Evaluating the Effects of HIV Self-testing used Professional Rapid Test Kits among MSM in Some Areas of China.

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Research Article

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Abstract

With rapid expanding of HIV self-testing (HIVST) among unprofessional people has many unknown hidden dangers. This research for the first to survey the feasibility of urine, oral mucosal transudate (OMT) and finger blood rapid HIV testing kits were used for HIVST by non-professionals MSM in China. Total 274 valid questionnaires were received from 313 MSM participants, including 263 completed urine HIVST, 61 completed OMT HIVST and 17 completed blood HIVST. The average age of participants was under 30, about 80% were unmarried, more than 80% with an education level above Grade 9 but more than 50% people had never heard of the rapid HIV test. There were significant differences in the key information understanding accuracy between HIVST. The accuracy rates were 18.0–80.6%. When the HIVST result was positive, more than 80% chose to seek confirmation. When the test was negative, 60.5% (159/263) participants of urine self-test and 32.8% (20/61) of OMT self-test chose regular retesting. When the test was ineffective, more than 80% chose to retest. In addition, 54.1% of the 146 voluntary participants to accept blood HIVST, followed by 15.8% accept blood and urine HIVST and 14.4% accept only urine HIVST. The main reason for choosing blood HIVST was "accuracy", while the main reason for choosing urine HIVST was "convenience". This findings lays a scientific theoretical basis for further carrying out HIVST in China.

Introduction

Since WHO issued guidelines on HIV self-testing (HIVST) in 2016[1], implemented HIVST countries increased from 13 in 2017 to 28 in 2018, and 18 of them are middle and upper income countries. The countries with HIVST support policies increased from 16 in 2016 to 59 in 2018. In China, the state Council issued the "Thirteenth Five-Year Plan (2017–2022)" for HIV prevention and control in 2017, indicated that China will "explore strategies to promote HIVST through selling HIVST kits in pharmacies and online" [2].

Untill July 2019, the first and the only one authority HIVST kit was approved by Chinese State Food and Drug Administration, which was HIV-1 urine antibody (colloidal gold assay) test kit [3]. The National Health Commission issued the "Implementation Plan for the Prevention of the Spread of HIV/AIDS (2019-2022), which proposed "health and drug regulatory departments should formulate the guideline for the HIV/AIDS self-testing and relevant policies supervision, carry out online appointment testing consultation services to promote HIVST in September 2019 [4]". And the Chinese center for disease control and prevention STD and AIDS prevention and control Association issued "AIDS self-testing guide manual" to provide technical guidance in October 2019[5].

However, each hour of 2017, about 220 rapid HIV test kits were sold to do HIVST by a single online pharmaceutical store in China, without monitoring and the majority were blood-based rapid testing kits for clinical professionals [6]. This rapid expanding of HIVST among unprofessional people has many unknown hidden dangers. Therefore, it is the first survey and research the feasibility of urine, Oral mucosal transudate (OMT) and finger blood rapid HIV testing kits were used for HIVST by non-professionals MSM in China, from November 2018 to March 2019. In accordance with the "Technical

specifications for WHO prequalification of Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional use and/or self-testing" [7], we evaluated the understanding ability of key information in manual, the interpretation ability of simulation results, and the operation ability of HIVST. At the same time, we also evaluated the preference of the people for urine, blood and OMT. In order to lay a scientific theoretical basis for further carrying out HIVST in China.

Results

Participants characteristics

Total 274 valid questionnaires were received from 313 MSM participants, including 263 participants completed urine HIVST, 61 participants completed OMT HIVST and 17 participants completed blood HIVST. Among the participants who completed urine HIVST with an average age of 28.8 years (the oldest was 58 and the youngest was 17), 85.9% (226/263) were unmarried, 77.2% (203/263) were Han nationality, 89.7% (236/263) had an education level above junior middle school, but 59.70% (157/263) had never heard of the rapid urine HIV test. In addition, 61 participants who completed OMT HIVST with an average age of 29.3 years (the oldest was 54 and the youngest was 19). 77.1% (47/61) were unmarried, 75.4% (46/61) were Han nationality, 82.0% (50/61) had an education level above Grade 9, 32.8% (20/61) had heard of the rapid OMT HIV test but don't understand (Table 1).

