WILLINGNESS TO USE ORAL PRE - EXPOSURE PROPHYLAXIS AMONG HIV - NEGATIVE PEOPLE WHO INJECT DRUGS IN HANOI, VIETNAM

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Oral Pre - Exposure Prophylaxis (PrEP) is a highly efficacious HIV prevention strategy. Little is known about the willingness to use oral PrEP among people who inject drugs (PWID). This paper describes factors associated with the willingness to use oral PrEP among PWID in Hanoi, Vietnam. We conducted a cross - sectional survey of 184 HIV negative PWID through chain referrals from the community and the Methadone Maintenance Treatment clinics. Selection criteria included reported injection for 12 months before the survey, HIV negative status identified by Quick HIV Test with finger prick, and urine positive for morphine. Structural equation model (SEM) was used on the basis of an adapted Information - Motivation - Behavioral Skills (IMB) model. One - fourth of participants were aware of PrEP, and upon description, 47.5% all participants of the study expressed their willingness to take oral daily PrEP. Main reasons of not willing to take PrEP included assuming that PrEP is unnecessary (53.1%) and concerning about side - effects (30.6%). There was a positive significant path from motivation to PrEP willingness ($\beta = 0.78$; p < 0.001). Another significant path existed from perceived barriers to willingness to take oral daily PrEP ($\beta = 0.207$; p < 0.001), which means that PWID who recognized challenges were more willing. A substantial number of HIV negative PWID are willing to take oral daily PrEP although the awareness of this effective prevention strategy is still limited among PWID. Future implementation of PrEP among this population needs to address both motivation and perceived barriers.

Keywords: Drug Use, PWIDs, PrEP, and Willingness

I. INTRODUCTION

The recent guidelines on PrEP comprising the daily self - administration of antiretroviral medication for HIV prevention¹ provides an opportunity to reduce HIV transmission. For the last several years, results from several studies and randomized trials indicated that taking PrEP daily would reduce HIV transmission among high - risk populations.²⁻⁴ Based

guidelines encouraging people who inject drugs to use PrEP1. Additionally, some evidence recommended that PrEP should be part of a comprehensive package of HIV prevention interventions for people who inject drugs.^{6–8} In Vietnam, the HIV prevalence was estimated at approximately 0.3% in the general population aged from 15 to 499. Specially, the percentage

on estimations, about one seventh (14%) of

people who inject drugs (PWID) worldwide are

living with HIV.5 In 2014, the Center for Disease

Control and Prevention (CDC) released

was far higher in PWID (14%) and only 61.5%

of them have learned about their HIV - status.9

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According to our knowledge, currently there are two ongoing pilot projects providing PrEP for men who have sex with men (MSM) as a HIV prevention trial in Vietnam. 10,11 Existing implementation of PrEP was exceedingly rare. The challenges were noticed not only at structural - level factors (resource limitations such as advocates, researchers and financial investment) 11 but also individual - level notes mentioned in another study in the region (limited knowledge and lack of awareness about PrEP in risk population, ensuring adherence, side effects). 12

Though there have been an increasing number of studies on PrEP, few of them have examined the acceptability of and willingness to use PrEP among drug users at risk for HIV.13 Most studies on PrEP focus on men who have sex with men (MSM).14-18 As far as we have done research, six studies to date discuss the willingness to use PrEP among people who inject drug (PWID). 19-24 In a study among PWID in Ukraine in 2012, 86% (n = 128) of participants who injected drug were willing to take PrEP20. In another study in 2014 (n = 351), the percentage of PWIDs in Massachusetts who reported willingness to take PrEP was 47%.19 One study in Vancouver in 2015 presented a lower overall willingness among PWID to take PrEP, approximately 35.4% of 543 participants.21 In addition, two more recent studies in Washington (2016) and New Haven (2016) indicated a low percentage of PWID who had ever heard of PrEP, 13.4%,²² and 18%^{23,24} respectively. Despite efficient reduction of HIV incidence with oral PrEP in PWID, as of 2016, there has been no published report of willingness to use PrEP among PWIDs in Thailand¹² as well as in other Asia countries. In Vietnam, two studies were published discussing about PrEP interest and willingness to take PrEP, but focused on the

