Federal Ministry
for Economic Cooperation
and Development

Opioid substitution therapy in Nepal

Learnings from building a national programme

A publication in the German Health Practice Collection

Published by: giz Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

German Health Practice Collection

Working together to generate and share learning

The German Health Practice Collection (GHPC) is a joint initiative of the German Federal Ministry for Economic Cooperation and Development (BMZ) and its implementing agencies, the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH and KfW Development Bank (KfW), which are known collectively as German Development Cooperation (GDC). Since 2004 the Collection has involved experts working in German-supported health and social protection programmes in a collaborative knowledge management process, seeking to identify, document and share knowledge generated during the implementation of programmes around the globe.

From 'good practice' to learning from implementation

In 2015 the Collection shifted its emphasis from trying to capture 'good practice' towards generating new knowledge about the delivery of development interventions. Guided by 2-3 key questions, each case study in the Collection analyses how German programmes and their partner institutions have approached a specific development challenge, how they dealt with difficulties and adapted their approaches accordingly, and what they learned in the process about effective implementation.

Creating ownership through a collaborative process

Since its establishment more than a decade ago, the Collection has helped to catalyse a vibrant community of practice among health and social protection experts through its inclusive and participatory selection and production process.

Each year GIZ and KfW staff from around the world are invited to submit and jointly discuss proposals for experiences they believe should be documented in detail. Through their active participation in the selection process, they help to turn the Collection into a co-creation whose case studies reflect issues and themes which the community regards as worthwhile.

Guided by this assessment of the proposals' merits, BMZ decides which proposals will be documented. Professional writers are contracted to develop the case studies in cooperation with programme staff and their partner institutions, and in close consultation with GHPC's Managing Editor. Prior to publication, independent peer reviewers who are international experts in their fields review the case studies and comment upon the new insights which have been generated.

www health.bmz.de/good-practices

@HealthyDEvs

fb.com/HealthyDEvs

More information about the German Health Practice Collection can be obtained by contacting the Managing Editor at ghpc@giz.de or by visiting the Collection's homepage health.bmz.de/ghpc where all case studies, as well as related materials, are available for download.

■ ***Front cover photo:*** *Opioid substitution therapy is available at seven public hospitals and four NGO-run sites in four regions of Nepal. Here, a nurse passes a dose of liquid methadone to an OST patient at an NGO-run site in Kathmandu.*

Contents

Executive summary 4

Out of harm's way 6

Reducing the harmful effects of opioid dependence 8

Harm reduction comes to Nepal 11

Building an opioid substitution therapy programme in Nepal 15

Results 30

Learning from implementation 31

Peer review 33

Acknowledgements 34

References 35

Acronyms and abbreviations

ART	Antiretroviral Therapy
BMZ	Federal Ministry for Economic Cooperation and Development, Germany (Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung)
GDC	German Development Cooperation
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH
M&E	Monitoring and Evaluation
NCASC	National Centre for AIDS and STD Control
NGO	Non-Governmental Organisation
OST	Opioid Substitution Therapy
SPARSHA	Society for Positive Atmosphere and Related Support to HIV and AIDS in Nepal
SSU	Social Support Unit
TUTH	Tribhuvan University Teaching Hospital
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

Executive summary

Box 1. Key Learnings

It is possible to build a national OST programme in a setting where the legal, technical and financial prerequisites are weak or absent. International models need to be adapted at governance, programme, and service delivery levels in order to establish a tailor-made policy framework, financing arrangements and quality clinical and social services.

When there is not a clear political commitment to harm reduction, expanding OST is likely to be slow and inefficient. OST should ideally be launched with an agreed plan for national scale-up, moving from the establishment of model sites to the gradual extension of standardised services. A robust M&E system is crucial to generate local evidence of effectiveness.

Introducing OST as part of a national HIV strategy can help to get the service started, but does not guarantee its longer-term sustainability. When launched as an HIV prevention intervention, there is a risk that OST becomes dependent on HIV-related funding and administered as a vertical programme. Instead it should be embedded in a broader public health- and human rights-oriented drug policy committed to comprehensive health care for people who use drugs.

Ex-drug users have a central role to play not only in advocating for treatment and rehabilitation services, but in actually delivering them. The direct involvement of ex-users in the provision of psychosocial support in OST programmes can help to close an enormous service gap in settings where few social workers are available.

This case study explores learnings generated during the establishment of Nepal's national opioid substitution therapy (OST) programme, a process which has been led by the government of Nepal and Nepalese civil society organisations with support from German Development Cooperation and other international development partners.

The challenge: Injecting drug users in Nepal lack harm reduction interventions

The estimated 52,000 people in Nepal who inject drugs face a range of health problems, including an elevated risk of blood-borne infections: nationally 6.3% of people who inject drugs are HIV-positive and between 22 and 47%, depending on the region, are infected with hepatitis C. People who are dependent on drugs struggle to access comprehensive health and psychosocial care. The government plays a limited role in the provision of treatment and rehabilitation services. Privately-run programmes are of variable quality, are unaffordable for many, and generally favour abstinence-based approaches which are associated with high relapse rates. Although Nepal was the first country in Asia to allow harm reduction interventions for people who inject drugs, it has not fully embraced a public health approach to drug use.

The response: Building a national opioid substitution therapy programme

Since 2009, through a series of technical cooperation projects on harm reduction implemented on behalf of Germany's Federal Ministry for Economic Cooperation and Development (BMZ), the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) has worked with national and international partners to expand the availability of OST in Nepal. Starting from an existing pilot project authorised by the Ministry of Home Affairs, and informed by Germany's own experience with OST, advisors with the harm reduction projects have systematically built up six pillars of a sustainable national OST programme.

In order to strengthen the **policy framework** and to position OST as a public health intervention, the project advocated for the Ministry of Home Affairs to share responsibility for OST with the Ministry of Health and to allow the service to be administered at public hospitals and by non-governmental organisations (NGOs). Key policy documents – e.g. management guidelines, clinical guidelines and standard operating procedures for the provision of psychosocial support services – were developed and approved. The project helped to secure **stable financing** for a scaled-up OST programme from the Global Fund to Fight AIDS, Tuberculosis and Malaria, which has been covering the costs of medical and psychosocial support services for OST patients in Nepal since 2011.

At the same time, the project improved the **clinical provision of substitution therapy** by training a cohort of OST doctors and nurses according to a standard curriculum, providing continuous on-the-job coaching, and working with the German company CompWare Medical to set up fully automated methadone dispensing machines with integrated patient documentation systems at each OST site. In the absence of qualified social workers, the project trained ex-drug users working for NGOs to provide **psychosocial support services** to OST patients. A training curriculum and standard operating procedures to guide the work of Social Support Units were developed through a participatory process. Training curricula for both medical and social support staff emphasise OST as one part of **comprehensive care for people who inject drugs**. OST patients are referred for additional services as needed, including screening for HIV, tuberculosis and hepatitis.

To strengthen systems for **monitoring and evaluating** OST, the project supported the establishment of patient record-keeping systems at OST sites and built the organisational capacity of two local institutions to take over the training and supervision of Medical and Social Support Units following the end of German support for harm reduction in mid-2016.

What has been achieved

- OST has been elevated to the status of a national programme under the Ministry of Health and is implemented in cooperation with the Ministry of Home Affairs in accordance with country-specific policy documents aligned to international standards.
- Through continuous sensitisation and advocacy for OST, harm reduction approaches for people who inject drugs have attained greater prominence in Nepal and have added weight to civil society-led efforts to reform national drug policy.
- Innovative approaches which bring together governmental and non-governmental actors in the delivery of OST (e.g. NGO-run sites and the provision of psychosocial support by ex-drug users) have been integrated into the design of the national OST programme.
- Using approved national training curricula developed by the project, more than 60 clinicians and 90 ex-drug users have been trained to work in the OST programme. Tribhuvan University Teaching Hospital and the NGO Recovering Nepal have assumed responsibility for training and supervising OST Medical and Social Support Units.
- Psychosocially-assisted OST is provided on a decentralised basis at seven public hospitals and four NGO-run sites to approximately 900 patients in four regions of Nepal. Both methadone and buprenorphine are approved for use.

Out of harm's way

Tucked away on a steep hillside, behind a five-story building in a residential area of central Kathmandu, is a patch of overgrown grass that a decade ago served as a 'shooting gallery.' Dozens of people would gather day and night to buy, smoke and inject drugs – often sharing needles and other equipment with one another – and would sleep in the grass under the open sky. Neighbours resented the presence of these unwelcome visitors, but rarely called the police for fear of retaliation.

Today, the building right next to this former shooting gallery is home to SPARSHA Nepal,[1] a dynamic community-based organisation which offers a wide range of clinical and psychosocial support services to people living with HIV, many of whom are current or former drug users. More than 200 people are enrolled in anti-retroviral therapy (ART) at the SPARSHA clinic and another 70 are being treated for tuberculosis. An on-site crisis-care facility offers housing and support for people being initiated onto ART and a new unit is being set up to test for and advise people infected with hepatitis C. Since its founding, in 2002, more than 1,500 people have sought and received services from SPARSHA.

Prashant Maharjan and Rajesh Desar are among them. In their early twenties, Prashant and Rajesh are close friends who grew up on the outskirts of Kathmandu and began using drugs while still in school. At the urging of their families, they tried to quit and entered an inpatient rehabilitation programme together. But as is the case for many people who are dependent on opioids, abstinence-based treatment did not work for them. 'In rehab, they told us what to do down to every last detail,' Prashant explains. 'But as soon as we came out, we started using again.'

Last year they decided to try a different approach and enrolled in a newly-launched opioid substitution therapy (OST) programme at SPARSHA. Every day they pay a visit to a small OST clinic where a nurse calls up their files on the computer and an automated dispensing machine measures out their prescribed doses of liquid methadone, a long-acting opioid which reduces symptoms of withdrawal and limits their cravings for drugs. They meet at least once a week, individually or in small groups, with a trained counsellor and are also seen periodically by the programme's medical doctor, who monitors and adjusts their methadone doses and can refer them to the SPARSHA clinic for other health services they might require.

■ *Opioid substitution therapy can bring stability to the daily lives of people dependent on opioids. Since enrolling in OST, Prashant Maharjan and Rajesh Desar have been able to resume their studies.*

[1] Society for Positive Atmosphere and Related Support to HIV and AIDS in Nepal

The World Health Organization (WHO) recommends OST as an effective intervention for reducing illicit opioid use and the harms associated with it, and for improving the quality of life of people dependent on opioids. Patients who are stabilised on OST are less likely to inject drugs – and therefore less likely to become infected with blood-borne viruses, such as HIV and hepatitis C – and more able to manage normal daily routines, including work, studies and family life. OST has had precisely this effect on Prashant and Rajesh. Since enrolling in the programme, the two young men have resumed their studies and are managing to keep up with their school work – something that a year ago was impossible. As a reward for their good performance in the programme, the SPARSHA counsellors arranged for them to participate in a computer training course, which they successfully completed, and are now helping them to find part-time jobs.

'Our approach is to deal with the whole person,' says Prawchan K.C., SPARSHA's programme manager. 'It isn't enough to simply give people methadone and expect them to keep coming back.' He explains how SPARSHA's medical and social support teams work together to assess the health and psychosocial status of each client and to develop individual treatment plans that respect clients' needs and wants. The OST programme at SPARSHA is still young – 80 patients are currently enrolled – but it has already distinguished itself as a promising model for integrating opioid substitution therapy into comprehensive health and social support services for people who use drugs.

It has also showcased the positive effects that harm reduction interventions can have for communities as a whole. According to K.C., local residents were sceptical when SPARSHA informed them about the new OST programme, fearing the prospect of active drug users once again gathering in the neighbourhood. Now, they accept it: they have seen how well-organised, professional services for people who use drugs actually reduce the level of crime and disorder in the area and how they dramatically improve the lives of families affected by drug dependence. Where a shooting gallery once polarised the community, the young and energetic team at SPARSHA is now helping to break down the stigma and discrimination against people who use drugs by encouraging local residents to access basic health care services at the SPARSHA clinic.

Prawchan K.C., the programme manager at SPARSHA Nepal, where the medical and social support teams strive for high patient retention rates in the OST programme by providing professional services with a personal approach.

The OST site at SPARSHA is one of 11 such sites currently operating at public hospitals and through non-governmental organisations (NGOs) across Nepal as part of a national OST programme overseen by the Ministry of Health. Since 2009, German Development Cooperation (GDC) has been a key technical partner in this effort, drawing upon Germany's own experience with OST and working closely with government and civil society partners to expand OST in Nepal from a small pilot project to a sustainable national programme.

This case study is about the development of psychosocially-assisted opioid substitution therapy in Nepal over the period 2009 to 2016. It explores two key questions: How can the approach to OST which has been established in an industrialised country such as Germany be applied in the context of a low-income country like Nepal? And what new knowledge has been generated along the way that might be useful for other countries seeking to introduce or expand OST?

Reducing the harmful effects of opioid dependence

More than 246 million people worldwide are estimated to have used illicit drugs and, of these, over 27 million are considered to be problem drug users – people who either suffer from a drug use disorder or are dependent on illicit drugs. Nearly half of these – 12.2 million people – inject drugs (UNODC, 2015).

