

# HATiP

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# HIV and TB in Practice in India: Integrating TB/HIV care and other essential health services into 'targeted interventions' for drug users

By Theo Smart

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**There** are over one billion individuals living in India, each with their own face, their own story, and their own needs.

But most public health interventions are generally designed to serve the needs of the many – which are considerable in a country like India. Poverty and a variety of social issues act as barriers to quality health services, that India, a middle-income country, does have the capacity to provide. With so much to be done to improve the quality and access to the health system for so many, the complicated health problems of a minority as marginalised and stigmatised as injecting drug users (IDU) can easily be neglected. At the same time, it can be difficult to convince drug users to seek out care from an understaffed, under-resourced, and unsympathetic health service where they can very easily get lost in the system.

"A drug injector's life is complex and affected by multiple adverse social and health consequences. The IDU and his sexual partner may require many things: primary health care, shelter, drug... treatment, food, HIV counselling, employment opportunities, Hepatitis B and Hepatitis C and antiretroviral treatment (ART)... It is important to link the various agencies offering help and provide coordinated services to IDUs," according to an operational manual on 'targeted interventions,' produced by India's National AIDS Control Organisation (NACO).<sup>1</sup>

NACO, working together with community-based and non-governmental organisations (CBOs and NGOs), is making an effort to see that the health needs of people who inject drugs are addressed through its 'targeted intervention' (TI) programme which offers harm reduction services, a basic package of care, and, as noted in the above quote, facilitates referrals to other services. Some sites also offer opioid substitution therapy (OST) though at present this service only reaches around 4800 clients, though NACO has plans to do more in the future, promising to scale up OST to 40,000 people by 2012.

NACO has also signed onto a nationwide framework to implement TB/HIV collaborative activities for all people with HIV and TB.

Nevertheless, a number of health workers, researchers and clients reported to this writer significant barriers for some drug users accessing ART, TB/HIV services and care for hepatitis C, during a visit to India in December 2009. More funding, training and

support is needed to strengthen and capacitate these community-based organisations to help them effectively link drug users to the full range of services, and to sensitise the Indian health services to better respond to the needs of drug users.

## HIV and the national response

In India, only 0.36% of the adult population is HIV-infected, but in a country the size of India, that still adds up to 2.3 million people living with HIV – the third-highest burden of HIV in the world.<sup>2</sup>

However, the geographical distribution of HIV in the country is quite heterogeneous, with two-thirds of the HIV infections reported in six of India's twenty-nine states (Andhra Pradesh, Tamil Nadu, Maharashtra, Manipur, Nagaland and Karnataka). HIV is more common in urban centres but has recently begun spreading to rural areas.<sup>3</sup>

The HIV epidemic is primarily concentrated in marginalised populations that NACO refers to as 'high risk groups' with a prevalence of 4.94% in female sex workers (FSW) and an even higher prevalence in men who have sex with men (MSM) and transgendered people (7.3%), as well as IDUs (9.19%).<sup>4</sup>

However, since the majority of HIV infections in India have been sexually acquired, NACO is also justifiably concerned about the infection spreading to the general population and thus keeps a close eye on 'bridging populations' such as truckers and migrants who are often the clients of sex workers.

NACO was established in 1992 to implement the first National AIDS Control Programme (NACP-I).<sup>5</sup> The first stages of the programme laid the foundations for India's AIDS response, opening almost two thousand integrated HIV counselling and testing centres (ICTCs) in healthcare facilities; and launching a prevention of parent-to-child transmission programme (PPCTP) and then a programme offering free antiretroviral therapy (ART) in 2004 at selected hospitals in the country.

## Emergence of the 'targeted interventions' policy

NACP-II saw the completion of a nationwide project mapping the distribution and demographics of the high risk groups, which helped guide the development and launch of the 'Targeted Interventions' (TIs) through NGOs that were working with high risk groups: commercial sex workers (CSWs), MSM, IDUs and the bridge populations (truckers and migrants). The Targeted Interventions are community-based, often peer-led, and encouraged to adopt a 'rights-based' approach – seeking to empower their clients while delivering a basic package of services including a behaviour change programme, management of STDs and condom promotion. Other services are tailored to the specific HRG being targeted (see below).

Over the years, there has also been significant outside investment in community-based responses in India; for instance, the European Commission and DFID provided major support for Sharan (one of the very first CBOs providing services to drug users). In November 2002, Bill Gates visited India and announced the launch of the ten-year Avahan India AIDS Initiative Programme, which would eventually lead to hundreds of millions of dollars being channelled to community-based organisations – staffed primarily by HRG members – to strengthen their capacity to develop and provide more effective prevention, treatment and care services to their own peers in India. Over time, NACO will be taking over providing support for the Avahan sites, though there are reportedly significant operational challenges integrating all of these services into NACO's TI framework.<sup>6</sup> Regardless, the Avahan project has helped strengthen civil society in India and the reach of health services into marginalised communities.

NACP-III plans to further develop the programme's infrastructure, systems and human resources, expanding the national strategic information system to better respond to changes in the epidemic, and to provide better care and treatment to more PLHIV.<sup>7</sup> This will mean expanding NACO's treatment services, which presently are highly centralised, and generally located in medical colleges, district hospitals and non-profit charitable institutions. There are currently over 5000 ICTC (HIV testing) sites, and over 261,806 PLHIV on ART at 217 ART centres, and 280 ART link centres (which do not initiate treatment but can provide follow-up care).<sup>8</sup>

Finally, NACP-III hopes to dramatically reduce the incidence of new infections, primarily by preventing infections by achieving saturation coverage of the most-at-risk populations with an increased number of TI sites.<sup>9</sup> But reaching 'saturation' for a hard to reach and difficult-to-measure population is a logistical challenge — and this may be especially true for IDUs, since drug usage can change rapidly based upon the availability of drugs. For instance, there are new epidemics of drug use in some parts of the country, such as Punjab, near the borders of Pakistan.

