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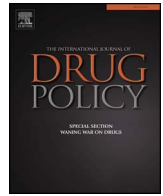
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## Research Paper

## Service providers' adherence to methadone maintenance treatment protocol in China

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## ABSTRACT

**Background:** Methadone maintenance treatment (MMT) programs have expanded rapidly in China during the last decade. However, variance in service providers' practice may have an impact on the quality of care received by the patients. This study examined Chinese service providers' adherence to the MMT protocol and its associated factors.

**Methods:** The study used baseline data from a randomized intervention trial implemented in MMT clinics in five provinces of China. The data were collected from January 2012 to August 2013. A total of 418 service providers from 68 MMT clinics participated in the study. Demographic and job-related characteristics were collected. The providers' adherence to the MMT protocol, MMT knowledge, negative attitudes towards people who use drugs (PWUD), and perceived institutional support were assessed.

**Results:** The average adherence score was  $36.7 \pm 4.3$  (out of 9–45). Fewer providers adhered to the protocol items where communications with patients or families were required. After controlling for potential confounders, adherence to the MMT protocol was positively associated with perceived institutional support (standardized  $\beta = 0.130$ ;  $p = 0.0052$ ), and negatively associated with prejudicial attitudes towards PWUD (standardized  $\beta = -0.357$ ;  $p < 0.0001$ ). Reception of national-level MMT training was not associated with higher level of adherence to protocol.

**Conclusion:** The findings suggest the potential benefits of providing institutional support to MMT providers to enhance their level of adherence to the MMT protocol. Intervention effort is needed to reduce negative attitudes towards PWUD among MMT service providers to achieve greater consistency with best-practice recommendations.

## Introduction

A large body of literature has shown the efficacy of methadone maintenance treatment (MMT) for treatment of drug addiction and subsequent reduction in HIV risk behaviors and infection (Avants, Margolin, Usubiaga, & Doebbrick, 2004; Sullivan, Metzger, Fudala, & Fiellin, 2005). In acknowledgment of the evidence, the Chinese government called for the use of MMT programs to mitigate opiate use and HIV epidemic in the country in 2004 (Sullivan et al., 2015). An evaluation of the pilot programs has shown a reduction in heroin use and drug-related crime and an increase in employment and healthy family relationships among the patients (Pang et al., 2007). The success of the pilot programs has led to a rapid scale-up of the MMT system in China, expanding from the initial eight pilot clinics to 785 clinics in 28 provinces by the end of 2015 (National Center for AIDS/STD Control and Chinese Center for Disease Control and Prevention, 2016). Despite the

progress that MMT programs have made in the country, MMT providers are facing challenges that reduce the efficacy of the programs, including lack of training, inadequate knowledge and skills in addiction treatment, misunderstanding about the goals of harm reduction, as well as confusion regarding management of comorbidities (Lin et al., 2010; Yin et al., 2010). Although the Chinese government has issued national guidelines and clinical protocols for management of MMT patients (China Ministry of Health and China Ministry of Public Security and China Food and Drug Administration, 2006), the adherence with the practice guideline is highly variable (Yin et al., 2010). For example, even though the national guideline recommended 60–80 mg daily dose for maintenance stage patients, MMT providers in China usually prescribed a lower than suggested dosage (Sullivan et al., 2015). Some physicians even adjust MMT dosage based on patients' demand (Lin & Detels, 2011). The uncertainties in medical practice and the gap between the best-practice recommendations and clinical practice may

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contribute to high patient drop-out rate and suboptimal treatment outcomes (Cao et al., 2014; Shen et al., 2016).

Treatment protocols are considered as one of the most influential and effective tools to promote evidence-based medicine (Grol & Grimshaw, 2003; Saja, 2013). Effective implementation of treatment protocol was found to improve the quality of care by reducing practice variation, improve clinical outcomes, and reduce the frequency of monitoring and healthcare cost (Mazrou, 2013). A study was conducted in the U.S. Veterans Affairs (VA) health system to examine the impact of consistent adherence to guideline recommendations in drug treatments. It was reported that patients attending clinics where guidelines were more consistently adhered to had a greater reduction in heroin and cocaine use than those attending less guideline-adhered clinics (Trafton, Humphreys, Harris, & Oliva, 2007). Nonetheless, compliance with clinical practice guideline is challenging as it depends on a variety of factors (Quaglino, 2008). Previous studies conducted in the U.S., Canada, European, and African countries have revealed several reasons for physician's non-adherence to clinical guidelines, including lack of awareness or familiarity with the recommendations, perceived usefulness of the guideline, disagreement with the guidelines, or perceived difficulties in applying the guideline in daily practice (Amoakoh-Coleman et al., 2016; Arts, Voncken, Medlock, Abu-Hanna, & van Weert, 2016; Cabana et al., 1999; de la Sierra, Zamorano, & Ruilope, 2009; Quaglino, 2008). It was also reported that physician's compliance with clinical guidelines depended on their personal beliefs and attitudes, availability of support system, and training in clinical guidelines (Sharif, Samara, Titi, & Awartani, 2015).