Injecting drug use is associated with a range of health challenges. Approximately 13% of injecting drug users (1.65 million people) are living with HIV and just over half (6.3 million people) are infected with hepatitis C (UNODC, 2015). People who inject drugs are also at risk of developing other health problems, including injuries (e.g. bruising, scarring, damage to veins and arteries) and infections (e.g. abscesses) related to their injecting practices (WHO, 2009b). Compared to the general population, people who inject drugs are at a higher risk of dying, primarily as a result of drug overdoses and infectious diseases (UNODC, 2015).

The harmful consequences of injecting drug use extend beyond individual users. HIV can readily be transmitted to sexual partners through unprotected sex. Households with one or more members who inject drugs may be economically disadvantaged as a result of lost income and drug-related expenditures. People who inject drugs are both socially stigmatised and almost universally criminalised: many are detained or incarcerated at some point in their lives, sometimes for long periods (UNAIDS, 2014).

Turning the page on repressive drug control policies

Since the early 1960s the global drug control regime has favoured a repressive approach, criminalising the production, sale and consumption of illicit drugs. Increasingly, however, efforts to eradicate drug use are seen to have backfired. While drug production, supply and use have continued to rise, punitive policies have undermined human rights, fuelled corruption, crime and violence, led to high levels of incarceration, and worsened public health and safety. As a result, there are growing calls for more humane and effective policies which are based on evidence, rather than ideology, and grounded in the principles of public health and a respect for human rights (Global Commission on Drug Policy, 2014).

Harm reduction is central to drug control policies which prioritise people's health and welfare. When adequately resourced and implemented at sufficient scale, harm reduction measures such as needle and syringe programmes, opioid substitution therapy, supervised drug consumption facilities, and overdose prevention and reversal contribute to significant public health improvements (Global Commission on Drug Policy, 2014). Such interventions are best undertaken as part of comprehensive strategies which also include prevention, counselling and rehabilitation services for people who use drugs.

First pioneered in European cities in the 1980s in response to the emergence of concentrated HIV epidemics among people who inject drugs (Cook, Bridge & Stimson, 2010), harm reduction is now reflected in national policy in 91 countries worldwide. Not only is it understood as a critical HIV prevention measure – outside Sub-Saharan Africa, 30% of new HIV infections occur among people who inject drugs (UNAIDS, 2014) – but it is also increasingly seen as an essential part of realising the highest attainable standard of health for people who use drugs (Harm Reduction International, 2014).

Despite being endorsed by WHO, the Joint United Nations Programme on HIV/AIDS (UNAIDS), and the United Nations Office on Drugs and Crime (UNODC), harm reduction does not yet enjoy consensus support within the United Nations system. While it is actively championed by a cohort of countries which have successfully integrated such approaches into their national drug control strategies, harm reduction is at the same time strongly opposed by others which maintain that it sustains drug dependency. The outcome document adopted by the United Nations General Assembly Special Session on the World Drug Problem, held in April 2016, reflects this tension: it includes references to specific interventions which minimise 'adverse public health and social consequences of drug abuse,' but stops short of mentioning harm reduction by name or endorsing it as an essential element of countries' drug policies.

Soaring HIV infections drive expansion of opioid substitution therapy

Opioid substitution therapy is one of the public health interventions which has been proven to reduce the harmful effects of opioid dependence, including the spread of HIV and hepatitis through injecting drug use. Long before it was promoted as an HIV prevention measure, however, substitution therapy (sometimes referred to as 'maintenance therapy') was known in the medical community as a form of treatment that could stabilise the lives of people dependent on heroin and other opioids.[2] The provision of regular doses of a long-acting opioid, such as methadone, helps opioid-dependent persons avoid the cycles of intoxication and withdrawal common with shorter-acting opioids. As a result, they no longer experience cravings and are less likely to inject (and less likely to overdose), they no longer need to spend time (and money) acquiring illicit opioids and they are less likely to engage in criminal activities to finance illicit drug use. They are also more likely to be able to maintain normal daily routines, hold down a job and participate in family life.

Although small methadone maintenance programmes were in existence in a handful of European countries in the 1960s, the availability of OST in Europe expanded rapidly during the 1990s as the scale of the HIV epidemic among people who inject drugs became apparent. By the turn of the century, OST was available in more than 25 European countries (Cook, Bridge and Stimson, 2010), including Germany (see Box 2), as well as in a number of high-income countries outside Europe, including Australia, Canada, New Zealand and the United States. In the decade which followed, OST became available in a growing number of middle-income countries, including China, Kyrgyzstan, Iran, Malaysia and Ukraine.

As OST began to be implemented at a larger scale, its effects were studied carefully. Methadone maintenance programmes were found to reduce HIV risk behaviours and HIV infections, to reduce the use of illicit opioids, and to generate higher levels of treatment retention than abstinence-based approaches. Summarising the scientific evidence in a review of harm reduction approaches in 2005, WHO backed the effectiveness of OST as a critical element of strategies to prevent the spread of HIV among people who inject drugs (WHO, 2005). The same year UNAIDS published for the first time a list of core harm reduction interventions, which included OST (Cook, Bridge & Stimson, 2010).

Box 2. Opioid substitution therapy in Germany

Opioid substitution therapy was legalised in Germany in 1992, following years of contentious debate and sustained advocacy efforts on the part of medical doctors and relatives of people who used drugs (Michels, Stöver & Gerlach, 2007). It is now a recognised form of medical treatment, paid for by Germany's statutory social health insurance and available at private medical practices, inpatient facilities and specialised outpatient centres countrywide. Over 77,000 people were enrolled in substitution therapy in Germany in 2015 (Federal Institute for Drugs and Medical Devices, 2016).

OST is regulated under the country's main Narcotics Law and implemented according to guidelines approved by the German Medical Association. To provide OST, medical doctors must have supplementary training in pharmacology and drug dependence and make annual submissions to the national Substitution Register, maintained by the Federal Opium Agency (Pfeiffer-Gerschel et al., 2014).

Psychosocial care services, insofar as they are deemed necessary for individual patients, are considered part of treating opioid dependence. As these are decentralised to the state and community level, there is significant variation in terms of the organisation, financing and scope of available services across the country. In general, however, the approach to drug-related treatment in Germany depends heavily upon cooperation between professional groups, including social work, psychology, psychiatry and other medical fields (Pfeiffer-Gerschel et al. 2014).

[2] In the 1920s, for example, the United States briefly experimented with a series of 'narcotic clinics' which dispensed morphine and other drugs to patients with opioid dependence (Lowinson et al., 2004). Around the same time, in the United Kingdom, the high-level Rolleston Committee recommended that doctors be permitted to prescribe morphine and heroin to opioid dependent persons (Mars, 2003).

Substitution therapy can work anywhere

Opioid substitution therapy was attracting growing interest and attention, but an unanswered question remained: could it be implemented as effectively in developing and transitioning country contexts as it could in industrialised countries, where the approach had been studied most intensively? In 2008 the results of a collaborative research study sponsored by WHO (Lawrinson et al., 2008) provided an answer. In a longitudinal cohort study involving 726 OST patients from Australia, China, Indonesia, Iran, Lithuania, Poland, Thailand and Ukraine, patients showed high levels of treatment retention, significant and marked reductions in reported use of heroin and other illicit opioids, reductions in HIV exposure risk behaviours and criminal activity, and improvements in physical and mental health. The authors' conclusion – that OST in low- and middle-income country settings can achieve outcomes comparable to those in high-income country settings – unequivocally supported the expansion of OST globally.

From this point on, countries with populations of injecting drug users were strongly encouraged to introduce and scale-up OST programmes. In 2009 WHO, UNODC and UNAIDS published a *Technical Guide* (WHO, UNODC & UNAIDS, 2012) to assist countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users, including OST. A number of European countries with experience with OST, including Germany, began providing bilateral support to partners in low- and middle-income countries to develop their own national programmes.

In 2014 OST was available in 80 countries, including many in Asia, where traditional staunch support for law enforcement-oriented drug policies has gradually given way to a willingness to test harm reduction approaches (Harm Reduction International, 2014; Reid & Crofts, 2013). However, the number of OST sites and the proportion of people in substitution therapy is substantially higher in high-income countries than in low- and middle-income countries. Improvements in the scale and quality of OST programmes are therefore an urgent priority in order to maximise their public health benefits (Harm Reduction International, 2014).

Harm reduction comes to Nepal

Patterns of drug use in Nepal

Although the use of cannabis in Nepal dates back centuries, the modern history of drug use in the country begins in the 1960s with the advent of heroin (UNAIDS & UNDCP, 2000). The evolution of heroin use in Nepal mirrored a broader pattern throughout Asia, with smoking and 'chasing' (inhaling) gradually giving way, by the late 1980s and early 1990s, to injecting (Reid & Crofts, 2013). The introduction in 1990 of the synthetic opiate buprenorphine, easily available in injectable form, accelerated the trend towards injecting drug use (UNAIDS & UNDCP, 2000). In subsequent years the use of relatively inexpensive pharmacological drug cocktails, which combine an opioid such as buprenorphine with a sedative and an antihistamine, has become increasingly common (Kinkel & Kramarz, 2013; Ojha et al., 2014).

Drug use in Nepal – a country with a population of approximately 28 million people – appears to be increasing rapidly. In 2007 there were an estimated 46,000 users of illicit drugs (not including marijuana), including more than 28,000 injecting drug users (Government of Nepal, 2008). By 2013 the numbers had nearly doubled. The Central Bureau of Statistics estimates that there are approximately 52,000 injecting drug users out of a total population of 91,500 users of 'hard drugs.' While opioids are the category of drugs most commonly used, polydrug use is widespread: 83% of drug users in Nepal report using more than one drug (Government of Nepal, 2013).

Drug users in Nepal are young – three-quarters are between the ages of 15 and 29 – and overwhelmingly male (93%). Notably, more than half live in a household with both parents and 29% are married. More than 40% have some secondary education and another 34% have completed secondary school. While the greatest number of drug users live in the Kathmandu Valley, significant numbers can be found in other parts of the country (Government of Nepal, 2013). Nine of the 15 districts with high concentrations of drug users are on the border with India (Sinha, Adhikari & Karmacharya, 2009).

A growing public health concern

Cannabis use in Nepal has largely been regulated by traditional norms and has reportedly not generated major social or public health problems (Government of Nepal, 2013), but the same has not been true of the classes of drugs which have arrived over the past decades. As in all countries, problem drug use in Nepal is exacting a large private toll on both people who use drugs and their families. However, it is the role of injecting drug use in transmitting HIV and hepatitis that has ultimately catalysed a response to opioid dependence in Nepal.

■ *In Nepal the pharmacological ingredients needed to mix a so-called South Asian Cocktail are relatively easy to obtain and cheaper than heroin.*

The first case of HIV was documented in Nepal in 1988 and, over the course of the 1990s, infections spread rapidly among people who inject drugs. A 1999 study of more than a thousand drug users in 19 major urban areas found that one-third were infected with HIV and more than half with hepatitis C. Sixty-five per cent of injecting drug users reported sharing injection equipment (Upreti, 1999, cited in UNAIDS & UNDCP, 2000). In 2002, an Integrated Biological and Behavioural Surveillance survey conducted by the Ministry of Health found that 68% of injecting drug users in Kathmandu Valley were HIV positive. The following year similar surveys conducted in Pokhara and the Eastern Terai found HIV prevalence of 22% and 35% respectively (NCASC, 2010).

Subsequent rounds of the survey, conducted every two years (NCASC, 2015c-e), have revealed a gradual decline in HIV prevalence (see Figure 1), a fact which likely reflects both AIDS-related deaths and a decline in new HIV infections (Harm Reduction International, 2014). Nationally, HIV prevalence among people who inject drugs is currently estimated at 6.3% (NCASC, 2015c). Hepatitis C remains an acute crisis for people who inject drugs, with prevalence ranging from 22% in Kathmandu Valley to 47% in the Eastern Terai (NCASC, 2015c-e).

The early response

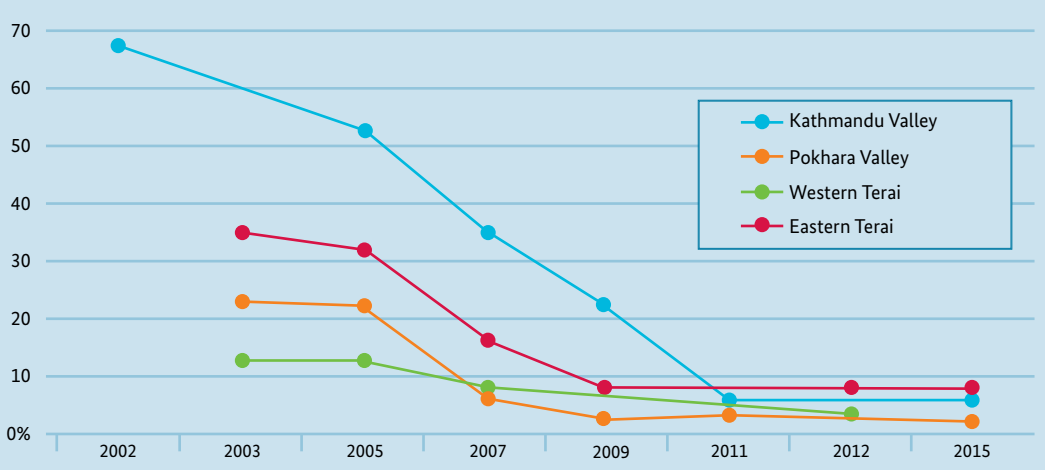
Nepal's concentrated HIV epidemic emerged at a time when little attention was being paid to the needs and rights of people who use drugs. Responsibility for drug control policy lay solely with the Ministry of Home Affairs, which pursued a law enforcement-oriented approach to its stated goal of 'Zero Drug Use' and showed scant interest in public health aspects of drug use. The Ministry of Health, for its part, had little direct involvement in drug control policy and planning and played no meaningful role in the prevention or treatment of substance use disorders (UNAIDS & UNDCP, 2000).

