The validation and evaluation of anti-HIV testing algorithm used in mobile clinic setting for men who have sex with men in metropolitan Bangkok, Thailand

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Abstract

Background: Same-day anti-HIV testing algorithm is recommended by Thai National Guidelines. We compared performance characteristics of algorithms used in a mobile clinic and a facility-based clinic for men who have sex with men (MSM) in Bangkok.

Methods: Mobile clinic samples collected from 4 saunas and 2 spa venues were tested by Alere Determine™ HIV 1/2, followed by DoubleCheck Gold™ Ultra HIV 1/2 and SD Bioline HIV 1/2 3.0. All samples were re-tested at the Thai Red Cross Anonymous Clinic (TRCAC) by Architect HIV Ag/Ab or Elecsys HIV combi PT, followed by Alere Determine™ HIV 1/2 and Serodia HIV 1/2. Non-reactive samples were tested by Aptima nucleic acid amplification test (NAAT) and reactive/inconclusive samples were tested by less-sensitive immunoassays (IA) and HIV-1 RNA to detect acute HIV infection (positive NAAT or non-reactive IA/positive HIV-1 RNA).

Results: Of 233 MSM, 36 (15.5%) had HIV infection diagnosed using mobile clinic algorithm. Two additional acute HIV cases (1 positive NAAT and 1 reactive Architect with detectable HIV-1 RNA) were diagnosed using TRCAC algorithm. The mobile clinic algorithm had a sensitivity of 94.9% (95% CI: 82.7, 99.4) and a specificity of 100% (95% CI: 98.1, 100).

Conclusion: Use of whole blood on rapid test kits demonstrated satisfactory performance and allowed same-day HIV test result through a mobile clinic model. For populations with high HIV incidence, careful history taking to define the window period is crucial and repeat testing must be encouraged if the testing algorithm does not include 4th generation anti-HIV assay or NAAT.

Keywords: HIV testing algorithm, men who have sex with men, HIV, mobile clinic, Thailand

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Introduction

In the last decade, HIV has been spreading among men who have sex with men (MSM) on a global level.[1] HIV prevalence among MSM in Bangkok increased significantly from 17.3% in 2004 to 30.8% in 2007[2] and remained high at 31.3% in 2010.[3] In 2015, 47% of new adult HIV infections in Thailand occurred in MSM.[3] Thailand has committed itself to end the HIV epidemic as a public health threat by 2030 using the Test and Treat strategy.[4] The current Thai National Guidelines which recommended immediate antiretroviral therapy (ART) for all HIV-positive people regardless of CD4 count have already been implemented countrywide since October 2014.[4] An ambitious target was also set for 90% of MSM to receive an HIV testing in the past 12 months by 2016.[4]

Anti-HIV testing algorithm which provides same-day HIV test result is currently recommended by Thai National Guidelines in order to facilitate immediate referral to

antiretroviral therapy after a confirmed HIV diagnosis is made by consistent reactive results from 3 different anti-HIV tests.[5] To scale-up access to HIV testing among key populations, mobile clinics to hot spots using whole blood on 3 rapid HIV test kits is commonly used in Thailand. For MSM in Bangkok, mapped hotspots are venues frequently visited by MSM which mainly include saunas and spas.[6] We compared performance characteristics of anti-HIV testing algorithm using rapid test kits in a mobile clinic setting to an algorithm containing 4th generation immunoassays and nucleic acid amplification test (NAAT) used in a large facility-based HIV testing clinic in Bangkok.

Methods

Study population, sampling, and eligibility

Mobile clinics to 4 saunas and 2 spa venues in the hotspots for MSM in Bangkok were conducted during July 2011 – August 2012. Mobile clinic was conducted consecutively once a week among the 6 venues. MSM who visited the venues and fulfilled the inclusion criteria were approached by study staff about their interest in HIV testing and sexually transmitted diseases screening. Eligible participants were Thai men, age over 18 years old who reported having sex with another man at least once in their lifetime, i.e., men who have sex with men or MSM. Those who had interest were enrolled into the study after they provided informed consent. Participants were first asked to complete a self-administered questionnaire about sexual behavior, partner status, religion, education, and income before they received pre-test counseling. This was followed by an on-site HIV testing and post-test counseling including condom use as a method of continued HIV prevention. Those who were HIV-positive were promptly referred to antiretroviral treatment centers. This study was approved by the institutional review board of the Faculty of Medicine, Chulalongkorn University in Bangkok, Thailand.

