hiv & aids treatment in practice

Intensified case finding: developing an action plan

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Scaling up ICF

Intensified case finding (ICF) is an activity intended to detect possible TB cases among people living with HIV as early as possible. TB is under-diagnosed in people with HIV, and a major cause of death. It is strongly encouraged by the World Health Organization, but as Dr Haileyesus Getahun of WHO's Stop TB department noted, “there is disconnect between policy and implementation.”

The Global Plan to Stop TB proposed several steps to move from policy into implementation and a few more were suggested at a Gates Foundation/WHO/PEPFAR sponsored meeting to develop accelerated TB/HIV plans on collaborative TB/HIV activities, that involved international experts and TB and HIV programme managers from 6 sub-Saharan African countries (Kenya, Rwanda, Ethiopia, Zambia, Namibia, and South Africa), held March 2007 in Washington DC:

- Since this is an intervention that will mostly be employed in HIV-related services, the national AIDS programme (NAP) should liaise with NTP to develop protocols and standard operating procedures
- Access needs to be assured to all available TB diagnostic services including smear microscopy, chest x-ray and rapid culture for those with suspected TB
- National targets should be set for the proportions of patients who are screened and diagnosed in different settings
- A monitoring and evaluation system for intensified case finding needs to be developed to inform programme performance
- An implementation plan must be developed to achieve targets, including human resources, physical infrastructure, the training of staff, equipment, and health commodities management.

At the end of the 2007 HIV Implementers' Meeting in Kigali Rwanda, several sub-Saharan African countries reported progress towards ICF implementation. But most countries still have a long way to go.

“I can't think of a country that meets the criteria of having good standard operating procedures, national case finding targets or model monitoring and evaluation systems,” said Dr Jay Varma of US CDC, Bangkok. “But one impressive example is India, which has set up an extensive ICF network around its voluntary counselling and testing centres (VCTCs) which covers tens of thousands of patients.”

"The Revised National TB Control programme (RNTCP) and the National AIDS Control Organization (NACO) in India do have policies in place for cross-referral of patients," Dr Soumya Swaminathan of the Tuberculosis Research Centre (ICMR) in Chennai, India told HATIP.

"HIV-positive (and negative) clients at VCTCs are now routinely questioned regarding TB symptoms and referred to the nearest microscopy centre for diagnostic workup. This has led to a significant increase in case finding for TB (about 5% of TB patients in the country are those referred from VCTCs). What is lacking is the continued look out for TB in ART clinics and other sites where HIV-positive people are followed up. There is no protocol for this."

But the integration of ICF into HIV testing and counselling in India (and the scale of the undertaking is staggering) could provide a model for expansion into other health settings.

Intensified case finding through VCT centres in India

"This is not about research. This is a story of nationwide scale up in a big place," said Dr Puneet Dewan of WHO's office in Southeast Asia, who described the scale-up of a ICF programme for TB within VCTCs in India during a symposium at the Union World Conference on Lung Health in November 2007.

The ICF programme started in 2003, with a pilot project in five centres across four districts in the state of Maharashtra, where the TB symptom-based screening tool was developed. Counsellors were trained to use a simple questionnaire asking whether the person attending the VCT clinic had had a cough for more than three weeks, or a fever, weight loss, night sweats, unexplained swelling in the neck and armpit. The referral mechanism, and the operational aspects such as training, recording and reporting were also developed at this time.

The pilot went well, so the project was scaled up into the VCT network in 2005. The timing was opportune, since between 2004 and 2006, the number of VCT centres quadrupled in India (to over 4,000 facilities). Uptake of screening at the VCTCs has been increasing over time, with 74% reporting screening their clients by the second quarter of 2007.

Dr Dewan reviewed some of the critical components in the programme's success.

"Training has been a massive undertaking," said Dr Dewan. The programme has trained over 20,000 medical officers, more than 3,300 VCT counsellors and more than 2,000 TB programme staff.