Despite the growing number of people dependent on drugs, Nepal did not have a specialised drug treatment sector and few professionals (e.g. medical doctors, psychiatrists, psychologists, social workers) with expertise in the field. Those treatment and rehabilitation services which were available were abstinence-oriented and run exclusively by NGOs and other private actors, with no public funding and only minimal government oversight. Approaches and standards varied widely, and many programmes were operated on a fee-for-service basis, leading to inequities in access (UNAIDS & UNDCP, 2000). Availability of drug treatment facilities fell far short of demand, and options outside the Kathmandu Valley were particularly limited. Drug users were subject to discrimination and stigma at all levels of society: drug dependence was seen as a character weakness or moral flaw, rather than as a chronic disease requiring treatment.

Different from some countries, however, official opposition to harm reduction approaches in Nepal was never absolute, and the government's practice of outsourcing many programmes and activities to civil society actors created a certain amount of space for innovative, politically-sensitive approaches to be tested out at a small scale (UNAIDS & UNDCP, 2000). In 1991 a Kathmandu-based NGO began providing sterile injection equipment to drug users – the first such programme in Asia (Reid & Crofts, 2013). And in 1994 a doctor at the Lagankhel Mental Hospital in Kathmandu launched a pilot methadone maintenance programme (see Box 3) – another first in the region – which ran for eight years before being shut down in 2002 (Lawyers Collective, 2007).

By the late 1990s the country's policies were beginning to catch up to the changing reality on the ground. The National Drug Demand Reduction Strategy for 1996-99 for the first time endorsed OST as a treatment option for people with opioid dependence and set an enrolment target for the methadone programme at the Mental Hospital. It also acknowledged the need for a multisectoral response to drug use, including better integration of information about HIV in drug education programmes. At the same time, the new National HIV/AIDS Control Strategy, developed by the National Centre for AIDS and STD [3] Control (NCASC) under the Ministry of Health, recommended NGO-led needle and syringe programmes as an HIV prevention measure and called for consideration of the consequences of the country's drug control policy on the spread of HIV (Lawyers Collective, 2007).

Figure 1: HIV prevalence among people who inject drugs in Nepal, by region, 2002-2015



Source: National Centre for AIDS and STD Control, 2015b

[3] STD stands for Sexually Transmitted Disease.

By the turn of the century, harm reduction approaches officially had a 'foot in the door' – on paper and, to a limited extent, in practice – although support was thin and many officials reportedly continued to question the rationale for such measures, regarding them as counterproductive (UNAIDS & UNDCP, 2000).

Civil society on the move

By the time the methadone programme ended, in 2002, major changes had taken place within the community of people who use drugs. The rapid growth in the number of drug users over the course of the previous decade had been accompanied by a proliferation of abstinence-based treatment programmes. For some people these programmes were successful and, by the late 1990s, a small but growing number of 'ex-users' were organising themselves into support groups, establishing NGOs and even opening rehabilitation centres of their own. In the face of official inertia, ex-users increasingly took it upon themselves to support one another to remain abstinent and to help others who wanted to stop using drugs.

Over time, this vibrant self-help community became increasingly politicised. Recovering Nepal, the national organisation of people who use (or used) drugs, was established in 2001 and quickly moved to the forefront of advocacy efforts to secure access to free, evidence-based treatment and care for drug users. Through demonstrations, sit-ins and other interventions its members succeeded in drawing the attention of the media, government officials, international organisations

Box 3. One step forward, two steps back: Nepal's first methadone maintenance programme

At its peak the methadone programme at Lagankhel Mental Hospital enrolled more than 200 patients. Doses were administered to patients on a daily basis, in tablet form, and taken under direct observation of a doctor or nurse. Apart from a small fee for the methadone itself, the programme was free of charge for patients (Lawyers' Collective, 2007; UNAIDS & UNDCP, 2000).

In 2002, after running for eight years, the programme abruptly shut down for reasons that have never been fully established. Resource constraints, the diversion of methadone to the illicit market and negative public opinion have all been advanced as possible explanations (Ambekar et al., 2013). Their treatment interrupted, many of the methadone patients reportedly resumed drug use. Anecdotal evidence suggests that overdose deaths were common. What's more, the ex-methadone patients who resumed injecting drugs were at particularly great risk of contracting HIV if they did not use sterile equipment: at the time the programme closed, HIV prevalence among injecting drug users in Kathmandu was estimated at 68%.

■ *Spreading the word about methadone as an alternative to abstinence-based treatments for opioid dependence.*

The legacy of Nepal's first methadone programme is complex. On the one hand, the programme represented the first formal acknowledgment in Nepal that medically-assisted treatment may be indicated for persons with chronic drug dependence for whom abstinence-based approaches have failed. On the other hand, the programme did little to build broader support for OST among the community of people who inject drugs, political authorities or the general population. The programme was focused solely on the medical side of treatment and did not offer any psychosocial support services. It did little to educate and sensitise people who inject drugs about the goals of substitution therapy and the possibility that, for many, the treatment might be a life-long necessity. The abrupt closure of the programme, and the difficult years which followed for ex-methadone patients, deepened the sense of mistrust that civil society groups felt towards the medical and political establishment in the country.

and the population at large to the rights of people who use drugs and the need for expanded services. The HIV epidemic had been the spark, but the resulting movement was much broader in orientation.

Faced with growing pressure, the Ministry of Home Affairs in 2005 established a Technical Working Group which brought together, for the first time, a range of stakeholders to provide input into the country's drug control strategy. In addition to representatives from UNODC, the police and narcotics control bureau, the working group also included a doctor from the psychiatry department at the Tribhuvan University Teaching Hospital (TUTH) with experience treating substance use disorders and representatives of Recovering Nepal.

Civil society used its seat at the table within the working group, as well as its voice on the streets, to continue pushing for free treatment and rehabilitation services for drug users. At the same time development partners were showing a willingness to support elements of a comprehensive package of services for people who inject drugs as a way to prevent the spread of HIV. In 2007 a needle and syringe exchange programme funded by the United Kingdom's Department for International Development and the United Nations Development Programme began rolling out countrywide. The same year the Ministry of Home Affairs, with support from UNODC, re-launched opioid substitution therapy, this time at TUTH.

The German contribution

Abroad, as at home, Germany supports a balanced drug policy which incorporates elements of prevention, counselling and treatment, harm reduction and repression. It works closely with international institutions such as UNAIDS, UNODC, WHO and the Global Fund to Fight AIDS, Tuberculosis and Malaria, as well as bilaterally with partner countries, to reduce the availability and illegal consumption of drugs and to minimise the harmful effects of drug dependence.

■ *Representatives of civil society organisations gather in front of the United Nations building in Kathmandu in 2005, demanding an expansion of affordable drug treatment programmes.*

HIV prevention and treatment has been a top priority for Germany in its international development work. Since 2002 GDC has been supporting the implementation of programmes which apply lessons from Germany's own domestic expertise in harm reduction in partner country contexts to address the dual public health challenges of injecting drug use and HIV.

Nepal is one of the countries where GDC has worked closely with government and civil society partners to strengthen harm reduction approaches. Between 2009 and 2016, through a series of technical cooperation projects commissioned by the Federal Ministry for Economic Cooperation and Development (BMZ), and implemented by the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ),[4] GDC has sought to share the experiences and the know-how generated from setting up and implementing OST in Germany and to adapt it, in consultation with partners, to the Nepalese context.

The following chapter describes in detail what was done, how and why, with a focus on the challenges encountered during implementation.

[4] In 2011 the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) merged with Deutsche Entwicklungsdienst (DED) and Internationale Weiterbildung und Entwicklung (InWEnt) to form the new Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ). Throughout this publication, for the sake of clarity, we refer to GIZ as the organisation which provided technical support to the OST programme in Nepal, even during the period prior to 2011.

Building an opioid substitution therapy programme in Nepal

From pilot project to national programme

GDC became involved with OST in Nepal in early 2009 in the context of a regional project on methadone substitution[5] which aimed to share German expertise in OST with countries in Asia which were introducing programmes as part of their national HIV prevention strategies.

The project was structured as a public-private partnership between GIZ and CompWare Medical, a German company which manufactures IT-based dispensing and documentation systems for opioid substitution therapy. Under the auspices of this partnership GIZ built the capacity of clinical staff and social workers to implement methadone substitution programmes, while CompWare Medical provided the dispensing systems and training in their use. In February 2009 the Ministry of Home Affairs signed a memorandum of understanding with GIZ and CompWare Medical, and Nepal became the first partner country in this regional project.

While the initial vision was to provide time-bound, narrowly-focused technical assistance to Nepal's existing opioid substitution programme as a contribution to HIV prevention efforts, the focus of German support evolved over time. As the performance of the pilot sites improved and financing became available via the Global Fund to provide OST at a larger scale, it became clear that further technical assistance could assist government and civil society partners in Nepal to make the transition to a full-fledged national programme. In 2011 BMZ commissioned GIZ to continue German support for OST through a bilateral harm reduction project,[6] implemented in cooperation with the Ministry of Health as the primary political partner.

A flexible, needs-driven approach

From the very beginning the advisors leading the harm reduction project pursued a flexible and pragmatic approach: the broad goals of the project were clear, but there was no blueprint to follow.

The German technical and medical advisors – who between them had decades of experience with OST and harm reduction in industrialised country settings – were new to Nepal,

Advisors with the harm reduction project: Bikash Nepal, Patricia Kramarz and Ujjwal Karmacharya.

but brought with them an understanding of the elements which allow opioid substitution therapy to be delivered in a high-quality manner in Germany (see Box 4). Their Nepalese colleagues, who had been at the forefront of the movement for evidence-based drug policies in the country, could visualise how each of these elements might be translated into the Nepalese context.

Together the project team took the OST site at TUTH as its starting point and set out to demonstrate that substitution therapy could be provided in Nepal in accordance with international standards. 'It was not a question of adopting the German model per se,' explains Patricia Kramarz, a harm reduction expert with 20 years of experience who led the work in Nepal from 2009 to 2014 as the chief technical advisor for GIZ, 'but a matter of figuring out how these standards could be met in the best possible way in Nepal.' The team worked on multiple fronts simultaneously, often making progress in one area while experiencing setbacks in another.

The remainder of this chapter considers in detail how GDC, along with its government and civil society partners and other international institutions, sought to build up in Nepal the six pillars of an OST programme and what happened along the way.

[5] The project was carried out under the auspices of the public-private partnership programme develoPPP.de, implemented by GIZ on behalf of BMZ.

[6] The official title of this project was 'HIV Prevention for People who Inject Drugs.' It was extended in 2014 as a thematic area under the Nepali-German Health Sector Support Programme. For the remainder of the publication the term 'harm reduction project' is used to refer to the German-supported work on harm reduction in Nepal over the period 2009-2016.

Pillar 1: Working towards a policy framework for OST

For OST to have a public health impact it needs to be implemented at a large scale, ideally reaching at least 40% of the population of opioid-dependent people who inject drugs (WHO, UNODC & UNAIDS, 2012). Optimising the coverage of OST requires, among other things, robust political commitment: substitution therapy must not only be tolerated by authorities, it must be endorsed and actively championed. Ideally it should be embedded in a policy approach to drug dependence which is rights-based and public health-oriented. One of the major goals of the harm reduction project was therefore to build and sustain political support for OST among Nepalese authorities, including those responsible for public health.

The challenges were formidable. In 2009, when GDC first began supporting OST in Nepal, drug policy was squarely in the domain of the Ministry of Home Affairs. Consistent with the ministry's law enforcement orientation, narcotics control measures took clear precedence over the prevention and treatment of drug dependence. Officials in the Ministry's Drug Control Programme were suspicious of harm reduction approaches in general – perceiving these as contradictory to the Ministry's stated goal of a 'drug-free Nepal' – and did not have a full understanding of the goals of substitution therapy. An overriding concern was that methadone could get diverted from OST sites to the illicit market.

CompWare's MeDoSys methadone dispensing and patient documentation system allows for liquid methadone to be dispensed securely and quickly. Nepal was the first low-income country to use the system.