## Overview of drug use in India

Determining the size of a population that engages in behaviour that is criminalised has bedevilled many researchers and programmes — and often society doesn't want to hear the results when they become available. For instance, the previous government, while it was in office, suppressed results from a combined set of surveys on drug use in India, that were finally published by the UN Office on Drugs and Crime (UNODC) and India's Ministry of Social Justice (MoSJ) in 2004, eighteen months after the report was completed.<sup>10,11</sup>

### Patterns of drug use vary across India

According to NACO's sentinel surveillance system, there are currently 186,000 active IDUs (defined as someone who has injected within the last three months) in the country. Injecting drug use has long been concentrated in the northeastern states of the country, but there are IDUs throughout India, especially in the major urban centres. Timely data on drug-using behaviour throughout India will be critical to implement interventions to prevent new HIV transmission in these settings since HIV (and hepatitis C) can spread very rapidly when a new group of users begin sharing injecting equipment. However, NACO is expanding its surveillance sites to include more areas where there is known to be significant drug use.

Meanwhile, in other areas there are reports that injecting drug use has been decreasing over the last decade.

"If you take Chennai, when we started our work in 1999, the estimated IDU population was around 10,000 but that number has fallen dramatically," said Dr Pramod K. Singh, who is the TI team leader for the Tamil Nadu State AIDS Control Society.

"Yes, it has come down. The population now is 1000 to 1100 injecting drug users," confirmed Dharmaraj Gasper, Director of the Hoper's Foundation Drop-in Centre in Chennai. He stressed that patterns of drug usage are changing.

"The demand expanded about the time of Rajiv Gandhi's assassination 1991 and a lot of people started injecting drugs and using pharmaceutical drugs. It was peaking, and HIV-infections started increasing, at the time we started the drop-in centre in 1997," he said. "But we have many people who are what we call 'shadow users' — people who shift between alcohol, pharmaceutical drugs and brown sugar/heroin, smoking or injecting practices depending upon the price or quality."

"The only thing that we have in Chennai are the pharmaceuticals, very little of heroin. The current situation is that it is very costly - the common man cannot afford to buy heroin right now," said Dr Pramod K. Singh.

"People switch to other drugs when heroin is not available," said Dr Venkatesan Chakrapani, a researcher who works with the Indian Network for People Living with HIV (INP+). "And they usually have a mix of 3 or 4 drugs such as CAT (*Calmpose* (diazepam), *Avil* (pheniramine, an antihistamine with strong sedative effects) and *Tidigesic* (buprenorphine) or PAT, made up of *Phenergan* (promethazine, another antihistamine), *Avil* and *Tidigesic*, or a painkiller, something like spasmoproxyvon, a combination of paracetamol and one synthetic opiate. They call it 'ESP:'"

Because it is more expensive (and potent), people tend to pool their resources when buying heroin and then share both the drug and usually the injecting equipment.<sup>12</sup> However, with the cheaper pharmaceuticals, smaller groups of two or three friends usually mix the drugs and share them — and may not perceive sharing equipment with someone they are close to as putting them at risk of HIV. But contaminated equipment is not the only thing putting drug users at risk of HIV and other infections.

### Sexual risk-taking among IDUs

Among IDUs in India, sexual risk-taking behaviour — with commercial sex workers, under the influence of drugs, and often unprotected — is extremely common, according to several studies.<sup>13,14</sup> Even though a study in IDUs and their wives in Chennai found that the most significant risk factors associated with HIV in the male partners were injecting-related, nearly 60% of them had also reported sex with female commercial sex workers, and 30% reported that the first time that they had sex with a commercial sex worker.<sup>15</sup>

HIV transmission to the female partner is common. In the late 1990s, a study in Manipur, 45% of the wives of HIV-positive injecting drug users were found to be infected with the virus and none of these women had injected drugs themselves.<sup>16</sup> The study in Chennai found that 11 out of 68 (16%) of the wives tested were HIV-infected.<sup>17</sup> And during a visit to the National Institute of Epidemiology in Chennai, which was involved in the previous study, workers reported that 18 out of 85 (21%) wives of HIV-infected IDUs have now tested positive there — and that some of the children — born before the women knew their status and PPCTP could be initiated — are HIV-infected as well.

Injecting drug use among women is much less common in India, but many of the women who inject support themselves through commercial sex work — and do not always insist on condoms if they get paid more.<sup>18</sup> "There are also IDUs who engage in same-sex behaviour though we do not know whether it is because of money or because of their sexual orientation," said Dr Chakrapani.

### Drug users and prisons

IDUs also have a much greater risk of being imprisoned — which compounds many health-related risks. According to one of Dr Chakrapani's studies that involved focus group discussions with IDUs who had been to prison, drugs are readily available, but clean syringes are not, resulting in up to 30 inmates sharing a single syringe.<sup>19</sup> The risk of being exposed to HIV and hepatitis C in prison would thus seem to be much greater — reliable data is difficult to come by, but the prevalence in prison is significantly higher than the general population.<sup>20</sup> Another danger in overcrowded prisons is the much greater risk of being exposed to TB. Health services within prison are extremely limited.

### Access to health care

But even outside of prison, access to health care can be poor — and another partial explanation for falling numbers of IDUs in some settings could be that many who were HIV-infected in the 1990s simply died before getting onto ART, which has only become widely available in the last few years. A recent study from Chennai reported that HIV-positive IDUs have a 3-fold higher risk of death than IDUs without HIV.<sup>21</sup> Another study suggested that rollout of ART has taken longer to reach IDUs. In 2007, a study in Manipur reported that less than 5% of the people accessing ART in the government's programme were current injecting drug users, even though at least 49% of reported AIDS cases in this region were believed to have acquired HIV through injection drug use.<sup>22</sup>

### Other major health issues affecting drug users: hepatitis and tuberculosis

There has been very little in the way of a targeted multisectoral response from the government on other major issues affecting drug users — possibly because there has been little local research to demonstrate the need.