But that has a downside: "This is like an oil tanker. It can't turn very easily, and so minor alterations of the [symptom screening] algorithm

driven by external advice, is not something that the programme is really interested in doing."

After screening, "if a patient is a suspect with symptoms, they're referred to a microscopy centre, which is not a standalone facility but is usually within the same health centre," said Dr Dewan. "The programme uses the same routine referral form that is used throughout the entire health system, so there are no new screening forms."

The counsellor then records referrals on a line list. At the end of the month, this is given to the TB programme staff who check the TB programme records, the laboratory register, the TB register, to they see if that patient has completed their referral, been evaluated, been diagnosed with TB, and started treatment.

That information is then given back to the counsellor who compiles that onto a monthly HIV VCT TB/HIV report. The HIV status of the client referred is not given to the TB programme, since it is known only to the counsellor, who then stratifies the data by HIV status when they produce their overall final report.

Between January 2006 and June 2007 the VCTCs tested over 860,000 people with HIV, and over 2,350,000 people who tested HIV-negative. Five per cent of the people with HIV (~43,000) and 2.7% of the people who were HIV-negative (close to 63,000) have been referred for TB diagnosis. One out of five referrals have been diagnosed with TB, and close to 18,000 started on TB treatment.

Another feature of the Indian programme is that the TB programme still seems to be the major driver in the process in India, because it has more programme management capacity. For example, according to Dr Dewan, the local TB programme managers are responsible for the training of all the staff involved, including the HIV programme staff, and monitoring is fed back to the national TB programme.

Dr Joseph Odhiambo of CDC/KEMRI said the National AIDS Programme in Kenya has started to become more engaged in TB/HIV collaborative activities. "When collaborative TB/HIV activities started in Kenya, they were primarily driven by the TB programmeme, but the HIV programme is taking ownership of [ICF]. This will go a long way to improve collaboration, and implementation of collaborative activities."

Checklists may need adaptation for some clinical care settings

One challenge for implementation that Dr Odhiambo identified is that different ICF tools may be needed at different levels of HIV care. For instance, a TB-specific checklist may be simple to employ in a HIV

counselling and testing site, but in routine healthcare settings (hospitals, primary care clinics, etc), history taking and physical examinations need to take into account a variety of possible conditions (see the annex for a Zambian examination checklist that integrates TB screening elements along with other routine signs and symptoms).
Syndrome-based patient management is essential in clinical settings. For instance, in South Africa, the PALSA PLUS programme is now being rolled out countrywide to all the nurse-run primary healthcare facilities. PALSA PLUS's approach stresses the need for integrated diagnostic guidelines that address TB but also seek to identify other common respiratory diseases that require management (one iteration of their algorithm can be downloaded here). After all, treatment of other potentially life-threatening respiratory conditions can't wait for the TB diagnosis.

Fear of poor treatment outcomes and resistance

Some programmes and providers may be slow to implement ICF because TB control guidelines formerly recommended a less aggressive approach when cure rates are low.

"This is the fundamental challenge of TB control. Do you try to find more cases if you cannot guarantee that those patients will be cured?" said Dr Varma.

So should ICF only be rolled out with DOTS or once a reliable community-based mechanism for adherence support has been put in place and TB control programme targets are met? Evidence from Zambia suggests that with good adherence support treatment outcomes are no worse in those found by active (ICF) compared to passive case finding — with a treatment success rate of 83.8 among active cases (although the number of cases was small) (Nota).

This is much higher than the cure rates for people with TB/HIV reported in the Global TB Report 2008 (which still showed success rates in excess of 50%). "I strongly suspect cure rates in an ART clinic will be much higher than the cure rates in the general TB clinic – if you support patients, they do well," said Dr Francois Venter of of the Reproductive Health and HIV Research group at the University of the Witwatersrand, Johannesburg.

Introducing ICF into overstretched health systems

Another challenge will be to introduce ICF into overburdened clinical settings where staff may see any new programme as "extra work."