Mobile clinic HIV testing algorithm

HIV testing algorithm used in the mobile clinic included three different rapid HIV antibody detection test kits performed sequentially (**Figure 1**): First (M1), Alere Determine HIV™ 1/2 (Immunochromatography, Abbott Laboratories, USA) (M1), Second (M2), DoubleCheck Gold™ Ultra HIV 1/2 (Immunochromatography, Orgenics, Ltd., Israel) (M2), and Third (M3), SD Bioline HIV1/2 3.0 assay (Immunochromatography, Standard Diagnostics, Inc., Korea) (M3). The sequence of the HIV test kits was based on 2014 Thai National Guideline for Anti-HIV test, namely, the first test was selected as screening test since it was most sensitive and the second and third tests were most specific and with different antigen compositions or different testing principles. Tests were conducted on-site in the saunas or spa venues using EDTA whole blood which was tested immediately after blood collection. For initial screening, M1 was used. If the M1 test result was non-reactive, the participant's HIV status was interpreted as negative and no further testing was needed. When the M1 test result was reactive, the sample was further tested with the second test, M2. If M2 was discordant, both tests (M1 and M2) were repeated. If both were non-reactive, the result was

interpreted as negative. If one test was reactive and the other was non-reactive, we reported inconclusive result. In contrast, if both tests were reactive, the sample was further tested with M3. If all three rapid tests showed reactive results, the sample was concluded as positive. Discordant result (M1, M2, and M3) was described as inconclusive.

Before applying this HIV testing algorithm to participants in the saunas and spa venues, validation and evaluation of the mobile clinic algorithm was performed on 391 leftover samples from clients who came for HIV testing at the Thai Red Cross Anonymous Clinic (TRCAC). HIV test results of these samples using the mobile clinic algorithm and the routine TRCAC algorithm (described below) were comparable, thus supporting the study team to implement this testing algorithm in the field.

Thai Red Cross Anonymous Clinic HIV testing algorithm

All samples collected from the mobile clinics were re-tested by an HIV testing algorithm routinely used at the TRCAC which is the largest facility-based HIV testing center in Asia located in the center of Bangkok. TRCAC HIV testing algorithm was depicted in **Figure 2**. Fourth generation antigen-antibody test kits of either Architect HIV Ag/Ab (Chemiluminescent microparticle immunoassay or CMIA, Abbott Laboratories, USA) or Elecsys HIV combi PT (Electrochemiluminescence immunoassay or ECLIA, Roche Diagnostics GmbH, Penzberg, Germany) was used as first or screening test (T1). If reactive, it would be followed by Alere Determine™ HIV 1/2 as second test (T2), and Serodia HIV 1/2 (Particle Agglutination, Fujirebio Inc., Japan) as the third test (T3). Sample was initially screened for HIV using T1. If result was non-reactive, the sample was interpreted as negative. If result was reactive, the sample was further analyzed with T2 and T3. Inconclusive result was reported if any of T2 and T3 was non-reactive. A positive result was reported if all three tests showed consistent reactive results. Both T1 and T2 tests were repeated in case of a discordant result. A negative result was interpreted after both repeated tests produced non-reactive results. If results were still discordant, they were described as inconclusive.

To further identify acute HIV infection, all non-reactive samples were tested by NAAT using Aptima HIV-1 RNA assay (Gen-Probe Inc., San Diego, CA, USA). For positive or inconclusive samples, 2nd generation enzyme immunoassay (2nd G EIA) (Genscreen HIV 1/2, Bio-Rad, Marnes la Coquette, France) was performed. For 2nd G EIA non-reactive samples, HIV-1 RNA viral load (COBAS® AMPLICOR HIV-1 Monitor Test, v1.5, Roche Molecular Systems, Inc., Branchburg, NJ 08876 USA) was subsequently performed. Acute HIV infection was diagnosed when positive NAAT was detected among 4th generation (CMIA/ECLIA) non-reactive samples or when non-reactive 2nd G EIA was detected along with detectable HIV-1 RNA among positive/inconclusive samples. HIV test results in the mobile clinic algorithm and the TRCAC algorithm were compared. Discordant results were confirmed with Aptima.

Statistical analysis

STATA 11 ((STATA Corp, College Station, TX, USA) was used to analyze the data. Proportions were calculated using 95% confidence intervals (CI).