Local and international organisations working in the field of HIV prevention, care and treatment in Nepal were strong proponents of OST, but worked largely in parallel to the drug control sector. Cooperation between the Ministry of Health and the Ministry of Home Affairs was limited. While harm reduction interventions, including OST, were reflected in national HIV control strategies, the health sector had neither the political mandate nor the resources to implement OST as a public health intervention.

Box 4. Six pillars of Germany's approach to opioid substitution therapy

For the purposes of this case study a conceptual framework was developed which highlights the key features of Germany's approach to opioid substitution therapy. It is informed by the work of Ingo Michels, Heino Stöver and Ralf Gerlach (2007), who were among the first to describe the history and provision of OST in Germany.

1. **Legal framework:** OST is embedded in a rights-based, public health-oriented legal framework which regards drug dependence as a treatable disease.
2. **Sustainable financing:** Persons with opioid dependence wishing to enrol in treatment do not experience financial barriers to access.
3. **Quality in delivery:** OST is provided in a decentralised, well-regulated, client-focused manner by qualified medical personnel.
4. **Psychosocial support:** OST is accompanied by psychosocial support services available via a coordinated network of governmental and non-governmental actors, including self-help groups of current and ex-users.
5. **Integration in general health system:** Linkages exist between OST programmes and the general health system, including for care of co-morbidities such as HIV, hepatitis and tuberculosis.

Resolving security concerns

The immediate priority for the harm reduction project was to build confidence among officials at the Ministry of Home Affairs that it was possible to administer methadone in a secure manner to large numbers of patients. 'It was clear that we needed to find a solution to the counterparts' main concerns,' recalls Patricia Kramarz, 'otherwise it would be impossible to move further.'

The answer came in the form of MeDoSys, CompWare's methadone dispensing and patient documentation system. The machines combine tamper-proof hardware – bottles of liquid methadone are mounted inside a locked chamber – with automated precision dispensing and a software-based medical record system which makes it easy for a small clinical team to treat large numbers of patients. Compared to hand pumps and paper-based records, the MeDoSys system, with its back-up power sources and state-of-the-art features, went a long way to minimising fears about fraud and diversion. Once officials at the Ministry were satisfied with the performance of this equipment at the OST site at TUTH, it was possible to refocus the discussion on the political and institutional framework conditions for OST at a larger scale.

Shifting the terms of debate: from crime to health

The next priority was to advocate for a greater role for the Ministry of Health in the planning, implementation and oversight of the OST programme. In this task the harm reduction project advisors joined forces with other actors, including local civil society organisations, which had long been advocating for evidence-based drug policies, and medical doctors from TUTH. The combination of international expertise and local networks and know-how proved to be powerful.

Together this loose network of 'OST champions' worked to build up the understanding of OST as a public health intervention aimed at treating the disease of drug dependence. These advocacy efforts took a variety of forms: regular meetings and briefing sessions with government officials, participation in inter-ministerial working groups, support for a national harm reduction conference in 2009, and the organisation of study tours to Germany for Nepalese officials to observe how OST fits into Germany's comprehensive approach to drug dependence.

There was also a huge amount of behind-the-scenes 'shuttle diplomacy' aimed at breaking down the mutual wariness between the two ministries. Victories were hard fought and sometimes short-lived, according to Saroj Ojha, the head of the psychiatry department at TUTH and the doctor who ran the OST site. 'At first all the meetings were at the Ministry of Home Affairs. We explained time and again that methadone is a form of *treatment* and that the Ministry of Health needs to be present,' he recalls. 'Then, once the health officials were finally invited to meetings, they didn't come! At that time they simply didn't prioritise OST.'

By 2010 contact between the two ministries had increased considerably and deepened even further thanks to the preparation of the country's proposal to the Global Fund, in which OST was highlighted as a leading intervention. According to Ujjwal Karmacharya, a civil society leader who has worked with the harm reduction project since 2009 – first as a partner and then as a technical advisor with GIZ – this was a major breakthrough. 'Finally, through this process, everyone who needed to be at the table was at the table. There was a series of consultations and it was agreed that OST should be a top priority in the proposal.' Karmacharya had worked for years towards this goal. 'This was the point where I felt that OST was a national programme.'

By the time the proposal was submitted and approved, a fundamental shift had taken place: OST was now regarded as a shared responsibility of the two ministries (see Box 5), with the Ministry of Home Affairs responsible for licensing, procurement, and supply chain management, and the Ministry of Health responsible for implementation of OST through public hospitals.

Laying the groundwork for a national programme

While the success of the Round 10 proposal to the Global Fund marked an important milestone in the history of OST in Nepal, it was also a fragile one: there was a tacit agreement between the two ministries, but the division of responsibilities was not formally codified. Much depended upon the willingness of individual officials to allow the programme to continue and, as a result of chronic political instability in the country, there were frequent changes of key personnel at both ministries. Because OST was a relatively unknown intervention and occupied a grey zone in terms of policy, each new incumbent raised questions about OST's underlying rationale and needed to be educated afresh.

Anan Pun, the head of Recovering Nepal and an internationally renowned harm reduction advocate, put it succinctly: 'Even though the evidence for OST has long been settled, the moral debate is still not over.'

Between 2010 and 2013, harm reduction project staff redoubled their advocacy efforts – both to keep the two ministries on board and to encourage them to formalise an operational basis for OST. Financing from the Global Fund would allow a significant scale-up of OST services and it was important to define the standards and parameters for this expanded programme. Working closely with representatives from both ministries and UNODC to draft operational guidelines for the OST programme, project advisors advocated strongly for provisions which would allow OST to be provided in a decentralised manner (i.e. in community settings), with a mandatory role for Social Support Units (SSUs). The role of NGOs in the administration of OST sites was a particular sticking point, as the government preferred to see substitution therapy confined to government hospitals. With time, however, officials at both ministries recognised that a hospital-based programme would never attain the desired coverage and that NGOs were uniquely positioned to reach and convince people who use drugs to enter the programme.

In 2014 the Ministry of Home Affairs officially approved the *Management Guidelines for Opioid Substitution Therapy in Nepal*. Among the key provisions:

- OST may be provided at hospitals (public and private), by private practitioners and by authorised NGOs;
- Both methadone and buprenorphine are authorised as substitution drugs;
- SSUs are a mandatory component of opioid substitution therapy in Nepal;
- OST sites should be linked via referral networks to other medical and social services;
- OST should be free of charge for patients;
- Staff at OST sites should be trained in the specific needs of women who use drugs and measures should be taken to encourage their enrolment in OST; and
- Take-home doses are permitted under specific circumstances (e.g. periods of bereavement, hospitalisation, and incarceration).

The endorsement of these guidelines marked the first time that the rules, standards and procedures for all aspects of OST were brought together in a single overarching document. Compatible with the WHO guidelines for psychosocially-assisted OST, the guidelines provided a formal basis for the expansion of OST and outlined the standards against which the programme is monitored.

Box 5. Two ministries, one national programme

Fanindra Pokharel (top) and Dipendra Singh (bottom)

A decade ago the idea of a harm reduction programme jointly overseen by Nepal's ministries of health and home affairs would have been unthinkable. Today, it is a reality: the two ministries acknowledge each other's roles and work together to implement and oversee the national OST programme.

Where harm reduction was once regarded with suspicion, officials responsible for drug prevention and treatment at the Ministry of Home Affairs now cautiously accept the appropriateness of a national OST programme. 'The Ministry of Home Affairs wants to see a drug-free country,' says Under Secretary Fanindra Pokharel, 'but as long as there are people using drugs there is a need to give them services. OST is a new and alternative treatment for drug dependence for people in our country.'

For its part, the Ministry of Health has long been open to OST as an HIV prevention measure, but did not have experience actually implementing substitution therapy until about four years ago, when cooperation with the Ministry of Home Affairs and financing from the Global Fund opened the door to an expansion of OST through public hospitals. Dipendra Singh, the director of the National Centre for AIDS and STD Control, envisions a future in which OST is fully integrated into the public health system. 'OST must become a core service in our hospitals, not a special service,' he says. 'There are some people in our society for whom this is a must.'

Pillar 2: Securing stable financing for the OST programme

Opioid substitution therapy should be financially accessible for those who need it. To achieve optimal coverage and treatment outcomes, it should ideally be provided to patients free of charge. Moreover, OST should only be initiated in cases where there is a 'realistic prospect' of financial viability (WHO, 2009a), to reduce the likelihood of interruptions to treatment.

In Germany, the costs of OST are covered through social health insurance schemes. In Nepal, where health insurance is just being established and there are high levels of out-of-pocket expenditure, a different financing mechanism was required. In order to expand OST from a pilot to a national programme in such a setting, it was necessary to come up with an interim financing model that would ensure uninterrupted access to treatment once patients were enrolled in the programme.

In early 2009, when GDC began working on harm reduction in Nepal, the OST site at TUTH was being supported financially and technically by UNODC. However, this support was intended to enable the re-introduction of OST on an emergency basis, not to underwrite the establishment of a national programme. At the end of 2009 UNODC phased out its financial support for OST and the pilot project faced imminent closure: the government of Nepal was not in a position to take over the operating costs.

Aware of the disastrous consequences of the abrupt closure of the previous methadone maintenance programme in 2002, GDC stepped in with bridge funding to keep the OST sites running in the short term. At the same time, it actively supported members of Nepal's Country Coordinating Mechanism in the preparation of a proposal to the Global Fund which would potentially secure longer-term support for OST. Technical advisors with the harm reduction project lobbied for OST to feature prominently in the package of comprehensive services being proposed for people who inject drugs. In this advocacy process, they drew heavily on the findings of a scoping study, conducted in 2009 by Recovering Nepal with support from the German BACKUP Initiative,[7] which highlighted the main drug-related service needs and service gaps in 15 districts of Nepal with high concentrations of people who use drugs (Sinha, Adhikari & Karmacharya, 2009).

The proposal submitted to the Global Fund in August 2010 assigned high priority to harm reduction measures for people who inject drugs. It called for OST to be scaled up in nine additional districts of Nepal, alongside other services for people who inject drugs, and set a target of 2,500 people on substitution treatment by 2015 (CCM Nepal, 2010). The country proposal was approved for funding in December 2010 and implementation began in July 2011. The first principal recipient, the Ministry of Health, would assume responsibility for the medical side of the OST programme (e.g. medicines, clinical personnel, other operating costs linked to service delivery in public facilities), while the second principal recipient, the international NGO Save the Children, would cover the costs related to the SSUs operated by NGOs. GDC, through the harm reduction project, would provide capacity building and technical support.

Global Fund financing has been a game changer for OST in Nepal. While it does not provide long-term financial security comparable to that in industrialised country settings where OST has been fully integrated into health systems, it has brought about a degree of financial predictability which had previously been lacking. Not only has it ensured that the programme can keep operating, but it has also acted as an engine for its scale-up and is concentrating greater attention on the need to monitor the quality of services. OST's prominent position in the Global Fund-supported national HIV control strategy has also helped to consolidate political support for the programme.

Despite this, the question of OST's long-term sustainability looms large: if Global Fund support is not renewed, or is significantly curtailed, it is questionable whether the OST programme would be able to survive. The government of Nepal's financial contribution to the programme is negligible at present. Recent discussions suggest that the government is considering taking over the costs of procuring methadone and buprenorphine,[8] but for OST services to continue uninterrupted another development partner would need to step in and take over operating costs for both the Medical Units and Social Support Units.

[7] Commissioned by BMZ, GIZ's BACKUP Health (formerly known as the German BACKUP Initiative) provides needs-oriented technical support to organisations in partner countries to access and make use of Global Fund financing for HIV, tuberculosis and malaria.

[8] Personal communication, GIZ Nepal.

Pillar 3: Strengthening the medical side of opioid substitution therapy

A large-scale OST programme requires a decentralised cadre of health workers trained in the use of pharmacological drugs to treat substance use disorders, a set of clinical standards to guide their approach to treatment, and a system for providing professional training and clinical oversight. In Nepal, none of these elements were present when OST was re-launched in 2007. The field of 'addiction medicine' was all but unknown in the country – apart from a few psychiatrists at TUTH who had worked with patients with alcohol dependence – and treatment of substance use disorders barely featured in the medical curriculum. Not only were medical professionals unfamiliar with medically-assisted treatment for drug dependence, but the idea of working with people who use drugs was also unappealing: there was little prestige in caring for patients with complex medical and social needs who occupy a stigmatised position in society.