"This is the unfortunate reality where staff are burned out, morale is low, training is inadequate and there remains a lack of integration between

HIV and TB services, Dr Krista Dong , Programme Director of iTEACH at Edendale Hospital in KwaZulu Natal, told HATIP.

Recently, Dr Dong and colleaguespublished an operational assessment of TB/HIV care delivery at the facility, which serves 1 million Zulu-speaking people, up to half of whom are HIV-positive (Dong). They found that important procedures were not performed in the wards, while requests for TB diagnostic testing were sporadic, indicating that doctors lacked uniform knowledge and application of diagnostic protocols.

To address these issues, they improved staff training, developed quick and easy reference tools on TB/HIV care guidelines, and hired a new cadre of lay health workers called TB Warriors.

“Our 'TB Warriors' assist the doctors (house staff) to make the diagnosis. The Warriors make sure there are sputum cups and request forms on the ward, routinely ask the doctors if have any TB suspects and provide blank 'rounding lists' to docs so they can list their suspects after their afternoon work rounds."

"They go to the bedside of patients on the list with cups for sputum and if [the coughs] are non-productive the warriors arrange for sputum induction. They hand-carry the sputum to the lab, get the results (including available culture results) daily and bring the sputum result to the bedside and place it on the top of the patient file.”

“Before we started the warrior programme, the TB microbacteriologic coverage at the hospital was one of the lowest in the country: as low as 20-30% of TB suspects, were having sputum sent to the lab,” said Dr Dong. “But only a few months after starting with 2 lay persons, we now have one of the highest TB bacteriologic coverages in the country."

So the TB warriors serve as the link between general case finding in the hospital wards and diagnosis — and the team has just gotten funding to hire two more warriors to serve the Medical Out Patient Department and they hope to expand the coverage to all the hospital’s services.

Similar programmes could smooth the introduction of ICF into other overburdened health systems.

“We do not need professional nurses! Just well trained and supported persons – for whom there is accountability,” said Dr Dong.

Making the diagnosis: challenges

After identifying a suspect, there is a significant risk that the process will stop there. Large numbers of patients may be lost between screening and diagnosis unless reliable mechanisms are put in place to make sure that people suspected of TB make their referral and repeated visits.

Community-based mechanisms (see more below) may help support the person suspected of having TB through this process.

Collecting sputum on site (or at the suspect's home) is another approach, especially if the site is more convenient for the patient, and making certain that the specimens are delivered to the lab.

"We did this in 2000 in Cambodia: one spot sputum collected during a routine home visit," said Dr Michael Kimerling of the University of Alabama at Birmingham. "Simple concept, simple to do, but you must convince the TB programme to accept this approach. With the new WHO policy on the adequacy of a single smear positive result, this is very doable and should be done."

Community-based workers can perform some of these activities (Peters, Ya Diul) though any lay health worker engaged in sputum collection needs to be trained how to do it safely (a future HATIP issue will address TB infection control).

Finally, it is crucial to pair the results with the patient. Even in hospitals, patients sometimes return home before results come back from the lab. So at Edendale, the TB Warriors are also TB trackers. "I instruct them to to take 2 or even 3 cell phones numbers for each TB suspect. Write their details as if it is your own family member who will go untraced and die unless you fill the register properly," said Dr Dong.

Weak laboratory infrastructure and systems and challenging diagnoses

Some clinicians worry about sending in specimens or making more referrals for diagnosis — especially on the basis of non-specific symptoms — when laboratories are already having trouble keeping up with current requests or when it seems virtually impossible to make a conclusive diagnosis on the basis of laboratory findings.

For instance, Dr Dong said that few doctors bothered with ordering microscopy at Edendale "because it was nearly impossible to get a result back on a simple sputum smear. The lab turnaround time was longer than the average hospital stay. So patients were either discharged or dead before a smear result could be obtained."