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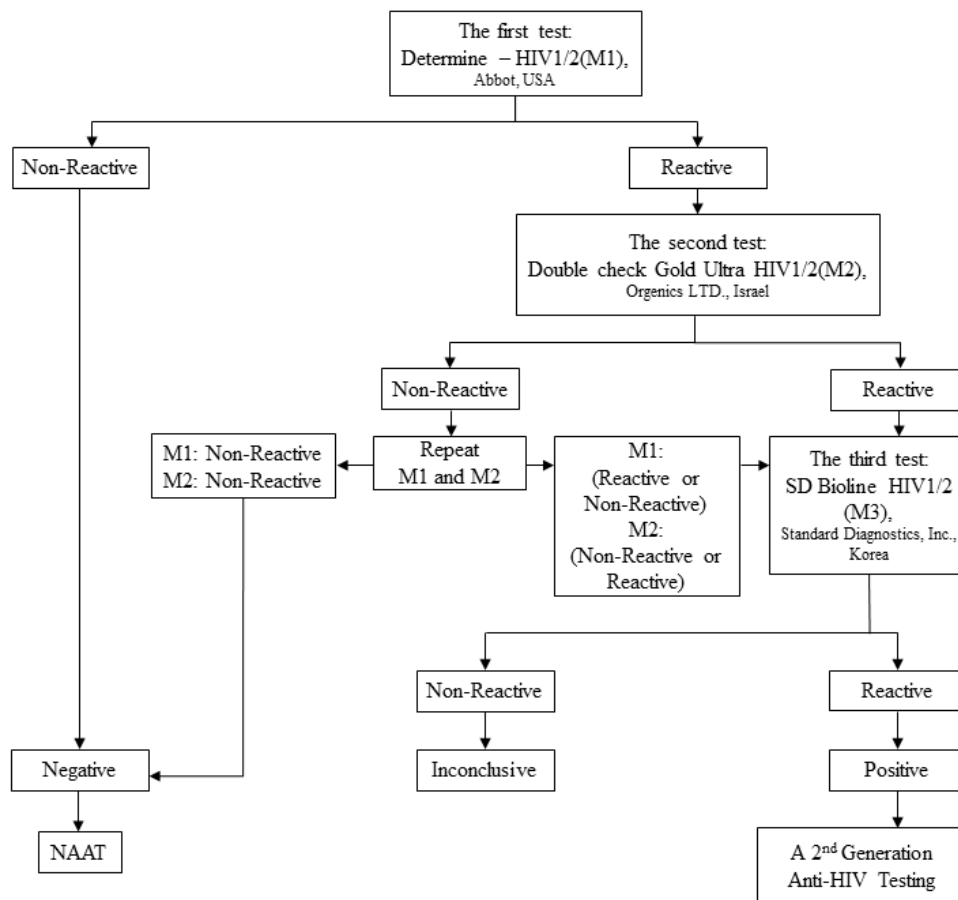**Figure 1. HIV testing algorithm in a mobile clinic**

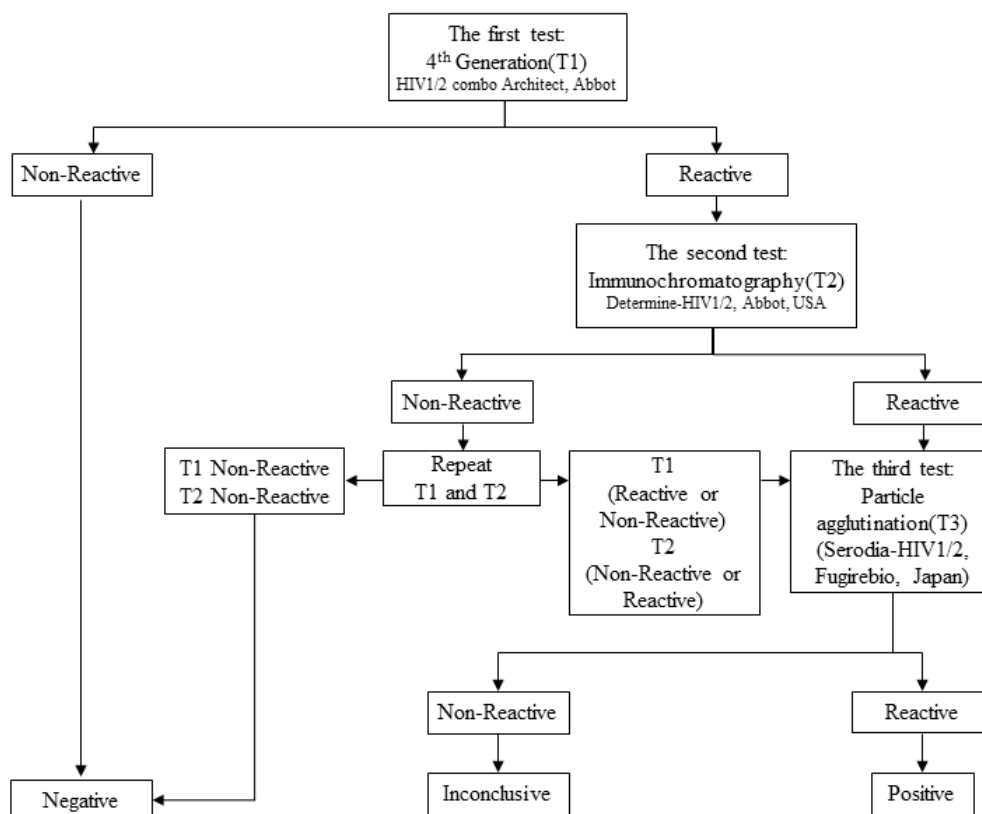**Figure 2. HIV testing algorithm at the Thai Red Cross Anonymous Clinic**