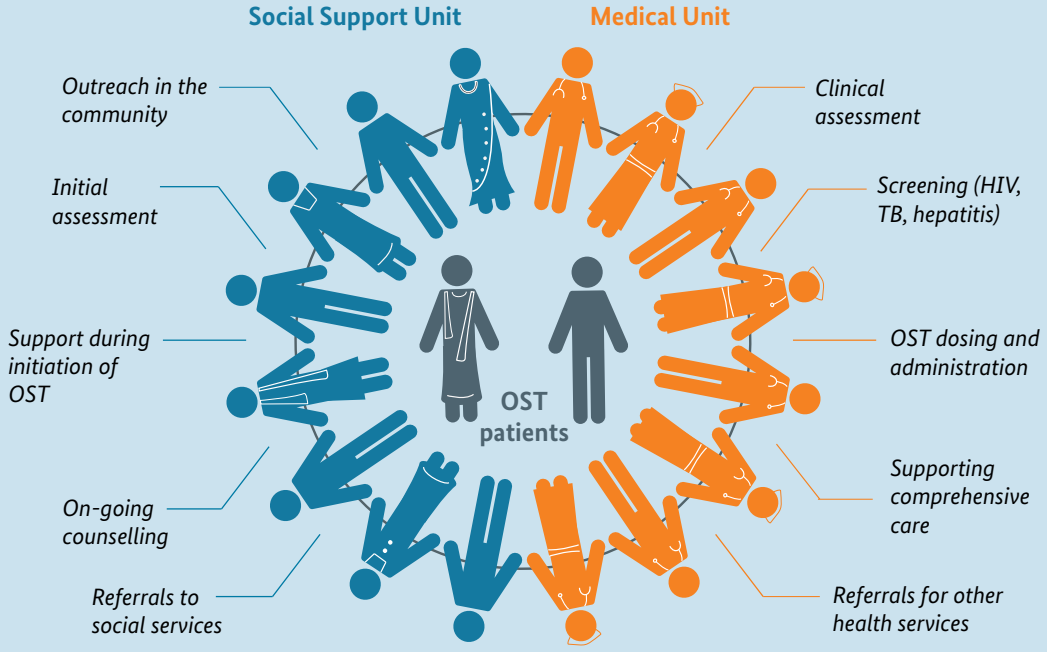
One of the fundamental challenges which needed to be tackled in Nepal was the development of a cohort of trained, motivated health workers who could not only implement the medical aspects of OST (i.e. setting and dispensing doses), but who were also committed to the broader vision of OST as part of comprehensive health services for people who use drugs.

On-the-job training for doctors and nurses

A major focus for the harm reduction project was to build the capacity of clinical teams to provide professional, high-quality substitution therapy. Between 2009 and 2011 and again from 2012 to 2014, full-time medical advisors (German OST doctors employed by GIZ) worked side-by-side with their Nepalese counterparts in OST sites. 'At the time we started in 2009, the role of medical advisor wasn't very clearly defined,' says Hans-Günther Meyer-Thompson, the first medical advisor. 'It was basically about bringing in outside expertise and helping the Nepalese colleagues to build up their programme.'

Both Meyer-Thompson and his successor, Hans-Tillman Kinkel, found that the best way to do this was to get directly involved in the day-to-day work of the OST sites. They provided sustained on-the-job training to doctors and nurses on all aspects of OST, from patient intake and assessment to the initiation of substitution therapy and the stabilisation of patients on maintenance doses. They worked with the clinical teams on systems for medical recordkeeping, intake procedures, follow-up appointments and patient monitoring, linkages with the SSUs (see Figure 2), and the establishment of referrals linkages with other health services.

Figure 2. Model of integrated care at OST sites in Nepal



In addition to the technical expertise which they shared with their Nepalese colleagues, the medical advisors also embodied the traits which are required to be a specialist in this field: putting patients' needs at the centre, being a good listener, acting in a non-judgmental manner, and treating the whole person. They emphasised client literacy, teaching patients how OST treatment works and how to integrate it into their daily lives and routines. In many respects this role modelling was as important as the clinical training: a number of young doctors and nurses had the opportunity to train alongside experienced professionals and subsequently committed themselves to careers in this field (see Box 6).

Formalising a training curriculum

As new OST sites began to open, thanks to Global Fund financing, clinical teams had to be prepared to run them. On-the-job training, while still valuable, would no longer be sufficient. Moreover, a growing programme demanded a more standardised approach. 'When there were just two sites, in Kathmandu and Pokhara, the programme ran on the experience of the individual doctors,' said Sagun Pant, the psychiatrist who heads the OST programme at TUTH. 'They were the veterans. But once the programme expanded there was more pressure to follow a uniform approach.'

With support from the harm reduction project, a training curriculum (NCASC, 2014) for doctors and nurses was developed in 2012, informed by both international OST standards and clinical evidence from the existing OST sites in Nepal. The eight-day course gives health workers the theoretical background and practical training they need to offer substitution therapy as part of comprehensive health care for people who use drugs.

The curriculum is certified by the National Centre for AIDS and STD Control which, under the *OST Management Guidelines*, is responsible for training clinical personnel. In a critically important and hard-fought achievement, the

Box 6. A new generation of OST clinicians

Sagun Pant (top) and Seema Bhatta (bottom).

When Sagun Pant completed his medical training, opioid substitution therapy had barely made inroads in Nepal. 'Drug dependence is covered as part of psychiatric medicine and I had a few ideas about OST, but didn't know very much,' Pant admits with a smile. Now, a decade later, he is one of Nepal's leading experts in the field, training and providing professional support to a growing cohort of OST clinicians across the country as the head of TUTH's OST programme.

Pant's involvement with OST was somewhat accidental. In 2012, when he became a psychiatric resident at TUTH, he began working closely with Hans-Tillman Kinkel, the harm reduction project's medical advisor at the time. In addition to treating patients at the TUTH OST site, Pant helped to develop the first training curriculum for OST clinicians in Nepal and, subsequently, to design an innovative e-learning course linked to the curriculum. Later, Pant led the process of developing Nepal's first clinical guidelines for OST.

'As an OST doctor I see people change,' says Pant. 'I see patients who are mentally sound, physically fit, have money in their pockets and are part of society again. Of course there are frustrating aspects, too,' he continues. 'Slips are the rule. Patients relapse. My role is to say, "OK, you slipped. Let's try again."'

Seema Bhatta is another young Nepalese who sees her professional future in the field of OST. A nurse by training, Bhatta is the engine that drives the day-to-day operation of the OST programme at SPARSHA Nepal: dispensing medication to enrolled patients, working with the OST doctor and social workers on patient intake, overseeing drug supplies and the MeDoSys system, and tracking patient compliance and flagging cases for follow-up.

'This is a whole new experience,' says Bhatta. 'It's very different from working as a nurse in a hospital setting.' She completed her nursing education in India, where psychiatric nursing is part of the standard curriculum, but didn't set out to specialise in this area. Now that she's discovered the field, however, she thinks she has found a direction for her career. 'I like what I'm doing. I feel like I'm making a difference in the community and a contribution to harm reduction in Nepal.'

NCASC has authorised TUTH to train medical teams, using the curriculum, on its behalf. As the NCASC does not have the technical expertise in OST to conduct such clinical trainings itself, it was essential to gain its approval for a qualified service provider to play this role. To date, approximately 60 doctors, nurses and medical residents have completed the training and been certified by the NCASC as OST clinicians.

In 2014 the training curriculum was extended through the development of an innovative e-learning course which can be used both individually and in groups. The course is comprised of eight modules, each of which is built around the complex health needs of an individual patient. This case study approach goes beyond a narrow focus on the medical treatment of opioid dependence and shows what a holistic approach to comprehensive medical, psychiatric and social care for people who use drugs entails. The course modules are now used during the standard clinical trainings, and are also provided to doctors and nurses in electronic form as an additional resource they can use in their daily work.

Setting standards and institutionalising systems for training and supervision

In early 2015 a final milestone was achieved: the adoption of clinical guidelines for OST in Nepal (NCASC, 2015a). In 2014 the Ministry of Home Affairs had approved the use of buprenorphine in substitution therapy – a medication with which most Nepalese OST teams had no experience. NCASC asked TUTH to develop a set of clinical guidelines which doctors could use to make decisions about appropriate courses of treatment for opioid dependent persons. The guidelines, which were modelled on WHO's *OST Guidelines for Southeast Asia* (2008), address all aspects of treatment, including how and when to initiate substitution therapy, how to adjust or taper doses, common side effects and drug interactions.

Clinical teams at new OST sites are now trained according to a standard curriculum and are expected to provide OST in compliance with accepted clinical guidelines. The challenge in the coming years will be to improve systems for monitoring the quality of OST services. Since 2014 TUTH has gradually taken over the institutional responsibility for training, supervising and supporting OST medical teams. OST doctors who have questions about how to handle particular cases can turn to the physicians at TUTH for guidance. A regular schedule of supervisory visits is planned, but had not yet been initiated at the time this case study was developed.

A queue at an OST site in Kathmandu. Patients enrolled in the programme must go in person every day to collect their doses of methadone or buprenorphine.

It is also TUTH's role to keep Nepal's growing community of OST clinicians abreast of important developments in the field by, among others, ensuring that the training curriculum and clinical guidelines are up to date.

Pillar 4: Professionalising the approach to psychosocial support

Opioid substitution therapy is more than just a medical treatment. While methadone or other opioid substitutes may be enough to bring stability to the daily lives of some patients, many require additional psychosocial support to work through a range of issues which underpin and/or have been caused by their drug dependence: relationship problems, run-ins with the law, the loss of a job, tensions within the family, a traumatic experience. For this reason, the international standard is for psychosocial assistance to be provided alongside medically-assisted treatment for opioid dependence.

In many countries such assistance is the domain of professional social workers and psychologists, but in Nepal this was not an option: according to a 2006 WHO assessment of mental health resources, there were a total of six qualified psychologists in all of Nepal (0.024 per 100,000 population) and not a single social worker in this field (WHO, 2006). What Nepal lacked in trained social workers, however, it made up for with its well-organised and motivated community of ex-drug users. Affiliated to a range of different community-based organisations and harm reduction NGOs, and linked together under the umbrella of Recovering Nepal, ex-users were not only vocal advocates for evidence-based drug treatment services, they also formed informal support groups whose members cared fiercely for one another.

At the time the harm reduction project began in Nepal in 2009 the outlines of a peer-driven approach to psychosocial support were already visible, if somewhat chaotic. With agreement from the Ministry of Home Affairs and the TUTH doctors, an NGO was managing the 'social side' of the OST programme at the TUTH site, but its approach was largely improvised.

'We realised that an SSU was needed,' says Saroj Ojha, the psychiatrist who ran the site at that time, 'but we had no idea what this should look like or how it should work.' The physical set-up was challenging – the dispensing room was tiny and there was no space nearby where OST patients could meet with the NGO staff – and the relationship with the clinicians and the hospital administration was not always smooth. 'The hospital didn't want drug users on the hospital premises,' recalls Kumar Lama, a project manager with the NGO. 'Most of the patients had problems and there was anti-social activity going on. People would sleep in the street, and sometimes sell and use drugs right there. We had three staff members on hand, but it was hard to handle the situation.'

Clarifying roles and setting standards for Social Support Units

In the absence of established psychosocial services and trained social workers, advisors with the harm reduction project attempted something quite unique in a developing country setting: to support and train groups of ex-drug users to provide psychosocial support in the context of OST. There were two main priorities: first, to bring structure to the work of the SSUs which were already active at OST sites by defining roles and setting operational standards, and second, to build a cohort of lay social workers by training ex-drug users in the basic principles of social work.

Between 2013 and 2015 GIZ brought together in a series of working sessions in Kathmandu a group of civil society activists and ex-users from Nepal with two German experts from the Faculty of Social Work and Health at the Frankfurt University of Applied Sciences and the NGO Deutsche AIDS-Hilfe. While they were new to Nepal, the Germans knew from their own experience the types of psychosocial support elements which should ideally accompany OST.

A social worker (left) with the NGO Saarathi speaks with an OST patient after his morning dose. Psychosocial support services are a mandatory element of OST in Nepal.

In discussion with them, the Nepalese partners saw how the work they were already doing at the OST sites could be formalised and re-structured to meet these different needs. Together, this working group came up with a set of standard operating procedures for the SSUs (NCASC, 2016) which describe their core functions, the principles which guide their work, the types of services they provide, and how these are organised and implemented.

'It was a very good learning process,' says Heino Stöver, head of the Institute for Addiction Research at the University of Applied Sciences in Frankfurt. 'It wasn't something bureaucratic. We developed the basic structure together: what services are needed, what the current situation is in Nepal, what resources they can draw upon from formerly drug-dependent persons in their communities.' The resulting document, endorsed by the National Centre for AIDS and STD Control, acted as a resource for existing SSUs as they re-structured and began to professionalise their work, and as a road map for other NGOs that would start working as SSUs in the future.

'These standard operating procedures spell out the basic standards,' says Apurva Rai, of SPARSHA Nepal. 'We now have clarity about job descriptions. It's clear what services we provide, how these should be carried out and by whom. And we have a basis for supervision and monitoring – we can make sure that certain things are present, where and when they should be.'

Training ex-users to work as lay social workers

The next step was to develop a curriculum which could be used to train staff of SSUs in the basic principles of outreach, peer education and counselling work. While it was clear that a stand-alone course could never be a substitute for in-depth professional training, the idea was to introduce participants to some of the fundamental principles governing the relationship between professionals and patients. 'We focused on the things that must be kept in mind when engaging with patients,' explains Heino Stöver. 'There are a handful of key areas where a professional must check his or her own behaviour, like how you reflect on your own role, the messages you send out about yourself, and how to maintain a professional distance.'

