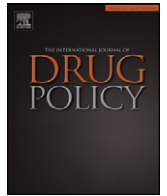




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Policy analysis

A harm reduction paradox: Comparing China's policies on needle and syringe exchange and methadone maintenance

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ABSTRACT

Background: China has launched methadone maintenance treatment (MMT) and needle and syringe exchange programmes (NSEP) as part of the country's HIV prevention strategy amongst injection drug users. MMT is expanding, with backing from multiple government ministries, however, NSEP have received less political support and funding.

Methods: Semi-structured, serial interviews were conducted with key informants, knowledgeable about China's harm reduction policies. Concurrent content analysis allowed for revision of the interview guide throughout the data collection process. This was combined with a systematic analysis of official government policy documents on NSEP and MMT, including white papers, legal documents, and policy statements.

Findings: Early consensus between public security and public health sectors regarding methadone's dual use in HIV prevention as well as method of drug control created broad institutional support for MMT programmes amongst policy makers. In contrast, NSEP were seen as satisfying only the HIV prevention goals of the public health sector, and were perceived as condoning illicit drug use. Furthermore, NSEP's roots in China, as an experimental collaboration with international groups, created suspicion regarding its role in China's drug control policy. NSEP and MMT's distinct paths to policy development are reflected in the complex and occasionally contradictory nature of China's harm reduction strategy.

Conclusions: These discrepancies highlight the need for a more politically sustainable and comprehensive integration of harm reduction projects. Recommendations include improved evaluation methods for NSEP, NSEP-MMT cross-referral system, and stronger NSEP advocacy within the non-profit and public health sectors.

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Introduction

Unsafe drug injection has been the main contributor to HIV transmission in Asia, and HIV infection amongst injection drug users (IDU) accounts for nearly half of all new infections on the continent (Bao & Liu, 2009; Open Society Institute, 2008). Recent research shows that IDU-driven epidemics may play a key role in 'seeding' generalised transmission of HIV through dual risk groups such as IDU who purchase sex or commercial sex workers who inject drugs (Saidel et al., 2003). In 2007 IDU made up the single largest risk group amongst cumulative reported HIV/AIDS cases in China (40.7%); however since 2009 heterosexual transmission is thought to have replaced injection drug use as the predominant mode of transmission, suggesting that this seeding effect may already be taking place (Gill & Oakie, 2007; Grassly et al., 2003). This

underscores the importance of targeted HIV prevention amongst primary risk groups such as IDU in order to avert a generalised epidemic in China and the greater Asia region.

Epidemiologists found evidence of an epidemic in China beginning in the mid-1990s; however, it was not until 2002 that the government mobilised resources to combat it. In the aftermath of the panic surrounding China's 2003 severe acute respiratory syndrome (SARS) outbreak, public health took on a new significance in government policy (Gill & Oakie, 2007), ushering in an era of relative political openness and collaboration with international organisations. The State Council AIDS Working Committee, an interagency committee formed to streamline the government's AIDS policy, created an opportunity for a rare partnership between the Ministries of Health and Public Security and this resulted in experimentation with progressive strategies including needle and syringe exchange programmes (NSEP) and methadone maintenance treatment (MMT) (State Council, People's Republic of China, 2001, 2006a). The Chinese interagency committee's commitment to such programmes has now resulted in a national harm reduction

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programme that is to date more ambitious than many of the countries where these methods originated (Hammett et al., 2008; International Harm Reduction Development [IHRD], 2008; Lurie & Drucker, 1997; Marsch, 1998; Strathdee, 2004; Sullivan & Wu, 2007).

However, whereas MMT has enjoyed broad political support and consistent scale-up in China, NSEP continues to face obstacles in its regular operations (IHRD, 2008). Contrasting programmatic outcomes between NSEP and MMT reveal the pragmatic consensus-building process that has made each programme possible. This paper explores the origins, patterns of scale-up, and challenges in operating NSEP and MMT as they operate in China, to better understand the nature of government support and its implications for these two harm reduction intervention strategies. It also extends policy recommendations to enhance existing strategies and harmonise HIV and drug misuse related goals shared across sectors of the Chinese government.

