. Adherence clubs were started in Khayelitsha to maximise clinic efficiency and improve support for stable patients on chronic ARVs.

The adherence clubs meet every two months and are run by trained lay health workers who dispense pre-packed ART, after weighing club members (up to 30 people), and screening them for signs and symptoms of opportunistic infections or symptoms (referring problems to a clinician). Club members' waiting times are reduced, and the club also reduces the number of visits to a clinician or nurse. Early results of this pilot project are promising and it is expected that adherence clubs will play a major role in alleviating workload from over-burdened clinics.

For more information, see Khayelitsha Annual Activity Report 2008-2009 available at <http://www.msf.org.za/>

Resources

MSF Khayelitsha 2008-2009 report

http://www.msf.org.za/Docs/Khayelitsha/Khayelitsha_Report_2008-2009.pdf

about HATIP

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