These were indeed key challenges for the SSUs. The informal approach to peer support that had sprung up spontaneously among Nepalese NGOs in this field had no theoretical grounding. Many of the ex-users had limited education. The fact that they came from a drug-using background gave them a lot of credibility and enabled them to reach people who might otherwise never seek out services, but it did not, per se, qualify them to counsel others. It also presented certain risks, including that regular direct contact with active drug users could lead ex-users to relapse or that they might struggle to remain objective about others' situations given their own personal histories.

Social Support Unit staff try to reduce the side consumption of illicit drugs among OST patients, while also educating them about ways to minimise risk if they do continue injecting. Here, a social worker counsels a patient on safer use.

A detailed training curriculum (Recovering Nepal, 2015), aligned to the standard operating procedures, was jointly developed by a core group of civil society activists working in this field and the visiting German experts. It is comprised of 18 modules which can be used singly or in combination, depending on the need. The curriculum includes background modules on drugs and drug dependence, HIV, tuberculosis and hepatitis, and substitution therapy, as well as sections on user-friendly services, motivational interviewing, how to work with families, reaching out to female patients, and making referrals to community services. Emphasis is placed on practical skills: how to handle interactions with patients, how to ask questions, and how to help patients set goals. Throughout, the curriculum reflects an awareness of the particular challenges facing ex-drug users being trained as lay professionals in the field of drug treatment and offers guidance on ways to reduce the likelihood of relapse.

A group of master trainers, working alongside the German experts from the Frankfurt University of Applied Sciences and Deutsche AIDS-Hilfe, has used the curriculum to conduct trainings for staff of SSUs at all new OST sites, as well as for those working at already existing OST sites. Approximately 90 staff from 11 different organisations have taken part in these sessions, which are supported financially by the Global Fund via Save the Children.

Institutionalising support for Social Support Units

The strategy which has been pursued in Nepal of building up the skills of ex-users to provide psychosocial support services as part of an OST programme was an innovative response to a fundamental problem. However, it remains to be seen whether these lay social workers will be able to develop their skills to the point where they can provide quality psychosocial support services on their own, rather than in combination with more highly-trained experts as is the case in Germany. On this point people closely involved with the project hold differing views. Some believe that the generally low level of education among ex-users will prove to be a constraining factor – that even with continuous training and support it will not be possible to rise above a certain level. Others believe that it is possible to provide a viable basis for the provision of psychosocial support through training in counselling and ethics.

Given these open questions, the importance of systematically monitoring the work of the SSUs, both at individual OST sites and across the programme as a whole, is an important priority in the coming years. As German support draws to an end in mid-2016, responsibility for training, supervising and monitoring the work of SSUs has gradually been transferred to Recovering Nepal. GDC has provided direct capacity-building support to the organisation to help it develop the tools and systems needed to play this role.

Pillar 5: Positioning OST as part of comprehensive care for people who inject drugs

OST was introduced to Nepal as an HIV prevention measure, but the health needs of people with opioid dependence go far beyond the prevention and treatment of HIV. The harm reduction project has sought to facilitate linkages between OST sites and other types of health services so that patients enrolled in substitution therapy have access to comprehensive care.

When GDC first started supporting OST in Nepal, the OST patients at TUTH were reluctant to seek out health services and were not well accepted by staff at the specialised clinics for people infected with HIV and tuberculosis. 'People who injected drugs were seen as unreliable and unable to follow through properly with long-term treatments for tuberculosis and HIV,' explained Hans-Günther Meyer-Thompson, the project's first medical advisor, 'but we know as soon as they are stabilised on methadone, they can comply.' The team invested a lot of effort in the initial phase of the project in building relationships with the directors of other vertical health programmes, educating them about OST and convincing them to accept the OST patients into treatment. This approach, based on direct personal negotiations, was successful to a degree and marked the start of an informal referral system between the OST programme and other parts of the health system.

Once the OST programme began to grow, the challenge was to figure out how to facilitate referral networks and patient documentation across a larger number of sites. When new OST sites opened up in public hospitals or NGOs, they were not always welcomed by hospital administrators and clinicians. Representatives of NCASC, staff with the harm reduction project and the local SSU would conduct awareness and sensitisation meetings with administrative and clinical personnel at hospitals prior to the commencement of OST services, and used these sessions to stress the importance of providing non-discriminatory care to OST patients. The doctors and nurses

who were trained by TUTH to provide OST services were also taught about common health problems facing people who use drugs, instructed to conduct thorough clinical examinations when enrolling patients into the programme, and encouraged to refer patients to other services as appropriate. The blended e-learning course, described earlier, was also designed to help clinicians who needed guidance treating patients with multiple, overlapping health issues.

These and other efforts (see Box 7) were guided by Hans-Tillman Kinkel who, as medical advisor to the project from 2012 to 2014, helped to shift the emphasis from a narrow HIV-focused intervention to one promoting comprehensive care for people who inject drugs. 'When you are working with people with complex health needs, the outcomes can only be good if you are offering comprehensive care,' he said recently. 'Patients often have multiple health problems: some need

Box 7. 'Exploding the silence around hepatitis C'

In Nepal, as in many parts of the world, hepatitis C has overtaken HIV as the most acute health crisis facing people who inject drugs. 'The reality is that people are living with HIV, but dying of hepatitis,' says Anan Pun, the head of Recovering Nepal, referring to the large number of people who inject drugs who are infected with both diseases. Effective - but expensive - new direct-acting antiviral treatments for hepatitis are out of reach for all but the richest Nepalese, and outdated ART regimens which are contra-indicated for people with HIV-hepatitis co-infections are still in widespread use.

The harm reduction project has helped to galvanise action around the hepatitis C epidemic, including through support for two important clinical studies which are informing the development of a national hepatitis treatment protocol. The first, conducted in 2013, generated evidence about the prevalence of HIV, hepatitis B and hepatitis C, and factors affecting responsiveness to hepatitis C treatment (Kinkel et al., 2015). The second, implemented by GIZ with additional support from the Global Fund, Gilead (USA) and Natco (India), is validating a treatment model for hepatitis C care employing direct-acting antivirals recently available in Nepal.

■ *In some regions of Nepal nearly every second person who injects drugs is infected with hepatitis C. Activities supported by the harm reduction project have focused national attention on the epidemic.*

The GIZ Hepatitis C Treatment Validation Protocol – the first direct-acting antiviral-based model rolled out to manage hepatitis C mono-infection and HIV-hepatitis C co-infection in the developing world – is breaking ground with impressive outcomes. Thus far the GIZ-initiated 'Nepal Model' for community-based hepatitis C therapy has treated over 150 patients, including those with HIV and/or cirrhosis, in Kathmandu and three other districts of Nepal. By utilising community-based ART and OST sites, the study has diagnosed, treated and monitored patients for outcomes and toxicity. Early outcomes predict over 90% hepatitis C cure in these most at-need and difficult to treat cohorts. Best practices from the Nepal Model may show the way forward to extending hepatitis C care to at-need communities worldwide.

The project also supported the adaptation and translation of a training manual on HIV and hepatitis C co-infection, originally developed by the Treatment Action Group (New York) and the Thai AIDS Treatment Action Group. The Nepali version of the manual has been distributed widely and used as the basis for training workshops on HIV-hepatitis co-infection for people who inject drugs, civil society activists and health workers alike.

'The hepatitis C studies have lit a fire in the community,' says Apurva Rai, of SPARSHA. 'They've opened up a totally new discussion at national level about the need for updated HIV guidelines and the introduction of hepatitis C treatment guidelines, and are informing advocacy efforts for new ART regimens. Doctors used to treat HIV in their own fashion, but now patients are coming to them and asking whether the regimens they're on are the right ones. Helping to update HIV care and explode the silence around hepatitis C are some of the most important contributions GIZ has made.'

anti-depressants, some need primary care to treat an ulcer, while others need an antibiotic for a skin infection. A methadone programme aimed at HIV prevention is a good way to get a foot in the door in terms of addressing the health needs of people who use drugs,' he continues, 'but ideally this needs to advance into a comprehensive programme to provide primary health care to people who inject drugs.'

According to people close to the programme, there is still some way to go until the clinicians working at the OST sites fully take on board their role in the provision of comprehensive care. At present, doctors are contracted to support the OST sites for a certain number of hours per week; reportedly, many of them view their responsibility quite narrowly, as limited to setting and monitoring patients' methadone and buprenorphine doses. Another problem is that, while OST services are provided free of charge, other primary health care services which OST patients may require are not. Even when OST doctors refer their patients onward, there is no guarantee that they will be able to afford the additional services.

Viewed through the lens of comprehensive care, the 'one-stop-shop' model, where everything from primary health care to disease-specific treatments is available at a single location, is a particularly promising approach. Compared to stand-alone OST sites, patients are more likely to seek and receive the care they need because services are close by, are free of charge, and are provided in a respectful and non-discriminatory environment. At present only SPARSHA Nepal offers OST as part of an integrated set of services.

Pillar 6: Ensuring quality and monitoring programme outcomes

The early years of Nepalese-German cooperation on harm reduction were focused on laying the groundwork for a viable national programme: optimising the OST pilot sites, building political support and securing longer-term financing. Later on, as the programme began to grow and become more standardised, increasing attention was paid to systems for monitoring service quality and managing the programme as a whole. In general, however, these remain some of the weakest aspects of the OST programme and will require continued investment in the years ahead.

Management challenges in a complex programme set-up

Because the OST programme is under the joint authority of two different ministries, the institutional set-up for programme management is particularly complex. Roles are now much clearer than they were five years ago, but the programme still lacks formalised coordination structures and procedures suitable for its size and scope.

The roles and responsibilities of different actors are described in the *Management Guidelines for Opioid Substitution Therapy in Nepal*, but as these pertain to overall programme management they place more emphasis on legal aspects (e.g. licensing of sites, authority to import controlled substances, supply chains and drug storage) than on health-related aspects (e.g. monitoring treatment outcomes, clinical oversight). More attention is paid to the powers of the Ministry of Home Affairs to authorise (or suspend) the operation of OST sites than to the role of the Ministry of Health in providing technical leadership to the programme. The guidelines do not mention the management arrangements which should govern the programme as a whole, apart from describing a 'central monitoring committee'[9] convened by the Ministry of Home Affairs which should make biannual monitoring visits to each OST site.

In practice, the OST Technical Working Group remains the main coordinating structure which brings together representatives of both ministries and the other institutions that play roles in overseeing, implementing, and financing the programme in Nepal. Working Group meetings are called on an as-needed basis rather than according to a regular schedule; at one point a year passed between meetings. Many aspects of programme management continue to take place through informal discussions and in small groups, with problems and challenges addressed re-actively, rather than pro-actively. 'OST has become everyone's responsibility and no one's responsibility,' observes Ujjwal Karmacharya of the harm reduction project. 'We have been in the middle trying to tie together all the partners.'

[9] Comprised of representatives of both ministries, stakeholder organisations, and an OST doctor.

Since the start of Global Fund financing there have been several 'crisis points' with potentially serious consequences for the smooth functioning of the programme that illustrate the limitations of current programme management arrangements: the failure to procure methadone in a timely manner led to a near stock-out of supplies in 2012 and late disbursement requests to the Global Fund resulted in gaps in the payment of OST doctors' salaries in late 2014. More recently there have been months-long delays in the issuance of licenses by the Ministry of Home Affairs for new OST sites to open in accordance with the scale-up plan. In each of these cases it has been necessary to find quick fixes and to then work on longer-term solutions.

The overall performance of the OST programme would be greatly enhanced by regular meetings of the Technical Working Group or similar steering body. The fact that this has not yet emerged, despite the best efforts of project advisors, suggests that there is still insufficient political ownership on the part of government counterparts. OST is now accepted, but not yet championed, by Nepalese authorities.

More focus needed on the quality of services

Challenges related to overall programme management are mirrored in limitations in the routine monitoring of programme performance.

The clinical guidelines and standard operating procedures for SSUs, developed with German support (and described earlier), set forth the standards according to which OST services should be implemented in Nepal. They are accompanied by comprehensive training curricula which are used to prepare clinical staff and lay social workers for their roles and responsibilities in the provision of psychosocially-assisted OST. These represent important framework documents for the OST programme as a whole and have brought much-needed standardisation to the provision of OST.

The harm reduction project has also helped to introduce systems for clinical recordkeeping at site level: the MeDoSys systems record the doses dispensed to each patient (and can automatically generate various types of summary reports, as well as manage patient documentation), while specially designed paper records are used by clinical staff and social workers to record patients' clinical and personal histories, the results of intake assessments, and details of treatment plans. These contributions have helped to systematise the day-to-day operations of OST sites and are an important step towards a case management approach.

The MeDoSys system registers the doses dispensed to each patient as part of a comprehensive patient documentation system, making it easy to track compliance and identify drop-outs.

Less attention has been paid thus far to the use of routinely collected data to monitor and analyse the day-to-day performance of the programme. Are patients being initiated and stabilised at appropriate levels of methadone and buprenorphine? Which substitute drug is most suitable for users of different pharmacological cocktails? What proportion of OST patients is continuing to use illicit opioids on the side? What factors lead some patients to drop out once initiated on treatment? What frequency of counselling is optimal for keeping patients stabilised in the programme? Some service providers, such as SPARSHA, are pursuing a data-driven approach to OST, but at many other sites this has not yet become the norm.

