Study Protocol

Randomized Community Trial

Community Based Screening for HIV Self Testing in Female Sex Workers in 23 Priority Districts in Indonesia **(CBS HIVST in FSW)**

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Developed by:

Kerti Praja Foundation (Yayasan Kerti Praja)

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Study Title	Randomized Community Trial Community Based Screening for HIV Self Testing in Female Sex Workers in 23 Priority Districts in Indonesia
Protocol Development Group	Prof. dr. D. N. Wirawan, MPH (Chair) dr. Made Ady Wirawan, MPH, PhD Dr. dr. Anak Agung Sagung Sawitri, MPH dr. Ida Ayu Narayani, M.Sc
Implementing Institution	Kerti Praja Foundation (Yayasan Kerti Praja) Denpasar, Bali, Indonesia Phone: 0361 728 916, 728 917, 4458641 Email: kertiprajafoundation@gmail.com
Funding Organization	United Nations Population Fund (UNFPA)
Contributors	dr. Pande Putu Januraga, DrPH Dinar SM Lubis, MPH, PhD
Consultant	Robert Magnani, DrPH
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Prof. D.N. Wirawan, MD, MPH
Chair Protocol Development

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Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
BB	Beach Boys
cRCT	Community Randomized Control Trial
CRF	Case Report Form
FSWs	Female Sex Workers
GFATM	Global Fund to Fight AIDS, Tuberculosis, and Malaria
GOI	Government of Indonesia
HIV	Human Immunodeficiency Virus
HIVST	Human Immunodeficiency Virus Self-Testing
IRB	Institutional Review Board
IU	Implementing Unit
KAPs	Key Affected Populations
KOLs	Key Opinion Leaders
MoH	Ministry of Health
MSM	Men who have Sex with Men
NGO	Non-Governmental Organization
OW	Outreach Worker
OFT	Oral Fluid Test
PLHIV	People Living With HIV
PrEP	Pre-Exposure Prophylactic
PWID	People Who Inject Drugs
SIHA	Sistem Informasi HIV dan AIDS
SOP	Standard Operating Procedure
STI	Sexually Transmitted Infection
T&T	Test and Treat
TB	Tuberculosis
UNAIDS	United Nations Program on HIV and AIDS
WHO	World Health Organization
YKP	Yayasan Kerti Praja (Kerti Praja Foundation)

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A. BACKGROUND

1. The HIV Epidemic in Indonesia

Until recently, Indonesia was among the few countries in which annual numbers of new HIV infections continued to rise (MoH, 2016). The latest epidemic modeling update indicated that except among men who have sex with man (MSM), annual numbers of new HIV infections had stabilized and begun to decline. However, with the current epidemic trajectory there would still be over 40,000 new HIV infections in the year 2030 (MoH,2016). Indonesia is not yet on course to end HIV and AIDS by 2030.

Although there has been a significant increase in the number of persons being treated for HIV/AIDS, the 108,479 people receiving ART as of December 2018 amounts to only 17 percent of the estimated number of PLHIV in the country (MoH, 2018). This makes Indonesia a performance "outlier" when compared to countries at comparable levels of gross national income (GNI) and health system development. The lack of more rapid progress has recently led key development partners to question Government of Indonesia (GOI) commitment to meaningfully addressing HIV and AIDS.

Insufficient HIV testing remains a barrier to increasing ART coverage. The number of HIV tests performed annually has risen steadily in recent years, reaching 3,077,653 in calendar year 2018 (MoH, 2018). However, pregnant women account for a sizeable proportion of the increased number of persons being tested. While commendable, the case detection "yield" from testing pregnant women is relatively low. More effective case finding strategies need to be implemented to reach population sub-groups with higher HIV incidence and prevalence, including key affected populations (KAPs) such as female sex workers (FSW). Unless Indonesia can significantly increase its volume and efficiency of HIV testing, it will not be able to reach the first "95" of the UNAIDS 95-95-95 framework – that is, 95% of PLHIV know their HIV status.

The main rationale is Indonesia's concentrated epidemic transmission of HIV infection among KAPs, specifically FSWs. In 2016 it is estimated that there are 226,791 female sex workers throughout Indonesia (Table 1) and around 5,254,065 clients access their service per year (MoH, 2017). This mode of transmission continues to clients' sexual partner and moreover, their babies. Lowering the transmission of HIV infection from FSW to their clients would simultaneously lower its transmission to their sexual partners and furthermore their babies.

In 2012, the estimated number of FSW and distribution FSW by "direct" (i.e., brothel-based) and "indirect" status is presented in Tabel-2. In 2016, the estimated number of FSW was not grouped into direct and indirect because it was considered that most of FSWs had shifted to becoming indirect due to Indonesia's national policy to close brothels. Due to this policy, most FSWs have become hidden and hard to reach, thus increasing the challenge of increasing HIV testing uptake among this sub-population. Many commercial sex transactions have become underground, especially given the new popularity of digital platforms to sell sexual services. This phenomenon has created a new demand to identify alternative strategies for increasing HIV testing uptake among FSW.

Table 1. Estimated number of female sex workers (2016)

No	Province	Female Sex Workers		
		Point Estimate	Lower Estimate	Upper Estimate
1	Aceh	2,710	583	7,570
2	Sumatera Utara	14,234	8,079	21,943
3	Sumatera Barat	12,783	8,901	17,797
4	Riau	7,181	4,569	9,796
5	Jambi	4,544	1,986	7,188
6	Sumatera Selatan	7,630	4,235	11,323
7	Bengkulu	1,304	566	3,255
8	Lampung	7,532	4,534	10,717
9	Kep. Bangka Belitung	3,313	1,072	5,645
10	Kep. Riau	4,705	3,273	6,664
11	DKI Jakarta	21,405	17,444	25,386
12	Jawa Barat	25,281	17,806	34,220
13	Jawa Tengah	8,938	3,566	18,599
14	DI Yogyakarta	3,511	1,356	6,181
15	Jawa Timur	12,672	6,244	24,661
16	Banten	5,476	3,552	8,012
17	Bali	5,188	3,431	6,955
18	Nusa Tenggara Barat	2,127	1,131	3,212
19	Nusa Tenggara Timur	1,470	141	3,998
20	Kalimantan Barat	11,593	6,231	17,316
21	Kalimantan Tengah	5,208	1,580	11,181
22	Kalimantan Selatan	9,148	4,559	14,662
23	Kalimantan Timur	14,034	8,879	19,459
24	Kalimantan Utara	2,219	1,243	4,128
25	Sulawesi Utara	3,059	898	7,275
26	Sulawesi Tengah	6,052	1,663	10,801
27	Sulawesi Selatan	15,303	7,711	23,144
28	Sulawesi Tenggara	2,058	642	5,400
29	Gorontalo	746	111	2,722
30	Sulawesi Barat	1,376	250	3,076
31	Maluku	1,741	846	3,550
32	Maluku Utara	155	0	1,367
33	Papua Barat	542	326	1,780
34	Papua	1,553	706	5,330
	NATIONAL	226,791	128,114	364,313

Source: Ministry of Health (2016)

Table 2. Estimated number of direct (brothel) and indirect female sex workers (2012)

No	Province	Direct FSW	Indirect FSW
1	Aceh	2,179	929
2	Sumatera Utara	9,032	5,116
3	Sumatera Barat	3,089	2,197
4	Riau	3,643	2,758
5	Jambi	3,937	1,641
6	Sumatera Selatan	3,740	1,719
7	Bengkulu	1,235	1,403
8	Lampung	1,172	845
9	Kep. Bangka Belitung	481	472
10	Kep. Riau	1,195	1,312
11	DKI Jakarta	15,395	23,386
12	Jawa Barat	18,106	10,876
13	Jawa Tengah	13,205	10,023
14	DI Yogyakarta	1,945	706
15	Jawa Timur	14,381	10,459
16	Banten	2,798	1,365
17	Bali	3,378	3,464
18	Nusa Tenggara Barat	2,888	4,566
19	Nusa Tenggara Timur	7,245	6,427
20	Kalimantan Barat	1,695	2,150
21	Kalimantan Tengah	1,490	1,071
22	Kalimantan Selatan	845	1,476
23	Kalimantan Timur	1,041	759
24	Sulawesi Utara	1,315	1,360
25	Sulawesi Tengah	983	776
26	Sulawesi Selatan	1,646	1,627
27	Sulawesi Tenggara	913	1,096
28	Gorontalo	486	373
29	Sulawesi Barat	344	299
30	Maluku	1,233	1,082
31	Maluku Utara	535	635
32	Papua Barat	777	871
33	Papua	2,199	1,592
	NATIONAL	124,546	104,831

Source: Ministry of Health (2013)

2. HIV Testing Among FSW

Getting sufficient numbers of FSW tested for HIV has proven challenging globally (Tokar et al., 2018). While there is a sizeable literature on the efficacy of HIV prevention interventions for FSW (Kerrigan et al., 2015; Shahmanesh et al., 2008; Wariki et al., 2012; Wirtz et al., 2014), there is limited global evidence on the question of how best to increase rates of HIV testing among FSW. Although the WHO (2015) has recommended community testing approaches to supplement HIV testing at health facilities, the available evidence as to efficacy with FSW specifically is quite limited. A recent systematic review (Tokar et al., 2018) reported finding of 10 studies that examined recent testing in response to FSW HIV promotion interventions. Reported HIV testing uptake were varied, for example in Canada it was reported that 76% FSW had HIV test within the last one year (Deering et al., 2015), while in China only 22% FSW reported taking HIV test within the last one year (Park et al., 2011). Some reported barriers for FSW accessing HIV test service were financial, time, stigma, discrimination, low-risk perception, fear, lack of accessibility, reluctance from health service

providers to offer HIV testing and limited human resource. This literature review also showed that social support from peers and manager could increase HIV testing uptake in FSW (Tokar et al., 2018)

Community based HIV-testing has been implemented in some countries such as Vietnam (Nguyen et al., 2019), Uganda (Ortblad et al., 2018), Malawi and Zimbabwe (Napierala et al., 2019). Non-governmental organizations in Indonesia had conducted study or pilot project on HIV test in men who have sex with men (MSM) outside health facility (Hidayat et al., 2019). This study was done to find an alternative to facility-based HIV testing, however MoH has been rather conservative in supporting non-health facility-based approach outside of mobile clinic testing which involves trained healthcare professional to perform HIV testing procedure according to the algorithm developed by the government. Mobile clinic testing strategy gave out insufficient result, especially in terms of linking those with positive HIV result for further follow-up and initiation of treatment. Cost-effectiveness of this approach was also doubted, at least in Jakarta (Cantelmo et al., 2019). This study found that the cost needed for mobile testing to identify at least one HIV positive case among FSW was almost six-times fold higher compared to finding similar target among transgender and MSM, and seventeen-times fold higher than those for identifying one HIV positive case among people who inject drugs (PWID). For the effective use of resource, this study suggested modification of the test frequency, time, and location for FSWs in Jakarta. In addition, this study also recommended the need for alternative strategies to increase HIV test uptake among FSW.