Defining MMT and NSEP

China's MMT programme refers to a national network of clinics providing daily oral doses of methadone to relieve narcotic craving whilst suppressing symptoms associated with opiate withdrawal (Ministry of Health, 2008). The method posits that by taking methadone, clients can lessen the frequency of heroin injection and thereby reduce the associated risks of disease transmission through unsafe injection. Advocates assert that MMT programmes also indirectly reduce drug-related criminal activity and improve social and employment stability (IHRD, 2008; Ministry of Health, 2008). Needle and/or syringe exchange as defined by Sullivan and Wu, refers to "fixed locations including pharmacies, hospitals or designated needle exchange centres, from where IDU can obtain clean needles and syringes," and can also include the secondary exchange activities of injection equipment from machines or exchangers/peer leaders who deliver the products to IDU in the community (Hammett et al., 2007). Some NSEP provide additional services such as distribution of cotton, alcohol swabs, cookers; counselling on safer injection, wound care, and referrals to drug treatment programmes (Normand, Vlahov, & Moses, 1995). The rationale driving NSEP is that provision of sterile injection equipment can reduce the occurrence of unsafe equipment sharing that leads to the spread of blood borne diseases (Hagen & Thiede, 2000). Advocates also point out that NSEP can provide drug users in the community with educational and referral services. Since the 1990s there has been a consensus amongst the scientific community that NSEP can reduce the spread of HIV without increasing drug use (Goldstein, 1998; Henderson, Vlahov, Celentano, & Strathdee, 2003; Lurie & Drucker, 1997; National Institutes of Health, 1997; Remis, Bruneau, & Hankins, 1998; Watters, Estilo, & Clark, 1994; Wodak & Cooney, 2006). However, debate on this topic persists in policy circles both in China and in the West.

Methods

Over a two-year period from 2007 to 2009, key informants were invited to take part in interviews. Interviewees were from organisations contacted by the first two authors in the course of collecting preliminary data for epidemiological research grants to prevent transmission of blood borne diseases amongst IDU. Each stakeholder was informed that they could refrain from commenting on sensitive issues and that no personal identifying information would be used in the final report. Interviews were conducted by the first author between March 2008 and June 2009 and recorded as shorthand notes, which were later transcribed into a word processing programme to facilitate key term searches. A broad topic guide allowed for greater flexibility to explore a range of issues but

helped to maintain a focus on differences between NSEP and MMT, roles of different government industries in China's harm reduction programmes, and suggestions for future programmes. Prior to intervention-specific questions, definitions of key interview terms were explained to each participant.

Eighteen key informants representing nine establishments participated in interviews. They included individuals from the National Centre for Disease Control and Prevention (Beijing, $n=2$), government operated MMT clinics (Kunming, Kaiyuan, Beijing; $n=6$), independently operated NSEP (Beijing, Kunming, Kaiyuan; $n=3$), municipal level departments of public security (Kunming, $n=2$), and mandatory and voluntary detoxification centres (Kunming, Kaiyuan; $n=5$).

In addition a web-based search was conducted in both English and Chinese for publicly available government documents, including white papers, legal documents, and policy statements. Iterations of Boolean searches were used involving various combinations of the terms: "drugs," "narcotics," "drug control," "opiate addiction," "medical maintenance treatment," "methadone," "injection drug use," "China," "disease control," and "public health" and "HIV/AIDS." Relevant peer reviewed articles published in both languages were also included after searching Pubmed/Medline and China Academic Journals (CNKI) databases using the same search terms listed above.

Differences in approaches to MMT and NSEP

A key distinction is the international attention garnered by MMT in the form of publications, recognition from international drug policy groups—Director Zunyou Wu of the Chinese National Centre for AIDS/STD Control & Prevention (NCAIDS) was awarded the International Harm Reduction Association's Rolleston Award for significant contributions to the field (IHRD, 2008)—and study tours by health experts from Russia, Vietnam, and Malaysia (Malinowska-Sempruch & Bartlett, 2006). On the other hand, coverage of China's NSEPs is largely confined to the foreign media (French, 2006; Jacobs, 2010; Watters et al., 1994) and Zunyou Wu himself has described NSEP as an emergency measure that "will only be used in places where methadone maintenance is not available" (State Council, People's Republic of China, 2001).

