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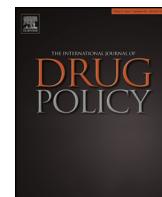
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Research Paper

Integrating antiretroviral therapy in methadone maintenance therapy clinics: Service provider perceptions

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ABSTRACT

Background: Using methadone maintenance therapy (MMT) clinics to deliver antiretroviral therapy (ART) is an effective strategy to promote treatment initiation and adherence for HIV-positive drug users. This paper describes the implementation barriers perceived by service providers for an intervention pilot designed to integrate ART services in MMT clinics.

Methods: The study was conducted in six MMT clinics in Sichuan province, China. Two service providers selected from each of the six clinics underwent training in administering ART. The trained providers delivered ART-related services in their clinics. A focus group was conducted among the service providers to assess their experiences and perceived challenges in delivering integrated services.

Results: Barriers at policy, institutional, provider, and client levels were identified. Policy level barriers included household registration restrictions and a lack of insurance coverage for testing expenses. Inefficient coordination between treatment sites and MMT clinics was an obstacle at the institutional level. Insufficient training and added workload were barriers at the provider level. Finally, conflict with daily dosing habits was identified as the primary reason that clients did not accept ART.

Conclusion: Although integrating ART into MMT clinics is beneficial, multilevel barriers to implementation need to be addressed. This study documents the need for treatment transferability and insurance coverage, protection of client confidentiality, proper provider training, coordination with treatment sites, and individualized ART service for MMT clients.

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Introduction

Globally, there has been a major challenge to engage people who inject drugs (PWIDs) in appropriate HIV treatment and care (Chakrapani, Velayudham, Shunmugam, Newman, & Dubrow, 2013; Wolfe, Carrieri, & Shepard, 2010; Zhang et al., 2011a). Specific treatment gaps exist in late testing for HIV, low uptake of antiretroviral therapy (ART), low treatment adherence, treatment discontinuation, and the burden of managing comorbidities such as hepatitis C and tuberculosis for PWID (Altice, Kamarulzaman, Soriano, Schechter, & Friedland, 2010; Lucas, Griswold, Gebo, Keruly, & Chaisson, 2006; Wolfe et al., 2010; Wood et al., 2007). In China, the ART coverage for PWID (42.7%) is significantly lower as compared with those infected sexually (61.7%), and those infected through plasma donation or blood transfusion (80.2%).

Subsequently, PWID have a higher mortality than individuals infected through different modes (Zhang et al., 2011b). In view of such challenges, many investigators are seeking effective strategies to increase ART uptake and adherence in PWID populations.

An emerging body of research demonstrates that providing methadone maintenance therapy (MMT) clinic-based care is an effective approach to promote ART treatment and thus enhance clinical outcomes for HIV-positive PWID (Brust et al., 2011; Nahvi et al., 2012; Uhlmann et al., 2010). MMT clients are in contact with service providers on a daily basis for methadone administration, allowing counselors to monitor the rate of routine HIV testing and CD4 counts (Achmad et al., 2009). Directly observed ART by MMT service providers has been shown to be efficacious in improving adherence and decreasing viral load (Berg, Litwin, Li, Heo, & Arnsten, 2011; Maru, Bruce, Walton, Springer, & Altice, 2009). Moreover, a recent study in Vietnam proved that providing MMT services along with ART for HIV-positive PWID was cost-effective (Tran et al., 2012).

Yet discrepancies remain between this evidence-based approach and real-world service delivery. Previous studies

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have identified specific challenges associated with MMT-based ART administration, such as the need for staff time to coordinate with ART providers, medication handling, storage, and dispensation, and patient absentees, who miss methadone doses as well as ART medications (Sorensen et al., 2012).

During the past ten years, a comprehensive national MMT program has been established in China. As of April 2012, 747 MMT clinics have been built nationwide, cumulatively covering more than 350,000 drug users (Cao et al., 2013). The MMT program in China offers a strong platform to provide ART services to enrollees. However, integrating ART into such a widespread MMT system may pose particular challenges for policymakers, healthcare institutions, and service providers. There is little experience with how to integrate two such disparate treatment approaches, especially within the Chinese context. To achieve effectiveness and long-term sustainability of the integrated services, it will be necessary to pinpoint and address the challenges before universally adopting ART in the current MMT system. The objective of this study is to identify the challenges associated with delivering integrated services from the perspective of MMT service providers. The findings could shed light on implementation issues related to the future expansion of integrated services.