FSWs community are at greater risk of not only HIV infection, but also stigma, discrimination and violence. They first face stigma and discrimination due to engaging in sex work itself, or from HIV stigma, particularly in contexts of HIV burden, which later affect their access to HIV testing (UNAIDS, 2016). The latest WHO guidelines have highlighted HIV self-testing (HIVST) as important tool to identify more people with undiagnosed HIV and at high risk of HIV infection. Protection of privacy and confidentiality is one of the advantages of this modality which allows for removing stigma as barriers to access services. HIVST has been shown to be acceptable across varieties of population globally including for FSWs community (King et al, 2013). Oral fluid HIVST is an alternative to traditional HIV testing services in the facility or other healthcare provider testing (UNAIDS, 2016).

3. **HIV Self-testing Using Oral Fluid Test**

One oral fluid test modality (OraQuick™) is currently waiting for the registration approval from Ministry of Health and expected to be available by March or April 2020. Evaluation of OraQuick™ in Thailand showed sensitivity of 90.14% (95%CI 80.74-95.94) and specificity of 99.13% (95%CI 97.78-99.76) (Rasmi et al., n.d.). A study assessing the acceptability of oral fluid rapid HIV 1 and 2 antibody test (OraQuick™) among key populations for HIV infection such as men who have sex with men (MSM), beach boys (BB), female sex workers (FSWs), and people who inject drugs (PWID) in Sri Lanka showed high level of acceptability for the test (Karawita et al., 2017). In China, most-at-risk populations showed high acceptability of oral fluid HIV rapid testing (OraQuick™), with suggestion for appropriate pricing and increased public health education through awareness campaigns that address concerns about its accuracy and safety (Xun et al., 2013). HIV-self testing kit distribution through key opinion leaders (KOLs) was feasible and oral self-testing was highly acceptable among urban MSM population in Nigeria (Tun et al., 2018). Linkage to treatment can be achieved with active follow-up and access to a trusted community clinic that offers HIV treatment and is MSM friendly (Tun et al., 2018).

4. **Role of Outreach Worker in HIV Self-testing Using Assisted and Unassisted Method**

In a study which assessed implementation and scale-up to HIV self-testing programs for female sex workers in Malawi and Zimbabwe, there were difference in preferences for how to access HIV self-testing, depended on how supportive the existing program infrastructure was (Napierala et al., 2019) In Zimbabwe, where there was a detailed understanding of the context of female sex workers and a ready framework to implement and evaluate HIV self-testing strategies, high acceptability (76%) and high accuracy of HIV self-testing was reported (Napierala et al., 2019). In contrast, peer-distribution models were favored by female sex workers in Malawi and female sex workers in Zimbabwe who were not engaged in the program (Napierala et al., 2019). Another study in Kampala (Uganda) evaluated HIV self-testing performance and results interpretation among FSWs who performed unassisted HIV self-testing, showed that misinterpretation of HIV self-test results were common among FSWs: 23% (12/56) of FSWs interpreted HIV-negative self-test results as HIV positive and 8% (3/37) of FSWs interpreted HIV-positive self-test results as HIV negative (Ortblad et al., 2018). The concordance between FSWs' instructions was 73% (95%CI 56% to 86%) for HIV-positive self-tests and 68% (95%CI 54% to 80%) for HIV-negative self-tests (Ortblad et al., 2018). This finding suggested training on use and interpretation of HIV self-test for the unassisted method might be necessary to prevent errors and to avoid the negative consequences of false-positive and false-negative HIV self-test results among FSWs.

5. Study Purpose

The study proposed in this protocol directly addresses the need to get more Indonesian FSW to "know their status" by providing an alternative, convenient HIV testing option in non-threatening community settings. In the Indonesian context where a reactive HIV test result using the MoH-mandated triple rapid test algorithm is needed to qualify for GoI-financed ART, community screening is seen as a mechanism for enabling FSW to conveniently determine their status and a facilitation mechanism for taking action based upon the community screening result, whether that entail going to a health facility for a confirmatory test in the case of a reactive screening result or adopting stronger prevention measures in the case of a non-reactive screening result, including PrEP as this prevention method is rolled out in Indonesia.

The study will produce scientifically strong evidence as to whether two alternative models of community HIV screening among FSW (assisted and unassisted) result in (1) increased rates of formal HIV testing at health facilities and (2) increased rates of treatment initiation in districts in which the community screening intervention is added to the existing FSW community outreach model.

Two alternative study protocols are described in this document. The bulk of this document presents a protocol for a community randomized controlled trial (cRCT), which is the preferred research design option. However, due to a delay in procurement of the OraQuick® rapid HIV test kits that are to be used in the study, there may be insufficient time to undertake a full cRCT.[1] Accordingly, a contingency protocol that can be implemented in a shorter period of time is also presented.

6. Study Objectives

The primary objectives of this study will provide answers to the following five (5) questions:

1. Does the proportion of FSW who know their HIV status increased?

[1] All research activities must be completed by 31 December 2020.

2. Does the introduction of community HIV screening among FSW increase the rate of HIV testing at health facilities?
3. Does "assisted" or "unassisted" community HIV screening among FSW result in a larger increase in the rate of HIV testing at health facilities?
4. Does "assisted" and "unassisted" community HIV screening among FSW results in a larger increase in the rate of HIV positive case finding?
5. Does the introduction of community HIV screening among FSW increase the rate of initiation of ART?

The secondary objectives of this study will provide answers to the following two (2) questions:

1. What is the acceptability of community-based self-screening for FSWs participating in this study?
2. What is the satisfaction of FSWs participating in this study towards delivery of community-based self-screening?

B. STUDY DESIGN

1. Design Summary

A Community Randomized Controlled Trial (cRCT) will be used for this study to explore in the HIVST evidence for FSWs in Indonesia with tests and treatment results in intervention acceleration districts compared to control districts with the current standard of care. In the trial, it is recommended the candidates will be tested using two approaches (assisted and unassisted), the latter via direct, fixed and other means of distribution system. A direct distribution system is where and FSW participant is directly given and HIVST by a peer, and a fixed distribution system is where the FSW participant collects the HIVST from a fixed point such as health clinic. Other distribution system may be implemented using courier services such as GO-JEK, etc. This trial aims to determine the acceptability, effectiveness and safety of these HIVST delivery approaches compared with standard of care for improving HIV testing coverage and knowledge of HIV status.

The study will be undertaken in the 23 "acceleration" districts in the National AIDs Program. These are: Kota Medan, Deli Serdang, Kota Palembang, Kota Bandar Lampung, Kota Tangerang Selatan, Tangerang, Kota Jakarta Selatan, Kota Jakarta Timur, Kota Jakarta Pusat, Kota Jakarta Barat, Kota Jakarta Utara, Bogor, Kota Bekasi, Kota Bandung, Kota Depok, Kota Semarang, Kota Surakarta, Kota Malang, Kota Surabaya, Kota Denpasar, Kota Makassar, Kota Sorong and Kota Jayapura. These are districts with high HIV prevalence among HIV key populations, including FSW, and have comprehensive ongoing HIV-TB intervention packages consisting of both health services and community prevention and support programs. As for the FSWs program, these 23 priority districts already implementing a comprehensive outreach package (reach to test and simplified case management for FSWs living with HIV). Table 3 below shows Global Fund targets for FSW HIV testing in 23 priority districts for 2019-2020. Table 4 shows achieved target of HIV testing per semester in 2018-2019 and estimated numbers of direct and indirect FSW in 2012 (MoH, 2013). Table 5 shows achieved target of outreach per year in 2018-2019 in 23 priority districts.

The flowchart of the study is presented in Figure 1. Randomization was carried out among the 23 priority districts in this study with a ratio of 2:1 (that is, 2 intervention districts per 1 control district). The details of randomization are explained in section B.4 of this document. **The assigned 15 intervention districts and 8 comparison districts** are described in Table 6. Potential participants in the intervention area will be screened through the inclusion and exclusion criteria established for

this study. The criteria for participants who are eligible for this study are explained in section B.3 of this document and Annex2.

According to the Indonesian Ministry of Health's current recommendation, HIV blood test at an authorized health facility is still the current practice for HIV diagnosis. Both participants in the intervention and comparison area will be offered for HIV blood test at a health facility. Participants in comparison areas and participants in intervention areas who agree to take HIV test at a health facility will then be managed further according to the existing guideline or "standard of care." For participants in intervention areas who refuses to have her blood drawn for HIV test at a health facility will then be offered self-testing using OraQuick®. Participants will then fill and sign the informed consent to participate in CBS study.

Next, participants will be offered to do the test assisted or unassisted. If the participant chooses to perform the test assisted, the PL/PE will help her from filling in a baseline survey, performing the test, and filling in a post-test survey. If the participant chooses to perform the test unassisted, there will be two options for the participant to get the test kit. First, PL/PE will deliver the test kit for the participant, help with filling in the baseline survey on the spot and give information about uploading test results and the post-test survey, along with a hotline number to call for any questions and concerns, including follow-up steps after participants have received the results. The second method, participants will be given a link online which will entitle information of this study, eligibility criteria, informed consent, baseline survey, link to order a test kit, link to upload result and link to fill in the post-test survey. Participant who chooses this second method will also be given hotline number should there be any further inquiries.

Participants with reactive or indeterminate result resulting from either assisted or unassisted methods will be encouraged to get a confirmatory test at a health facility. A confirmatory test will also be suggested for participants with non-reactive result. The difference between these two result groups will be the level of encouragement given to do the confirmatory test. While participant with reactive or indeterminate results will be strongly encouraged, participants with a non-reactive result will be suggested for a confirmatory test. These suggestions are derived from Indonesia's current guideline on HIV detection, where the confirmatory test is to be done at the health facility using the HIV blood test.