Despite the efforts to scale up the MMT clinics in China, there is currently a paucity of information regarding how adherent are MMT providers to the guidelines in the country. Even though the factors involved in physician's adherence to guideline have been extensively studied in Western countries for chronic conditions and in emergency care settings (Arts et al., 2016; Ebben et al., 2013), limited studies have been conducted in MMT settings in China. To fill the gap in the literature, the study was conducted to document Chinese MMT providers' level of adherence to clinical guidelines and to assess various factors that are associated with the level of provider adherence. The findings of this study will help to develop strategies for effective guideline adherence and management for MMT programs in China.

## Methods

### Participant recruitment

The study used the baseline data from a randomized intervention trial, which was implemented in five provinces in China (Sichuan, Guangdong, Shaanxi, Jiangsu, and Hunan). The randomized controlled trial was designed to train MMT service providers to deliver individual counseling sessions with their patients to promote their treatment engagement. The protocol of the trial was registered with clinicaltrials.gov (identifier: NCT01760720). Sixty-eight MMT clinics were randomly selected from the five provinces. To recruit MMT service provider participants, the research staff approached the service providers in person in each of the selected MMT clinics. In a typical MMT clinic in China, there are usually six providers (including doctors, nurses, and pharmacists) who provide direct services to patients, and all of them were invited to participate in the study. Supporting staff, such as security personnel, accountants, and/or cleaners, were excluded. To be eligible for the study, a service provider had to be (1) 18 years or older and (2) currently working at one of the participating MMT clinics. When recruiting service providers, our research staff used a standard recruitment script to introduce the study purpose and procedures in detail. The participants were assured of confidentiality and their right to refuse participation without affecting their employment status at the clinic. Written informed consent was obtained from each respondent. A total of 418 service providers participated in this study with a refusal rate of less than 5%.

### Data collection

The data were collected between September 2012 and August 2013. The service providers were surveyed individually in private rooms at the clinic. The assessment was conducted using the computer-assisted self-interviewing (CASI) method that the providers read survey questions on a laptop screen and directly entered their responses to a computer database. A study interviewer was on standby to provide assistance during the assessment. Each assessment lasted approximately 45–60 min. The participants received 30 yuan (USD 4.7) for their participation. The study received approval from the Institutional Review Boards from each participating institute.

### Measures

Relevant *demographic information* was collected, including age, gender, and years of education. The survey asked the participants about their *professional profile*, including profession (e.g., doctor, nurse, and others), professional background in MMT-related areas (including detoxification, mental health, and HIV/STD), their years of service at MMT clinic, as well as whether they have received national-level MMT training.

Provider's *adherence to the MMT protocol* was measured by a 9-item instrument that was developed based on China's national MMT guidelines (China Ministry of Health and China Ministry of Public Security and China Food and Drug Administration, 2006). The measure contained statements regarding how a provider treated his or her patients in certain situations, which are presented in Table 2. Experts from the Secretariat for the National MMT Working Group (a group stationed in the National Center for AIDS/STD Control and Prevention, Chinese Center for Disease Control and Prevention. The group is responsible the overall coordination, monitoring, and supervision of MMT programs in China; Yin et al., 2010) confirmed the accuracy and relevancy of these items. Responses were recorded on a 5-point scale ranging from (1) "never" to (5) "quite often" (possible range = 9–45). A higher score indicated a higher level of adherence to the MMT protocol (Cronbach alpha = 0.72).

*MMT knowledge* was assessed using 19 true-or-false questions originally developed by Caplehorn, Irwig, and Saunders, 1996. The questions were adapted by the study team based on the MMT national guideline (China Ministry of Health and China Ministry of Public Security and China Food and Drug Administration, 2006). The instrument covered various topics regarding MMT eligibility, treatment goal, appropriate dosage, potential side effects, and management of overdose. Sample items included "the purpose of current MMT programs is to achieve abstinence" and "most patients require an average of 60 mg methadone per day for stable treatment". Participants were asked to determine if each statement was true or false, and they received one point for each correct response (range = 0–19). Correct answers to these questions were confirmed by MMT experts in China.