Table 1. Characteristics of HIV-positive and HIV-negative clients of the Thai Red Cross Anonymous Clinic who contributed leftover samples for evaluation of the mobile clinic HIV testing algorithm

Characteristics	Categories	Total (% [95% CI]) (n=391)	HIV Positive (% [95% CI]) (n=101)	HIV Negative (% [95% CI]) (n=290)	p-value
Sex	Male	79.79(75.80,83.79)	82.18(74.65,89.70)	78.96(74.25,83.68)	0.49
	Female	20.20(16.21,24.20)	17.82(10.30,25.34)	21.03(16.32,25.75)	
Sexual Orientation	Homosexual	28.39(23.90,32.88)	52.47(42.66,62.29)	19.65(15.06,24.25)	**<0.001**
	Heterosexual	59.33(54.44,64.22)	27.72(18.92,36.52)	70.34(65.06,75.63)	
	Bisexual	5.11(2.92,7.31)	7.92(2.61,13.23)	4.48(2.09,6.87)	
	No Sex	1.02(0.02,2.02)	-	1.38(0.03,2.73)	
	No answer	2.56(0.98,4.13)	3.96(0.13,7.79)	2.07(0.42,3.71)	
	Missing	3.58(1.73,5.43)	7.92(2.61,13.23)	2.07(0.42,3.71)	
Client partner	Male	45.52(40.57,50.48)	68.31(59.17,77.46)	37.24(31.65,42.83)	**<0.001**
	Female	42.20(37.28,47.12)	11.88(5.52,18.24)	52.76(46.98,58.53)	
	Male and female	5.11(2.92,7.31)	7.92(2.61,13.23)	4.48(2.09,6.87)	
	No sex	1.02(0.02,2.02)	-	1.38(0.03,0.27)	
	No answer	2.56(0.98,4.13)	3.96(0.13,7.79)	2.07(0.42,3.71)	
	Missing	3.58(1.73,5.43)	7.92(2.61,13.23)	2.07(0.42,3.71)	
Age (years)	Median (IQR)	31 (27,39)	31 (27,38)	33 (27,40)	0.32
Marital Status	Single	65.47(60.74,70.21)	68.32(59.17,77.46)	64.48(58.95,70.02)	0.20
	Married	21.23(17.17,25.30)	13.86(7.07,20.65)	23.79(18.87,28.72)	
	Divorce	5.11(2.92,7.31)	4.95(0.68,9.21)	5.17(2.61,7.73)	
	Widow	1.28(0.16,2.40)	2.97(0,6.31)	0.69(0,1.65)	
	No answer	4.09(2.12,6.06)	3.96(0.13,7.79)	4.14(1.83,6.44)	
	Missing	2.81(1.17,4.46)	5.94(1.29,10.59)	1.72(0.22,3.23)	
Education	No Education	0.25(0,0.76)	0.99(0,2.94)	-	**0.002**
	Junior High School or lower	12.02(8.78,15.26)	18.81(11.13,26.49)	9.65(6.24,13.07)	
	Senior High School or Vocational certificate	19.95(15.97,23.93)	24.75(16.27,33.24)	18.27(13.81,22.74)	
	Diploma	8.44(5.67,11.21)	6.93(1.94,11.92)	8.96(5.66,12.27)	
	Bachelor's degree	38.11(33.27,42.94)	28.71(19.82,37.61)	41.38(35.68,47.07)	
	Master's degree or higher	11.00(7.88,14.11)	2.97(0,6.31)	13.79(9.80,17.78)	
	No answer	7.16(4.59,9.73)	9.90(4.03,15.77)	6.21(3.42,9.00)	
	Missing	3.07(1.35,4.79)	6.93(1.94,11.92)	1.72(0.22,3.23)	
Income (Baht)	≤ 10,000	25.06(20.75,29.38)	39.60(29.99,49.22)	20.00(15.37,24.62)	**<0.001**
	10,001-20,000	31.97(27.33,36.61)	29.70(20.72,38.69)	32.76(27.33,38.19)	
	20,001-50,000	17.65(13.85,21.44)	4.95(0.68,9.21)	22.07(17.27,26.86)	
	≥ 50,000	5.37(3.13,7.61)	2.97(0,6.31)	6.21(3.42,9.00)	
	No answer	16.37(12.68,20.05)	14.85(7.86,21.84)	16.90(12.56,21.23)	
	Missing	3.58(1.73,5.43)	7.92(2.61,13.23)	2.07(0.42,3.71)	