Key information understanding evaluation

There were significant differences in the key information understanding accuracy between urine and OMT HIVST. The accuracy rates were 31.6% (83/263) to 80.6% (212/263) and 18.0% (11/61) to 77.1% (47/61), respectively. The most confusing of urine HIVST were "unsuitable for antiviral treatment people" and "use within 30 minutes after unpacking", and the comprehension correct rates were 31.6% (83/263) and 32.7% (86/263). In OMT HIVST, the most incomprehensible were "After one sample, wait 30 minutes for a second sample" and "After adding the sample for 30 minutes, the result is not accurate", with the comprehension correct rate of (18.0% (11/61) and 32.8% (20/61) (Table 2).

Additionally, the comprehension correct rates of urine, OMT and blood rapid test results were 62.4%~79.5%, 57.4%~88.5% and 17.7%~88.2%, respectively. The most accurate understand was "if there is no C line and no test line, it is invalid", while the inaccurate understand were "if there is no C line, it is invalid" and "if there is no C line and the test line appear, it is invalid". Especially for the interpretation of "HIV infection cannot be excluded when the test is negative" and "HIV infection cannot be confirmed when the test is positive", the comprehension correct rate both less than 50% (Table 2).

When the HIVST result was positive, more than 80% chose to seek confirmation from medical institutions (urine 84.4% (222/263) and OMT 80.32% (49/61)). When the test was negative, 60.5% (159/263) of participants in the urine self-test chose regular retesting, but only 32.8% (20/61) of participants in the

OMT self-test chose regular retesting. When the test was ineffective, more than 80% chose to retest (urine 83.7% (220/263) and OMT 83.60% (51/61)).

Results analog pictures discriminant evaluation

The participants had good interpretation accuracy (86.9%~98.1%) with the results analog pictures of strong reactivity, non-reactivity and invalid (no quality control line, no test line), but had low accuracy (32.7%~68.9%) with the simulation pictures of weak reactivity and invalid (no quality control line, no test line) results.

HIVST operation evaluation

The urine HIVST performance with the highest accuracy during the self-detection evaluation. 82.1% (216/263) participants could perform all the urine HIVST steps correctly, 11.0% (29/263) had an operation error of one step and 6.9% (18/263) had multi-step operation error. The "add 3 drops urine to the sample area in the test card" with lowest correct rate was 88.2% (232/263) (Table 3).

The operating accuracy of OMT and blood HIVST were 11.5% (7/61) and 23.5% (4/17), respectively. Especially with the low operate accuracy in "slightly gargling with warm water before collection" and "two wiping time 5-6s" of OMT HIVST, "add 1 drop of whole blood to the add sample hole" and "read the result after 30 minutes" of blood HIVST (Table 3).

Self-test method acceptance

54.1% (79/146) of the 146 voluntary participants to accept blood HIVST, followed by 15.8% (23/146) to accept blood and urine HIVST, 14.4% (21/146) to accept only urine HIVST. Among them, the main reason for choosing blood HIVST was "accuracy" (57/146), while the main reason for choosing urine HIVST was "convenience" (39/146).

Discussion

Non-professionals using professional rapid HIV testing reagents for HIVST may have problems. The stages of sample collection, testing and result interpretation[8-10] may affect the test accuracy. In this study, MSM participants were asked to do HIVST using rapid HIV testing kits without any assistance or guidance. The results showed that MSM can better complete urine HIVST with the operation accuracy rate is 82.1%, which is consistent with the research of Roger B. Peck et al[11]. However, the operating errors were common in OMT and blood HIVST, the operating accuracy rate were only 11.5% and 23.5%, respectively. Studies have shown that the high error rate in OMT HIVST is due to the complex OMT collection and test process, the too numerous descriptions in the instructions to users' failure to read or understand carefully[12]. And the most common error in blood HIVST was "reading results after 30

minutes", perhaps due to participants were anxious to know their infection status and immediately interpreted the results when the test strip display. This is different from the study of Mohammed Majam and Smith P[13,14], which operational errors mainly occurred in the blood collection and sampling process. In addition, during the urine HIVST, the most mistakes were "adding 3 drops of urine to the sample area of the test card", which may be due to some participants did not read the instructions carefully. Therefore, this study suggest that the clear, understandable and interesting instructions should be used to improve the feasibility of non-professionals HIVST[11].