"Why aren't they looking at this particular risk group and broadening out the package of health services they should be getting? Possibly, one of the reasons is that we're not making a strong enough case for it," said Professor Charlie Gilks, who heads UNAIDS in India. "As regards to hepatitis, we've done very little standard hepatitis work, even to define the extent of hepatitis B and C. Some user groups will tell you that there is an enormous amount of hepatitis C here. There are some surveys, which are really based upon some convenience samples, but we haven't gone out to do some properly representative surveys."

Indeed, Hoppers Foundation's staff are very worried about hepatitis C.

"Ninety per cent of our clients are infected with hepatitis C," said Mr Gaspar. "This is a real problem; people are dying because of hepatitis C. For HIV, we can refer them to the ART centre and if they start with ART they are okay, they are fine. But what about hepatitis C?"

Treatment for hepatitis C in India is rarely available. Professor Gilks noted one case in Tihar Prison, where UNODC is piloting care for about 60 IDUs including opioid substitution therapy.

Another case in point is tuberculosis — where the lack of research has made it difficult to demonstrate the relative importance of the condition in drug users compared to the rest of the population.

### TB in India

India has the highest burden of TB in the world with 1.9 million cases annually because of its large population, though it ranks at 17<sup>th</sup> among the 22 high burden country in terms of TB incidence rate per 100,000 inhabitants.<sup>23</sup>

But India is acting aggressively to improve the management of TB in the country. In 1997, the country launched the Revised National TB Control Programme (RNTCP), and it quickly became the largest TB programme in the world, completing DOTS expansion in 2006 (achieving full nationwide coverage). The programme has had dramatic success: in 2008, the programme believes it detected about 72% of the smear positive TB cases, increased the cure rate from 25% (pre-RNTCP) to 86% and cut the TB death rates 7-fold from 29% to 4%.

A large part of the TB programme's success has been due to its decentralisation throughout the health services. The RNTCP sought to end the old system of centralised clinical services for TB. The

remaining stand-alone TB clinics in India are relics of a bygone era and are not the primary entry point to care — but there are around 400,000 treatment sites in the general health system. One doesn't need to seek care from a TB specialist. Any type of doctor can treat TB. In fact, the district TB officer could be a gynaecologist and doesn't necessarily need to be a chest physician. Likewise, any health centre could be a DOTS centre and there are 12,000 microscopy units set up all over the country.

"Somewhere there's a little tiny NGO somewhere, in a slum or tiny village, which has a microscopy unit set up and provides treatment for three people — they're also a DOTS centre," according to Dr Puneet Dewan of WHO India office.

### Challenges for India's TB programme

Despite its success, the TB programme does face some major challenges. First and foremost is that India will continue to have a high burden of TB cases for many years to come because approximately 400 million people in the country are believed to be latently infected.<sup>24</sup> Another issue is that a large proportion of Indians still seek out care for their symptoms from private physicians (outside of the government system), and the quality of care they provide can be variable. That, plus the fact that TB drugs are widely available at Indian pharmacies — are blamed for one of the TB programme's biggest challenges: drug-resistant TB. Again, India has the world's highest burden of MDR-TB: 131,000 cases annually.

Poverty and social exclusion are driving much of the TB epidemic in India, with studies finding that TB was almost twice as common among the poor and marginalised groups.<sup>25,26</sup>

According to Dr Manivannan Muniyandi, a health economist working with the Tuberculosis Research Centre in Chennai, the health seeking behaviour among many in the population is also driven by poverty. He found that TB patients who couldn't afford to seek out private care sooner, waited about a month before seeking out care from the government system. Once they come in for care, it usually only takes the TB programme about a week to diagnose and put them onto treatment (notably private care took *much* longer).

RNTCP's operational research agenda includes studies of interventions to improve case detection and diagnosis among 'vulnerable populations' making special mention of tribal and urban slum dwellers. Although obviously, a 'socially excluded group' there has been little to no published research on the burden of TB in Indian drug users.

Globally, IDUs have 10 to 30-fold greater chance of becoming infected with TB — and TB is likely under-diagnosed, since many of the IDUs with HIV could have hard to diagnose smear-negative and extrapulmonary TB. Drug users are at even more risk if they have been through the prison system — especially in India: one study of 249 inmates at a prison near Delhi found HIV in 3, syphilis in 11, 12 with hepatitis C, 28 with hepatitis B and 25 with pulmonary TB.<sup>27</sup>

### TB services for injecting drug users

There have been a couple of reports on the delivery of services to drug users. One described treatment adherence to DOTS when given with OST and nutritional support at one of the Sharan sites (described later in this report).<sup>28</sup>

More recently, Dr Chakrapani conducted a study on access to TB/HIV care among people who have injected drugs in Imphal for UNODC.<sup>29</sup> However, it is not clear to what extent the sample is representative of the IDUs in other regions of India. The study involved a convenience sample of 97 people with TB who had injected drugs at least once *within the past year* — only 16.5% had injected within the previous month. 57.7% were in private care (and

paying for treatment), 30.9% were attending NGO DOTS centres that have been providing more aggressive TB case finding (Avahan's SASO sites) and only 11% were receiving care through government DOTS centres or referral hospitals. Nevertheless, it still took the majority (73.1%) over four weeks to get onto treatment.

But Dr Chakrapani stressed that his findings may not be generalisable for IDU across India for a few reasons: "IDUs in Imphal are more likely to be educated, living with their family, and relatively well connected to NGOs/CBOs working with IDUs." In fact, many of the participants with HIV were already connected with healthcare settings before they developed TB.

However, one of Dr Chakrapani's findings was that many of the subjects were "initially reluctant to visit the government DOTS centres, because it could be interpreted by acquaintances that they have TB and could be seen as a 'proxy' for HIV infection (in Manipur)."

This would suggest stigma is delaying access to appropriate TB care. When this is combined with already poor health-seeking behaviour, there is a good chance that many active drug users simply never make it into care.