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Results

Pre-implementation validation and evaluation of the mobile clinic HIV testing algorithm

Evaluation of the mobile clinic HIV testing algorithm compared with reference algorithm at TRCAC included 391 leftover samples from clients who visited TRCAC during June 01-July 31, 2011. Demographic data of these clients were shown in **Table 1**. Majority was male (79.79%), heterosexual (59.33%), and reported being single (65.47%). Median age (Interquartile Range; IQR) was 31 years (27-39), 49.1% completed bachelor's degree or higher and 57.03% had monthly income lower than 20,000 baths (571 USD). Sex orientation, client partner, education and income were different between HIV-positive and HIV-negative clients (p<0.001, p<0.001, p=0.002, and p<0.001,

Table 2. Sensitivity and specificity of the mobile clinic HIV testing algorithm based on leftover samples from the Thai Red Cross Anonymous Clinic clients

		Reference method	
		Positive	**Negative**
Index method	Positive	101	1*
	Negative	0	289
	Total	101	290

Sensitivity of 100% (95% CI: 96.41, 100) and specificity of 99.65% (95% CI: 98.09, 99.99)

* First test result was reactive but the second and the third tests were nonreactive.

Table 3. Characteristics of HIV-positive and HIV-negative MSM participants enrolled from saunas and spa venues in Bangkok

Characteristics	Categories	Total % (95% CI) (n=233)	HIV Positive % (95% CI) (n=39)	HIV Negative % (95% CI) (n=194)	p-value
Sex	Male	99.57(98.72,100.00)	100	99.48 (98.47,100.00)	1.00
	Trans woman	0.43(0.00,1.27)	0	0.51(0.00,1.53)	
Sexual Orientation	Heterosexual	19.31(14.21,24.42)	5.13(0.00,12.18)	22.16(16.27,28.05)	**0.01**
	Homosexual	52.36(45.90,58.82)	74.36(60.40,88.31)	47.94(40.85,55.02)	
	Bisexual	28.33(22.50,34.15)	20.51(7.61,33.42)	29.90(23.40,36.39)	
Client partner	Male	48.07(41.60,54.53)	69.23(54.48,83.98)	43.81(36.78,50.85)	0.19
	Female	1.29(0.00,2.74)	0	1.55(0.00,3.30)	
	Male and female	40.77(34.41,47.13)	28.20(13.82,42.59)	43.30(36.27,50.33)	
	lady boy no transsexual and male	1.29(0.00,2.74)	0	1.55(0.00,3.30)	
	lady boy no transsexual and female	1.29(0.00,2.74)	0	1.55(0.00,3.30)	
	male, female and lady boy no transsexual	3.43(1.08,5.79)	2.56 (0.00,7.62)	3.61(0.96,6.25)	
	no answer	3.86(1.37,6.35)	0	4.64(1.66,7.62)	
Age (years)	Median (IQR)	27.11 (22.78,32.20)	24.24 (22.28,28.59)	27.55 (23.07,32.89)	0.08
Sexual Organ	Male	91.84(88.30,95.38)	94.87(87.82,100.00)	91.24(87.23,95.25)	0.79
	Transgender	0.43(0.00,1.27)	0	0.51(0.00,1.53)	
	No answer	7.72(4.27,11.18)	5.13(0.00,12.17)	8.25(4.35,12.15)	
Marital Status	Single	74.25(68.59,79.90)	69.23(54.48,83.98)	75.26(69.14,81.38)	**0.01**
	Regular male partner	11.16(7.09,15.23)	25.64(11.68,39.60)	8.25(4.35,12.15)	
	Regular female partner	6.87(3.59,10.14)	0	8.25(4.35,12.15)	
	No answer	7.72(4.27,11.18)	5.13(0.00,12.18)	8.25(4.35,12.15)	
Religion	Buddhist	83.26(78.43,88.09)	79.49(66.58,92.39)	84.02(78.82,89.22)	0.41
	Christian	3.43(1.08,5.79)	5.13(0.00,12.28)	3.09(0.64,5.55)	
	Muslim	5.15(2.29,8.01)	10.26(0.56,19.95)	4.12(1.30,6.94)	
	Other	0.43(0.00,1.27)	0	0.51(0.00,1.53)	
	No answer	7.72(4.27,11.18)	5.13(0.00,12.18)	8.25(4.35,12.15)	