Results analog picture discriminant evaluation showed that the strong reactive and non-reactive results with the highest interpretation accuracy, while the weakly reactive results with low interpretation accuracy, which was consistent with the relevant research results[9,11,12,15]. Especially, the more complex invalid results of "no quality control line /T line, with test line /C line" is far lower than the invalid results of "no quality control line /T line, no test line /C line". In this regard, relevant studies have shown that use different symbols for test lines and control lines could increase the results interpretation accuracy[11]. Therefore, it is suggested that clear, simple and easy to distinguish symbols can improve the results interpretation accuracy.

According to the evaluation results of participants' understanding the cautions, operation processes and results interpretation in the reagent instructions, more than half questions with less than 70% comprehension accuracy rate, which was consistent with the relevant domestic studies[12]. However, the study of Gresenguet[15] showed most people could correctly understand the instruction information. It may be the reagent instructions used in this study were full of words and contained technical terms, which led to participants' inability to accurately identify and effectively understand while simple and understandable colloquial descriptions of instructions were used in Gresenguet's study. More important, the low understanding accuracy of "HIV infection cannot be ruled out if the test result is negative, and HIV infection cannot be confirmed if the test result is positive" will affect the users' subsequent solutions choice. Remind us again, using easy to understand instructions is more conducive to non-professional users to accurately understand the key information.

This study found when the HIVST results were reactive more than 80% people choose to confirm by medical institution, when the results were nonreactive most people choose to regular retest, and when the results were invalid more than 80% people choose to test again. It is suggested that HIVST can help to find more HIV infected people, to some extent[12,16].

If provided some help to HIV self-testers such as simple instructions and video tutorials, the HIVST results can be highly consistent with professional medical and health workers [17]. Studies showed the OMT HIVST accuracy is 97.0%[18], 92.5% [12], and 83.3% [19]. In this study, the HIVST accuracy of urine, OMT, and blood were 96.9% (255/263), 91.8% (56/61) and 100% (17/17). There was no factors affecting the HIVST accuracy by evaluation results analysis, the possible reasons were the HIV antibody content different between urine, OMT, and blood which due to the interfering substances of urine and OMT, and also may be because of the small sample size in this study.

Studies have shown that the urine of HIV-1 infections is unlikely contain infectious HIV-1, the risk of transmission of HIV-1 by urine is low to nonexistent[20]. And the urine sampling is non-invasive and painless which can improve testers to choose and acceptance. In this study, we found if HIVST was conducted again, 54.1% MSM tended to choose blood test reagents, 15.8% to choose blood and urine test reagents, 14.4% choose urine test reagents, and the reasons were people believes blood test is more accurate but urine test is more convenient. It is consistent with the study results of Witzel et al. [21] and Lippman et al. [22], which also showed that HIV blood test in MSM was more acceptable because of MSM believe it more accurate. However, the research of Marley et al. [81] showed 72.8% MSMs accepted OMT test because convenience, painless, easy to collect samples and test [23], while only 15.1% MSMs considered choosing OMT test in this study because the urine test also has the characteristics of above and and HIV antibodies in urine samples is very stable, can directly test [24]. So the MSMs be inclined to choose more convenient urine and more accurate blood.

In conclusion, this study for the first time to evaluated the understanding ability of key information in manual, the interpretation ability of simulation results, and the operation ability of HIVST, and the preference for urine, blood and OMT, when unprofessional MSMs used professional rapid test kits for HIVST lays a scientific theoretical basis for further carrying out HIVST in China.

Methods

Ethical requirement

The research was reviewed and approved by the ethics review committee of the center for STD and AIDS prevention and control of Chinese center for disease control and prevention (Project No. X171103483). All methods were performed in accordance with the relevant guidelines and regulations. All the documents during study are strictly confidential, and the identities of the participants in study were strictly confidential and free to opt out at all stages of the investigation.

Setting and population

This study was conducted in three HIV testing sites of MSM community organizations in Guiyang of Guizhou Province and Nanning of Guangxi Zhuang Autonomous Region. There are independent testing and consulting rooms to provide a private space for participants. Inclusion criterias for study participants were no mental illness or consciousness disorder, voluntary and willing to signed informed consent. Exclusion criterias were unwilling to sign informed consent, have been diagnosed with HIV or AIDS.