groups of male sex workers and transgender women. 10,25

Evidence from previous studies showed that the tendency to take PrEP was higher among younger injection drug users and those with no fulltime job, but there was no consistency between studies.^{21,22} Perception of HIV related risks or having high - risk behaviors were the motivation to use PrEP in various studies. 19,21,22,24 These studies illustrated that people sharing needles or requiring help for injecting were more willing to use PrEP because they were more aware of their own HIV infection risk and understood that PrEP would be beneficial for them. Similarly, sex workers and people who had multiple sexual partners were more willing to take PrEP.^{21,22} However, potential side effects of long - term PrEP regimens as well as the requirement of adherence to a daily regimen, presented noticeable barriers to the acceptability of PrEP among people who inject drugs. 19,21 Moreover, co - pay for PrEP - related expenses and being afraid of increasing HIV risks behaviors due to being on PrEP were also potential barriers. 19 A range of other barriers were identified in the literature, but in this study we focused on the quantity of barriers, in which these characteristics contributed to barriers in general equally. We hypothesized that these characteristics are connected with information and motivation as shown in Figure 1.

So far little research has applied a hypothesized model to examine predictive factors of willingness to take PrEP among high - risk drug users(p).^{23,26} The basic Information - Motivation - Behavioral Skills (IMB) model has been widely applied in previous studies as a theoretical framework for pattern of behavior - based intervention. However it has been less used in studies on willingness to use PrEP, particularly external aspects of the model

influence willingness.23 which may Therefore, this study aimed to describe the willingness to take PrEP of PWIDs as well as to generate a conceptual framework to address predictive factors of willingness to take PrEP. To develop a theoretical framework for this study, we firstly kept the basic hypotheses of the IMB model that motivation and information would be associated with the willingness to use PrEP. Then we examined the correlation between motivation and information, expecting that there would be no significant correlation (as with the basic IMB model). As discussed in previous literature, external factors developed in our framework were factors directly influencing the willingness to take PrEP.

II. SUBJECTS AND METHODS

1. Participants and Procedures

A cross - sectional survey was conducted to collect data from 184 HIV - negative people who inject drugs in Hanoi, Vietnam. Eligible participants were those who (1) were age 18 or older; (2) born as male; (3) reported injection during 12 months before the survey, (4) tested HIV negative by Quick HIV Test with finger prick (Alere Determine HIV 1/2), and (5) tested positive with morphine in urine drug analysis.

Convenience sampling did recruitment from January to December 2016. Potential participants learned about the study through peer educators, counselors at Methadone Maintenance Treatment (MMT) clinics, and through former participants who had completed the study. Potential participants were invited to the study office at Hanoi Medical University to take part in a brief screening, which included a short demographic and behavioral questionnaire, a Quick HIV Test (Alere Determine HIV 1/2), and a urine analysis (Multi - Drug One Step Screen Test Panel). Those

who met the inclusion criteria were invited to

participate in the interviews after their informed consent was obtained. Face - to - face interviews using a structured questionnaire took place in a private room and lasted from 35 to 45 minutes. Upon completion, each participant received 220,000 Vietnam Dong in compensation (equivalent to 10 US dollars) and three coupons to recruit other acquainted PWID who they thought might potentially be eligible for the study. For each successful referral of an eligible participant, they would receive an additional 150,000 Vietnam Dong (equivalent to 7.5 US dollars).

2. Measures

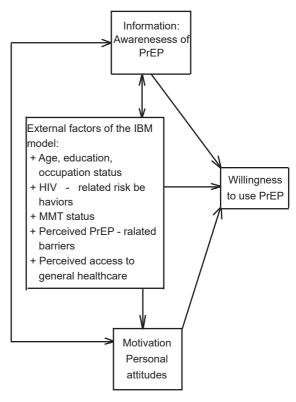


Figure 1. An adapted Information - Motivation - Behavioral Skills (IMB) framework

- Demographic characteristics included age in years, level of education, occupation, monthly income, and marital status.
- Information on PrEP was a single variable based on participants' awareness of PrEP.