*Negative attitudes toward people who use drugs (PWUD)* were measured by a 5-item instrument (National Center for Education and Training on Addiction Flinders University, Adelaide Australia, 2006). The five questions were: 1) "to what extent are adverse life circumstances likely to be responsible for a person's problematic drug use?", 2) "to what extent do you feel sympathetic towards PWUD?", 3) "to what extent do you feel concerned towards PWUD?", 4) "to what extent do PWUD deserve the same level of medical care as people who do not use drugs?", and 5) "to what extent are PWUD entitled to the same level of medical care as people who do not use drugs?". Each item was scored on a 5-point Linkert scale from (1) "not at all" to (5) "very much". After the items were reverse-coded, a higher summary score indicated a higher level of negative attitudes toward PWUD (Cronbach alpha = 0.74).

*Perceived institutional support* was measured by a 9-item instrument that has been developed and validated in a previous study to measure

Chinese service providers' perceived level of support from the clinic. The instrument measured the availability of monetary support, opportunities for in-service training and/or promotion, accessibility to self-protection materials, and entitlement to benefits and vacation days (Li et al., 2007). The items included 1) "you are concerned about your personal security during work", 2) "you have sufficient health insurance coverage if you were infected by HIV on your job", 3) "your institute provides opportunities for continuous education and in-service training", 4) "your institute has enough equipment and medicines for occupational exposure protection", 5) "you have the opportunity to be promoted", 6) "your clinic has sufficient budget to maintain daily operation", 7) "you can enjoy most of the public holidays", 8) "you are paid less than the colleagues working in other departments"; and 9) "in general, the head of your institute thinks much of your department". Responses were recorded on a 5-point scale ranging from (1) "strongly agree" to (5) "strongly disagree". Scores were the sum of ratings with a higher score indicating a higher level of perceived institutional support (Cronbach alpha = 0.76).

### Data analysis

All analyses were performed using SAS statistical software version 9.4 (SAS Institute Inc., Cary, NC, USA). First, the distribution of providers' demographic characteristics, professional profiles, MMT knowledge, negative attitudes towards PWUD, perceived institutional support were analyzed descriptively. Specifically, we calculated the number and percentage of providers responded the highest level of adherence to each item of the adherence to MMT protocol scale. Second, Pearson's correlation coefficients were calculated to examine the relationships among demographic characteristics, professional profiles, MMT knowledge, negative attitudes towards PWUD, perceive institutional support, and adherence to the MMT protocol. Third, multiple linear regression analysis was performed with the provider's adherence to MMT protocol score, controlling for the simultaneous effects of provider's demographic characteristics, professional profiles, MMT knowledge, negative attitudes toward PWUD, perceive institutional support. Standardized coefficients and their significance levels were reported.

### Results

**Table 1** summarizes the characteristics of the study sample. Among the 418 providers, approximately two thirds were women (63.4%). The participants' mean age at the time of the study was 39 years old. About half of the sample (50.9%) received college or higher degree. About one third (36.1%) of the providers were doctors and 28.5% were nurses. The providers who had professional background in MMT-related areas (including detoxification, mental health, and HIV/STD) represented 59.8% of the sample. On average, the participants had served 3.6 years in the MMT clinic. Slightly less than half (48.1%) of the providers reported receiving national-level MMT training. The mean and SD of MMT knowledge, negative attitudes towards PWUD, and perceive institutional support scales are also presented in **Table 1**.

Among the 418 participants, only 78 (18.7%) reported "often" or "quite often" adhere to all the nine MMT protocol items. The average adherence score was  $36.7 \pm 4.3$  (out of 9 to 45). **Table 2** shows the providers' level of adherence to the MMT guidelines. The majority of the providers (79.3%) in this study were compliant with the confidentiality requirement that they never shared patients' information with other individuals. Most providers reported that they introduced the risk and benefit of MMT to patients in detail before initiating MMT (73.0%) and supervised the process of urine sample taking for morphine test (67.2%). Approximately half of the providers (46.9%) conducted physical examinations on patients on a regular basis. Relatively fewer providers conducted personal counseling with a patient if he/she had positive urine morphine test for three consecutive visits (27.8%),