However, for people with HIV in general, NACO and RNTCP are working together to offer TB/HIV collaborative activities.<sup>30</sup> These activities are to be phased in gradually over the next several years, and will include HIV screening of all TB patients, cotrimoxazole for all TB patients with HIV, ART for all coinfecting people with extrapulmonary TB and stage IV HIV disease, and to anyone with pulmonary TB and CD4 cell counts below 350. Meanwhile, people will be screened for TB (intensified case finding) at all the ICTC sites, as well as the ART centres and community care/ART link centres — and sites providing care for people with HIV are expected to implement some basic TB infection control measures (though it is not clear how this is being enforced).

The guidelines even make reference to eventually engaging the CBO/NGO's who delivering the Targeted Interventions to high HIV risk populations. But with a couple of notable exceptions, these activities have yet to be incorporated and made a routine part of the minimum package of services offered by Targeted Interventions.

### NACO's Targeted Initiatives for injecting drug users

At present, NACO is focused on expanding the network of Targeted Interventions for IDUs (which the TI guidelines define as anyone who as injected within the last three months) and making certain they can deliver the current minimum package of preventive and basic health services and establish working linkages to other care sites as needed.

"Harm reduction is the policy in our programme for injecting drug users at the IDU Targeted Interventions," said Sophia Khumukcham, who is the technical officer at NACO for IDU Targeted Interventions. "Along with the basic TI package, we have needle/syringe exchange programmes, our peer counselling program, abscess management and reference services for other health services. And we have certain centres that have been accredited to provide OST."

To help establish such services, NACO has produced clear and concise operational guidelines for CBO/NGOs implementing Targeted Interventions for the high-risk groups, including IDUs.<sup>31</sup> In addition to describing the key IDU intervention strategies, the guidelines explain the step-by-step process of:

- 1 Starting-up an IDU Targeted Intervention, beginning with a rapid situation and response assessment, community outreach and mapping, and how to set up and run a drop-in centre;

- 2 How to deliver the key interventions: from prevention activities (running a needle exchange programme, condom promotion and behaviour change); to providing care (primary care/STI management and establishing a referral system) to creating an enabling environment — which involves local community sensitisation, and working with law enforcement;
- 3 How to set up an OST programme, including the minimum requirements to become a site, how to go about getting accreditation and how to implement OST;
- 4 How to manage and monitor the programme, including making a case for using a computerised management information system (though not necessarily providing adequate funding for this — there were no computers in the Targeted Interventions visited for this report), and a monitoring and evaluation system.<sup>32</sup>

The guidelines also itemises staffing requirements, explains job functions and responsibilities, lists salaries and describes costing for the various interventions.

NACO is establishing Targeted Interventions for drug users in areas where there are at least 150-500 IDUs. According to Ms Khumukcham, "at the end of NACP-II, there were only 92 Targeted Interventions, and the majority of them were in the northeast. Now we have scaled up to 220 Targeted Interventions serving drug users in the country — and this includes 9 in the Punjab" [where drug injecting has more recently begun]. NACO plans to have 380 TI sites in place by 2012 to provide services for 190,000 IDUs.

However, whether the plan will really "saturate" this 'risk group' with prevention and care services is unclear — especially when there are many more shadow users than active IDUs at any point of time, who appear to be part of the same community and to routinely use the services Targeted Initiatives provide.

### Opioid substitution therapy in India

NACO has recognised the critical importance of providing opioid substitution therapy (OST) — both for prevention and to improve adherence to treatment. According to the country's ART guidelines, "OST is the most effective treatment for opioid dependence, and results in substantially higher retention rates, suppression of drug use and improved psychosocial functioning. Its use in the context of HIV treatment has been associated with improved adherence to and outcomes of treatment. Detoxification and abstinence-based programmes are unlikely to achieve similar levels of clinical effectiveness and may prove counterproductive in the context of ART. *If possible, stabilization of substance use with substitution treatment is recommended prior to the commencement of ART.*"<sup>33</sup>

#### A buprenorphine-based system

But scale-up has been slow, especially considering that the first substitution therapy pilots, using buprenorphine, were launched in 1997.<sup>34</sup> During the next ten years, access to OST was increasingly offered by CBO/NGO's working with IDUs — but a little over a year ago, NACO took on OST as a national programme. At present, however, OST is still based on buprenorphine — methadone is not yet available.

"At the time when our proposal for OST was passed by all of the ministries, when it got the clearance from the Expenditure Finance Committee — in June 2008 — methadone had not yet been approved by the government," said Ms Khumukcham. "Plus, we had experience with buprenorphine, so we started with that."

#### Indian guidance on delivering OST services

The TI guidelines list some of the basic steps required to set up an OST site, but NACO has also published separate, more detailed

guidelines on delivering OST. These deal with how to assess clients, staffing requirements, how to administer the drug and provide follow-up. The guidelines include standardised intake forms, consent forms, prescription forms, a checklist for side-effects, and referral forms.

There are also standardised forms to keep track of the medication, with a simple client dose sheet, a dispensing register and daily stock register to be maintained by the nurse, and a central stock register kept by the project coordinator noting when stock comes in and when he gives it to the nurse. The guidelines note that there needs to be "storage space for drugs, e.g., cupboard for OST, STI drugs, and other material," but do not demand secure vaults and alarm systems as in some countries.

However, not all of the NGOs that were dispensing OST when NACO took over the programme have been able to continue. Previously about 63 sites were distributing OST to 6000 clients, but after government inspection only 47 were accredited. This has since increased to 50 delivering OST to 4800 clients but is well below the 40,000 target for the end of 2012.

### Challenges in scaling up OST in India

"The issue is: can we scale it up?" said Dr Neeraj Dhingra, the Assistant Director General of NACO. "To scale it up more quickly, can we engage the many government hospitals which are already acting as de-addiction centres?"