Figure 1. Study Flowchart

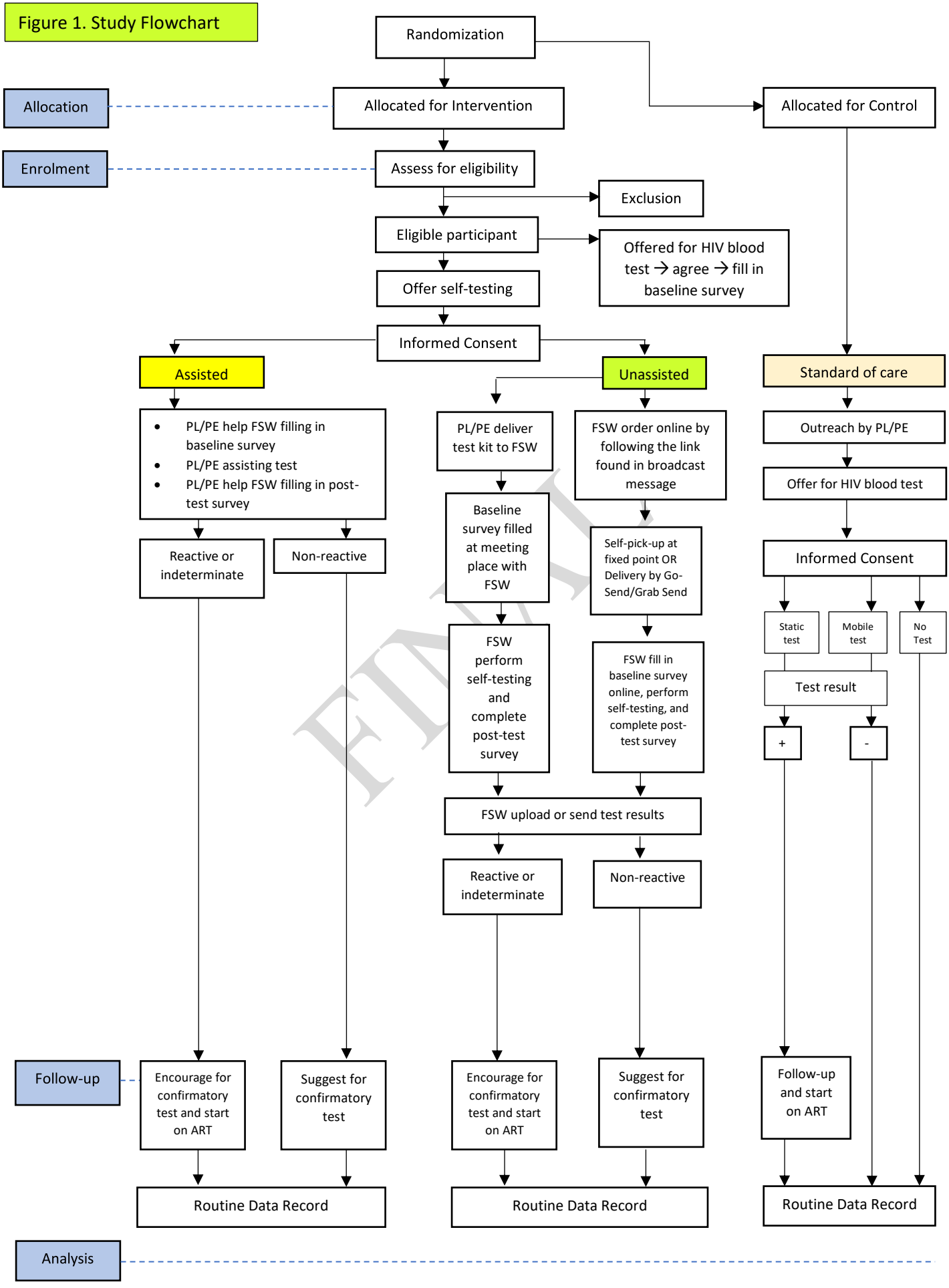


Table 3. Global Fund HIV testing targets in 23 districts for 2019-2020

No	Province	Districts	Region	Target of HIV Testing			
				P3	P4	P5	P6
1	Sumatera Utara	Kota Medan	1	904	904	1,002	1,002
2	Sumatera Utara	Kab. Deli Serdang	1	406	406	450	450
3	Sumatera Selatan	Kota Palembang	1	1,371	1,371	1,520	1,520
4	Lampung	Kota Bandar Lampung	1	393	393	435	435
5	Banten	Kota Tangerang Selatan	1	223	223	247	247
6	Banten	Kab. Tangerang	1	820	820	909	909
7	DKI Jakarta	Kota Jakarta Selatan	1	536	536	594	594
8	DKI Jakarta	Kota Jakarta Timur	1	877	877	973	973
9	DKI Jakarta	Kota Jakarta Pusat	1	1,341	1,341	1,486	1,486
10	DKI Jakarta	Kota Jakarta Barat	1	1,318	1,318	1,461	1,461
11	DKI Jakarta	Kota Jakarta Utara	1	1,431	1,431	1,586	1,586
12	Jawa Barat	Kota Bogor	2	474	474	525	525
13	Jawa Barat	Kota Bekasi	2	248	248	275	275
14	Jawa Barat	Kota Bandung	2	582	582	645	645
15	Jawa Barat	Kota Depok	2	374	374	415	415
16	Jawa Tengah	Kota Semarang	2	510	510	565	565
17	Jawa Tengah	Kota Surakarta	2	172	172	190	190
18	Jawa Timur	Kota Malang	3	84	84	93	93
19	Jawa Timur	Kota Surabaya	3	1,173	1,173	1,300	1,300
20	Bali	Kota Denpasar	3	1,407	1,407	1,559	1,559
21	Sulawesi Selatan	Kota Makassar	3	1,444	1,444	1,600	1,601
22	Papua Barat	Kota Sorong	4	438	438	485	485
23	Papua	Kota Jayapura	4	786	786	871	871

Table 4. Achieved target of HIV testing per semester in 23 priority districts (2018-2019)

No	Kab/Kota	Region	Achieved target of HIV testing per semester
1	Kota Denpasar	3	982
2	Kota Makassar	3	866
3	Kota Palembang	1	694
4	Kota Jakarta Utara	1	612
5	Kota Medan	1	575
6	Kota Surabaya	3	568
7	Kota Jakarta Barat	1	544
8	Kota Bandung	2	487
9	Kota Jakarta Timur	1	479
10	Kota Jakarta Pusat	1	473
11	Kota Jakarta Selatan	1	448
12	Kota Sorong	4	415
13	Kab. Tangerang	1	391
14	Kota Bogor	2	374
15	Kota Jayapura	4	323
16	Kota Bandar Lampung	1	319
17	Kota Depok	2	287
18	Kota Malang	3	243
19	Kota Tangerang Selatan	1	184
20	Kota Bekasi	2	158
21	Kota Surakarta	2	144
22	Kota Semarang	2	129
23	Kab. Deli Serdang	1	80

Table 5. Achieved target of outreach per year in 23 priority districts (2018-2019)

No.	Kab/Kota	Region	Achieved target of outreach per year
1	Kota Denpasar	3	5100
2	Kota Jakarta Barat	1	4947
3	Kota Jakarta Pusat	1	4004
4	Kota Palembang	1	3741
5	Kota Surabaya	3	3510
6	Kota Jakarta Timur	1	3157
7	Kota Jakarta Utara	1	3129
8	Kota Jakarta Selatan	1	2905
9	Kota Medan	1	2858
10	Kota Makassar	3	2683
11	Kota Bandung	2	2164
12	Kota Bogor	2	1961
13	Kota Bandar Lampung	1	1933
14	Kabupaten Tangerang	1	1374
15	Kota Semarang	2	1317
16	Kota Sorong	4	1220
17	Kota Surakarta	2	1190
18	Kota Depok	2	1107
19	Kota Tangerang Selatan	1	994
20	Kota Jayapura	4	983
21	Kabupaten Deli Serdang	1	939
22	Kota Bekasi	2	879
23	Kota Malang	3	877

2. Study Period

The study timeline is presented below. The study will be conducted from February 2020 to November 2020 (10 months). The preparatory activities will be conducted in February to March 2020. **The intervention will be implemented from April – October 2020 (7 months),** with the last one months of 2020 allocated for data analysis, report writing and a workshop presenting study findings.

Study timeline

Activities	Month									
	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov
1. Study preparation										
1.1 Recruitment of study personnel										
1.2 Ethics and permit										
1.3 Stakeholders mapping and engagement strategy										
1.4 Procurement of test kit										

Activities	Month									
	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov
1.5 Development of manual of operating procedure (SOP, questionnaire, study media, website, WhatsApp center, CRF forms)										
2.Implementation training										
3.Intervention										
3.1 Study kick-off										
3.2 Data collection										
4. Data analysis and report writing										
5. Workshop for study finding dissemination										

3. Eligibility Criteria

The target audience for the intervention to be evaluated are FSW in Intervention districts that meet the criteria outlined below.

Inclusion criteria

- Women, 18 years or older at enrolment
- Reports transactional sex (vaginal, oral and/or anal) at least once in the past month
- No HIV test in last 6 months
- Self-reported HIV negative OR HIV status unknown

Exclusion criteria

- Unwilling to participate for any reason
- Concurrently participating in another HIV prevention study

4. Randomization

Stratified randomization was carried out for the 23 priority districts involved in this study. First, sampling strata were created by sorting the mean average value of achieved HIV testing target per semester from 2018-2019 in each district from the largest to the smallest. The second step was to sort the districts into eight groups of three districts, except for the last group which will only consist of two districts. Randomization for intervention and comparison group were then carried out within these groups of eight with 2:1 ratio (2 intervention: 1 comparison).[2] The results of stratified randomization are presented in Table 6. In separate table, Table 7 contains 15 intervention districts and Table 8 contains 8 comparison districts.

[2] A 2-to-1 intervention to comparison district ratio was chosen in order to increase the likelihood of recruiting a sufficient number of FSW for community screening to reach the sample size target considering the relatively short time frame available for for study implementation.