Investigators are experienced peer education volunteers and have received rapid test training. Investigators understood the purpose and significance of the study, familiar with the investigation process and questionnaire, mastered the process and operation of urine, OMT and blood HIV tests.

Questionnaire design and key information understanding evaluation

Questionnaires were designed in accordance with the instructions of rapid HIV detection reagents used in this study. Questionnaire including basic information of participants (age, nationality, marital status, educational level, residence, etc.) and the understanding of key information in instruction (important steps, results interpretation, considerations and limitations, in the face of different self-test results may take actions).

Participants fill their own basic information in the first part, after viewing the instructions to answer and fill the questions about the key information in the second part. After completed the questionnaire, the investigators to check the questionnaire in time. If there are missing items or obvious errors in the questionnaire, the participants would be reminded to supplement and improve.

Results simulation pictures preparation and discriminant evaluation

Simulation pictures of test results such as weak reactivity, non-reactivity, and ineffectiveness (neither test line nor quality control line and only test line) were prepared in advance. The investigators showed the results simulation pictures to participants and asked them to interpret each simulation result, and recorded the interpretation results in the corresponding position.

Operation record table design and operation evaluation

Selected 15 participants who had never received HIV test were divided into urine test group, OMT test group and blood test group, with 5 people in each group. Each group of every participants was given a correspond rapid HIV testing service package and completed HIV testing. From the moment of participants open the package, researchers begin to record in detail the all operation errors in preparation, sampling, testing, results interpretation, waste disposal and so on, without any help or guidance during the whole evaluation process. After the evaluation, asked participants in detail about their problems and confusion during the whole test process. Finally, according to the results of operation and communication to design the operation records including key steps in urine, OMT and blood HIVST.

After signed the informed consent, investigators first provided the a urine testing service package (including a urine testing kit, instruction manual, disposable urine cup, disposable dropper, etc.). Under the premise of no guidance, all participants completed the urine HIV rapid testing by themselves. Afterwards, provided the OMT service package (including a OMT test kit, instruction manual, disposable oral swab, etc.) and blood testing service package (including a test kit, instruction manual, disposable blood needle, etc.) to some volunteer participants, and completed the HIV tests without any guidance. Investigators

carefully observed the operation of each specific step and filled in the operation record form, and filled the final results interpretation by participants in the "Self-Test Results" section. At the same time, investigators filled their own results interpretation in the "Professional Results" section.

Data analysis

Removing the questionnaires with missing key information or non-conforming, used EpiData 3.1 and double entry method to establish the database, and used SAS 9.4 conducted data consistency test. In this study, frequency and constituent ratio were used to represent enumeration data, while mean and standard deviation were used to represent measurement data. Univariate analysis was performed by chi-square test or Fisher's test, multivariate analysis was performed by Logistic regression, the test level $\alpha=0.05$.

Declarations

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Disclosure statement

Informed consent was obtained from all the study participants. No potential conflict of interest was reported by the authors.

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Tables

Table 1

Basic information of MSM participants for HIVST

		Urine		OMT		Blood	
		N=263	%	N=61	%	N=17	%
Age (years)	≤25	106	40.3	29	47.5	6	35.3
	26~35	105	39.9	17	27.9	8	47.1
	36~45	39	14.8	12	19.7	2	11.7
	≥45	13	5.0	3	4.9	1	5.9
Marital status	Unmarried	226	85.9	47	77.1	14	82.3
	Married	28	10.7	8	13.1	2	11.8
	Divorced or widowed	9	3.4	6	9.8	1	5.9
Nationality	Han	203	77.2	46	75.4	11	64.7
	Zhuang	32	12.2	12	19.7	6	35.3
	Others	28	10.6	3	4.9	0	0.00
Education	Grade 1-9	27	10.3	11	18.0	3	17.7
	Grade 10-12	71	27.0	11	18.0	4	23.5
	College or above	165	62.7	39	64.0	10	58.8
Know about rapid HIV test	Very familiar	5	1.9	3	4.9	2	17.6
	Know a little	35	13.3	30	49.2	13	76.5
	Just heard of	66	25.1	20	32.8	1	5.9
	Never heard of	157	59.7	8	13.1	0	0.0