There are several hundred centres run by the MoSJ and the Ministry of Health in India, offering detoxification, de-addiction and rehabilitation, but these abstinence-oriented services are underfunded, and the services they offer are minimal.<sup>35</sup>

There are referral linkages between OST sites and de-addiction centres — in fact, the stated goal of OST in India is to wean people off drugs within a year. It is not clear how strictly the programme will insist on this — according to Mr Gasper, complete abstinence is rarely achieved quickly, and when it is, "it is usually followed by a relapse shortly afterwards then we have to start all over again at a higher dose."

Another concern is that treatment of the drug user can be poor at some 'detox and de-addiction' sites.

"So many drug users have been put in inhuman conditions i.e. they are chained, beaten up. And in fact we have filed a case against one of the detox centres in Punjab because of the death of a drug user," said Ms Singh. "The other thing is that this only works when you have the involvement of drug users in the programme. Even if they put OST into government facilities they are going to have to factor in the community somehow. Only the community can draw these people in for services. Nobody else can."

"We have been struggling with whether this government facility will be able to give OST respecting the client's privacy, with the good attitude and the type of services that are at the [Targeted Intervention]," said Dr Dhingra. "So we have planned a feasibility study first — we would like to see how many of the government institutions, which are in proximity to the IDUs, can really take it on."

Some outside experts believe that if the programme started using methadone — and a pilot is being planned — NACO would be able to scale up OST more rapidly. But not everyone in India is convinced. One issue is that NGOs have a proven track record delivering buprenorphine but there is perception that methadone will be more complicated for them to deliver.

"We have quite a lot of people on a waiting list. The supply of buprenorphine is not the problem. Ever since the government has taken over the procurement of buprenorphine, the centres are flooded with medicine. But what is not in place and what is not there is the money or the funds to run the OST sites," said Shalini

Singh, who works for Sharan, the first NGO to provide OST. "The challenge is getting the qualified staff - say, nurses or doctors. Doctors are so poorly paid — and the prime time for a medical doctor to earn is the morning time. That's when you require the doctor's presence at the drop-in centre. And when you have such a low budget, you can't get them."

Workers at the OST sites visited for this report, agreed that the chief barriers for CBOs scaling up OST were the staffing requirements — particularly the difficulty recruiting qualified staff at the low rates the government is paying — and the need to set up drop-in centres convenient to IDUs, who are often in other districts.

"We have 100 clients on OST, and probably provide OST to another 100 clients in Chennai," said Mr Gasper. "The problem is the distance. Access to a drop-in centre should be one to two kilometres so they can walk to it. If we could set up a drop-in centre like this in south side or in central Chennai, more IDUs will have access to services. Travelling is the problem — from there to here, they have to spend 20 to 25 rupees a day. For that money they can go for one shot of heroin."

### The debate over methadone-based OST

Ms Singh acknowledged methadone might be cheaper than buprenorphine, but that it comes with other costs. "Methadone requires more monitoring, buprenorphine is an easier, safer drug, that doesn't have such significant interactions with ART and rifabutin. And leading advocates who are drug users in other countries prefer to take buprenorphine themselves — people need to listen to what the drug users want."

Rifampicin, a key drug used in TB treatment, reduces methadone levels. Efavirenz, nevirapine and some of the protease inhibitors may also reduce methadone levels, and rifampicin also reduces levels of nevirapine and protease inhibitors, leading to the recommendation that efavirenz is the preferred third agent in antiretroviral therapy for TB patients.

WHO's 2006 antiretroviral treatment guidelines recommended that if an NNRTI is being used in combination with methadone, the methadone dose should be increased by 5-10mg every 1-2 days in a step-wise fashion until withdrawal symptoms cease, with methadone dosage adjustment likely to be required seven days after starting ART.

This complex web of potential drug interactions in patients with TB/HIV coinfection, which requires close monitoring of opiate withdrawal symptoms in OST patients and prompt dose adjustment by clinicians with a good understanding of the drug interactions, is difficult to manage in any setting, especially where patients have a long journey to a clinic. The response to withdrawal symptoms in this situation is more likely to be an attempt to self-manage by resuming injecting drug use.

Buprenorphine has no clinically significant interactions with NNRTIs, but levels may be reduced by rifampicin, requiring a dose adjustment if opiate withdrawal symptoms occur.

As an alternative, rifabutin can be used instead of rifampicin, since this drug does not reduce methadone levels.

NACO also has concerns with safety— and whether India's drug control agencies will insist on prohibitively restrictive control of the drug.

"If the dosage is not properly regulated in methadone it can create problems. If there is even one problem, it could just destroy the whole OST programme. We need to be very careful of that," said Dr Dhingra. "The second issue is: are our NGOs capable of giving methadone without secure dispensaries? If they can, we will do it with the best ones that we have got. But we need to be very sure what systems and what procedures need to be set in place for

methadone. My gut feeling is that, if buprenorphine is giving the desired effect, why do we want to waste our time in setting up another system?

"It takes time for us to set up in India – it's a huge country. With buprenorphine we've already institutionalised a system. It's one thing if we find methadone can be easily incorporated into the existing without major changes. But if you ask me to change that whole system, I'll do it only if I'm convinced that methadone has much stronger beneficial effects than buprenorphine."

## Integrating TB/HIV into the Targeted Interventions

There also appears to be an ongoing debate the extent to which TB/HIV collaborative services can be integrated into the Targeted Interventions.

As noted earlier, most Targeted Interventions have been managing TB via referrals. Once TB is diagnosed, clients can choose their DOTS providers. In some cases, NGO sites, such as the Sharan and Hopers Foundation OST sites have been able to work out arrangements with DOTS providers to allow them to provide the TB treatment along with OST. In some cases, NGOs have become DOTS providers, like some of the Avahan sites.

But according to Dr Anjana Das of Family Health International (FHI) in India, which helps Avahan clinic develop clinical capacity, TB/HIV collaborative activities including TB screening have also been implemented at the Avahan Targeted Initiatives in Manipur and Nagaland (which are both high-burden IDU settings) – and intensified case finding is significantly increasing the number getting onto care.