Table 6. Allocated intervention group and comparison group

No	Kab/Kota	Region	Achieved target of HIV testing per semester (2018-2019)	Group
1	Kota Denpasar	3	982	Intervention
2	Kota Makassar	3	866	Comparison
3	Kota Palembang	1	694	Intervention
4	Kota Jakarta Utara	1	612	Comparison
5	Kota Medan	1	575	Intervention
6	Kota Surabaya	3	568	Intervention
7	Kota Jakarta Barat	1	544	Intervention
8	Kota Bandung	2	487	Comparison
9	Kota Jakarta Timur	1	479	Intervention
10	Kota Jakarta Pusat	1	473	Intervention
11	Kota Jakarta Selatan	1	448	Comparison
12	Kota Sorong	4	415	Intervention
13	Kab. Tangerang	1	391	Intervention
14	Kota Bogor	2	374	Intervention
15	Kota Jayapura	4	323	Comparison
16	Kota Bandar Lampung	1	319	Comparison
17	Kota Depok	2	287	Intervention
18	Kota Malang	3	243	Intervention
19	Kota Tangerang Selatan	1	184	Intervention
20	Kota Bekasi	2	158	Comparison
21	Kota Surakarta	2	144	Intervention
22	Kota Semarang	2	129	Comparison
23	Kab. Deli Serdang	1	80	Intervention

Table 7. Allocated intervention districts

No	Kab/Kota	Region	Achieved target of HIV testing per semester (2018-2019)	Group
1	Kab. Deli Serdang	1	80	Intervention
2	Kota Medan	1	575	Intervention
3	Kota Palembang	1	694	Intervention
4	Kab. Tangerang	1	391	Intervention
5	Kota Tangerang Selatan	1	184	Intervention
6	Kota Jakarta Barat	1	544	Intervention
7	Kota Jakarta Pusat	1	473	Intervention
8	Kota Jakarta Timur	1	479	Intervention
9	Kota Bogor	2	374	Intervention
10	Kota Depok	2	287	Intervention
11	Kota Surakarta	2	144	Intervention
12	Kota Surabaya	3	568	Intervention
13	Kota Malang	3	243	Intervention
14	Kota Denpasar	3	982	Intervention
15	Kota Sorong	4	415	Intervention

Table 8. Allocated comparison districts

No	Kab/Kota	Region	Achieved target of HIV testing per semester (2018-2019)	Group
1	Kota Bandar Lampung	1	319	Comparison
2	Kota Jakarta Utara	1	612	Comparison
3	Kota Jakarta Selatan	1	448	Comparison
4	Kota Bekasi	2	158	Comparison
5	Kota Semarang	2	129	Comparison
6	Kota Bandung	2	487	Comparison
7	Kota Makassar	3	866	Comparison
8	Kota Jayapura	4	323	Comparison

5. Recruitment and Sample Size

All FSW in intervention districts who meet study eligibility criteria will be offered community screening (see Section C below for intervention implementation guidelines). FSW in comparison districts will continue to receive the current standard package of interventions.

In to be able to detect a 10 percentage point difference in the rate of HIV testing at health facilities between FSW in intervention vs. comparison districts and have 95% certainty that a difference of that magnitude would not have occurred by chance and 90% certainty of detecting a difference of this magnitude if the difference was real/"the truth," the following sample of FSW will be needed in intervention and in comparison districts:[3]

$$n \geq [Z_{1-\alpha} (2P(1-P))^{1/2} + Z_{1-\beta} (P_1(1-P_1) + P_2(1-P_2)^2 / (P_1-P_2)^2] * deft$$

Where:

$Z_{1-\alpha}$ = the Z score for the level of statistical confidence, or statistical precision, desired (for 95%, Z = 1.96)

$Z_{1-\beta}$ = the Z score for the desired statistical power (for 90% one-sided test, Z = 1.282)

P_1 = the expected population proportion in the comparison group of districts (set = 0.5 – this is the worst-case scenario and will produced a sample size that is adequate irrespective of the actual proportion

P_2 = the expected population proportion in the intervention group of districts (set = 0.6 – assume minimum effect size to be realized of 10 percentages points)

$P = (P_1-P_2) / 2$

(P_1-P_2) = the magnitude of comparison-group differences (or change over time) to be detected with the specified level of precision and power (assumed to be +/- 10 percentage points)

deft = design effect to compensate for clustering at the district level (1.5 assumed).

The required sample size is thus n ≥ 635 per experimental group; ≥ 761 after 20% allowance for lost-to-follow up

[3] Source: Lwanga SK and Lemeshow S. Sample Size Determination in Health Studies: A Practical Manual. Geneva: World Health Organization.

Interpretation: we would need to recruit 761 FSW who self-test for HIV testing in the intervention districts and 761 FSW for HIV testing at health facilities in comparison districts to be able to detect a 10 percentage point difference in the rate of HIV testing at health facilities (intervention vs. comparison districts) to have 95% certainty that a difference of that magnitude would not have occurred by chance and 90% certainty of detecting a difference of this magnitude if such a difference existed.

In order to assess whether "assisted" or "unassisted" community HIV screening among FSW results in a larger increase in the rate of HIV testing at health facilities, we would need samples of size n ≥ 761 each of FSW who received assisted and unassisted screening in intervention districts, a total of n ≥ 1,522 FSW in intervention districts, plus n ≥ 761 in comparison districts.

Sample size requirements for the third question measurement pertains to the number of FSW who test positive for HIV at a health facility and are thus eligible to initiate treatment. This will depend upon (1) the number of FSW presenting at health facilities for testing and (2) the positivity rate among those tested. Sample sizes should thus be calculated accordingly. If we assume a testing positivity rate of 3%, it is apparent that the expected number of FSWs who would be eligible for treatment will be small and we will lack sufficient statistical power to make meaningful comparisons with comparison districts. For this reason, it is recommended that the impact of community screening among FSW be measured using SIHA data for FSW in both intervention and comparison districts. This estimate of impact derived in this way will be confounded if it were to be the case that interventions other than HIV self-testing were to be better implemented in intervention vs. comparison districts. It might be possible to minimize this potential bias by including measures of intervention implementation performance in the intervention and comparison districts in multivariable analyses. Thus, a large enough sample size is required to ensure sufficient power to determine the difference in the intervention and control districts.

C. THE INTERVENTION

1. General Description of The Intervention

FSW who meet the eligibility criteria will be offered for HIV blood test first. Participants who wish to take the test will then managed according to the current guideline for standard of care. Participants who disagree to take HIV blood test will then be offered screening test with Ora-Quick®. There will be with two options for community HIV screening by Peer Leaders: (1) in a convenient community setting assisted by PL/PE (assisted screening) or (2) in a setting of their own choosing without assistance from PL/PE (unassisted screening). FSW will also be able to access a community-based screening test by following online link from messages spread through WhatsApp number without having to come into contact with outreach workers. The saliva-based Ora-Quick® test kit will be used for community screening.

The community screening intervention will be implemented as an additional component to be added in intervention districts to the intervention package currently being implemented by UNFPA's Implementation Units (IUs). In "control districts" implementation of the UNFPA-supported GFATM will proceed without modification as concerns community screening.

2. Implementation Guidelines: Assisted Community Screening

For assisted community screening, which can only be undertaken with FSW with whom outreach worker (OW) have established face-to-face contact, the standard outreach process will entail:

a. For FSW that have not been tested for HIV for at least six (6) months at the time of outreach contact, (i) recommend HIV testing at a health facility, (ii) offer to facilitate making an appointment for testing to accompany them to a health facility for testing, and (iii) provide FSW

with a referral card to be submitted to the health facility in order to help track numbers of FSW that were tested for HIV.

b. For those that refuse or decline to go to a health facility for testing, offer community HIV screening and explain the process and benefits.

c. For those who decline community screening, remind them of the need for periodic testing to protect their health and offer to assist them with health facility testing and/or community screening at a later date.

d. For those who accept community screening, explain the test procedure and assist the client to perform the test providing as much assistance as is needed and/or requested, especially regarding interpreting the result.

e. For clients with reactive community screening results, (i) advise them to get a confirmatory test at a health (ii) offer to facilitate making an appointment for testing to accompany them to a health facility for testing, and (iii) provide FSW with a referral card to be submitted to the health facility.

f. For clients with non-reactive community screening results, (i) remind them of the need for protective behaviors (i.e., condom and lubricant use, periodic STI screening), (ii) remind them of the need for periodic HIV testing and reinforce prevention measures and (iii) offer a referral card in case FSW want a confirmatory test at a health facility (if there is concern about the accuracy of the community screening test).

g. The current procedures for tracking whether FSW were tested, and if positive for HIV had initiated treatment, will be unaffected by the community screening study.

3. Implementation Guidelines: Unassisted Community Screening

Because of differences in the structure of sex work and in the enabling environment in different districts, it will be necessary to develop the details of unassisted community screening on a district-by-district basis. Ideally, the same unassisted community screening intervention would be implemented in the same way in all intervention districts, but if this is not possible due to the factors outlined above, allowing some details to vary across districts is preferable to trying to implement a standard protocol that is expected a priori to fail in some locations.

For unassisted community screening, in which OW don't have face-to-face contact with FSWs, possible mechanisms for distributing Ora-Quick test kits entail:

a. Trained PE/PL identifying various online networks in which FSWs use to solicit their service.

b. Trained PE/PL building trust from FSWs to participate in the study.

c. Trained PE/PL send broadcast message containing brief information of the study, eligibility criteria for participation, step-by-step method to order the kit and have it delivered to their address, short link for description of how to use the kit (flier or short video), and mandatory baseline and post-test survey. Test kit delivery will be done by same-day delivery system (Go-Send/Grab Send) from selected places where the test kit will be stored (Implementing Unit Office or selected health care facilities) to client's address. Trained peer leader/peer educator could also distribute the test kit but not participating in the testing by assisting FSW during the test.

d. Trained PE/PL carrying out follow-up for FSWs being previously approached for the test. The same trained PE/PL is assigned to be the contact person/hotline for each FSW they approached and agreed to take the test.

e. FSW send/upload results of the test along with a completed post-test survey. Cash (mobile top-up) incentive will be transferred to FSW who send the test results and post-test survey. Every kit distributed will have unique code and FSW will be asked to fill it in both baseline and post-test survey to ensure one FSW is entitled to only one test kit.

f. For clients with reactive community screening results, (i) advise them (online) to get a confirmatory test at selected health facility (ii) offer to facilitate making an appointment for testing to accompany them to a health facility for testing, and (iii) provide FSW with a referral card to be submitted to the health facility. Another possible option is to have the referral cards within the test kit, therefore when FSW with reactive results do not wish for their result to be revealed other than towards the post-test survey platform and health officers, they can access health facility for confirmatory test. Information on what's needed to be done when one finds reactive test result has to be mentioned in detail within the instructional fliers or video.

g. For clients with non-reactive community screening results, (i) again online reinforce prevention measures, (ii) remind them of the need for periodic testing and (iii) offer a referral card in case FSW want a confirmatory test at a health facility (if there is concern about the accuracy of the community screening test). In the case where referral card is included within every box containing test kit, FSW with non-reactive result might still be able to bring the card to selected health facility to get a confirmatory test.

4. Implementation Guidelines for Control Group (Standard Program)

For the control group, there will be no new interventions implemented (that is, they will continue with "business as usual"). In each control site, there is an implementing unit (IU) responsible for conducting outreach for FSWs. The outreach target is set up for one year, meaning that a sex worker will only be outreached once in a year. The outreach packet should include condoms and lubricant distribution as well as HIV-AIDS education media distribution. Furthermore, each IU also has a certain number of HIV tests to fulfill every six months. To achieve the target, the IU should reassure sex workers to do HIV test at least once every six months. While it is possible for a sex worker to have HIV test in three months interval, only one test is count for a sex worker every six months. The test could be conducted at health facilities or mobile clinics. A mobile clinic could be conducted at any place where convenient to the participants, such as workplace or living space. For FSWs with reactive test results, they will then be referred to health facility to start on ART.