**Table 1**  
Sample description (N = 418).

	Number	%
Age		
18–30	105	26.5
31–40	121	30.5
41–50	113	28.5
51 or older	58	14.6
Gender		
Female	265	63.4
Male	153	36.6
Education		
High school (vocational school) and below	119	28.5
Associate degree	86	20.6
College degree	126	30.1
Graduate degree and above	87	20.8
Profession		
Doctor	151	36.1
Nurse	119	28.5
Others	148	35.4
Professional background in MMT-related areas		
Yes	250	59.8
No	168	40.2
Duration of MMT service		
Less than one year	66	15.9
More than one year and less than five years	239	57.5
Five years or longer	111	26.7
Reception of national MMT training		
Yes	201	48.1
No	217	51.9
<b>Scales</b>	Mean	SD
Adherence to the MMT protocol (9–45)	39.1	4.5
MMT knowledge (0–19)	14.0	2.0
Negative attitudes towards PWUD (5–25)	11.9	3.3
Perceived institutional support (9–45)	27.6	5.3

Note. MMT, methadone maintenance treatment; PWUD, people who use drugs.

**Table 2**  
Number and percentage of service provider adhere to the MMT protocol items (N = 418).

	Number	%
Never share information about patients with others	331	79.3
Introduce the risks and benefits of MMT to patients in detail before treatment initiation	305	73.0
Supervise the process of urine sample collection	281	67.2
Perform regular physical examinations for patients after initiation of MMT	196	46.9
Conduct a counseling session if the patient has three consecutive positive urine tests	116	27.8
Contact the patient or family member if he/she skips MMT for seven successive days	112	26.8
Find out patient's reasons for dropout	90	21.5
Do not change methadone dosage based on patient's demand	66	15.8
Discuss with patients about their treatment experience weekly	49	11.8

Note. MMT, methadone maintenance treatment.

contacted the patient or the family in case of missing MMT for seven consecutive days (26.8%), or found out the patients' reasons for dropping out from treatment (21.5%). Only 15.8% of the providers indicated that they would not change methadone dosage based on the patients' demand, and 11.8% of the providers had weekly discussions with their patient to check patients' treatment experience.

Pearson's correlation showed that adherence to the MMT protocol was positively associated with MMT knowledge ( $r = 0.103$ ;  $p = 0.0347$ ), perceived institutional support ( $r = 0.122$ ;  $p = 0.0127$ ), and negatively associated with negative attitudes towards PWUD ( $r = -0.367$ ;  $p < 0.0001$ ). Adherence to the MMT protocol was not found to be associated with any demographic or professional

**Table 3**  
Multiple linear regression on the adherence to MMT protocol score.

	Std. $\beta$	P-Value
Age (per year)	0.071	0.1809
Gender (female vs. male)	−0.010	0.8498
College degree (yes vs. no)	0.029	0.5747
Profession (doctor vs. other types of provider)	−0.083	0.1050
Professional background in MMT-related areas (yes vs. no)	−0.003	0.9580
Duration of MMT service (less than one year vs. one year and above)	−0.005	0.9089
Reception of national MMT training (yes vs. no)	0.003	0.9406
Knowledge of MMT (per point)	0.077	0.1069
Negative attitudes towards PWUD (per point)	−0.355	<b>&lt; 0.0001</b>
Perceived institutional support (per point)	0.122	<b>0.0091</b>

Note. MMT, methadone maintenance treatment; PWUD, people who use drugs; Std.  $\beta$ , standardized beta.

A P-Value < 0.05 is bold.

characteristics in the univariate analysis. MMT knowledge was associated with years of service on MMT ( $r = 0.246$ ;  $p < 0.0001$ ) and having received MMT national training ( $r = 0.105$ ,  $p = 0.0325$ ). MMT national training were more likely to be received by males ( $r = -0.114$ ;  $p = 0.0202$ ) and those who had served in the MMT clinic for a longer time ( $r = 0.265$ ;  $p < 0.0001$ ). The univariate association between MMT national training and adherence to protocol was not statistically significant. Table 3 summarizes findings from the multiple linear regression models for adherence to the MMT protocol. After controlling for potential confounders, negative attitudes towards PWUD (standardized  $\beta = -0.355$ ;  $p < 0.0001$ ) and perceived institutional support (standardized  $\beta = 0.122$ ;  $p = 0.0091$ ) remained significantly associated with level of adherence to the MMT protocol. Adherence to the MMT protocol was not significantly correlated with demographics, professional profiles, national MMT training, or knowledge of MMT.