For the Avahan programme overall (not just services for IDUs), the proportion of confirmed TB cases initiating treatment has increased from 56.8% to 87.7% (between the second quarter of 2008 and the first quarter of 2009).

"Intensified case finding is being carried out at the field level by peer educators and outreach workers, so this also covers those individuals who are not availing clinic services. The active TB screening in the field identifies TB suspects who are then referred to the clinic," said Dr Anjana. "Once at the clinic, the physician/nurse confirms the presence of TB symptoms before referring them to the nearest DMC (district microscopy centre) for sputum microscopy."

First, training materials on TB/HIV and a monitoring and evaluation framework had to be developed. Memorandums of understanding (MOUs) were drawn up between the sites and the local RNTCP units, linkages and referral systems established.

Then the NGO staff had to be trained.

"We developed a two-day TB training package for outreach workers and peer educators," she said. The clinic staff (physicians, nurses and counsellors) were trained using materials that RNTCP provides online [see training materials under <http://www.tbccindia.org/documents.asp>].

Dr Das believes ICF should be scaled up so all HRGs can be screened once in 3 months and that NGOs should develop better referral systems for completing diagnostic procedures and DOTS provision.

The success of the model has influenced the roll out of new RNTCP TB-HIV scheme for NGOs comprehensive care for the clients they serve (see box).

Until such a time as NACO integrates intensified case-finding into the Targeted Initiatives, RNTCP is offering a TB-HIV scheme to promote provision of essential TB screening and referral services by organisations dealing with high-HIV prevalence populations. The

scheme involves a grant of Rs 120,000 per NGO per 1000 population – the only trouble is, most IDU Targeted Interventions are much smaller than that.

But Dr Dhingra believes integrating these services into the Targeted Interventions might be a little over-ambitious – and he is afraid of setting up a system that may not be sustainable.

"The NGOs are supposed to refer the patients for TB diagnosis if they think they have symptoms or have them all checked out at first. But we don't want to burden NGOs too much in that respect – the thing is that we let them do the core job that they are doing," he said. "There's a danger that the NGO could lose its whole identity – its main job also is to get the IDU, and to get them OST and ART also."

Components of "Comprehensive TB Care for high-HIV risk populations"	
Intensified TB Case Finding:	<ul style="list-style-type: none"> <li>● TB symptom screening through outreach workers and peer educators at the time of each interaction with the member of target population &amp; referral of suspects for diagnosis &amp; treatment</li> <li>● TB symptom screening for clients attending these NGO clinics</li> </ul>
Patient friendly approach for diagnosis and treatment categorization	<ul style="list-style-type: none"> <li>● Sputum collection &amp; transportation or facilitated referrals</li> <li>● NGO staff to coordinate with the existing government health facilities for the diagnosis of smear negative pulmonary TB (for X-Ray) and extrapulmonary TB (for FNAC, etc)</li> <li>● TB treatment categorisation by NGO clinic medical officer</li> <li>● Undertake address verification before initiation of TB treatment</li> </ul>
Treatment provision	<ul style="list-style-type: none"> <li>● Treatment delivery to be organized by NGO by identification of appropriate community DOT provider in consultation with the diagnosed client/ DOT provision through NGO staff if convenient to the TB patient</li> </ul>
Adherence	<ul style="list-style-type: none"> <li>● NGO staff to ensure timely follow up of the patient and also undertake patients retrieval action in case of treatment interruption;</li> <li>● Coordinate with local RNTCP programme staff to ensure smooth transfer, in case of anticipated migration of patient</li> <li>● Monitoring, Supervision &amp; Recording (on treatment cards) by NGOs</li> </ul>
Monthly meeting: DTO/DNO and NGOs	<ul style="list-style-type: none"> <li>● Coordination</li> </ul>
Outreach activities by NGOs, outreach workers to include ACSM	<ul style="list-style-type: none"> <li>● Increase visibility of RNTCP for HRG (High Risk Group).</li> <li>● Community capacity building/CBO/community involvement in TB services</li> <li>● Advocacy with PLHA networks for TB control</li> </ul>

“So we’ve discussed the possibility of having a doctor come to the NGO facility, to see patients on a particular day, and within a few weeks, you can see all the clients at the site, because one infectious disease unit only caters to about 400 patients. Any doctor can do this in India. We can also train the infectious disease doctor to refer the cases with high index of suspicion to the district microscopy centre.”

“But we also need some special referral mechanism for them. It’s not as simple as you simply refer anyone with HIV to the clinic and he will get care. I know that it won’t work out like that. If you send an IDU and he has to wait there a few hours... it’s three to four hours. An IDU may run off.”

“Personally I would not at all be confident in TB/HIV integration at Targeted Interventions for drug injectors. There is a lot of capacity building required among the NGOs and its staff for this to happen,” said Mr Gary Reid, a specialist on drug use at WHO in India.

### The experience in the field: Sharan and the Hopers Foundation

Visits to some of the NGOs running Targeted Initiatives and OST sites found that capacity is indeed stretched — and there are a number of other operational challenges as well.

Sharan has set up numerous drop-in centres and services in India. At one time, it was running 19 sites offering OST, but it has given most of them over to NACO and State AIDS societies. It now has four sites providing OST to between 1000-1200 clients. Sharan TI-1 in Delhi is one of original the sites, that started out as a drop-in centre in the late 90s, and began providing OST in 2003. It has now been transferred to the government though there have been some painful adjustments in the process (see below). Hopers Foundation was initially linked with Sharan as well, but is now funded by the Tamil Nadu AIDS Control Society.

The care offered at both Sharan TI-1 and Hopers Foundation seemed attentive, though there are challenges at each site.

They both provide treatment on the premises for basic health issues, including abscesses and STDs. They do not provide HIV testing onsite, but rather take new clients and regular HIV-negative clients (routinely every three months) for HIV screening to the nearest counselling and testing centre (ICTC). In the case of the Sharan TI-1 site, the nearest ICTC was a 15-minute walk away.