Except for outreach, all above mentioned activities are incentivized. Below are details of incentives given to PL/PE based on current standard program:

1. Cash incentive of 70,000 IDR for every client who referred for HIV testing to health facilities.
2. Cash incentive of 25,000 IDR for every client taking the test after being reached through mobile outreach.
3. Cash incentive of 50,000 IDR for every client with positive confirmatory test starting on ART.

5. Incentives for Participation

Incentives will be given for different participation role in this study:

1. For all eligible FSWs participating in baseline survey will be given 50,000 IDR
2. For FSWs taking VCT and reporting the results will be given 100,000 IDR
3. For FSWs doing CBS AND uploading/sending test result will be given 100,000 IDR
4. For FSWs participating in post-test survey (both assisted and unassisted) will be given 50,000 IDR
5. Cash incentive 100,000 IDR for transportation and registration and/or fee for confirmatory test for CBS **reactive result** for FSWs who go to health care facility for confirmatory test (assisted and unassisted)
6. Cash incentive 100,000 IDR for transportation and registration and/or fee for confirmatory test for CBS **non-reactive result** for FSWs who go to health care facility for confirmatory test (assisted and unassisted)

Incentives will be given for different role of PL/PE in this study:

1. For PL/PE who assists FSWs for taking self-screening (including filling in baseline and post-test) will be given 150,000 IDR
2. For PL/PE who delivers test kit to FSWs who opt for unassisted screening AND obtain baseline survey on the spot will be given 100,000 IDR

Incentives will be given for health facility:

For collecting data on FSWs who do confirmatory test (assisted and unassisted). Funds to cover additional operational cost will be given to each implementing unit (IU) for delivering test kit via Go-Pay/Grab Pay Top-Up to client's address.

D. LINKAGE TO HEALTH SERVICES FOR ARV INITIATION

Outreach workers will navigate clients to health care facilities for confirmatory test and ARV initiation if the result is confirmed as positive. Health care facilities in each district will be selected by their readiness to offer Test & Treat (T&T). Clients who come for confirmatory test are expected to be started for ARV initiation on the same day of confirmatory test.

E. DATA COLLECTION PROTOCOLS

1. Baseline survey

A short baseline survey will be conducted at the time of initial outreach contact with FSW during the study period. The purpose of the baseline survey is to collect background information on FSW that may be used to assess whether FSW with different characteristics are more or less amenable to community HIV screening and HIV testing at health facilities. An application will be developed so that the survey can be completed and submitted to a server using mobile phones PL/PE/FSW. The following basic information will be gathered (see draft questionnaires for the baseline and post-test surveys in the annex of this protocol).

- Name (full name/initial)
- Age
- Date of birth

- Test Kit ID Number
- Education
- Marital status
- Age at initiation of sex work
- Number of clients last seven (7) days
- Methods of clients' recruitment (fixed facility, street, internet, online platform)
- Consistency of condom use
- Ever been tested for HIV
- When last time tested
- Ever been diagnosed with an STI (other than HIV)

In addition to these questions, FSW will be asked twelve (12) questions in the short version of anticipated HIV stigma scale (Reinius et al., 2017) designed to measure the extent to which participants anticipated negative intrapersonal and interpersonal consequences were they to contract HIV in the future. During data analysis, we will assess the ability of an index constructed from the data items collected to predict which FSW presented at health facilities for formal HIV testing. This will provide an estimate of the impact of anticipated stigma on HIV testing among FSW in Indonesia.

2. Post-test Survey

A short post-test survey will be conducted after the test has been taken. The purpose of post-test survey is to collect information of the experience of clients using the test kit and to record the test result. Some inquiries will be presented on a scale of 1-5, some inquiries will have binary answers (Yes/No, Reactive/Non-Reactive). The following inquiries will be made:

- The clarity of information being provided (flier or short video), on a scale of 1-5
- The easiness of test procedure, on a scale of 1-5
- Perceived accuracy of the test result, on a scale of 1-5
- The quality of response by the assigned contact person/hotline, on a scale of 1-5
- Clients' acceptance/perception towards the study procedure
- The likelihood of clients to recommend their peers to take the test, on a scale of 1-5
- Test result
- How likely is it that the client will get a HIV test at a health facility as a result of the community screening test, on a scale of 1-5
- Comments and suggestions.

3. Routine Recording

Because of limitations in the data recorded and reported by health facilities, the study will rely primarily upon data recorded by IU outreach staff. Modifications will be made to the data recording and reporting systems currently being used to facilitate collection of the data needed for the study in a manner that minimizes additional recording and reporting burden. The nature of the adjustments to be made will be different for "assisted" and "unassisted" community screening.

To capture the data needed for of this study, the following data need to be recorded:

No	Data Recorded	Intervention Group	Control Group
1	Number of FSW contacted via outreach that were at least 6 months since their last HIV test for whom testing at a health facility was recommended	Yes	Yes
2	Numbers of FSW offered for HIV test at health facility	Yes	Yes
3	Numbers agreeing and disagreeing to testing at a health facility	Yes	Yes
4	Of those agreeing to getting tested at a health facility, the numbers that actually went to a health facility and were tested for HIV	Yes	Yes
5	Number of FSW offered for OFT screening	Yes	No
6	Among FSW not agreeing to be tested at a health facility, the numbers that agreed to (1) assisted community HIV screening and (2) unassisted community HIV screening	Yes	No
7	Numbers that were actually screened, assisted and unassisted	Yes	No
8	The number of community screening tests that were reactive	Yes	No
9	Among FSW with reactive community screening tests, the numbers that were subsequently tested at a health facility	Yes	No
10	Number of FSW initiating ART	Yes	Yes

For **unassisted** approach, additional information will be gathered as indicated below:

1. Numbers of FSW who access the link online
2. Numbers of FSW who are deemed eligible
3. Numbers of FSW who fill in baseline survey and agree to participate
4. Numbers of FSW who agree to take HIV test at health facility
5. Numbers of FSW who request the kit being delivered vs picking-up at fixed location
6. Numbers of FSW who upload the test result
7. Numbers of reactive vs non-reactive test result
8. Numbers of FSW who complete the post-test survey

9. Among FSW with community screening tests, the numbers that were subsequently tested at a health facility (reactive OR non-reactive)
10. Number of FSW initiating ART

4. Numbering System for Test Kit and Other Instruments

a) Recording Test Kit ID

Every test kit will have a unique ID number, which will later be referred to as the Kit ID number. The Kit ID Number is to be filled in on all instruments and forms that are to be linked to the test results (e.g., baseline survey, test results form, post-test survey, routine data record in each IU, etc.). This number needs to be identified at all times to make sure that each participant is only assigned to one test kit, matching the kit with the results, and to track the stock of the test kit remained. The format of this ID kit will be "01-001", where the first 2 digits are to identify the number of the district in which participants take the test, and the last 3 digits are to identify which test kit the participant is using. This test kit ID will also be later used for each IU to track the distribution of the test kit. Every test kit being distributed, either in a fixed place or delivered through same-day delivery services, will be recorded and tracked by each IU. An MS Excel or MS Access form will be developed to record and track the Kit ID Number.

b) Recording temporary FSW ID

On the ground of confidentiality, participants' full name will not be revealed and used within this study. A new system to ensure the reliable yet confidential identification of study participants needs to be established. Every participant in the study will be assigned to a temporary FSW ID. The format will be **the first 4 letters of participants' names added by the date of birth (yy/mm/dd)**. For example, a participant named "INDRIYANTI" who was born on March 5^{th,} 1976, her temporary FSW ID will be "INDR760305". For FSW whose name contains only 3 letters, the number zero will be added after the last letter. For example, an FSW whose name is "AYU" and was born on March 5th1976, her temporary will be "AYU0760305". This temporary FSW ID will be used to ensure that each participant is only assigned to one test kit, to track test results, and to be filled in the baseline and post-test survey.

c) Matching Test Kit ID and temporary FSW ID

To match the test kit ID and temporary FSW ID, an automatic system needs to be developed to detect it precisely. This way, we can be sure that each participant only gets to participate in this study once (from receiving the kit, performing the test, and reporting the result).

d) Paper Based Data Collection

In the event that participants' data are collected by paper, a procedure to upload the data into the established online system will be developed. Each data manager in the IUs needs to conduct the procedure regularly. This is to ensure that all data are being captured thoroughly.

F. DATA ANALYSES

The data analyses to be undertaken will be directed to addressing the research questions laid out at the beginning of the protocol and statistical tests appropriate to each specific analysis will be performed to inform the interpretation of results. The specific steps in the data analysis will be as follows:

1. Compare the characteristics of FSWs who receive self-testing and blood testing.

2. Compare the characteristics of FSWs who receive assisted and unassisted self-testing.
3. Compare proportion of FSWs taking confirmatory test out of those who receive the test in the assisted and unassisted self-testing.
4. Compare the proportion of FSWs who receive HIV test out of those who got offered for the test (including self-testing) in the intervention group with proportion of FSWs who receive HIV test in the control group.
5. Compare the proportion of FSWs taking confirmatory test (including self-testing) out of those receive the test in intervention groups and control group.
6. Compare the proportion of HIV positive in the assisted, unassisted (intervention) and HIV positive in the control group.
7. Compare the proportion of ART initiation in the assisted, unassisted (intervention) and the control group.
8. Calculate the cascade of HIV testing and treatment.
9. Compare stigma scores and FSWs who went to a health facility for HIV testing between assisted, unassisted group.
10. Compare the HIV and STI risk behaviors between assisted and unassisted group.

G. CONTINGENCY STUDY DESIGN

Should the OraQuick® test kits not become available in sufficient time to conduct a full-scale cRCT, a smaller-scale study will instead be undertaken. The purpose of the smaller study is the same as the cRCT described above, and the same protocol described above will be implemented. But the comparison is achieved targets between before and after intervention – there will be no comparison districts. The study will be undertaken in three (3) districts. The three districts will be selected from different parts of Indonesia, and they are: Kota Bandung (west part of Indonesia), Kota Denpasar (central part of Indonesia), and Kota Makassar (center-east part of Indonesia).

The primary limitations of the smaller-scale study are (1) the districts were not randomly chosen and (2) the proportion of HIV testing before and after intervention that might not sufficient to produce a statistically significant result to prove the success of the intervention. This smaller-scale version of the study should be viewed as a demonstration or pilot project leading to a bigger study afterwards.