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The question used was: "Have you ever heard of pre - exposure prophylaxis or PrEP?". A dichotomous measure was used with a score of 1 if a participant had heard of PrEP, and a score of 0 if the participant had never heard of PrEP.

- Willingness to use oral PrEP was the outcome variable assessed by a five point Likert scale which ranged from 1 to 5 points, from "Not at all willing" to "Extremely willing", respectively.
- Motivation to use PrEP was constructed as a latent variable based on the three subscales by asking the following items: "How likely are you to remember to take PrEP daily?"; "How willing would you be to continue to take PrEP daily if you have side effects such as feeling nauseous, tiredness, fatigue, headaches, and dizziness?"; "How embarrassed would you be to take PrEP?". Responses to individual items ranged from 1 to 5 points. In the first question, items were scaled from "extremely unlikely" to "extremely likely". The second, scaled from "not at all willing" to "extremely willing" and the last question, scaled from "not at all embarrassed" to "extremely embarrassed".
- Risk behaviors for contracting HIV included drug use and sexual behavior, both were latent variables comprised of two indicators corresponding to: needle sharing, needle cleaning, condom use, and number of sexual partners.
- Perception of barriers towards PrEP use was assessed by a scale in which one point was given to each "Yes" response for the following items: difficulty remembering, travel/migration, alcohol/drug use, afraid spouse/partner might find out, afraid friends/community might find out, other difficulty. A dichotomous measure was also constructed in each item.
- Perception of access to health care was measured by a Likert scale including six items

in which response set was from 1 to 5 points, from "Extremely agree" to "Not at all agree" respectively. The scale was reversed in the data analysis to describe the higher point is the better perception of access to health care.

- Methadone Maintenance Treatment (MMT) status was also mentioned as an independent variable, with a score of 1 for participants who were currently enrolled in MMT, and a score of 0 for participants who were not being treated methadone.

3. Data analysis

Analyses were carried out in Mplus version 7.3127. Model fit was assessed with the comparative fit index (CFI),28 the root mean square error of approximation (RMSEA) and the standardized root mean square residual (SRMR).29 The CFI value reflected the improvement in fit of a hypothesized model over a real model among the measured variables, ranging from 0 to 1. A CFI value of 0.95 or greater is expected, indicating that the hypothesized model reproduced 95% or more of the co - variation in the data set. The RMSEA measures the lack of fit per degree of freedom, and values less than 0.08 indicate a relatively good fit between the hypothesized model and the observed data. SRMR values below 0.06 were generally regarded as indicative of good fit.

Factor analyses were used to assess the adequacy of each construct of the hypothesized model.³⁰ Then a structural equation model comprised of both latent variables and the outcome variable positioned with predictor variables, of which the model predicted both the intermediate variables and the outcome. In other word, we examined both direct and indirect prediction values of the outcome variable by MMT status, information about PrEP, age in years, perception of stigma towards addiction,

perception of barriers towards PrEP use, perception of access to health care. More than 10 data sets were arranged and the path models were examined simultaneously to develop the final model as below.

4. Ethiclal issues

Ethics approval and consent to participate
The study was approved by Institutional
Review Board (IRB) at Hanoi Medical University

(number: 144/HMURB on 18th July 2014) and Columbia University Medical Center.

Those who agree to participate in the study will be informed the purpose and aims of this study and ask for signing into their informed consent. Upon completion, each participant received 220,000 Vietnam Dong in compensation (equivalent to 10 US dollars).

III. RESULTS

1. Participant characteristics

Demographic characteristics of the 184 participants are presented in Table 1. The mean age was 32.2 years (SD = 7.3 years) and the majority of participants were between 30 - 39 years old (54.9%). Over half of participants reported their education as less than a high school diploma (56%). Approximately 80% reported having an unstable job and the mean monthly income was at 6.5 million VND (about 350 US dollars). Over one - third of participants were single (37.5%).