In order for the programme to become more robust, it is essential that these types of questions to be asked and answered – and that this information be used to guide the further development of the programme. NCASC is the institution that should provide technical leadership for the programme, but it has not fully assumed this role. Programme monitoring has been driven by external partners – first GIZ, then Save the Children on behalf of the Global Fund. Efforts to build the NCASC's technical capacity to manage the OST programme have yielded minimal results – offers to place a long-term advisor in the NCASC, for example, were not accepted – and the regular turnover of key staff in NCASC has undermined institutional learning. The Ministry of Home Affairs shows more initiative in monitoring the programme, including through unannounced site visits, but these are more oriented to uncovering procedural deficiencies (e.g. in methadone storage and dispensing) than on assessing treatment outcomes.

The issue of monitoring and evaluation is likely to remain a difficult one for the foreseeable future. As German support comes to an end, TUTH and Recovering Nepal will expand their responsibilities for monitoring and supporting the medical and social sides of OST, respectively, with financial support from the Global Fund via Save the Children. Both institutions are well-positioned to play these roles, given their direct involvement in the development of the framework documents and training curricula, and are motivated to do so.

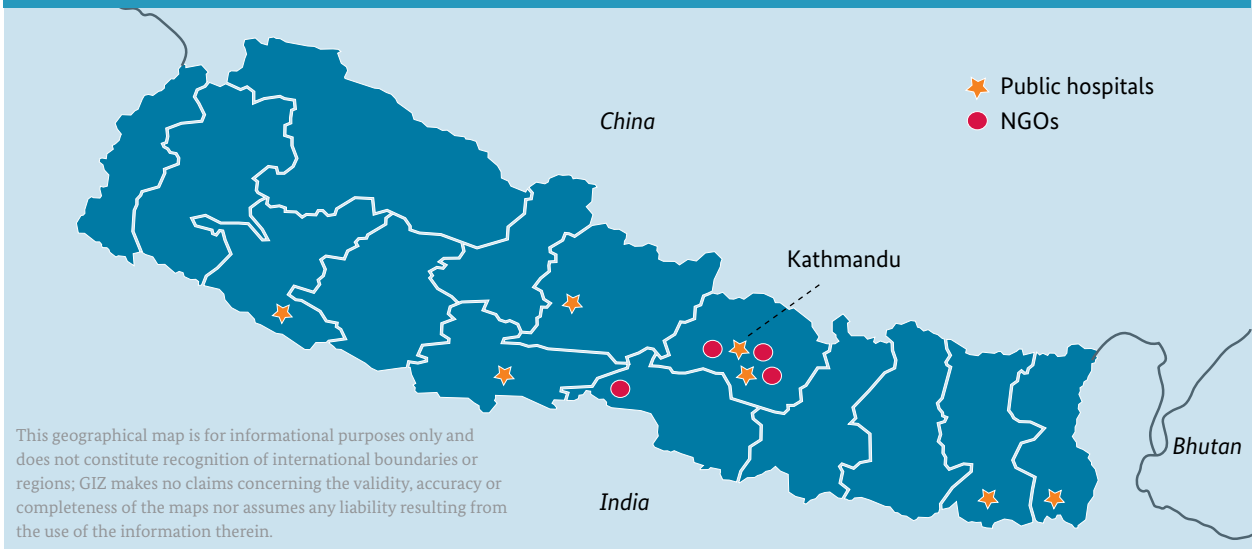
Still, in the absence of stronger central leadership for the programme as a whole, it is difficult to envision how better programme-wide monitoring and evaluation systems will be established in the near future. 'This is a real risk for the future,' says Bikash Nepal, an advisor with the harm reduction project. 'There has to be a mechanism to ensure the quality of the programme, to generate evidence about whether it is working, and then to communicate to people what it is accomplishing.'

Results

Between 2009 and 2016 German Development Cooperation supported the development of the fundamental elements of a national OST programme in Nepal. Key results[10] include the following:

- OST has been elevated to the status of a national programme under the joint authority of the Ministry of Home Affairs and the Ministry of Health as a result of successful advocacy and sensitisation efforts.
- OST is being implemented in accordance with country-specific policy documents (e.g. Management Guidelines, Clinical Guidelines, Standard Operating Procedures for SSUs) which have been endorsed at a national level.
- Innovative approaches to the delivery of OST – including NGO-run sites and the provision of psychosocial support by ex-drug users – have been tested and integrated into the design of the national OST programme.
- Training curricula for OST clinical and social support staff have been developed and endorsed by the NCASC. TUTH and Recovering Nepal have assumed responsibility for training and supporting OST clinical and social support teams respectively. A total of 62 doctors, nurses and medical residents and 94 SSU staff have been trained in OST and comprehensive health care for people who use drugs.
- Psychosocially-assisted OST is provided on a decentralised basis at seven public hospitals and four NGO-run sites in four of Nepal's five regions (see Figure 3). Preparations are underway to open two further sites at public hospitals; the scale-up plan envisions eight more NGO-run sites.
- As of May 2016, 887 people are enrolled in substitution therapy (868 men and 19 women). Since 2009, 3,527 people have enrolled in the programme (3,423 men and 104 women).[11]
- Both methadone and buprenorphine are available as substitution drugs. Approximately 9% of current OST patients now receive buprenorphine (which only began being dispensed in January 2016); the remainder receive methadone.
- MeDoSys dispensing systems, manufactured by CompWare Medical and procured through the national OST programme, are operational at all OST sites. There have been no methadone stock-outs. Methadone dispensing has continued uninterrupted, even following the devastating earthquake in April 2015.

Figure 3. Location of OST sites in Nepal, June 2016



[10] Data as of May 1, 2016.

[11] This figure may reflect one or more re-enrollments of the same patients.

Learning from implementation

This final chapter summarises the main learnings generated since 2009 when German Development Cooperation began providing support for Nepal's OST programme. Its insights may be relevant for other low-income countries which are planning to introduce or expand opioid substitution therapy.

It is possible to build a national OST programme in a challenging context

The experience in Nepal has shown that it is possible to build up the main pillars of a national OST programme in a low-income country where harm reduction approaches are permitted, but not embraced by authorities. It has demonstrated that a pilot project can serve as the nucleus of a much larger programme if a systematic approach is subsequently followed and investments are made in multiple critical areas simultaneously. Furthermore, it has shown that, given a sufficient commitment of time, an international organisation like GIZ can play a critical facilitation role between parties with different interests, helping to deepen engagement and build trust between government, civil society organisations and medical professionals who are all critical to the success of the programme.

After seven years of continuous advocacy, policy advice and capacity building, GDC will be leaving the field of harm reduction in Nepal with the fundamental elements of an OST programme in place. Patients are receiving medical and psychosocial care in accordance with officially-agreed standards, clinical and psychosocial support staff are trained by local institutions using approved national curricula, new OST sites are on track to be opened, and the programme is robust enough that services continued uninterrupted through the devastating 2015 earthquake. Viewed through a critical lens, however, the achievements appear fragile. A true picture of the viability of the programme will only be clear several years from now, well after GIZ has ended its technical backstopping role.

HIV can be an effective entry point, but a sustainable OST programme should be embedded in a public-health oriented drug policy

OST got its foot in the door in Nepal as an HIV prevention intervention and its scale-up is being financed by the Global Fund as part of the country's HIV strategy. Even in the absence of an overarching drug policy which recognises harm reduction,[12] it was still possible in Nepal to extend OST to a larger scale because of its link to the HIV epidemic. But OST is much more than an approach to HIV prevention: it should be part of a broader strategy for supporting and treating people dependent on opioids, whether they inject or not.[13] The experience in Nepal suggests that introducing OST as part of an HIV strategy is an effective way to get the service started, but may not be enough to guarantee its long-term sustainability.

If Global Fund financing is ever curtailed or cut off, it is far from clear how the OST programme would continue. The government of Nepal has little financial stake in the programme and has relied heavily upon technical support from external partners – first UNODC, and more recently GIZ and the Global Fund (via Save the Children) – to manage the programme.

For OST to truly be owned and led by the Nepalese government a broader sea-change in the country's approach to drug dependence is required. Unfortunately, the needs and rights of people who use drugs are still not prioritised in Nepal and efforts to reform the 1976 Narcotics Control Act – which GDC has actively supported – have not yet born fruit. OST's position as a special service – essentially, a vertical programme supported by external financing – makes it more vulnerable than it would be if it were reflected in a national drug policy with a public health and human rights orientation. Drug policy reform is a key challenge for the coming years – one whose resolution could help to secure the achievements of the OST programme and give it a stronger basis for the future.

[12] The 1976 Narcotics Act has not been amended since 1992 and maintains a strong law enforcement-orientation.

[13] Sustainable Development Goal 3 ('Ensure healthy lives and promote well-being for all at all ages') includes the following target: Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol.

Solid M&E systems are particularly important for public health interventions which face widespread scepticism and opposition

The experience in Nepal highlights the risks of not paying sufficient attention to monitoring and evaluating whether an OST programme is generating its intended results. Advisors invested so much effort into advocating for OST, building capacity to deliver services, and troubleshooting various implementation obstacles that this essential building block of M&E never took centre stage. Basic recordkeeping is in place, but the more sophisticated capacities of the MeDoSys patient documentation system are not being utilised to analyse programme performance. Qualitative data about patient experiences in the programme – including reasons for dropping out – are almost entirely lacking.

This type of information is vital – not only to improve the quality of the services, but also to deepen political and popular support for OST and to increase enrolment. OST remains a contested intervention in Nepal. Awareness is still relatively limited, particularly outside Kathmandu, and it continues to encounter strong resistance – including from hospital administrators, health workers, and the general public – when introduced into new communities. An important lesson from Nepal's OST programme – and one which may be applicable to other interventions regarded as controversial which target marginalised populations – is that it is not enough to convince decision-makers to allow a service to be provided: the approach must be sold much more broadly, ideally using local evidence of effectiveness.

Ex-users have a central role to play in both advocating for and delivering services

Another key learning is that there can be a large role for ex-users not only in advocating for services for people who use drugs, but also in actually delivering these services. In Nepal it was possible to build a formal implementation role for civil society organisations into the national service delivery model for OST and to create a cadre of lay social workers to work alongside clinical teams at OST sites.

The direct involvement of ex-users in the SSUs has improved outreach to a hard-to-reach target group and helped to close an enormous service gap while at the same time providing much-needed job opportunities for people seeking ways to reintegrate into society. It is one of the most innovative aspects of the Nepalese OST programme and one which could be applicable in other countries where there are few trained social workers available to provide psychosocial support services.

Embarking upon a pilot project without a clear commitment to national scale-up should be thought through carefully

The national OST programme in Nepal is not the result of a planned and orderly process. It grew in fits and starts, pushed forward by a determined network of OST champions and further enabled by financial backing from the Global Fund. It took years of lobbying and awareness raising to convince officials in the responsible ministries that the original OST sites could – and should – be scaled up. And it took significant effort to optimise the delivery of services at the already-operating sites so that these could eventually serve as models for a larger national programme.

Although this pragmatic and improvised approach was ultimately successful – and was, in effect, the only option given the limited support for OST on the part of the Nepalese authorities – it also came at a cost. Progress was slower and less efficient than it likely would have been had there been a clear commitment at the outset to scale OST up nationally. This would have allowed for a much more systematic process, including the development of key guidelines, standards and training curricula *before* the initiation of services; the establishment of model sites to test how best to adapt OST services to local conditions; the design of robust M&E systems; and the gradual extension of OST services in a standardised manner.

Countries that are considering introducing OST should think carefully about building outwards from a small pilot project. While pilots can offer a quick and flexible way to get a new approach going – particularly in places where official support is lacking – it can be very difficult to pivot from this starting point and to bring into place the various systemic elements (e.g. financing, legal framework, institutionalisation of training curricula and certifications, integration into health system) which are required for OST to work at a larger scale. The experience from Nepal suggests that, given the chance, it is preferable to introduce OST with the express intention of scaling it up to a national programme.

Peer review

Prior to publication each case study in the German Health Practice Collection is reviewed by two independent peer reviewers. In this case Christian Kroll, who until his retirement in 2012 was the Global Coordinator for HIV/AIDS with UNODC, and Daniel Wolfe, Director of the International Harm Reduction Development Program at the Open Society Foundations, acted as peer reviewers. The reviewers were requested to comment on the following questions:

- How can the approach to OST which has been established in an industrialised country, such as Germany, be applied in the context of a low-income country like Nepal?
- What new knowledge has been generated along the way that might be useful for other countries seeking to introduce or expand OST and for the wider community of practice in this field?

Both reviewers strongly recommended the case study as an important contribution to knowledge in the field of harm reduction. Their main findings are summarised below.

The described approach is guided by German experience, but adapted to the Nepalese context

According to the peer reviewers, the case study shows that it is possible to apply harm reduction measures such as OST in a low-income country such as Nepal, and that the knowledge, experiences and lessons learned in an industrialised country – in this case, Germany – can be drawn upon to shape an effective programme in a very different setting. At the same time, both reviewers stress that the achievements generated in this case are a reflection of the fact that the German experience was extensively and sensitively adapted to the political, economic, cultural and social circumstances of Nepal. A direct transfer of expertise is neither desirable, nor likely to succeed.