Table 2

Key information understanding evaluation

Operation cautions		Understanding accuracy	
		n	%
Urine (N=263)	Unsuitable for antiviral treatment people	83	31.6
	Use within 30 minutes after unpacking	86	32.7
	Read the results 15 minutes after adding samples	176	66.9
	Within the specified time, no matter the color is strong or weak, judged as the color	184	70.0
	Read the result within the specified time	205	78.0
	Do not read the results in dim light	193	73.4
	The test card should not be tilted	212	80.6
	HIV infection cannot be excluded when the test is negative	122	46.4
	HIV infection cannot be confirmed when the test is positive	132	50.2
OMT (N=61)	Do not sample immediately after eating, brushing, smoking and gargling	39	63.9
	After one sample, wait 30 minutes for a second sample	11	18.0
	Samples were collected from the upper and lower gingival lines	47	77.1
	Read the results 15 minutes after adding samples	43	70.5
	After adding the sample for 30 minutes, the result is not accurate	20	32.8
	HIV infection cannot be confirmed when the test is positive	25	41.0
Blood (N=17)	Diluent should be added after whole blood dripping	16	94.1
	Remove from packaging at room temperature and use within 30 minutes	2	11.8
	Read the results 30 minutes after adding samples	0	0.0
	Do not read the results in dim light	16	94.1
	The test card should not be tilted	17	100.0
	HIV infection cannot be excluded when the test is negative	4	23.5
	HIV infection cannot be confirmed when the test is positive	5	29.4
Results interpretation			
Urine	Both C line and T line appear, it is positive	164	62.4

(N=263)	Only C line appear and no T line, it is negative	164	62.4
	If there is no C line, it is invalid	185	70.3
	If there is no C line and no T line, it is valid	209	79.5
OMT (N=61)	Only the red C line appear, it is negative	54	88.5
	Both the red C line and T line appear, it is positive	48	78.7
	If there is no red C line, it is invalid	35	57.4
Blood (N=17)	Both C line and T line appear, it is positive	5	29.4
	Only C line appear and no T line, it is negative	3	17.7
	If there is no C line and the test line appear, it is invalid	6	35.3
	If there is no C line and no T line, it is valid	15	88.2

Table 3
HIVST operation evaluation

HIVST steps		Operation accuracy	
		n	%
Urine			
(N=263)	1. Collected urine and placed in cup for test	263	100.0
	2. Place the test card flat on the table	263	100.0
	3. Use disposable dropper to absorb urine	257	97.7
	4. Add 3 drops urine to the sample well in test card	232	88.2
	5. Wait patiently for 15 minutes	248	94.3
	6. Read result according to the appear line	257	97.7
	7. Place all materials used in the trash can after testing	243	92.4
OMT			
(N=61)	1. Gargle with warm water before collection	15	24.6
	2. Hold the oral sampler handle one end without touching the sampling end	54	88.5
	3. Used sampling end wiped from one corner to the other along the upper gum line	51	83.6
	4. Wipe along the upper gum line back to beginning	54	88.5
	5. Wipe time is about 5-6s	41	67.2
	6. Flip the oral sampler	47	77.1
	7. Used sampling end other side swabbed from one corner to the other along the lower gingival line	48	78.7
	8. Wipe along the lower gum line back to the start	55	90.2
	9. Wipe time is about 5-6s	42	68.9
	10. Insert the oral sampler into the sample processing solution tube	58	95.1
	11. Place the swab close to the tube wall and scrape up and down 6-8 times	44	72.1
	12. Add 4 drops sample solution to the sample well	44	72.1
	13. Read the results after 15 minutes	59	96.7
Blood			

(N=17)

1. Disinfect the local finge tip with alcohol cotton	14	82.3
2. Wait until the alcohol has evaporated completely	15	88.2
3. Pierced the fingertip skin with blood needle	16	94.1
4. Draw blood from fingertip with a straw	14	82.3
5. Add 1 drop blood to the sample well of test card	13	76.5
6. Add 1-2 drops sample diluent	15	88.2
7. Record the adding samples time	15	88.2
8. Read the results after 30 minutes	7	41.2