Data analysis will be done by comparing changes in outcome variables measured against results in the four semesters prior to the study in the 3 districts compared to the other 20 acceleration districts.

Analysis of outcome variables are similar with the cRCT approach as below:

1. Compare the characteristics of FSWs who receive self-testing and blood testing in 3 districts.
2. Compare the characteristics of FSWs who receive assisted and unassisted self-testing 3 districts.
3. Compare proportion of FSWs taking confirmatory test in the assisted and unassisted self-testing 3 districts.

4. Compare the proportion of FSWs who receive HIV test including self-testing in the intervention group with proportion of FSW who receive HIV test in the control group (in 3 districts before the intervention and other 20 acceleration districts).
5. Compare the proportion of FSWs taking confirmatory test (including self-testing) in the intervention group with proportion of FSW who receive HIV test in the control group (in 3 districts before the intervention and the other 20 acceleration districts).
6. Compare the proportion of HIV positive in 3 districts (assisted and unassisted) and HIV positive in the control group (in 3 districts before the intervention and other 20 acceleration districts).
7. Compare the proportion of ART initiation in 3 districts (assisted and unassisted) and the control group (in 3 districts before the intervention and other 20 acceleration districts).
8. Calculate the cascade of HIV testing and treatment.
9. Compare stigma scores and FSW who went to a health facility for HIV testing.
10. Compare the HIV and STI risk behaviors.

H. RESEARCH ETHICS AND PERMISSION

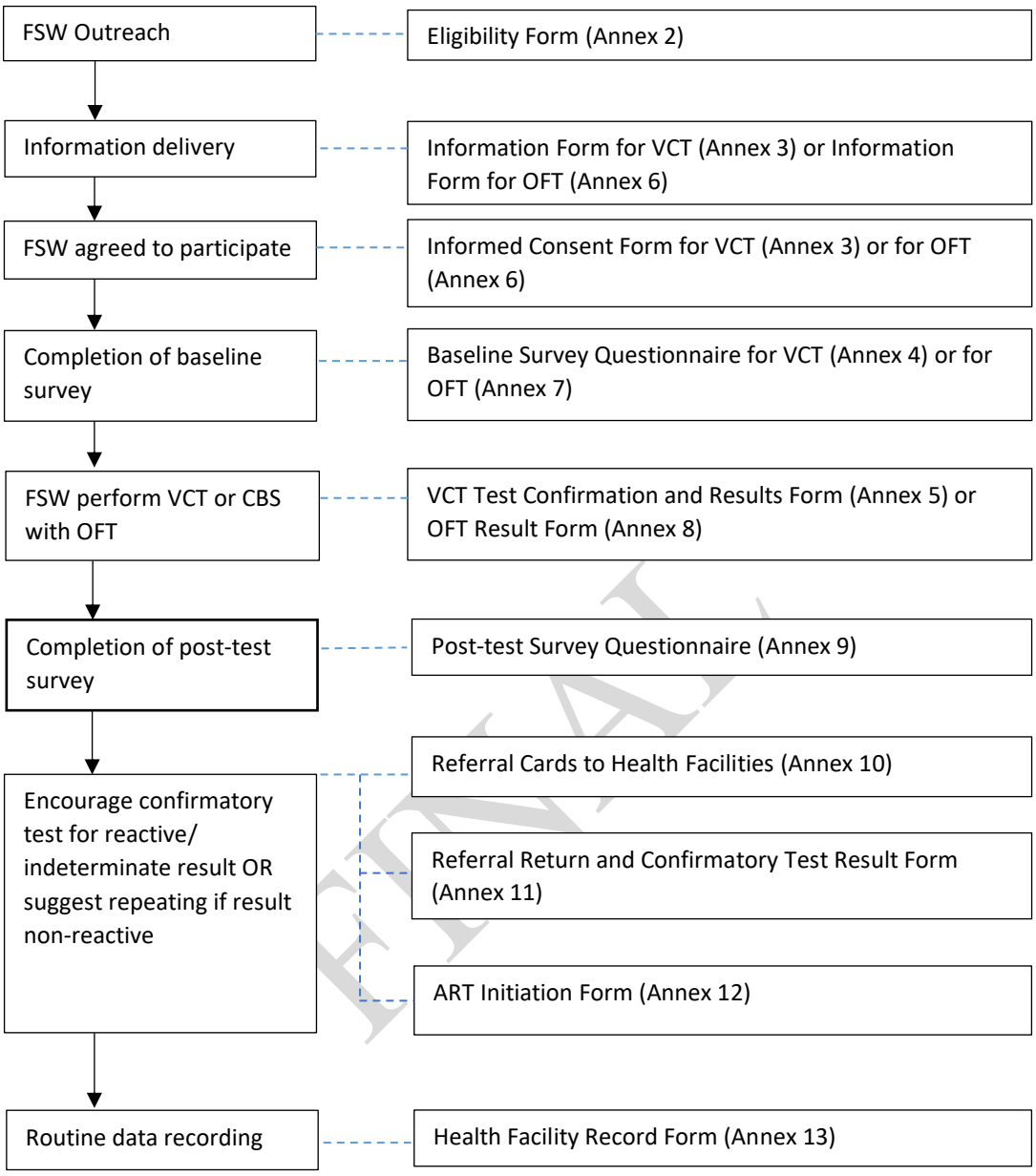
Participation in the study will be entirely voluntary. For the assisted testing, formal signed consent or witnessed verbal informed consent will be obtained by outreach workers. Records of informed consent will be managed /safeguarded using sealed envelope with unique number. To ensure the confidentiality, in the base line data only unique number will be recorded. A draft of the informed consent form can be found in Annex-3 of this protocol.

For unassisted screening, every study participant should fill in the check box of website or application to provide consent: "By signing this form/ticking this box, I understand that I am thereby agreeing to enroll in this study" and test kit is not sent out if the check box is not checked by the user.

This protocol will be reviewed by the Faculty of Medicine Udayana University Institutional Review Board (IRB) prior to study initiation. Approval of the protocol in either its original or modified form is required.

Research permission will be submitted to Department of Internal Affairs Republic of Indonesia, which will subsequently be referred to the licensing office in each provinces and priority districts.

Annex 1. Flowchart of Routine Data Recording



Annex 2. Eligibility Form

Eligibility Participants Form for Intervention

To be completed by PL/PE during FSW outreach

These checklists are to be completed by PL/PE during FSW outreach to assess the eligibility of FSW to participate in this study. If questions number 1-7 is answered "Yes", then participant is eligible for the study. If question number 8 is answered "Yes", then participant is not eligible for the study, but eligible for "blood test study in health facility".

No	Criteria inclusion	Yes	No
1	*Female, aged 18 years old or more*		
2	*Admit having transactional sex (vaginal, oral, or anal) at least once within the last one month*		
3	*Have never had any HIV test taken within the last 6 months*		
4	*Self-reported HIV Negative OR HIV status unknown*		
5	*Agreed to participate in this study*		
6	*Not currently participating in any other HIV prevention study*		
7	*After being offered for HIV testing in health facility, participant stated:* *A. Agree for HIV testing in health facility** *B. Not agree for HIV testing in health facility***		

Note:
***** Use information form for VCT
****** Use information form for OFT

Annex 3. *Informed Consent* Form (VCT)

Inform Consent Form

Community Based Screening for HIV Self-Testing in Female Sex Workers in 23 Priority Districts in Indonesia

Invitation

You will be invited to participate in study community-based screening for HIV self-testing in female sex workers in 23 priority districts in Indonesia (CBS in FSWs). This study uses a new approach to encourage people undertake HIV testing. For those who are detected infected, will get a treatment immediately.

CBS in FSWs conducted by research team in Kerti Praja Foundation (YKP) whereby dr. Pande Putu Januraga, M. Kes, DrPH as the principal investigator (PI).

You have to understand this study deeply before deciding whether you want to take part as a participant or not. Please read and grasp the following information and discuss it with somebody else if you want.

1. **What is the purpose of this study?**
   HIV infection has been more common among FSWs, LSL or shemale. The previous study defines that those groups are rarely undergo HIV testing because of many reasons. They, accordingly, loss an opportunity to obtain a cure early. Treatment of HIV early is fairly essential to prevent the infection become worst. It possibly, furthermore, decreases the transmission for their sex partner.
   The purposes of this study that identify some well- approaches to encourage many people specifically FSWs to undertake HIV testing, and for those had infected can start the HIV treatment immediately and continue to get cure regularly. The outcome of CBS' study will contribute for improving HIV program in Indonesia or even across countries.

2. **Why am I invited to participate in this study?**
   You qualified to participate in this study because you are a female sex worker (FSWs), your age is 18 or over, never been tested to HIV since the 6-last month, never been diagnosed infected or do not known the HIV status yet. Moreover, you do not want to take HIV blood-testing. For this study, it is expected at least 761 qualified FSWs to be a participant in Indonesia.

3. **If I get anxious to take part or if I want to withdraw to participate in this study, what can I do?**
   For this study, you never been forced to participate due to it is voluntary. Whatever your decision, it never influences your treatment has been received nowadays or later on. It will not influence your relationship with those medical staffs who are treating you as well.
   You can withdraw from this study after started or whenever without provide a reason.

4. **if I become a participant of this study, what will happen?**

If you do agree to participate, you need to give a signature or an agreement in inform consent form. This study is conducted in 23 districts/cities as the intervention group. 15 districts/cities preferred as intervention group while 8 districts/cities have been selected as the control group.

If you live in those control areas, outreaching procedure and HIV testing will be conducted as usual rely on implemented HIV procedure, such as through health services or mobile VCT. If the test result is reactive, you will be referenced to health facilities in regard to get treatment immediately.

If you live in those districts/cities who are intervened, and you do not want to undergo the conventional test (blood-testing), you will be offered a self-testing which is Ora-Quick®. It is recognized as screening test or rapid test whereby its test results can be known between 20-40 minutes. You can prefer to get screening test, assisted by PL/PE (**assisted screening**) or without assisted (**unassisted screening**).

For this study, you are asked to answer some preliminary questions before starting the screening test. You undertake the testing and report the test result afterwards. If you prefer conducting the test by assisted, they are required to help you to conduct the test completely. They assist you to answer the preliminary questions; undertake the screening test; report the test result. They help you to take confirmatory test as well and support you in terms of continually having HIV treatment.