Table 1. Demographic and behavioral characteristics of the participants (n = 184)

	Frequency	% or xX ± SD
Age		32.2 ± 7.3
< 30 years	25	13.6
30 – 39 years	101	54.9
40 – 49 years	47	25.5
≥ 50 years	11	6.0
Educational attainment		
Less than high school education	103	56.0
High school and above	81	44.0
Occupational status		
Having employment	155	84.2
Unemployment/ students	29	15.8
Monthly income (million VND)		6.5 ± 4.9
Marital status		
Single	69	37.5
Married/ cohabited with a partner	74	40.2
Divorced/ separated/ widowed	41	22.3

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	Frequency	% or xX ± SD
Sharing needles (past 3 months)		
(n = 183*)		
No	163	89.1
Yes	20	10.9
Use clean needles (past 3 months) (n = 183*)		
Always use new needles	120	65.6
Always clean needles before inject- ing	22	12.0
Always clean needles after injecting	30	16.4
Sometimes clean, sometime don't	7	3.8
Never clean needles	4	2.2
Number of sexual partners (past 3 months) (n = 183**)		
0 partner	70	38.3
1 partner	89	48.6
≥ 2 partners	24	13.1
Condom use (past 3 months) (n = 184)		
Not having sex in the past 3 months	70	38.0
All the time	24	13.1
Most of the time	7	3.8
Some of the time	10	5.4
None of the time	73	39.7
Currently on Methadone treatment		
No	158	85.9
Yes	26	14.1

SD: Standard deviation; VND: Vietnam Dong; *1 participants did not inject in the 3 months before the survey; **1 participants did not remember

A percentage of 24.5% participants had awareness of PrEP as a method to prevent HIV infection. After they were informed about PrEP, over one - third of all participants reported that they would not be willing to use PrEP at all (34.3%). About half of the PWIDs (47.5%) said that they were very or extremely willing to use PrEP (see Table 2). Among those who reported less than very willing to use PrEP, 44.7% thought that they did not need PrEP; 17.4% did not believe in the effectiveness of PrEP, and 29.6% were concerned about side effects. A significant number of participants reported that they

could not take pills daily (11.2%) or feared that others might think they were still using drugs (21.4%). A smaller number of participants (6.1%) feared that others might think they were HIV positive or having promiscuous sex (1%).

Table 2: Willingness to take PrEP among HIV negative PWID

	Frequency	%
Heard about PrEP (n = 184)		
No	139	75.5
Yes	45	24.5
Willing to use oral PrEP (n = 181*)		
Not at all willing	62	34.3
Not very willing	8	4.4
Somewhat willing	25	13.8
Very willing	37	20.4
Extremely willing	49	27.1
Reasons for for not willing to take daily oral PrEP (n = 98**)		
Do not think it will be effective	17	17.4
Concerned about side effects	30	30.6
Do not want to take a pill daily	14	14.3
Others may think I am HIV positive	6	6.1
Others may think I have my sexual behaviors	1	1.02
Do not think I need it	52	53.1
Other reasons (incl. others may think I am still using drugs)	9	9.2

^{*3} participants were not sure about their willingness; **including those were not at all willing, not very willing, somewhat willing and not sure about their willingness

2. Factor Analyses

Table 3 presents fit indexes for factor analysis models what were generated to test the adequacy of the constructs of the theoretical framework, the factor loadings, standardized error of indicator variables and reliability of constructs. The reliability of three constructs ranged from good to acceptable (cronbach $\alpha M = 0.8$; cronbach $\alpha D = 0.65$; cronbach $\alpha S = 0.87$), and all of factor loadings were significant with p < 0.001. The Confirmatory Factor Analysis for the motivation construct had an excellent fitting: CFI = 1.0; RMSEA = 0.0; SRMR = 0.0. The Exploratory Factor Analysis for two items of drug use behavior construct and sexual behavior also showed good fit (p < 0.001).