Hopers’ staff said that they have gotten about a third of their HIV-positive clients on opioid substitution therapy onto ART, at one of two ART sites, one six, the other eight kilometres away.

“Each site tries to provide accompanied referrals for other services: without it they will not go,” said Shabab Alam, who is the Sharan TI-1 site’s Project Director. However, this presents a problem for NGOs, because sometimes the client is too ill to walk — but the TI budgets don’t include funding for transporting clients for referrals.

“Most of the time because our client is not well, somebody has to take them in the rikshaw, And the Delhi government has not given any funding for transportation of clients or accompanied referrals in the budget,” said Mr Alam.

“We will pool our own money from our own pockets because in the project there is no money for travelling,” said Mr Gasper.

“There is some amount of cost attached to referrals and government budgets hardly have any scope, or if they do it’s limited and only facilitates referrals for say, 10 or 20 IDUs,” said Ms Singh. “So now you have to pick and choose and what would be the criteria? It’s like, who needs it the most?”

This clearly could affect the ability to get TB suspects in for diagnosis, and Ms Singh noted one other problem — “only our smear-positive clients are being diagnosed. We are struggling with

that, whenever a client comes in with the negative result, I try to send them again. Maybe I can talk to the doctor. If he is HIV-positive, it may require a culture — and you have to pay for that.”

Dr Chakrapani’s TB study noted the same thing in Imphal — people who require culture are referred to private labs — and the cost of culture ranges from 750 Rs (for solid culture which can take up to two months to 1700 Rs for liquid culture.

Mr Alam says that the switch to being funded by the state has been rather painful.

“Before this became a government site, we used to be able to provide more services, now there’s not enough funding, there’s not enough staff — it’s very difficult to run these projects,” he said.

One of the Sharan projects was the DOTS service that also provided OST clients with nutritional support — to great effect, but Ms Singh said that they had to discontinue the service once it became a government site.

Both Ms Singh and Mr Alam were concerned that the government’s TI / OST staffing guidelines were too restrictive.

“For oral substitution, you have to choose between a nurse and a counsellor. But our experience with OST has been, how can you do without a counsellor? And the nurse is equally essential. And the pay package for the staff is so low that you can’t get the qualified minimum requirement,” said Ms Singh.

“So if one outreach worker handles fifty IDUs, what kind of quality service are you providing — and he has to manage around twenty peer educators — who are from the community, in other words often active IDUs. So we have to think about the use of these resources to have as much impact as possible.

“Sometimes I feel like leaving this work because there are not enough resources, not enough staff - how should I do my work?” said Mr Alam. “For instance, what about TB infection control? The government and NACO need to think and talk about this — and the nurses and other healthcare staff also have their health rights to be considered. The government has only given the funding for one syringe and two needles [per client per visit] - and the requirement is more. I think it is around 3 syringes every day and 6 needles. The other day the clients were saying: ‘You are spreading HIV, you are not giving us our requirement.’ They think we are holding money back from them. But it is not our fault, whatever we are receiving we are giving to them.”

Such constraints can make it difficult for NGOs to provide the personalised attention that these clients require — or to keep track of just what happens with every referral. One of Dr Chakrapani’s recent studies in Chennai reported that doctors were still reluctant to put IDUs onto ART for fear that they wouldn’t adhere — and doctors said they could not tell who was a current drug user and who wasn’t. For this reason, many clients keep their drug using history secret — even some of those currently on OST.<sup>36</sup> A couple of clients at Hopers confirmed that this was indeed the case.

One, with HIV, was on opioid substitution therapy (for four months) as well as TB treatment, but not on yet on ART — despite the fact that he had a CD4 count of 22. In addition, although his DOTS provider had given Hopers his TB medicines, he had not been prescribed cotrimoxazole either. This was something that Hoper’s doctor could remedy once it was brought to his attention — but the staff attending to the client did not know that at the very least he should also have been receiving cotrimoxazole. Additional training, and patient registers that more closely keep track of essential TB/HIV services might help ensure that the clients are receiving all the care that they need.



## Knitting together a more supportive network

NACO acknowledges that people can fall through the cracks in the system still.

"When we're talking about smaller numbers, people do tend to get overlooked," said Dr Rahul Thakur, National Program Officer for the National AIDS Control Organisation (NACO). "Even if there are 180,000 people who inject drugs — in a country of the size of India — it is certainly possible that some could be missed."

He stressed that stigma often causes clients to go to doctors who treat them well but may not be well versed on government policy. But this is all the more reason to make certain that NGO staff are well-informed about TB/HIV care.

To some extent, NACO has placed the entire responsibility for making sure the IDU gets the essential services they need onto the CBO/NGOs — because they indeed seem to be the best bet for reaching IDUs and providing them with compassionate care. But it is important to remember that these organisations come out of under-resourced communities, and may need substantial support. Some develop more capacity than others, and it may be somewhat unreasonable to expect a consistently high quality of service.

TB/HIV remains a crisis for drug users and is only beginning to be addressed. At present, access to TB diagnosis and treatment services is not assured and certainly not oriented to drug users — though NACO is thinking about how to make services more convenient and accessible. But even with accompanied referrals, linkages to clinical services do not always go smoothly for IDUs — in particular where there is no budget when transportation is required. Meanwhile, other serious health issues affecting drug users, such as hepatitis C, have yet to receive due attention from the government. It's easy to recommend making referrals to hepatitis care, but difficult to do if no one is providing it.

India is working to increase access for people who inject drugs to HIV prevention, care and treatment and other essential care — and developed a new framework to introduce TB/HIV collaborative activities into HIV services.

Finally, while NACO has taken on coordinating many aspects of the care drug users are receiving, a more multisectoral response will be required to make certain this population receives.

In short, India is taking some important and positive steps but still has a long way to go before most drug users receive equitable access to truly holistic care.