On the other hand, there is 3 modes to get the KIT test if you prefer to undertake the test without assisted. Firstly, you can ask PL to deliver the KIT devices to your place. You fulfill the preliminary questions by your own, then conduct the test without assisted. Secondly, you can order it by online. Do not be hesitate because we created a CBS' website (teman-kita) for you that all information has been provided. The test information has been advertised by social media (Facebook, Instagram, Twitter) as well. Its information includes Ora-Quick® testing (KIT) that encourage you to order it. While you order it, you can prefer the method of KIT delivering. You fulfill the preliminary questions and asking to deliver the device through Gosend or Grabdelivery without paying. Or you can ask PL/PE which their names have been listed in the website to carry out the KIT test for you or you can pick the KIT devices up in the spots which set up by the research team.

Whatever your preferred method, you exactly must report the test result by take the result photo and send it to the research team via whats-app (WA) or upload it in the website. You asked, subsequently, to complete all questions after the test as well.

It is important to realize that self-testing (oral fluid test) is only a screening test in which it needs an additional test to ensure the result. If the test result is reactive or indeterminate, you expectedly must go to health facilities to get a diagnose and treatment. PL/PE can facilitate you to access health facilities or if you want, you can go alone. The information of test result and references health services can be found in the website.

As the explanation previously, you will be required to fulfill the question in the early and also at the end. In the early before starting the test, you will be asked to give some basic information about identity which are name, age, HIV test history, your behavior and your outlook of stigmatization. At the end, meanwhile, you should review the performance of Ora-Quick® test KIT. The reviewing of devices includes clearly information how to use it; the confidence of the result; giving recommendation for friends or not; the role of PL/PE while conducting the test; ensuring the test result by take confirmatory test in health facilities (for the result is reactive or indeterminate) and; your comment in concern to improve a similar

study further. You have to realize that your identity will put in secret whereby we use it only for CBS study. Your identity specifically name, even more, will be code during data processing to protect your personal privacy. You are freely to refuse to take part in this study or withdraw or postpone as a participant.

5. How is the funding for this study?

CBS study funded by United Nations for Population Fund (UNFPA).

6. Is there any risk if I participate in this study further?

You possibly feel uncomfortable or shameful while you are being interviewed or fulfill the questions. However, PL/P who have been known closely will assist you to finalize all steps in the study. If you prefer to be counted in unassisted group, all questions can be answered privately. Possibly, you are under the pressure, confusion, sad, angry if the test result is reactive. Access to health facilities, however, absolutely help you to start HIV treatment. So, all negative reaction might be can be overcome.

7. If I get suffer or injury or HIV complication due to this study, what can I do?

We do believe that you cannot get suffer or injury or HIV complication because of this study.

8. Can I get a benefit from this study?

Being participate, your HIV status will be acknowledged whether you are infected or not. Furthermore, if your test result is reactive, it leads you to ensure the diagnose freely without paying even If you decided to start the treatment. CBS study, indirectly, aims to increase knowledge and contributes to improve HIV program further.

9. Should I have to pay to take part as participant or will I get paid?

It is free or not paying anything to participate in this study. Laboratory test and HIV treatment provided freely for you. You will receive, furthermore, such amount of money as incentive due to your giving time and your participation. For your readiness to fulfill the questionary before and after the test, you can receive Rp. 100.000,-. If you conduct the testing and send the result for us (reactive, non-reactive or indeterminate) you will also be paid amount Rp. 100.000,-. If you decide to conduct the subsequent test in order to ensure the screening test result in clinics or another pointed health facilities, you will receive incentive amount Rp. 100.000,-.

10. Is my privacy protected?

There is only research team; peer leader; peer educator; medical staffs include doctor and those staffs who treat you, will know your participation in this study. identified Information as a participant will be kept in secret and only released by your permission or if it is required by law. Your personal identity will be deleted before sharing to other researchers who get involved in this study.

11. How about the result?

We have a plan to produce an article and published it in peer review journal. Or we precent it in the conference and professional forum if we have an opportunity. We are willing to publish the result routinely as well in annual report. The data will brighten the perspective of stakeholders about HIV among FSWs and leads them to develop a good health policy. Turning to the publications, your identity will not be released. The outcome of analysis will give it to you, if you want.

12. What will be happen to my treatment after the study?

You can continue to get treatment as usual based on the standard of services of Indonesians government even though study has been ended on schedule or not on schedule.

13. What can I do, if I am willing to discuss about this study deeply before I decide to participate or not?

If you want more information, you can discuss it with the principal investigator namely dr. Pande Putu Januraga, M.Kes., DrPH. Do not be hesitate to contact him in 081246180389.

14. Who should be contacted if I am worried about the implementation of this study?

This study has been approved by ethical commission of health-research of Medical faculty in Udayana University/ Sanglah hospital. If you are anxious or have a complaint about the implementation of CBS study, you can contact researchers' team or ethical commission of health-research of Medical faculty in Udayana University/ Sanglah hospital.

Principal investigator	dr. Pande Putu Januraga, M. Kes, DrPH. (+62 812 4618 0389)
Research coordinator	I Gusti Agung Agus Mahendra, MPH (+62 857 9236 0767)

Thank you for your time to consider whether you are going to participate or not

If you want to take part, please give a signature on the form agreement (next page).

This information page is given to you to save it.

The Agreement to Participate in The Study

The research of community-based screening HIV self-testing for the female sex workers in 23 prioritized districts or cities in Indonesia

1. I am .....
   are living in……
   agree to participate as the participant of the study that is explained on the form information participation is explained above (or it is attached on this form)
2. I acknowledge that I have read the form participants information, who explained why I have been chosen, the aim of the study, the nature and the possible risk of study, and the information form has given the explanation in detail, so I do understand it clearly.
3. Before signing this agreement, I have been given a chance to ask some questions in terms of each mental and physical risk which is possible I suffers as the consequence of participating and I have received the satisfied answers.
4. I understand that I can withdraw from this study anytime without influencing my relationship with health services of Non-Government Organization (NGO) who accompanied me right now.
5. I agree that the research data which is collected of this study can be published with give protection of my identity.
6. I agree that If I have questions concern on taking part as participants of this study, I can inform dr. Pande Putu Januraga, M. Kes, DrPH in +62 812-4618-0389, which is glad to answer my questions.
7. I acknowledge to receive a copy of the form agreement and the form of participant information.

Complaint can be informed to Kerti Praja Foundation, Phone: (0361) 728916.

_____

Canceler signature Writing in capital letter Date

_____

*****only be needed if you cannot read or blind*

Note: directly inputted to the system

The Revocation of Participation on The Study

Research of Community Based Screening HIV *Self-Testing* for Female Sex Workers in 23 priority regencies/cities in Indonesia

With this letter, I **CANCEL** the agreement to participate in the study that has been explained above and I understand that this cancellation **WILL NOT** be dangerous for the treatment or my relationship with Kerti Praja Foundation or my medical staffs.

_____ _____

Signature Date

_____

Writing the name in capital letter

Part of revocation of agreement if forward to:
dr. Pande Putu Januraga, M.Kes, DrPH
di Jalan Raya Sesetan No. 270, Denpasar, Bali, Indonesia

Annex 4. Baseline Survey Questionnaire (VCT)

Baseline Survey Questionnaire

Introduction

Thank you for your willingness to participate in this study and to answer this simple questionnaire. Your participation is greatly valued. Allow us to provide some more information regarding the survey.

Firstly, this study is part of a national study in evaluating the most appropriate method for HIV testing for female sex workers who are at least 18 years of age, have never been tested for HIV and have not undergone HIV testing in the last 6 months but would like to receive HIV blood testing at this time.

Secondly, your participation and personal information will be kept **confidential**. Only the research team will know you, and you will not be writing your name or any identifying information explicitly on this questionnaire.

Additionally, only the research team will know your answer. Each questionnaire has been given a code, such that your personal details will be safe and can only be accessed by the research team.

Thirdly, the findings in this study will be presented as a collective result, such that personal information will not be presented, including yours.

Fourthly, you may refuse to answer the questions given, however we will greatly appreciate if you answer all the questions, as it will assist us in generating better results.

Should you have doubts regarding a particular question or certain words in this questionnaire, do not hesitate the **contact us (at OW/PE's phone number: _____)** for further explanation. There is no right or wrong answer, please provide that answer that you consider most accurate.

Are you ready to begin?

Note: directly inputted to the system

Baseline Survey for All Participants (Blood testing at healthcare facility and HIV self-testing)

Participant Code Number		
Name of OW/PE (assisted)		
1.	Please write your full name or initials	
2.	What is your date of birth?	Day: ___Month: __ Year: ____
3.	Your age is	…… years old
		1. Did not attend school

4.	What was the education level you last received?	2. Did not complete elementary school/ equivalent
		3. Completed elementary school/equivalent
		4. Did not complete middle school/equivalent
		5. Completed middle school/equivalent
		6. Did not complete high school/equivalent
		7. Completed high school/equivalent
		8. Ever attended/completed bachelor studies
5.	What is your current marital status?	1. Never married
		2. Married (including unofficial marriages)
		3. Separated
		4. Widowed
		5. Divorced
6.	Do you have a consistent partner (boyfriend/husband) in the past month?	1. Yes
		2. No
7.	What was your age when you first engaged in sex with a client?	…….. (years of age)
8.	What is the approximate number of clients you had in the past 7 days?	…….. (people)
9.	How often do you use condom when engaging in sex with your clients in the past month?	1. Always
		2. Very frequent
		3. Often
		4. Sometimes
		5. Never

10.	Where do you usually look for or find your client (potential client)? **(CHOOSE ALL THAT APPLY)**	a. Location
		b. Streets
		c. Spa
		d. Café
		e. Karaoke
		f. Salon
		g. Bar
		h. Massage parlour
		i. On-line (web application, SMS, social media)
		j. Others, _____

11.	Have you ever experienced symptoms such as abnormal vaginal discharge, itching, or pain during sexual intercourse?	1. Yes 2. No 3. Not sure
12.	Have you ever been diagnosed with a sexually transmitted infection by a doctor in the past six months?	1. Yes 2. No 3. Not sure
13.	When was the last time you took an HIV test?	1. Never 2. 6 to 12 months 3. more than one year to two years 4. more than two years
14.	In the past one year, have you ever received an HIV test offer?	1. Yes ➔P.15 2. No ➔ P.17
15.	Did you agree or decline to undergo the HIV testing?	1. Agree 2. Decline ➔ P.16

16.	Why did you decline the HIV testing at that time? **(Choose all that apply)**		
	a. Afraid to have blood sample taken	1. Yes	2. No
	b. Fear of needle/injection	1. Yes	2. No
	c. Afraid of receiving a positive result	1. Yes	2. No
	d. Afraid that others might know about the results	1. Yes	2. No
	e. Uncomfortable while undergoing testing (crowd, time, etc)	1. Yes	2. No
	f. Live far from community health centre/hospital/clinic	1. Yes	2. No
	g. Embarrassed to undergo testing at the clinic	1. Yes	2. No
	h. Perceive to have low risk	1. Yes	2. No
	i. Other reasons, please mention	_____	