The project successfully bridged the divide between the health and security sectors

Both reviewers commented upon the fact that the project helped to bring about closer collaboration between the health and law enforcement sectors in Nepal, something that was critical for the success of the project. One reviewer drew particular attention to the role of Nepalese civil society organisations in bridging the divide between the two ministries, noting that this outcome could have remained elusive without their direct involvement. The other reviewer observed that the approach that was taken to negotiating the disparate interests of the health and security communities is likely to be of interest to development practitioners and civil society actors in other countries.

Providing OST as part of a comprehensive and integrated approach is the main challenge

One reviewer observed that, while substitution treatment itself is technically relatively easy to administer, it is much more challenging to integrate it into the broader health system and to ensure that it is accompanied by social support services. Continuous advocacy and capacity building will be required with all stakeholders in Nepal to draw closer to this ultimate goal. The other reviewer noted that the project in Nepal has supported certain approaches to comprehensive programming – such as working with family members of OST patients, training lay social workers, and treating the 'whole person,' not just the opioid dependence – which could usefully be applied or strengthened in industrialised countries, as well.

The case study generated several important insights into 'what works' in establishing a national OST programme

For development practitioners, policymakers and civil society organisations in other countries who are working to expand the availability of OST, the case study provides a number of insights into 'what can work.' Among the new insights noted by the peer reviewers are:

- **Advocacy and mobilisation of civil society:** Substitution treatment can be successfully established in South and South-East Asia through advocacy and mobilisation of civil society actors;
- **Integrated services:** There are significant benefits in bringing health systems and community organisations together to deliver integrated services for people dependent on opioids;
- **Public-private partnerships:** Public-private partnerships can play an important role in enhancing project implementation, in this case by addressing widespread security concerns regarding the diversion of the substitution drug and providing effective opportunities for data collection, fostering monitoring and evaluation efforts;
- **HIV as entry point:** Addressing HIV can be an important entry point for addressing other diseases, such as hepatitis C and tuberculosis; and
- **Financial sustainability:** There are development partners, such as the Global Fund, which are willing to invest in harm reduction approaches and are in a position to contribute to financial sustainability.

Acknowledgements

The Federal Ministry for Economic Cooperation and Development would like to thank Nepal's Ministry of Health and the Ministry of Home Affairs for years of close cooperation in the field of harm reduction. It would also like to thank CompWare Medical GmbH for its key role in the initial public-private partnership project on methadone substitution in Asia.

Many individuals contributed to the development of this publication. Thanks go to Paul Rueckert, head of the GIZ-implemented Support to the Health Sector Programme (S2HSP) in Nepal, and especially to the team responsible for harm reduction – Ujjwal Karmacharya, Patricia Kramarz and Bikash Nepal – who have been tireless champions for OST in Nepal over a period of many years. We are also grateful to Hans-Günther Meyer-Thompson and Hans-Tillman Kinkel, former medical advisors with GIZ, and to Heino Stöver of the Frankfurt University of Applied Sciences, for their contributions to the harm reduction project and to the development of this case study.

During a visit to Nepal, the author greatly benefitted from conversations with Fanindra Pokharel of the Ministry of Home Affairs and Dipendra Singh and Bhesh Pokharel of the National Centre for AIDS and STD Control, as well as with Saroj Ohja and Sagun Pant of the Psychiatry Department of the Tribhuvan University Teaching Hospital, Rajan Bhattarai of Save the Children, Anan Pun of Recovering Nepal, Prawchan K.C. and Apurva Rai of SPARSHA Nepal, and Kumar Lama and Bikky Khadghi of the NGO Saarathi.

We also acknowledge with thanks the assistance of Gloria Lai of the International Drug Policy Consortium. Viktor Siebert of the GIZ-implemented PROFILE project provided helpful feedback on the draft text.

We are grateful to Christian Kroll, who prior to his retirement in 2012 was the Global Coordinator for HIV/AIDS with UNODC, and to Daniel Wolfe, Director of the International Harm Reduction Development Program at the Open Society Foundations, for their valuable reviews of this case study.

This case study was researched and written by Karen Birdsall. The valuable inputs made by Anna von Roenne, the managing editor of the German Health Practice Collection, throughout the publication process are gratefully acknowledged.

References

Ambekar A, Rao R, Pun A and Kumar S (2013). The trajectory of methadone maintenance treatment in Nepal. *International Journal of Drug Policy* **24**, e57-60.

CCM Nepal (2010). *Proposal form – Round 10. Single country applicant. Sections 1-2.* Application to the Global Fund to Fight AIDS, Tuberculosis and Malaria. August 20, 2010.

Cook C, Bridge J and Stimson G (2010). The diffusion of harm reduction in Europe and beyond. *Harm reduction: Evidence, impacts and challenges.* Lisbon: European Monitoring Centre for Drugs and Drug Addiction.

Federal Institute for Drugs and Medical Devices (2016). *Bericht zum Substitutionsregister. Januar 2016.* Bonn: Federal Institute for Drugs and Medical Devices, Federal Ministry of Health.

Global Commission on Drug Policy (2014). *Taking control: Pathways to drug policies that work.* Rio de Janeiro: Global Commission on Drug Policy.

Government of Nepal (2008). *Hard drug users in Nepal. Some statistical facts: 2063.* Kathmandu: Ministry of Home Affairs.

Government of Nepal (2013). *Survey report on current hard drug users in Nepal - 2069.* Kathmandu: Central Bureau of Statistics, National Planning Commission Secretariat.

Harm Reduction International (2014). *The global state of harm reduction 2014.* London: Harm Reduction International.

Kinkel H-T et al. (2015). Prevalence of HIV, hepatitis B and C infections and an assessment of HCV genotypes and two IL28B SNPs among people who inject drugs in three regions of Nepal. *PLoS One*, 10(8):e0134455.

Kinkel H-T and Kramarz P (2013). Methadone statt South Asian Cocktail. *Dr. med. Mabuse* **203**, 55-57.

Lawrinson P et al. (2008). Key findings from the WHO collaborative study on substitution therapy for opioid dependence and HIV/AIDS. *Addiction* **103**, 1484-1492.

Lawyers Collective HIV/AIDS Unit (2007). *Legal and policy concerns related to IDU harm reduction in SAARC countries*. New Delhi: United Nations Office on Drugs and Crime, Regional Office for South Asia.

Lowinson J et al. (2004). Methadone maintenance. In Lowinson J (ed). *Substance abuse: A comprehensive textbook.* Philadelphia: Lippincott Williams & Wilkins.

Mars S (2003). Heroin addiction care and control: The British system 1916 to 1984. *Journal of the Royal Society of Medicine.* **96**(2), 99–100.

Michels I, Stöver H and Gerlach R (2007). Substitution treatment for opioid addicts in Germany. *Harm Reduction Journal* **4**(5).

Ministry of Home Affairs (2014). *Management guidelines for opioid substitution therapy in Nepal.* Kathmandu: Government of Nepal.

NCASC (2004). *National estimates of HIV infections 2003.* Kathmandu: Ministry of Health and Population, National Centre for AIDS and STD Control.

NCASC (2010). *National estimates of HIV infections 2009.* Kathmandu: Ministry of Health and Population, National Centre for AIDS and STD Control.

NCASC (2014). *Training curriculum for service providers: Comprehensive health care and opioid substitution therapy in Nepal.* 2nd edition. Kathmandu: Ministry of Health and Population, National Centre for AIDS and STD Control.

NCASC (2015a). *Clinical guideline for opioid substitution therapy in Nepal, 2015*. Kathmandu: Ministry of Health and Population, National Centre for AIDS and STD Control.

NCASC (2015b). *Fact sheet 7: HIV surveillance in Nepal, 2015.* Kathmandu: Ministry of Health and Population, National Centre for AIDS and STD Control.

NCASC (2015c). *Integrated biological and behavioural surveillance (IBBS) survey among people who inject drugs (PWID) in Kathmandu Valley, Round 6, 2015*. Kathmandu: Ministry of Health and Population.

NCASC (2015d). *Integrated biological and behavioural surveillance (IBBS) survey among people who inject drugs (PWID) in the Eastern Terai of Nepal, Round 6, 2015*. Kathmandu: Ministry of Health and Population, National Centre for AIDS and STD Control.

NCASC (2015e). *Integrated biological and behavioural surveillance (IBBS) survey among people who inject drugs (PWID) in the Pokhara Valley of Nepal, Round 6, 2015.* Kathmandu: Ministry of Health and Population, National Centre for AIDS and STD Control.

NCASC (2016). *Standard operating procedure for Social Support Unit in opioid substitution therapy (OST) programme Nepal.* Kathmandu: Ministry of Health and Population, National Centre for AIDS and STD Control.

Ojha SP et al. (2014). South Asian cocktail – the concurrent use of opioids, benzodiazepines and antihistimines among injecting drug users in Nepal and associations with HIV risk behaviour. *Harm Reduction Journal.* **11**(17).

Pfeiffer-Gerschel T et al. (2014). *2014 national report (2013 data) to the EMCDDA by the Reitox national focal point. New developments and trends. Germany.* Lisbon and Munich: European Monitoring Centre for Drugs and Drug Addiction and Deutsche Beobachtungsstelle für Drogen und Drogensucht.

Recovering Nepal (2015). *Training curriculum for staff in psychosocial support units (SSU).* Kathmandu: Recovering Nepal.

Reid, G and Crofts N (2013). Historical perspectives of drug use in Southeast Asia. In Rahman F and Crofts N (eds.) *Drug law reform in East and Southeast Asia.* Lanham, Maryland, USA: Lexington Books.

Sinha A, Adhikari M and Karmacharya U (2009). *New insights into the drug and drug service situation in Nepal. Summary from a needs assessment study, September 2009.* Lalitpur: Recovering Nepal.

Stöver H et al. (2016). Opioid-Substitutionstherapie und Harm Reduction in Nepal. *subLetter*. No. 2, April 2016.

UNAIDS and UNDCP (2000). *Nepal HIV drug assessment report. Drug use and HIV vulnerability. Policy research study in Asia.* Bangkok: Joint United Nations Programme on HIV/AIDS (UNAIDS) Asia Pacific Intercountry Team and United Nations International Drug Control Programme (UNDCP) Regional Centre for East Asia and the Pacific.

UNAIDS (2014). *The gap report.* Geneva: Joint United Nations Programme on HIV/AIDS.

UNODC (2015). *World drug report 2015.* Vienna: United Nations Office on Drugs and Crime.

WHO (2005). *Evidence for action: Effectiveness of drug dependence treatment in preventing HIV among injecting drug users.* Geneva: World Health Organization.

WHO (2006). *WHO-AIMS report on mental health system in Nepal. A report of the assessment of the mental health system in Nepal using the World Health Organization Assessment Instrument for Mental Health Systems (WHO-AIMS)*. Kathmandu, World

Health Organization and Ministry of Health and Population.

WHO (2008). Operational guidelines for the treatment of opioid dependence in the South-East Asia region. New Delhi: World Health Organization, Regional Office for South-East Asia.

WHO (2009a). Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence. Geneva: World Health Organization.

WHO (2009b). *Management of common health problems of drug users*. New Delhi: World Health Organization, Regional Office for South-East Asia.

WHO, UNODC and UNAIDS (2012). WHO, UNODC, UNAIDS technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users. 2012 revision. Geneva: World Health Organization.

Published by
Deutsche Gesellschaft für
Internationale Zusammenarbeit (GIZ) GmbH

Registered offices
Bonn and Eschborn,
Germany

PROFILE - Programme to Foster Innovation, Learning and Evidence
in HIV and Health Programmes of German Development Cooperation

Friedrich-Ebert-Allee 36
53113 Bonn, Germany
Tel. +49 228 44 60 - 0
Fax +49 228 44 60 - 1766

German Health Practice Collection
ghpc@giz.de
www.health.bmz.de/good-practices

Writer
Karen Birdsall

Design and layout
Karsten van der Oord

Printed by
Aksoy Print und Projektmanagement, Eppelheim
Printed on FSC-certified paper

Photo credits
Cover, p. 6, 7, 14, 18, 21, 22: © GIZ/Ujiwal Karmacharya
p. 11, 16, 23, 24, 28: © GIZ/Ingrid Chiron
p. 13: © GIZ
p. 15: © GIZ/Madan Koirala
p. 26: Saarathi

As at:
July 2016

GIZ is responsible for the content of this publication.

On behalf of
Federal Ministry for Economic Cooperation and Development (BMZ),
Division for health, population and social protection

Addresses of the BMZ offices

BMZ Bonn
Dahlmannstraße 4
53113 Bonn
Germany
Tel. +49 228 99 535 - 0
Fax +49 228 99 535 - 3500

BMZ Berlin
Stresemannstraße 94
10963 Berlin
Germany
Tel. +49 30 18 535 - 0
Fax +49 30 18 535 - 2501

poststelle@bmz.bund.de
www.bmz.de