Formal political and budgetary support for MMT can be identified in the language of the legal and strategic documents related to China's HIV control strategy. The HIV/AIDS Prevention and Care Regulations of 2006 for example, urges various departments "to take active and well prepared measures to implement community based drug-maintenance treatment" (State Council, People's Republic of China, 2006), and the new Drug Prohibition Law enacted by the Ministry of Public Security (MPS) in June 2008 (State Council, People's Republic of China, 2007) in which MMT is referred to more directly as "medical detoxification," signals unprecedented support within China's public security sector for methadone dispensation as part of China's drug control programme. In contrast, support for NSEP has been limited to provincial level statements, and as described by a behaviour change expert at NCAIDS, has never been codified as a part of national law as it is believed to be too controversial for national public security authorities to support (Liu, Sullivan, & Wu, 2007). Second, whereas MMT is administered by a centralised national working group under NCAIDS that includes representatives from the Ministry of Health (MOH), MPS, the State Food and Drug Administration (SFDA) and the Yunnan Institute for Drug Abuse, NSEP lacks any such national coordinating mechanism. Instead, implementation of NSEP is delegated to individual programmes, who consult an NCAIDS-authored 150 page *Implementation Guide on Needle Exchange Work* (National Centre for AIDS/STD Control & Prevention [NCAIDS], 2007). Lastly, whereas

MMT clinics are fully funded by central government as part of MOH subsidised services, 43% of all funding for NSEP in 2004 came from international organisations (Wu, Sullivan, Wang, Rotherham-Borus, & Detels, 2007b).

As a result of greater institutional support for MMT, its programmes are on a much broader scale than NSEP. According to statistics from NCAIDS internal reports as well as published data from the MPS, the respective coverage rates amongst non-incarcerated IDU for these two programmes was 4.8% and 1.9%, respectively, with an average of 156 IDU accessed per MMT clinic and 40 IDU per needle exchange station (Chinese Centre for Disease Control and Prevention [China CDC], 2008; Open Society Institute, 2008). In 2010 the United Nations Regional Task Force on Injecting Drug Use and HIV/AIDS for Asia and the Pacific, estimated that coverage rates for MMT had increased to 12.9% whilst the proportion of IDUs accessing NSP was only 1.7% (United Nations Regional Task Force on Injecting Drug Use and HIV/AIDS for Asia and the Pacific (2008)).

Policy origins of NSEP and MMT

NSEP were introduced in the early 2000 and were spearheaded by international organisations such as the World AIDS Foundation, the Ford Foundation, Australian Agency for International Development (AusAID), and the UK Department for International Development (DfID), with the ad hoc support of local authorities (Hammett et al., 2003; Hammett et al., 2008; IHRD, 2008). The collective monetary resources and experience provided by these foreign organisations were pivotal in China's early NSEPs. By leveraging their programme funding and capitalising on the interest in public health following the 2003 SARS outbreak, these international organisations successfully forged alliances with health bureaus and police departments in high prevalence provinces including Yunnan, Guangxi, and Xinjiang (Hammett et al., 2003; Hammett et al., 2005; IHRD, 2008; Lurie & Drucker, 1997; Wu et al., 2007a). Although these programmes were implemented by local CDCs; management, evaluation, and dissemination of the largely positive results was overseen by the international organisations. A study of fifteen NSEP in southern China later found that those receiving funding from international agencies had higher rates of needle distribution and collection than those that had not (Henderson et al., 2003).

Another early determinant of NSEP work in China was the existing commercial availability of injection equipment in Chinese pharmacies (Thomas, 2005). The fact that most NSEP provided free injection equipment to clients conflicted directly with the interests of pharmacies which were an alternative access point. "Needle social marketing" projects were developed as a compromise to allow IDU to bring used needles in exchange for vouchers for new needles at participating pharmacies, thus allowing NSEP funds to subsidise pharmacies for needles they provided to IDU. This pharmacy-based intervention strategy also shifted the debate away from the controversy of knowingly providing needles for injecting controlled substances and instead emphasised the opportunities for behavioural intervention created by the peer outreach components of NSEP (IHRD, 2008; State Council, People's Republic of China, 2006b; Watters et al., 1994). It would not be for another four years, however, that NCAIDS conducted the first scientific evaluation of needle social marketing, in which the largely favourable results were used to inform the development of national guidelines on NSEP (IHRD, 2008; State Council, People's Republic of China, 2006b; Sullivan & Wu, 2007). The legislation surrounding needle exchange in China therefore emerged ex post facto, following the demonstrated success of programmes that had operated in the legal void preceding formal recognition.