		α	β	SE	CFI	RMSEA	SRMR
М	Motivation	8.0			1.0	0.0	0.0
M1	Ability to remember daily		0.79*	0.05			
M2	Willing to take despite side effects		0.73*	0.05			
М3	Embarrassed when using PrEP		-0.74*	0.05			
	Drug use behaviorsa	0.65					
R1	Sharing needles and/or works		0.61*				
R2	Cleaning syringes and needles		0.61*				
	Sexual behaviorsa	0.87					
R3	Using condom (past 3 months)		0.82*				
R4	Had sex (past 3 months)		0.82*				

*p < 0.001; *Exploratory Factor Analysis was conducted in STATA; SE: Standard error; CFI: Comparative fit index; RMSEA: Root mean square error of approximation; SRMR: Standardized root mean square residual; PrEP: Pre - exposure prophylaxis

3. Structural Equation Analysis

The structural equation model was presented in Figure 2 after gradual adjustment. Fit indexes of the final model were excellent: CFI = 0.99; TLI = 0.99; RMSEA = 0.017; Chi - square = 48.6, df = 46. The path coefficient from motivation to willingness to use PrEP was strongly significant ($\beta > 0.78$; p < 0.001). Inversely, a weak correlation existed between perceived barriers of using PrEP and willingness to use PrEP ($\beta = 0.207$; p < 0.001). Furthermore, perceived access to general health care was also associated with the willingness to take oral PrEP ($\beta = 0.104$; p < 0.05). The final model predicted 66.8% of the variance in willingness to use PrEP.

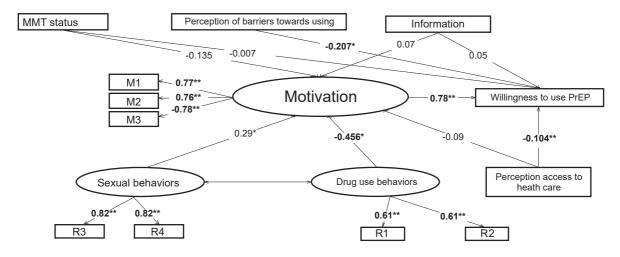


Figure 2. The structural equation model of factors associated with willingness on using PrEP among PWIDs (*p < 0.05; **p < 0.001)

IV. DISCUSSION

In this study, we developed a conceptual based pattern of Information - Motivation -Behavioral Skills (IMB). Our framework did not include all constructs of the IMB model, in which the Behavioral Skill construct was not mentioned as a central position. The behavioral skills construct was not measured due to the awareness of PrEP is still novel towards PWIDs, to clear understanding of multiple behavioral skills may require more meticulous counseling to PWIDs. So that was justified in the context of this study. Moreover, basing on data validation and previous knowledge, we ascertained that the developed framework is useful for predictable pattern of willingness to take PrEP among PWIDs in Hanoi, a typical urban pattern in Vietnam. The main predictor for willingness to take PrEP was motivation. Perceived barriers towards PrEP use associated positively with willingness. These findings prove that people who were more aware of barriers/challenges of PrEP use and PrEP - related information as well as sustaining higher motivation would be more willing to take PrEP.

By applying a structural equation model to predict factors associated with the willingness to use PrEP, we described the central role of motivation in influencing willingness to take PrEP; motivation was positively and directly associated with willingness. These findings were consistent with the classic IMB model31. In this study, motivation which was measured by likelihood of remembering to take PrEP daily, willingness to continue use regardless of side effects, and embarrassment. The aspect of willingness to continue use despite side - effects was described in the other study in Vietnam among transgender women, the study indicated that the number of people who willing to take PrEP fell down sharply in the side -

effect scenario.²⁵ To enhance motivation in general, the roles of peer educators may need considering.²⁵ Ensuring adherence was else emphasized among PWID population, while a recent trial showed efficacy certainly will increase greater adherence, only 56% of the study sample reported adherence to the study medication.¹² Our study again pointed out that the aspect of ensuring adherence contributed to PrEP motivation, which affects intensely to willingness of taking PrEP as well as factual effectiveness of PrEP strategies.