Methods

Integrated ART services

The study was conducted in Sichuan province, China. The contents and procedures of the integrated ART services were initially developed based on previous research (Achmad et al., 2009; Berg et al., 2011; Sorensen et al., 2012; Wolfe et al., 2010) and our experience with MMT providers and clients (Li et al., 2013), and were finalized collaboratively by the research team and local expert panel. The following services were designed to be delivered by the MMT clinics:

1. *Direct observed therapy*: clients on ART were encouraged to adjust their medication habits in conjunction with methadone dosage (e.g., taking ART under the direct observation of a service provider once a day).
2. *Reminder services*: all HIV-positive clients were provided reminders for routine CD4/viral load testing. Clients who were on ART were provided with in-person, phone, or text message reminders designed to enhance treatment adherence.
3. *Referral services*: treatment-eligible clients were counseled on how to link to the proper treatment site.
4. *ART-related counseling*: all clients were supported with understanding the effects and purpose of ART.

Pilot testing procedure

Six MMT clinics in Sichuan province were selected based on the current caseload of clients with HIV. Two service providers were selected from each of the six clinics (total = 12). Service providers were selected based on (1) gatekeeper endorsement, (2) co-worker recommendation, and (3) the service provider's medical experience. Among the 12 service providers identified, six were doctors, two were nurses, and the remainders were pharmacists or lab technicians. Four of the service providers had a bachelor's or higher degree at the time of recruitment. Two-thirds of the providers were women, and the age ranged from 25 to 50 years (average = 38.4).

The selected service providers participated in a two-day intensive group training on ART administration. The training was conducted by two AIDS specialists, with the content based on

the National Free HIV Antiretroviral Therapy training electronic handbook (China CDC, 2010). Essential components of the training included (1) the timing to initiate ART, regimen selection and dosage, (2) opportunistic infection and side-effect management, (3) enhancement of treatment adherence, and (4) mobilizing family/social support and local services. Specific issues that were discussed included the recruitment and retention of clients, protection of client confidentiality, the storage of ART regimens, medical record documentation, and utilization of local resources. Upon completion of the training, the service providers were required to deliver the four pre-designed ART-related services in their clinics.

Data collection

One year after the initial service provider training, a focus group was conducted with all trained service providers in the six MMT clinics. The focus group discussion was conducted in a private conference room and lasted for approximately 90 min. The discussion was moderated by two investigators who had completed training in focus-group facilitation, and was recorded by two observers. Before the focus group, the providers were informed of the study procedures, that the research was not part of their responsibilities as a staff member, and that their decision about participation would have no effect on their employment status. The focus group moderators followed a semi-structured discussion guide with open-ended probes. Discussion topics included general perceptions of MMT-based ART services, if the four types of predesigned services have been delivered and how they were delivered, barriers/facilitators to providing each service, services provided in addition to the four predesigned services, and suggestions for improvement. The discussion was audio recorded with all participants' verbal consent. The study received approval from the Institutional Review Boards of the University of California, Los Angeles, and the National Center for AIDS Prevention and Control, Chinese Center for Disease Control and Prevention.

Data analysis

The recording of the focus group discussion was later transcribed verbatim. Analyses of transcribed focus-group data were guided by grounded theory (Glaser & Strauss, 1967). A first draft of the code list was developed based on the focus group guidelines. Themes were identified in the context of the information conveyed by the participants (Sandelowski, 1986). The code list was modified based on themes that emerged from the transcripts during analysis. All transcriptions, coding, and analyses were completed in Chinese, and the results were later translated into English.

Results

At the onset of the study, all six clinics had established medical procedures for HIV-positive clients. The providers provided reminder services for those who were receiving ART, by checking in with clients on a bi-weekly or monthly basis to emphasize the importance of treatment adherence. Referral services for ART naïve treatment-eligible clients included establishing initial contact with ART treatment sites and/or arranging local public transportation. For all HIV-positive clients, the providers facilitated CD4 and viral load testing by obtaining and shipping blood samples to local testing sites. ART-related counseling services were provided as needed. Direct observation of ART dosing was perceived to be extremely difficult and was seldom if ever supervised. The specific challenges are summarized below.

Policy level barriers: residency restrictions and financial burden

According to the service providers, national ART policy requires PWID to possess local household registration (*Hukou*) or a temporary residency certificate to access free treatment and routine CD4/viral load testing. This requirement posed difficulties for migrants who could not provide a formal address or residency documentation. Moreover, the requirement limited service providers' access to the medical history of clients who were registered outside of Sichuan: "One of my clients had to return to his hometown to get CD4 testing every time. This is very inconvenient, so he has not had CD4 testing in a year and a half."