In contrast, the use of methadone for opiate substitution treatment was virtually unheard of in China until 2003 when NCAIDS decided to launch a pilot programme to investigate its potential as an official HIV control strategy (Pang et al., 2007; United Nations Task Force on Injection Drug Use and HIV/AIDS, 2010). Legalisation of government provision of a narcotic substance required determined lobbying by proponents to overcome factions opposed to MMT (Hammett et al., 2008). Several factors facilitated this, including existing scientific research demonstrating the efficacy of substitution treatment in reducing drug-related crime in addition to reducing HIV transmission (Gossop, Trakada, Steward, & Witton, 2005; Liu et al., 2007; Wu et al., 2007b), strong advocacy by public health 'champions,' (Hammett et al., 2008) and Hong Kong's relatively successful experience with MMT programmes (Newman & Whitehill, 1979). The fact that the scientific literature could demonstrate such programmes' ability to reduce drug-related crime allowed the public security sector to lend its support to MMT in a way they could not for NSEP. Furthermore inter-ministerial consensus was needed to pilot MMT because as a controlled substance methadone could only be distributed according to special measures dictated by relevant government agencies (Ministry of Health, Ministry of Public Security of China, & SFDA, 2006). The fact that the most contentious debates surrounding MMT were overcome before piloting began, established an early precedent for policy consensus amongst stakeholders and provided a consistent policy environment for later scale-up.

The public health vs. public security debate

Conflicting attitudes between public health and public security authorities regarding harm reduction are hardly unique to China (Thomas, 2005). However, its centralised policy making process and decentralised implementation process make consensus amongst the top leadership uniquely important for advancing new policies. The division of labour amongst the various departments overseeing harm reduction programmes further complicates the implementation process: MOH and SFDA oversee all blood testing and distribution of drugs and medical supplies. MPS operates all mandatory detoxification centres where individuals deemed addicted to drugs serve compulsory "treatment" terms, and the Ministry of Justice (MOJ) operates separate detention centres for individuals deemed 'addicts', who serve out longer sentences under the 2008 Drug Prohibition Law (Liu et al., 2007; State Council, People's Republic of China, 2007). Diverging goals amongst the responsible government agencies also drive decentralisation: whereas public health practitioners prioritise reducing the risk of infection from blood borne diseases amongst IDU, public security authorities are charged with enforcing laws against the sale and use of illicit drugs (Liu et al., 2007). As a result public security authorities have a more favourable view of MMT programmes, which are consistent with their stated aims of treating drug addiction as well as reducing demand for illicit drugs and incidence of drug-related crimes. In contrast they feel that NSEP address neither of these aims (Lurie & Drucker, 1997; Wu et al., 2007a).

These distinct views are reflected in the organisational structures of each programme. Whereas MMT clinics are operated by the government and jointly overseen by MOH, MPS, and SFDA, NSEP are implemented solely by district level health bureaus (the local branches of the MOH) and non-government organisations (IHRD, 2008). Public security officials admit confusion regarding their stance on NSEP; a member of the Yunnan provincial public security bureau stated in 2009 that:

... there is a conflict between the laws that we as public security must follow and the regulation about HIV prevention. There is

confusion as to what to follow in practice but it is important at the end to uphold the law (Reid & Aitken, 2009).

This confusion has resulted in police forces that tolerate some needle exchange activities whilst simultaneously using these sites to target active users for arrest. NSEP staff and participants frequently report being arrested or harassed near or around their exchange stations (Souder, 2004), and as described by key informants working as volunteer or staff at NSEP, secondary needle exchangers sometimes experience being tracked by police who follow them to find IDU for arrest (Cohen & Amon, 2008; Human Rights Watch, 2008).