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## WHO issues updated TB treatment guidelines

### Experts say lack of trials in TB/HIV patients 'striking'

Treatment regimens for tuberculosis should include an antibiotic of the rifamycin class for the full six months of therapy, according to new World Health Organization TB treatment guidelines.

They also recommend that treatment should be taken daily during the intensive, four-drug period of induction treatment, and that HIV-positive patients should take daily treatment for the entire duration of their tuberculosis (TB) therapy.

Antiretroviral therapy is endorsed in the guidelines for HIV-positive patients with active TB, regardless of their CD4 cell count.

The new guidelines also recommend provider-initiated HIV testing for all TB patients regardless of a country's HIV prevalence, and drug susceptibility testing for all TB patients with HIV at the beginning of a treatment course.

Earlier editions of the guidelines had supported only two months of rifamycin therapy, and thrice-weekly dosing during the intensive, two-month induction phase of TB therapy. The rifamycin class of antibiotics includes rifampicin (the drug most commonly used in TB treatment), rifabutin and rifapentine.

The release of the new guidelines coincided with the publication of a review article that expressed "serious concerns" about earlier guidance for the treatment of the infection in patients with HIV.

A systematic review and meta-analysis published in the May 1<sup>st</sup> edition of *Clinical Infectious Diseases* commissioned by the World Health Organization to assist in the development of the guidelines, showed that the best responses to TB treatment were seen in HIV-positive patients who received rifamycin-based therapy for at least eight months.

Daily, rather than intermittent dosing during the induction period, and the use of concurrent antiretroviral therapy were also associated with better outcomes in people with TB/HIV coinfection.

#### Duration of rifamycin therapy

Six months of treatment including a rifamycin is now endorsed by WHO for all TB patients.

They recommend that for the intensive, two-month induction phase of treatment, standard therapy should comprise isoniazid, a rifamycin, pyrazinamide and ethambutol.

Treatment for the following four months should comprise isoniazid and rifamycin.

According to the new WHO guidance, patients with HIV should receive a minimum of six months therapy.

The authors of the meta-analysis found that HIV-positive individuals who received only two months of treatment with a rifamycin had an 80% increase in their risk of death compared to patients who were provided with eight months of treatment (adjusted risk ratio [ARR], 1.8; 95% CI, 1.0-3.1,  $p = 0.03$ ). Only two months of therapy including this class of drug was also associated with a modest increase in the risk of treatment failure (ARR, 1.3; 95% CI, 0.4-4.1).

A moderate increase in the risk of relapse was associated with six months of such therapy compared to eight months (ARR, 2.4; 95% CI, 0.8-7.4).

#### Frequency of dosing

HIV-positive patients should receive their TB therapy daily for the entire duration of their treatment, according to the new WHO guidance.

Daily treatment is also recommended for all other patients during the two-month induction phase of therapy, and is preferred for non-HIV patients throughout the course of treatment. Three times a week dosing for this patient group should only be considered where every dose is directly observed. Daily dosing is recommended for all patients in HIV-prevalent settings.

The meta-analysis found that intermittent, thrice-weekly dosing during the initial treatment phase was associated with significantly poorer outcomes than daily treatment for patients with HIV.

"Our meta-analysis has demonstrated that rates of failure and relapse are lower if therapy is given daily during the initial intensive phase", write the authors of the review article.

This also showed that patients who received intermittent doses were more likely to experience treatment failure (ARR = 4; 95% CI, 1.5-10.4,  $p = 0.02$ ), and relapse (ARR = 4.8; 95% CI, 1.8-12.8,  $p = 0.002$ ).

#### Concurrent antiretroviral therapy

HIV-positive patients with TB are now recommended to start antiretroviral therapy as soon as possible, and within eight weeks of the commencement of TB therapy.

Antiretroviral therapy is also endorsed for all HIV-positive patients with active TB, regardless of their CD4 cell count.

The meta-analysis found that taking concurrent antiretroviral therapy was associated with reductions in the risk of treatment failure and relapse. However, these reductions did not meet the test for statistical significance.

#### Concern over lack of evidence

The authors of the meta-analysis were shocked by "the paucity of well-designed and adequately powered randomized trials of HIV-TB coinfection treatment. Despite the estimated annual incidence of 1.3 million persons with HIV-TB coinfection, very basic treatment questions remained unresolved."

Just six randomised, controlled trials and 21 cohort studies of sufficient quality to be included in their analysis were identified by the investigators. Moreover, most of these studies were small, the largest including just 553 patients.

"Randomized trials to address the questions raised by this review regarding treatment of active TB in HIV coinfecting patients are urgently needed", comment the authors.

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## Notices

### 2nd International Workshop on HIV Pediatrics

16 – 17 July 2010, Vienna, Austria

Website: <http://www.virology-education.com>

This workshop aims to bring together virologists, pharmacologists, pediatricians, obstetricians/gynecologists and other interested researchers to present and discuss the latest developments in the field of HIV Pediatrics, Drug Development, and Prevention of Mother to Child Transmission.

The program will include important topics such as:

- Rationale behind newly revised WHO pediatric antiretroviral treatment and prevention of mother to child transmission guidelines
- Prevention of mother to child transmission and program implementation
- Antiretroviral treatment of HIV in children, including adherence issues and managing children with treatment failure

- Co-infections in HIV-infected children, including vaccine-preventable diseases and immunization issues
- Complications of HIV infection in children, including metabolic and neurocognitive complications
- Adolescent HIV infection
- Interaction of nutrition and pediatric HIV infection and its treatment
- Psychosocial issues in pediatric HIV and families

*Important dates:*

*Registration Timeline (CET)*

*Early: 24 March - 7 May 2010*

*Regular: 8 May - 4 June 2010*

*Late: 5 June - 2 July 2010*

*On-site: 16 and 17 July 2010*

*Abstract submission: 24 March - 7 May*

## about HATiP

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The newsletter is edited by Theo Smart (Cape Town) and Keith Alcorn, NAM's Senior Editor (London).

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