They have managed to improve this considerably, but still "we cannot keep the TB sputum smear turnaround time to 24 hours or less. There are only two persons in the lab doing all the sputums for the 900,000-person catchment. We need enough staff in the lab," she said.

"In situations where diagnostic services [like bacterial culture] are simply unavailable, empiric treatment should be an option. National TB programmes are loathe to adopt this, however, because it goes against

a fundamental component of the DOTS strategy, which is standardised diagnosis," said Dr. Varma.

"I think all docs in Southern Africa give empiric therapy, possibly even to the majority of their patients – so I suspect hand wringing over whether to do it or not is a bit moot!" Dr Venter told HATIP.

So there can be no guarantee that identifying someone as a TB suspect will lead to a definitive diagnosis in each case. All that clinical teams can do is make diagnoses as best they can — and treat. Nevertheless, the community should lobby for adequate laboratory capacity to support ICF – and a rapid simple test that could diagnose smear-negative TB at the point of care.

Reaching out beyond health facilities

Unfortunately, many people only use public health services as a last resort.

"In some communities [in Kenya] people don't present to the healthcare setting because they think that severe TB symptoms are the first sign of HIV," said Dr Mukadi Ya Diul of Family Health International at the UWCLH. "If they have a prolonged cough, their first movement would be to go to the traditional healer to try to find out what is going on with them."

Dr Ayles estimated that in her door-to-door study, less than half of the people with TB had actually been to the health service.

In Western Kenya, "cough monitors" have sensitised the community, and then gone door-to-door using a more complex symptom screen. To date, they have screened over 45,000 persons and as a result 4,442 smear positive cases were identified and treated.

"We have to be more innovative, we have to find more cases outside the health services as well as inside the health services," said Ayles.

"Although the technical issues around intensified case finding for TB are challenging, we have a reasonable idea what is needed but the real question is not the science per se but how to design the programmatic approach with the patient and their family in mind," Dr Kevin De Cock, Director of WHO's Department of HIV/AIDS told HATIP.

"Programmes need to seriously consider how to make services safe and patient-friendly—the old days of shuttling patients around from service to service in search of answers and treatment need to be replaced with focused efforts to provide patient-centred prevention, care and treatment. Efforts to test and provide HIV care in the home have been

very successful and represent an example of thinking outside the box on this important issue."

Getting the HIV community to buy in to TB activities

In the meantime, healthcare workers engaged in providing care to people with HIV should start with the people sitting right in front of them. Getting HIV programmes to become more proactive about TB has long been a challenge, but this is changing as more and more people from the HIV community are calling for implementation of ICF.

“When we had a stake holders meeting in May, the preliminary draft of intensified case finding guidelines and intensified case finding tools – TB screening tools – were presented not by the TB programme but by the HIV programme,” said Dr Odhiambo. “This increasing recognition, that both the HIV and the TB programmes require each other in this process, is important for Kenya.”

“HIV infected persons are at increased risk for TB from the onset of HIV infection, and this risk only increases over time. HIV care programmes can and must integrate TB screening into longitudinal care,” said Dr Diane Havlir, chair of the TB/HIV working group of the Stop TB Partnership.

“Since cohort analyses of HIV-infected patients reveal high rates of TB both prior to and after initiation of ART, ICF in settings providing HIV care and treatment is a vital part of the package of essential TB/HIV services,” Dr. Tom Kenyon, Principal Deputy Coordinator and Chief Medical Officer for PEPFAR told HATIP.

“Moreover, the timely diagnosis and treatment for TB interrupts transmission and is an important protection measure for patients, healthcare workers and the community. PEPFAR strongly supports the rapid scale-up of ICF through partnerships with host country governments, implementing partners and our multilateral partners, including the World Health Organization and the Global Fund to Fight AIDS, Tuberculosis and Malaria.”

WHO’s Stop TB Department is in favour of HIV service providers taking up more TB services.