## Discussion

The study found a dissatisfactory level of adherence to the MMT guidelines among MMT providers in China, as only less than twenty percent amongst our study participants reported full adherence to the guideline. These results were in line with other studies among addiction physicians in other countries (Guillou Landreat et al., 2015; Wisniewski, Dlugosz, & Blondell, 2016). We believe that it is essential to improve the level of adherence to guidelines in order to ensure the quality of care and patient outcomes (Campos-Melady, Smith, Meyers, Godley, & Godley, 2017; Mazrou, 2013; Trafton et al., 2007). Some patterns of protocol adherence were identified. In particular, we found that a greater proportion of providers reported compliance with the protocol items related to medical ethics codes, such as informing patients of the risks and benefits of MMT and protecting patients' confidentiality. On the contrary, fewer providers reported adherence to protocol in the areas where personal communications were required. For example, the requirement to contact the patient and their families to find out the reasons for skipping doses and to conduct weekly discussions with patients about their treatment progress were the items that were least adhered to. It is worth noting that an overwhelming majority of the providers in the study prescribed MMT dosage based on the demand of patients just to avoid conflict. This finding could be explained by the earlier literature that MMT providers in China lacked communication skills to engage their patients (Lin & Detels, 2011; Lin et al., 2010). Additionally, the widespread presence of discomfort in working with PWUD may contribute to MMT providers' intention to avoid provider-patient interactions (Carlberg-Racich, 2016; Li, Wu, Cao, & Zhang, 2012). This finding calls for the urgent need for intervention effort to address MMT provider's negative attitudes and to enhance in-service training to improve the frequency and quality of

provider-patient communication.

We have observed several factors associated with lower levels of adherence to the treatment protocol. MMT service providers' attitudes towards PWUD can lead to significant variations in the way that decisions regarding patient care are made. It is important to reduce the negative attitudes towards marginalized patients among service providers to ensure the quality of care, which is universally true in all types of healthcare settings including MMT (Geibel et al., 2017). Increased institutional support is set to ensure uniformity as well as the quality of provision of care (Cabana et al., 1999). In MMT settings, in particular, guaranteed personal security during work and opportunities for continuing education and in-service training are required prerequisites to treat PWUD consistently and adequately (Guillou Landreat et al., 2015). These findings can inform intervention efforts targeting provider's negative attitudes and job-related support to achieve greater consistency with best-practice recommendations.

Reception of national-level MMT training was associated with better MMT knowledge. Contrary to our expectations, the training did not necessarily increase the level of adherence to the MMT protocol. Currently, national-level MMT training is conducted in traditional lecture style with emphasis on harm reduction-related policies, methadone pharmacokinetics, and clinical management of methadone overdose and side effects (Yunnan Institute for Drug Abuse, 2016). Such training may convey knowledge but may not be sufficient to transform providers' misconception about harm reduction, and it has minimal effect on the deep-rooted prejudices held against PWUD. Interactive teaching methods and multimedia education materials may result in better-prepared workforce to deliver high-quality maintenance service in accordance with the protocol (Busen, 2014). An exceptional example is an intervention designed to tackle MMT providers' negative attitudes towards drug use and to improve their communication skills (Li et al., 2013). The intervention demonstrated significant effects on MMT providers' frequency of interactions with their patients as recommended by the protocol (Li et al., 2013). In addition, multiple strategies, including ongoing technical support and supervision, reminders, provider self-assessments, awards, and penalty, should be in place to ensure that the protocol is adhered to at high standards (Beehler, Funderburk, Possemato, & Dollar, 2013; Kurumop, et al., 2013).

## Limitation

Several limitations should be noted in interpreting the results. First, this study employed a cross-sectional study design to examine the factors associated with providers' adherence to the MMT protocol. Therefore, it was not possible to draw a causal inference. With the data we had, we were not able to draw a conclusion whether the lack of adherence was due to unawareness of the protocol, diversity in interpretation, difficulties in complying with the protocol, or other reasons. In addition, the MMT national guidelines were released in 2006, although they were still in use at the time of the study, there could be some unclear and/or debatable items still included in the guideline, which could lead to confusion bias. The study was also limited in that it relied on self-report that could be subject to reporting bias. Although the study was conducted in five provinces of China, we should be cautious in generalizing the findings to other geographic locations and populations. Furthermore, the adherence to MMT protocol scale was developed specifically for the purpose of this study. The items generated from China's national MMT guidelines limited international comparisons.

## Conclusion

Successful implementation of the MMT protocol in daily practice is crucial for ensuring quality service provision to patients and their benefits. This study observed a suboptimal level of adherence to the protocol among MMT providers in China. Future studies are needed to

ascertain possible reasons for providers' non-adherence and seek strategies to improve the adherence level. Guideline implementation strategies should take into account the heterogeneous forces that can influence provider's practice. Improvements in institutional support, as well as reduction of negative attitudes towards PWUD among providers may result in greater adherence to the MMT protocol.

### Conflict of interest

All authors have no conflict of interest to declare.

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### Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.drugpo.2018.02.018>.

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