Whilst alleged police harassment has been reported by MMT clinic attendants, key informants who work as staff at these clinics described past instances of engaging in negotiations with their counterparts in the local PSB to request that police not target their clients for arrest. As several of the staff pointed out, MMT clients are far more defensible to the police because of the undisputed legality of taking methadone; whereas NSEP clients are assumed to be active users of heroin, a behaviour which is legally forbidden.

Evaluating harm reduction

The difficulty in tracking the disease status of current IDUs has contributed to debates regarding the impact of harm reduction interventions on HIV incidence. (Degenhardt et al., 2011; Grulich & Wilson, 2010; IHRD, 2008; Montaner et al., 2010; Palmateer et al., 2010; Reid & Aitken, 2009; Strathdee, 2004; Thomas, 2005). Even in well conducted cohort studies, self-selection bias, differential loss to follow up, and confounding by other prevention programmes, pose significant threats to validity. In addition, the political nature of harm reduction has rendered research funding for such programmes highly unreliable, further hindering effective and long-term evaluation studies that could otherwise justify their cost effectiveness. This is particularly the case in China where respect for scientific evidence and dependence on performance indicators for public official promotions make programme evaluations central to the policy making process (Wu et al., 2007b).

The evaluation challenges specific to MMT and NSEP reflect the fundamental differences in their operations. According to interviews with key informants at MMT clinics, to ensure the legality of government administered methadone, the national guidelines for MMT in China require the regular monitoring of clinic participants as well as mandatory testing for opiate use and annual disease monitoring for HIV, syphilis and HCV. Daily contact between methadone patients and MMT staff, inherent to clinic operations, allows for the collection of large amounts of data necessary for monitoring and evaluation. Moreover, routine testing of MMT clinic attendees can yield incidence rates of blood borne disease, which is the gold standard for evaluation of harm reduction programmes, in addition to measures of its impact on the illicit drug trade. A National Working Group evaluation report estimated that in 2008 alone, 3377 new HIV infections had been averted, 16.5 fewer tonnes of heroin had been consumed and that the illegal trade of heroin was reduced by 607 billion Chinese Yuan (Yin, 2009). Such reports provide a shared platform on which HIV prevention specialists and public security authorities can align their goals.

In contrast, national guidelines for NSEP in China require tracking of only two indicators: needle return rate (calculated as number of needles collected divided by the number distributed per time period) and the number of IDU accessed through outreach activities in a given amount of time (China CDC, 2008). Ideally NSEP would also collect information to capture changes in HIV transmission patterns amongst participants, but this would require

active tracking of NSEP clients and regular HIV testing, a task currently only available through China CDC certified testing sites that require personal identification. Self-identification in association with needle exchange activity places participants at risk of arrest and undermines a central NSEP tenet of participant anonymity. As a result, existing reports on disease outcomes amongst NSEP participants have been limited to cross sectional surveys utilising complex methods (China CDC, 2008; United States Centre for Disease Control [US CDC], 2006). Other variables may proxy for measures of programme efficacy, such as participants' self-reported disease status or AIDS knowledge, attitudes, and behaviours (KAB) However, true leverage over China's policy makers may lie in what is perceived as scientific evidence of reduced HIV transmission without a commensurate rise in illicit drug use. Future evaluations of NSEP effects on HIV transmission may benefit from alternative observational designs such as ecological studies in which HIV incidence rates in regions with and without NSEPs can be used to quantify the potential effects of such programmes, though such designs must carefully control for potential confounders that may distort measures of programme effect on the outcome.

Budgetary considerations

The ability of local government programmes to generate extra-budgetary revenue can often be a strong predictor of programme survival in China. This is due to the model of local self-reliance adopted during the economic liberalisation of the 1980 in which provincial governments were deliberately cut off from central support as a way to encourage optimisation of regional resources for economic growth (US CDC, 2006). Though an effective economic policy, such models have rendered many social services such as primary healthcare and education unaffordable for many Chinese, who must pay ever increasing fees. The fact that MMT clinics generate revenue by charging patients up to 10 RMB (about USD 1.60) per daily dose of methadone is significantly different from NSEP which do not provide tangible project returns. Whilst both types of programmes currently receive budgetary support from central agencies, a lack of financial sustainability for NSEP has not earned it any more support amongst central policy makers or local implementing officials.