Table 3. Characteristics of HIV-positive and HIV-negative MSM participants enrolled from saunas and spa venues in Bangkok (Continues)

Characteristics	Categories	Total % (95% CI) (n=233)	HIV Positive % (95% CI) (n=39)	HIV Negative % (95% CI) (n=194)	p-value
Education	Junior High School	12.45(8.18,16.72)	7.69(0.00,16.21)	13.40(8.57,18.23)	0.08
	Senior High School	20.60(15.37,25.83)	20.1(7.61,33.42)	20.62(14.88,26.36)	
	Diploma	5.58(2.61,8.55)	10.26(0.56,19.95)	4.64(1.66,7.62)	
	Bachelor's degree	39.48(33.16,45.81)	48.72(32.74,64.69)	37.63(30.76,44.49)	
	Higher than Bachelor's degree	9.87(6.01,13.73)	0	11.85(7.27,16.44)	
	No answer	12.02(7.81,16.22)	12.82(2.13,23.50)	11.85(7.27,16.44)	
Income (Baht)	≤10,000	42.92(36.52,49.32)	48.72(32.74,64.69)	41.75(34.76,48.75)	0.77
	10,001-20,000	30.90(24.92,36.88)	25.64(11.68,39.60)	31.96(25.34,38.57)	
	20,001-50,000	14.59(10.02,19.16)	17.95(5.68,30.21)	13.92(9.01.18.83)	
	≥50,000	4.72(1.98,7.46)	2.56(0.00,7.62)	5.15(2.02,8.29)	
	No answer	6.87(3.59,10.14)	5.13(0.00,12.18)	7.22(3.55,10.89)	
At sex debut	No answer/missing	12.45(8.18,16.72)	7.69(0.00,16.21)	13.40(8.57,18.23)	0.56
	Answer	87.55(83.28,91.82)	92.31(83.79,100.00)	86.60(81.77,91.43)	
	Median (IQR), years	17 (15,19)	16 (15,18)	17IQR (15,19)	0.34
Sexual with partner last month	No answer	14.16(9.65,18.67)	10.26(0.56,19.95)	14.95(9.89,20.01)	0.49
	No	14.16(9.65,18.67)	10.26(0.56,19.95)	14.95(9.89,20.01)	
	Yes	71.67(65.85,77.50)	79.49(66.58,92.39)	70.10(63.61,76.60)	
	Number of partner, Median (IQR)	3 (2,5)	3 (2,5)	3 (2,5)	0.77
Lifetime receptive sex	Oral	33.48(27.37,39.58)	48.72(32.74,64.69)	30.41(23.89,36.94)	**0.03**
	Anal	33.91(27.78,40.03)	51.28(35.31,67.26)	30.41(23.89,36.94)	**0.01**
	Neovaginal	0.43(0.00,1.27)	0.00(-)	0.52(0.00,1.53)	1.00
	No answer	29.18(23.30,35.07)	28.21(13.82,42.59)	29.38(22.92,35.84)	0.88
Lifetime insertive sex	Oral	46.35(39.90,52.80)	53.85(37.91,69.78)	44.85(37.79,51.90)	0.30
	Vaginal	21.89(16.54,27.24)	12.82(2.14,23.51)	23.71(17.68,29.74)	0.13
	Anal	50.64(44.18,57.11)	71.79(57.41,86.18)	46.39(39.32,53.46)	**0.004**
	Neovaginal	0.86(0.00,2.05)	0.00(-)	1.03(0.00,2.46)	1.00
	No answer	12.02(7.81,16.22)	5.13(0.00,12.18)	13.40(8.57,18.23)	0.18
Condom used with regular partner	No sex	7.30(3.93,10.66)	5.13(0.00,12.18)	7.73(3.94,11.52)	0.11
	Not used	15.88(11.15,20.61)	10.26(0.56,19.95)	17.01(11.68,22.34)	
	Sometime	21.03(15.76,26.30)	33.33(18.27,48.40)	18.56(13.04,24.07)	
	All time	29.18(23.30,35.07)	35.90(20.57,51.23)	27.84(21.48,34.19)	
	No answer	26.61(20.89,32.33)	15.38(3.85,26.92)	28.87(22.24,35.29)	
Condom used with temporary partner	No sex	8.58(4.96,12.21)	5.13(0.00,12.18)	9.28(5.16,13.39)	0.20
	Not used	4.72(1.98,7.46)	7.69(0.00,16.21)	4.12(1.30,6.94)	
	Sometime	16.74(11.91,21.57)	15.38(3.85,26.92)	17.01(11.68,22.34)	
	All time	45.49(39.05,51.93)	58.97(43.25,74.70)	42.78(35.77,49.80)	
	No answer	24.46(18.90,30.02)	12.82(2.14,23.51)	26.80(20.52,33.09)	