For HIV-positive clients, a set of initial physical testing has to be completed upon entry into an ART program. The testing, which includes basic chemistry, hepatitis serology, urinalysis, and kidney and liver function evaluation, costs approximately 1000 RMB (\$166.00 USD). The testing fee was not covered by China's "Four Free and One Care" policy (Sun et al., 2010) or current insurance schemes. Many service providers identified out-of-pocket testing expenses as a barrier to engage treatment-eligible clients: "You know the finance situations of drug users are generally poor. You ask them to pay for this one-time testing and get free ART, but they just cannot afford it. The testing fee has raised the threshold for many clients to access ART."

Institutional level barriers: coordination and confidentiality issue

There were coordination issues between the MMT clinics and ART treatment sites. The participants reported that they referred several treatment-eligible clients to local ART treatment sites (e.g., an infectious disease hospital), but the physicians turned them away because it was believed that the PWID would not adhere to treatment and would eventually develop drug resistance: "Patient mortality rate is one of their performance appraisal indexes, so they only want compliant patients, 'good patients.' People with a history of drug use do not adhere, and they always make trouble. It is a big headache for them."

Confidentiality was the major concern of clients who received ART-related services at MMT clinics. In some clinics, there was a shortage of private space to arrange direct observed ART and/or HIV counseling. In other clinics, even with private settings to administer ART medication and counseling, there was still a prevailing concern among clients that the "special treatment" would cause suspicion among other clients about their infection status: "There are many clients in our clinic, they line up for methadone. If one of the clients received some other pills, confidentiality cannot be guaranteed. Or if a doctor called the client to a small room every day, other clients would also figure out that he or she had some special problems, most likely AIDS."

Provider level barriers: lack of training and extra workload

The majority of service providers perceived that the brief training at the beginning of the study was inadequate to prepare them to deliver ART-related services. Many providers reported that although they had undergone the training, they still held doubts about the beneficial effect of early ART because of its side effects and potential risks to develop drug resistance. In addition, some service providers worried that if any side effects or a fatal accident occurred to a client during ART, the clients and their families would accuse them of malpractice: "Last time a nurse in our hospital was exposed to contaminated blood, she took ART for prophylaxis for a few days. The side effects were just horrible, the nausea and dizziness, she just could not stand it. She said she would rather get AIDS than take the medicine."

Without systematic training and clinical experience, some providers were uncomfortable providing ART-related counseling to their clients. Lack of training and professionalism contributed to a breakdown in communication between client and providers. The provider participants complained their clients were reluctant to consult them with HIV/AIDS-related issues or being impatient in the counseling sessions: "I think that the clients should consult the infectious disease hospital for ART-related questions, since they have expertise in this area. We obviously are not professional. If I had to provide counseling I am afraid that I would give the wrong information." Another provider said, "They didn't want to talk about HIV. They didn't need your reminder. Sometimes you were trying to give advice, and they were like 'I know, I know!' They sound very unhappy. You felt like the conversation was redundant and unnecessary."

Providers stated that if they had to provide integrated ART services, they would need more training and ongoing guidance, especially on the nature of ART pharmaceuticals, regimen selection, and side-effect management. In addition, some participants reported that their current workload and competing clinical duties would hamper the introduction of ART services into their practice: "I think there is a problem of the division of responsibilities. ART should be the infectious disease hospitals' responsibility. Our MMT clinic, after all, is not for HIV treatment. The ART thing is not part of our performance appraisal indexes, so you do not expect our doctors to go out of their way to provide ART services. There is only extra work and no benefit."

Client level barriers: misunderstanding and conflict with dosing habits

According to the service providers, misconceptions about ART were widespread among the PWID population. Furthermore, the side effects of ART experienced by their peers had a profound influence on their opinion of the treatment. Misconceptions often contributed to the delay in initiation of ART: "One client in our clinic saw his friend got festering sores all over the body, and died soon after he started ART. The word spread fast in their circle and intimidated other drug users from seeking ART."

Service providers stated that directly observing ART was their most difficult task, principally because observation conflicted with clients' everyday dosing habits. Also, there were some clients who did not visit the MMT clinic on a daily basis, in which case the clients would keep ART medication in their personal possession: "Most of my clients take one dose of ART in the morning and one dose late at night. The schedule simply does not match with the time they come to the clinic."