17.	**Where did you hear about HIV self-testing?** (Choose all that apply)		
	a. Staff/NGO/Foundation	1. Yes	2. No
	b. Friends	1. Yes	2. No
	c. Someone at the workplace (madam, security, etc.)	1. Yes	2. No
	d. Internet	1. Yes	2. No
	e. Social media	1. Yes	2. No

	f. Chain messages (broadcasted messages)	1. Yes	2. No
	g. Others, _____	1. Yes	2. No

QUESTIONS ON STIGMA

No	Question	Extremely Disagree	Disagree	Agree	Extremely Agree
	Personalized stigma				
1	Others will avoid touching me if I am infected with HIV				
2	I am worried that my family/friends/partner/husband/boss will end their relationship/contact with me if I am infected with HIV				
3	I am worried that I will lose my friends if I am infected with HIV				
	Concerns with Revealing Status				
4	Revealing to others that I am infected with HIV will pose a risk to me				
5	I have to conceal my status if I am infected with HIV				
6	I might have to be extremely careful to whom I reveal that I am infected with HIV				
	Concerns regarding public attitude				
7	I am afraid that I will be treated like an unwanted person if I am infected with HIV				
8	Most people believe that those infected with HIV are dirty				
9	Most people feel uncomfortable being around people living with HIV				
	Negative Self Perception				
10	I feel at fault if I am infected with HIV				
11	Others attitude towards HIV will worsen my feelings if I am infected with HIV				

12	I feel that I am not as good as others if I live with HIV				

Annex 5. VCT Test Confirmation and Result Form

FOLLOW-UP PARTICIPANT WHO CHOOSE TO PERFORM HIV BLOOD TEST AT HEALTH FACILITY

1	*If participant agreed to perform HIV blood test in health facility, did she really go for it? (**Needed to be validated at health facility**)*	1. Yes	2. No
2	Test result	1. Reactive	2. Non-reactive

Annex 6. Baseline Survey Questionnaire (OFT)

Introduction

Thank you for your willingness to participate in this study and to answer this simple questionnaire. Your participation is greatly valued. Allow us to provide some more information regarding the survey.

Firstly, this study is part of a national study in evaluating the most appropriate method for HIV testing for female sex workers who are at least 18 years of age, have never been tested for HIV and have not undergone HIV testing in the last 6 months but would like to receive HIV blood testing at this time.

Secondly, your participation and personal information will be kept **confidential**. Only the research team will know you, and you will not be writing your name or any identifying information explicitly on this questionnaire.

Additionally, only the research team will know your answer. Each questionnaire has been given a code, such that your personal details will be safe and can only be accessed by the research team.

Thirdly, the findings in this study will be presented as a collective result, such that personal information will not be presented, including yours.

Fourthly, you may refuse to answer the questions given, however we will greatly appreciate if you answer all the questions, as it will assist us in generating better results.

Should you have doubts regarding a particular question or certain words in this questionnaire, do not hesitate the **contact us (at OW/PE's phone number: _____)** for further explanation. There is no right or wrong answer, please provide that answer that you consider most accurate.

Are you ready to begin?

Note: directly inputted to the system

Baseline Survey for All Participants (Blood testing at healthcare facility and HIV self-testing)

Participant Code Number		
Name of OW/PE (assisted)		
1.	Please write your full name or initials	
2.	What is your date of birth?	Day: ___Month: __ Year: ____
3.	Your age is	…… years old
4.	What was the education level you last received?	9. Did not attend school
		10. Did not complete elementary school/ equivalent
		11. Completed elementary school/equivalent

		12. Did not complete middle school/equivalent
		13. Completed middle school/equivalent
		14. Did not complete high school/equivalent
		15. Completed high school/equivalent
		16. Ever attended/completed bachelor studies
5.	What is your current marital status?	6. Never married
		7. Married (including unofficial marriages)
		8. Separated
		9. Widowed
		10. Divorced
6.	Do you have a consistent partner (boyfriend/husband) in the past month?	3. Yes
		4. No
7.	What was your age when you first engaged in sex with a client?	…….. (years of age)
8.	What is the approximate number of clients you had in the past 7 days?	…….. (people)
9.	How often do you use condom when engaging in sex with your clients in the past month?	6. Always
		7. Very frequent
		8. Often
		9. Sometimes
		10. Never

10.	Where do you usually look for or find your client (potential client)? **(CHOOSE ALL THAT APPLY)**	k. Location
		l. Streets
		m. Spa
		n. Café
		o. Karaoke
		p. Salon
		q. Bar
		r. Massage parlour
		s. On-line (web application, SMS, social media)
		t. Others, _____
11.	Have you ever experienced symptoms such as abnormal vaginal discharge,	4. Yes
		5. No
		6. Not sure

	itching, or pain during sexual intercourse?	
12.	Have you ever been diagnosed with a sexually transmitted infection by a doctor in the past six months?	4. Yes
		5. No
		6. Not sure
13.	When was the last time you took an HIV test?	5. Never 6. 6 to 12 months 7. more than one year to two years 8. more than two years
14.	In the past one year, have you ever received an HIV test offer?	3. Yes ➔P.15 4. No ➔ P.17
15.	Did you agree or decline to undergo the HIV testing?	3. Agree 4. Decline ➔ P.16

16.	Why did you decline the HIV testing at that time? **(Choose all that apply)**		
	j. Afraid to have blood sample taken	3. Yes	4. No
	k. Fear of needle/injection	3. Yes	4. No
	l. Afraid of receiving a positive result	3. Yes	4. No
	m. Afraid that others might know about the results	1. Yes	2. No
	n. Uncomfortable while undergoing testing (crowd, time, etc)	3. Yes	4. No
	o. Live far from community health centre/hospital/clinic	3. Yes	4. No
	p. Embarrassed to undergo testing at the clinic	3. Yes	4. No
	q. Perceive to have low risk	3. Yes	4. No
	r. Other reasons, please mention	_____	

17.	**Where did you hear about HIV self-testing?** (Choose all that apply)		
	h. Staff/NGO/Foundation	3. Yes	4. No
	i. Friends	3. Yes	4. No
	j. Someone at the workplace (madam, security, etc.)	3. Yes	4. No
	k. Internet	3. Yes	4. No
	l. Social media	3. Yes	4. No
	m. Chain messages (broadcasted messages)	3. Yes	4. No
	n. Others, _____	1. Yes	2. No

STIGMA QUESTION

No	Question	Extremely Disagree	Disagree	Agree	Extremely Agree
	Personalized stigma				
1	Others will avoid touching me if I am infected with HIV				
2	I am worried that my family/friends/partner/husband/boss will end their relationship/contact with me if I am infected with HIV				
3	I am worried that I will lose my friends if I am infected with HIV				
	Concerns with Revealing Status				
4	Revealing to others that I am infected with HIV will pose a risk to me				
5	I have to conceal my status if I am infected with HIV				
6	I might have to be extremely careful to whom I reveal that I am infected with HIV				

Annex 7. OFT Result Form

Number of KIT's Code	0	1	-	0	0	1
Participant's Code						
Test Methods	1. assisted					
	2. unassisted					
Test result	1. Reactive					
	2. Non-reactive					
	3. Indeterminate					

Annex 8. Post-test Survey Questionnaire

KIT Code		**0** **1** **-** **0** **0** **1**
Participant Code (First 4 letters, year, month, day)		
Name of OW/PE		
1.	Please write your full name or initials	
2.	How was the clarity of the information about HIV test kit you received/obtained? **(Select one answer)**	1. Extremely unclear 2. Unclear 3. Fairly clear 4. Clear 5. Extremely clear
3.	When you performed HIV self-testing, was there any person (peer) who assisted you?	1. Yes 2. No
4.	How easy was performing an HIV test using the self-testing kit given? **(Select one answer)**	1. Extremely difficult 2. Difficult 3. Fairly difficult 4. Easy 5. Extremely easy
5.	What was the reason that **prevented you from testing** using the test kit provided?	1. Extremely difficult 2. Difficult 3. Fairly difficult 4. Easy 5. Extremely easy
6.	**This question only applies for those who underwent the self-testing assisted by OW/PE.** How would you rate the given support by OW/PE /contact people who accompanied/contacted you during HIV self-testing? (**Select an answer**)	1. Extremely unclear 2. Unclear 3. Fairly clear 4. Clear 5. Extremely clear
7.	This question only applies if your test results are negative. How much do you want to take an HIV test regularly after taking this test?	1. Extremely not in favour 2. Less in favour 3. Fairly in favour 4. In favour 5. Very in favour
8.	How was your experience in performing this HIV self-testing (saliva test)?	1. Extremely unpleasant 2. Unpleasant 3. Fairly pleasant

		4. Pleasant
		5. Extremely pleasant
9.	How sure are you with the accuracy of this test	1. Very doubt
		2. Less sure
		3. Fairly sure
		4. Sure
		5. Very sure
10.	How was your test result?	1. Positive
		2. Negative
		3. Indeterminate
11.	How much do you want to confirm your test results to the healthcare facilities?	1. Extremely unlikely
		2. Fairly unlikely
		3. Fairly likely
		4. Likely
		5. Extremely likely
12.	How likely are you to recommend your peers to undergo the screening test that you just performed?	1. Extremely unpleasant
		2. Unpleasant
		3. Fairly pleasant
		4. Pleasant
		5. Extremely pleasant
13	How much do you trust the accuracy of the test result	1. Extremely unsure
		2. Fairly unsure
		3. Fairly sure
		4. Sure
		5. Extremely sure
14.	What was your test result?	1. Positive ➔ P.13
		2. Negative ➔ P.14
15.	If you are extremely unlikely or unlikely to visit a healthcare service, what are the reasons?	
16.	What is your opinion regarding this HIV testing method?	
17.	What are your suggestions for HIV self-testing?	
18.	What are your suggestions and comments to improve the procedure of this study?	
Note: directly inputted to the system		

Annex 9. Referral Cards to Health Facilities

Referred Card of Health Services

Dear ….

medical staff,

……..

Name : …….

Age : …….

Address : …….

No. Kit code : …….

To receive medical treatment of HIV

IU Organisation: ……. _____ date ___/___/___

Signature PL/PE Signature client

Annex 10. ART Initiation Form

ART Initiation Form

I hereby provide my signature below to state that I have understood my condition and diagnosis given by the physician and I give consent to initiate ARV therapy starting from today and will comply with the treatment plan given to me.

_____ Date. ____/____/____ _____ Date. ____/____/____

Physician's name and signature Patient's name and signature

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