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Table 3. Characteristics of HIV-positive and HIV-negative MSM participants enrolled from saunas and spa venues in Bangkok (Continues)

Characteristics	Categories	Total % (95% CI) (n=233)	HIV Positive % (95% CI) (n=39)	HIV Negative % (95% CI) (n=194)	p-value
STI history	No	76.39(70.90,81.89)	66.67(51.60,81.73)	78.35(72.51,84.19)	**<0.001**
	Yes	4.29(1.67,6.91)	5.13(0.00,12.18)	4.12(1.30,6.94)	
	Not sure	6.44(3.26,9.61)	23.08(9.61,36.54)	3.09(0.64,5.55)	
	No answer	12.88(8.54,17.21)	5.13(0.00,12.18)	14.43(9.45,19.42)	

Table 4. The sensitivity and specificity evaluation of HIV screening results from mobile HCT when compared to the TRCAC algorithm which included NAAT and/or less sensitive HIV immunoassay to detect acute HIV infection.

		Reference method	
		Positive	Negative
Index method	Positive	37	0
	Negative	2	194
	Total	39	194

Sensitivity of 94.9% (95% CI: 82.7, 99.4) and specificity of 100% (95% CI: 98.1, 100)

respectively). HIV-positive clients were more likely to report homosexual orientation (52.47% vs. 19.65%, p<0.001) and have lower than bachelor's degree education (28.71% vs. 41.38%, p=0.002) than HIV-negative clients.

As shown in **Table 2**, the mobile clinic algorithm comprising 3 rapid tests exhibited sensitivity and specificity of 100% (95% CI 96.41-100%) and 99.65 % (95%CI 98.09-99.99%), respectively. Despite one false positive result by the first test of mobile clinic algorithm, accuracy remained sufficiently high to support the implementation of this algorithm in the mobile clinic setting.[7]

Performance characteristics of the mobile clinic HIV testing algorithm in the field

During July 2011 to August 2012, 233 MSM were enrolled and received HIV testing through mobile clinics. HIV infection was diagnosed by the mobile clinic HIV testing algorithm in 39 MSM (16.7%). We found 11 of 58 MSM (19%) have never been tested for HIV before. Demographic details of participants were presented in **Table 3**. Median age (IQR) was 27.1 years (22.78-32.20), 49% completed bachelor's degree or higher and 74% had monthly income lower than 20,000 baths. HIV-positive clients were more likely to perceive themselves as homosexual men (74.36% vs. 47.94%, p=0.01) than HIV-negative clients. Median age (IQR) at first sex was 17 years (15-19) and no difference between HIV-positive and HIV-negative (p=0.34). During one month before being enrolled in the study, 71.6% MSM had sexual activities with at least 2 partners. HIV-positive MSM practiced insertive anal sex more than HIV-negative (71.79% vs. 46.39%, p=0.004). 35.9%

HIV-positive and 27.84% HIV-negative used condom with regular partner (p=0.11). For condom used with temporary partner, we found 58.97% in HIV-positive and 42.78% in HIV-negative (p=0.2).

Two acute HIV cases were unable to be diagnosed by the mobile clinic HIV testing algorithm. One acute HIV case was diagnosed only by NAAT and the other was diagnosed by reactive Architect and detectable HIV-1 RNA. These 2 cases also had p24 antigen detected by HIV-1 p24 antigen assay (ABL Inc., Kensington, MD, USA). The mobile clinic HIV testing algorithm therefore demonstrated a sensitivity of 94.9% (95% CI: 82.7, 99.4) and a specificity of 100% (95% CI: 98.1, 100).