Logistical difficulties to engage clients in integrated services included frequent changes in contact information, which hindered the delivery of telephone and message reminders, and clients trying to minimize time spent in the MMT clinic due to their work schedule: "Our clients are always in a hurry. They hope to take methadone and leave within a minute. If you are a little bit slow, they would start yelling 'You! Faster!' Usually they have taxis waiting outside. If you keep them waiting long, the taxis will recharge the initial charge." Please note that the aforementioned client level barriers were based on health providers' perception and reports, not directly collected from clients.

Discussion

Developing and implementing a successful MMT clinic-based ART program requires a comprehensive approach. There are several key recommendations for developing or improving treatment services that can be gleaned from our results.

First, we identified policy level obstacles that restricted treatment access. As supported by other studies, residency restrictions remain a challenge for migrants, despite the free HIV treatment and care provided nationwide (Hesketh, Ye, Li, & Wang, 2008; Lam & Johnston, 2012). This finding calls for policy changes to allow for transferability of treatment across administrative borders within the country. The cost of pre-ART physical testing has been a barrier to accessing treatment. Monetary compensation, health insurance compensation, and/or coverage of pre-ART testing expenses could be cost-effective strategies to facilitate ART initiation not only for MMT clients, but also for other patients living with HIV in the country.

Changes must also be made at the institutional level to facilitate effective implementation of integrated ART services. To begin, efforts should be made to assure clients that ART-related services will not result in a breach of confidentiality. For example, a private room inside a clinic might be rearranged to facilitate supervised dosing, and brief counseling to all clients would render the ART services less distinguishable and less stigmatized. Secondly, oversight and coordination among different healthcare settings, including MMT clinics, HIV testing sites, and treatment sites, is essential to avoid delays in treatment provision. In China there is a set of indicators to evaluate the performance of HIV/AIDS prevention and treatment work. For example, AIDS treatment site providers are required to achieve a certain survival rate among ART patients (State Council AIDS Working Committee Office, 2007). It was noted that the performance appraisal indicators, although well intended, might lead to rejecting service to certain patients who were perceived to be uncompliant. Instead of setting arbitrary appraisal indexes, building organizational trust and a blame-free culture has been identified as the key to optimize staff performance and productivity (Bahrami, Hasanpour, Rajaeepour, Aghahosseni, & Hodhodineghad, 2012).

Service providers expressed a lack of expertise in AIDS treatment, which reduced their comfort level in delivering the integrated ART services. In reality, it is impractical to require MMT providers to possess a complete understanding of ART, which includes knowledge of HIV pathogenesis, the human immune system, disease stages, and treatment options over a short period of time. It is suggested that MMT providers pair up with local AIDS specialists and play an auxiliary role to engage clients to ART and provide support for treatment adherence. This approach once again requires coordination among different agencies. Additionally, as the integrated service in the pilot was managed without increased manpower, the MMT providers had to bear extra workload and responsibilities. Compensation for integrated services, both financially and academically, would be an important issue to consider for future adoption of the service model in order to maintain staff morale and commitment.

The most significant challenge identified was direct observation of ART, including concerns about breach of confidentiality and conflicted dosing habits. It was determined that directly observing therapy, as a long-term intervention strategy, requires significant up-front planning and flexibility (Sorensen et al., 2012). Alternatives such as motivational interviewing, contingency management, pill boxes, calendar marking, or cell phone reminders could be practiced in lieu of or in tandem with direct observation. It is recommended that MMT service providers work with individual clients to understand the underlying reasons for skipping medication and best manner to develop personalized treatment plans.

There are several limitations to this study. First, it is possible that the participants did not express their honest opinion in the focus group due to the influence of other participants. Second, the findings may not be generalizable to other areas in which the economic situation and insurance policies may differ considerably from those

in Sichuan province. Third, the client level challenges reported in the study, such as misconceptions about ART and conflict with dosing habits, were actually based on perception of health providers and may not represent the clients' point of view. Lastly, the sample size of the study was relatively small. Nonetheless, the study illustrates several paths for developing and improving integrated ART services at a larger scale.

In conclusion, given their accessibility to and daily contact with clients, MMT providers are in a unique position to provide a range of HIV treatment and care services. Efforts should be made to address the challenges identified in this study in order to effectively deliver integrated ART services and make a broad public health impact.

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Conflict of interest statement

All authors have no conflict declared.

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