Conclusions

The most revealing pronouncement to date on the future of harm reduction in China was the Second Five-Year Action Plan of 2006, which specified target coverage rates for both MMT and NSEP by 2011 (State Council, People's Republic of China, 2006a). Most of the support for harm reduction measures still comes from the national level ministries, who ultimately play only a symbolic role over NSEP and MMT programmes and whose participants still face interference from local law enforcement agencies. Nonetheless, the new national Drug Prohibition Law passed in 2008 made explicit mention of harm reduction for the first time by specifying "medicinal drug treatment" (a reference to MMT) as an acceptable form of drug treatment, further solidifying crucial support from the public security sector. Partly in response to these shifts, experts at NCAIDS confirmed that the organisation has begun to advocate a complementary scheme in which MMT will be concentrated in urban areas with NSEP operating more in remote rural areas. Whilst this approach might maximise IDU coverage, it misses opportunities to strengthen and improve China's overall harm reduction programme, ideas for which are provided below.

Integration of NSEP and MMT

Referral systems to link IDU encountered through NSEP outreach efforts have been proposed as a way to integrate the two programmes. The NSEP do not require personal identification and can deliver services in the community and are therefore effective at accessing active IDU and difficult to reach populations who may for various reasons be ineligible or unwilling to access MMT. A referral system could also encourage harmonisation of data collection systems and improve overall knowledge of IDU behaviours. One limitation of an integrated system, however, would be the eligibility for MMT programme participation, which requires that individuals serve at least one term in a compulsory isolated drug treatment centre. Since this would limit referral services only to those IDU who have ever been arrested, the authors also recommend that MMT programme eligibility be extended to all voluntary participants who are deemed by a licenced physician at the MMT clinic to be suffering from opioid addiction. In addition, public security officials must be forbidden from access to patient information collected by MMT clinics in order to grant patients assurance that their personal security will not be threatened as a result of MMT attendance.

Biomarker indicators for evaluation of NSEP

In order to conduct evaluation capable of generating political support, distribution of rapid HIV test kits to NSEP staff could provide a way for them to obtain data on key biomarkers such as HIV whilst preserving values such as client anonymity. The Chinese CDC has not approved these test kits for large scale testing because of inconsistent findings regarding test sensitivity and specificity (US CDC, 2008, 2006), and in order to minimise missed opportunities for post-test counselling and treatment referral, which is standard in the existing VCT system. As a method of primary screening and rapid surveillance work, however, oral tests are gaining credibility in the public health community to access mobile or underground populations because they can be conducted on-site and produce immediate test results. In the event that such test kits come into practice amongst NSEP in China, however, monitors will need to exercise caution so as not to minimise the self-selection bias that drove the debate over the Vancouver needle exchange study (Bruneau et al., 1997; Schetcher et al., 1999; Strathdee et al., 1997). If NSEP attendees are systematically higher risk IDU as in the case of the Vancouver study, if baseline rates of needle sharing are already high, and if exposure to HIV interventions is considered fixed for the duration of the study, multivariate model derived estimates may fail to control for residual confounding of the relationship between NSEP use and HIV status. Careful study design and unambiguous interpretation of findings will be essential for meaningful evaluation of NSEP.

Greater institutional support for NSEP

Finally, greater advocacy for NSEP from supporters within the government and non-government sectors will be critical for building cross-sector support for NSEP. Pre-requisites will include the development of more independent and participatory civil society organisations working in needle exchange, a formal policy mechanism for NSEP, similar to the MMT national working group, and close collaboration between civil society and NGOs to advocate for NSEP. In 2008 NCAIDS oversaw the operation of 897 NSEP operating in 26 provinces, servicing an estimated 36,000 IDU a month. This large-scale programming may signal shifting priorities in public health as practitioners adapt practices to the situation on the ground.

Such policy changes will play an important role, not only for the expansion of harm reduction programmes in China, but to build institutional capacity for carrying out more community-based, participatory work for the control and prevention of drug use related HIV transmission. China has already earned international credibility as a world leader in MMT. Consideration of the policies suggested could further improve what is already a dynamic and far-reaching harm reduction response to HIV amongst drug users in the world's most populous country.

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