Discussion

We have demonstrated that the HIV testing algorithm using whole blood on rapid test kits had satisfactory performance and allowed same-day HIV test result to be available to MSM tested in hotspots in Bangkok through a mobile clinic model. The prevalence of HIV among Bangkok MSM at these hotspots was 16.7% and up to 19% have never been tested for HIV. The percentage of Thai MSM who had HIV testing in the past 12 months increased from 15% in 2010 to 26% in 2012 and to 29% in 2014.[4] These levels are still much far below the 90% target that the country set to achieve by 2016. Sub-national analysis shows that better progress has been made in selected provinces where the community-led rapid HIV testing algorithm with same-day results has been introduced in drop-in centers and mobile HIV testing clinics where hotspots have been deployed. In Chonburi, where Service Workers IN Group (SWING) Foundation and Sisters Foundation have actively provided community-led rapid HIV testing service, HIV testing coverage among MSM doubled from 14% in 2010 to 29% in 2014. Similarly, HIV testing coverage increased distinctly in Chiang Mai from 30% in 2010 to 46% in 2014 with community-led rapid HIV testing service provided by Caremat Foundation.[4] The implementation of the rapid testing algorithm in these provinces was endorsed by the results of the validation and evaluation we reported in this study which supported similar data reported previously.[8,9] Priority has been set in Thailand AIDS Response Progress Report 2015 to further expand options of HIV testing including community-led HIV testing and self-testing of HIV to increase percentage of key populations knowing HIV status.

Advantages of rapid HIV test kits over machine-based HIV testing assays include the availability of same-day HIV test results regardless of the number of clients or amount of

samples at the testing site, the ability to use whole blood and skip the centrifugation process, and the potential for non-medical technologists to be trained and qualified to perform the test in a community-led setting.[10-12] We identified one false reactive test result among 391 samples tested during the optimization process. The false reactive result may be the consequence of over-interpretation by the technician according to the manufacturer's instruction to read the red line within the possible window period as reactive in Determine HIV 1/2.[13] The three-test algorithm recommended in our National Guidelines can, however, assist to prevent the final false positive result of HIV diagnosis.[14]

Although rapid HIV test kits become more frequently used to expand access to HIV testing, the major limitation is that these tests may not detect HIV during the acute infection stage. Diagnosis of 2 acute HIV cases among our MSM participants were missed by the rapid HIV testing algorithm used in mobile clinics. One case had reactive result to Architect HIV Ag/Ag, one of the 4th generation immunoassays (4th G EIA) in the TRCAC algorithm which could detect both p24 antigen and HIV antibody, but non-reactive to the second and third tests. Another case was found to be positive by NAAT only and non-reactive to 4th G EIA. We discovered that these 2 patients were reactive to p24 antigen and had detectable HIV-1 RNA. For key populations with high HIV incidence, careful history taking to define the window period is crucial. Repeat anti-HIV testing must be encouraged, especially if the HIV testing algorithm does not include 4th G EIA or NAAT.

Our results may not be generalized to other rapid HIV testing algorithms using different test kits. Modifications to the rapid HIV testing algorithms would need additional optimization and evaluation to be performed prior to large-scale implementation. We have shown that the process could be simply and quickly conducted in any large facility-based HIV testing clinic. Performance characteristics of one HIV testing algorithm could be different when tested in different populations.[15-17] Our study was conducted among MSM in metropolitan Bangkok with high HIV prevalence and may only represent performance characteristics of the testing algorithm in high prevalence populations.

There was at least one study using rapid HIV-testing and reported false negative results. Acute and recent HIV-infection was the most common cause of false negativity.[18] Recently, there are many strategies to include key population. Self-testing may miss diagnose HIV because most of these are 3rd generation such as immunochromatography. So, for key populations with high HIV incidence, careful history taking to define the window period is crucial. Repeat anti-HIV testing must also be encouraged, especially if the anti-HIV testing algorithm does not include a more sensitive 4th generation assay or NAAT.

In summary, we have demonstrated that the HIV testing algorithm using whole blood on 3 rapid test kits had high sensitivity and specificity, and allowed same-day HIV test result to be available on-site. Scale-up and exploration of this rapid HIV testing algorithm in MSM and other key populations are urgently needed to achieve the ending HIV epidemic goal within the next 15 years.

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