Another factor presented in the IMB model was PrEP - related information. Though it was not significant in this study, it is consistent with the findings of previous studies which also applied the IMB model to examine the willingness to take PrEP among PWIDs,23 and to identify factors influencing health behavioral change such as ART adherence 32. Another study applying the IMB model on ART adherence, motivation in relation to ART adherence differed between non - drug - using people and current drug - using one.33 Whereas current drug users showed that more information led to the greater ART adherence, non - drug users did not.33 It posits that information play substantial roles towards drug users to change health behaviors. Existing studies in the field of PrEP also supported that sufficient knowledge about PrEP is critical to enable successful PrEP implementation.26 Thus, attention should be paid to clearly define and measure what specific information about PrEP was known in various contexts.

As previous literature has demonstrated, we also observed characteristics that might be correlated with willingness to use oral PrEP including age, educational attainment, occupational status, drug use, sexual behaviors, and motivation and barriers to taking

PrEP. In other words, willingness to use PrEP is multifaceted, which is why we expanded the external indicators of the IMB model. This study found that greater perception of barriers may enhance willingness to take PrEP which differs from previous findings from other studies. 19,21 This inconsistency could be explained by the fact that our study measured quantity of barriers as level of perceived barriers anticipated when using PrEP; we did not focus on specific barriers such as side effects of long - term PrEP regimens, or demands of adherence to a daily regimen as some previous studies did.21 However, our findings contribute to the body of literature on barriers to PrEP and their perception. Perceived HIV risk was also mentioned in several studies as a factor enhancing willingness to use PrEP. 19,24 In this study, we divided HIV risk into drug use and sexual behavior. We found that neither have a direct effect to willingness to take PrEP, which is inconsistent with previous findings. 19,21 High - risk behaviors were not found as direct pathways to willingness to take PrEP but these were significantly correlated with motivation. It should be noted that perceived sexual behaviors may enhance PrEP - related motivation related to willingness.

Regardless of increasing recommendations for PrEP use among high - risk populations from recent intervention trials and CDC guidelines, a small number of people who inject drugs in Vietnam were aware of PrEP as a method to prevent HIV. Particularly, findings from our study indicated that about three - fourths had never heard of PrEP, and about half of them were willing to take PrEP when they were informed about it. The far lower number of people presented in another study in Vietnam among transgender women.¹⁰ These numbers might be reflected a lack of awareness and

belief that PrEP would be helpful, also, this is a considered challenge for future implementation of PrEP among these populations in Vietnam as well as in the other region. 10,12,26 To start with, researches which focus on education and willingness of taking PrEP are important to improve feasibility of PrEP implementation. The second lesson learned from our study that it is necessary for future PrEP studies for PWID to address the roles of PrEP - related barriers, as well as how to enhance PrEP motivation.

This study has some limitations. Firstly, our study has yet to provide particular constituents of PrEP - related information. Likelihood of measuring on the information component might be let up. Especially, in case a group of participants have not yet been aware about PrEP due to its novelty. Secondly, we quantified perceived barriers as a total point of barriers which were given that corresponding to level of perceived barriers, quality characteristics of barriers were not identified in our study. This should be further clarified in future qualitative studies and interventions. Finally, the limitation is that due to potential unrepresentative sampling, we conducted a convenience sampling method to recruit participants for the study. Despite these limitations, this study provided a preliminary predictive model for awareness of and willingness to use PrEP among high - risk populations in urban settings of developing countries.

IV. CONCLUSION

Findings from this study indicate the importance of improving dissemination of PrEP - related information and enhancing the motivation of high - risk populations. In addition, material barriers were identified as factors that may have potential influence on the willingness to enroll in PrEP.

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LIST OF ABBREVIATIONS

CDC: Disease Control and Prevention;
PrEP: Pre - Exposure Prophylaxis; MSM:
Men who have sex with men; FSW: Female
Sex Worker; PWID: People Who Inject Drug;
MMT: Methadone Maintenance Treatment;

IMB: Information - Motivation - Behavioral Skill Model; SEM: Structural Equation Model; CFI: Comparative Fit Index; TLI: Tuker - Lewis Index; RMSEA: Root Mean Square Error of Approximation; SRMR: Standardized Root Mean square Residual.