"Screening PLHIV for TB, and depending on the outcome of the screening, to provide them with isoniazid preventive therapy and with proper TB treatment should be a core function of any HIV care service,” Dr Mario Raviglione, Director of WHO's Stop TB Department, told HATIP.

"In the last 2-3 years many countries particularly in sub-Saharan Africa demonstrated that successful and rapid scale-up of HIV services to TB patients such as HIV testing and the provision of cotrimoxazole

preventive therapy and antiretroviral treatment for HIV-infected TB patients is possible," he went on.

"These experiences and best practices have to be nurtured and have to be used as models to scale up TB prevention, diagnosis and treatment services to PLHIV so that we can prevent unnecessary deaths from a curable disease"

Again, the approach needs to be patient-centred, as Krista Dong et al wrote in the *Journal of Infectious Diseases*: “for coinfected patients living in poverty, maximizing programme coordination should reduce some of the challenges facing patients seeking HIV and TB care. A system that is responsive to patient needs may help to restore hope and encourage patients to participate in their own treatment success. When patients are empowered and made responsible for their care, they are less likely to experience treatment default.”

"People living with HIV are faced with a number of threats - TB is one of the most serious and in the past they have often faced serious challenges in accessing and benefiting from life-saving TB services,” said Dr. De Cock.

“There are an unprecedented amount of resources being devoted to HIV and TB programmes and now is the time for programmes and communities to work together to address key technical challenges such as intensified case finding, isoniazid preventive therapy and infection control in a way that is patient-centred ...to ensure that patients and their families do not fall in the "gap" between the two programmes."

Grass roots, community-based organisations must be included as stakeholders, and people with HIV should be empowered to help reduce the burden of TB in their community.

“HIV programmes have scaled up dramatically because of strong community-based organisations, who are involved in advocacy, support, testing, care, and treatment. [We] need to engage these groups in ICF, and these groups (i.e., the HIV community) needs to recognise why ICF should be a high priority. Community or faith-based organisations could use [a simple tool] to screen HIV persons in the community and bring them to TB diagnostic services,” said Dr Varma.

“HIV patients already gather together frequently in day care centres and support groups so their baseline exposure to TB is already high. In fact, implementing TB screening into such groups would be a way of keeping the entire group safe.”

In addition, community-based organisations, PLHIV networks and community groups can help generate demand for TB screening among people living with HIV. One place to start is to make certain that people

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with HIV are aware that they should be screened for TB regularly and that they have a right to demand it as part of their routine care, and if they aren't being adequately screened, if their symptoms are not being investigated, then they should hold their healthcare provider and service accountable.

"Not screening people with HIV for TB is tantamount to medical malpractice," said Mark Harrington of the Treatment Action Group at a session during the UWCLH.

And yet, thus far, there has been relatively little pressure from community-based organisations and from people living with HIV to promote more regular screening for TB (or other activities to reduce the burden of TB in people with HIV, such as IPT or infection control).

"Maybe we emphasise too much that TB kills people with HIV rather than saying there are several simple positive actions that individuals can take and that communities can and should demand access to — that can protect people from infection, help prevent active disease from developing, and can identify disease early and improve the chances of cure," Dr Charlie Gilks, Coordinator of Antiretroviral Treatment and HIV Care at WHO's HIV/AIDS Department, told HATIP.

Just like HIV testing and counselling, ICF should thus be seen as a potentially life-saving intervention that is an essential part of HIV services — and that can be implemented *today*.

At the same time, there needs to be a renewed focus on advocacy demanding accountability for ICF implementation from the national government, the public health system, and the local clinic. Likewise, even though external advice and guidelines may not sway programmes to adopt more sensitive evidence-based screening tools, the local community can demand it.

Finally, global TB/HIV activism must demand low cost point-of-care TB diagnostic tools, which could remove the obstacles between screening and diagnosis and move TB diagnosis from the reference lab directly to wherever people at risk of TB/HIV are, in the community or their homes.

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