A. Introduction

In 2014, UNAIDS launched the 90-90-90 target, “the fast track target”, for achieving the vision of “Ending the AIDS Endemic by 2030”. It is also mentioned by Sustainable Development Goals (SDGs) target, launched in 2015, – i.e. end AIDS as a public health threat by 2030. Those working in the field of HIV, including policy makers, programmers, governments and community-based organisations operate within the framework of global HIV targets.

HIV epidemic in Indonesia is one of the fastest growing in Asia. Total number of new HIV infections in 2016 (48,000 people) is 10 times higher compared with the case in 2004 (<3,000 people). In addition, since 2010, AIDS related death in 2016 (38,000 people) have increased by 68%. There are estimated to be 630,147 people living with HIV/AIDS in Indonesia in 2015. In recent years, the primary driver of the HIV epidemic has shifted from transmission through injecting drug use to sexual transmission. Most HIV infections in Indonesia are concentrated in five key affected population groups: 1) people who inject drugs (PWIDs); 2) female sex workers (FSWs); 3) men who have sex with men (MSM) and male sex workers; 4) transgender (Waria); and 5) clients of sex workers/high risk men. According to various surveys, HIV prevalence in MSM (8-10%), transgender people (waria) (20-40%), female sex workers (FSWs) (8-20%), especially direct FSWs and their clients, and people who inject drugs (PWID) (36-40%) continues to be high. West Java, Jakarta and Bali report the highest concentration of HIV cases in the country. Most of the at-risk populations are in urban and peri-urban areas.

A Test & Treat (T&T) strategy is a strategy to initiate ART immediate after being diagnosed as HIV positive. Modelling and observational studies support that the ‘Test and Treat’ (T&T) strategy of expanded voluntary HIV testing and immediate initiation of ART on HIV diagnosis is likely to result in a decline in rates of HIV transmission. HATI study will be one of the first to systematically evaluate strategies to improve the implementation of a T&T strategy in a concentrated epidemic in Asia.

HATI (Test & Treatment HIV AIDS in Indonesia) study has been conducted in Indonesia since August 2015. This is an implementation study to increase number of HIV testing people and number of people on ARV, especially among key population – i.e. men who have sex with men (MSM), female sex worker (FSW), transgender, and inject drug user (IDU). This study is conducted in four provinces in Indonesia – i.e. Jakarta, Bandung, Yogyakarta, and Bali.

Phase 1 of this study – i.e. observational phase, has finished and resulted in a recommendation to do some intervention for phase 2. The intervention consists of (1) Oral Fluid Testing in Bali; (2) Simplify ARV Initiation in Bandung, Bali, Yogyakarta; (3) CBO based Intervention in Yogyakarta; (4) SMS Reminder in Jakarta, Bandung, Bali, Yogyakarta; and (5) Motivational Interviewing in Bandung and Jakarta. The recruitment participants have ended in 31 December 2018 and study now in follow up participants.
The study has collected some data to achieve the primary objectives which are to assess the impact of enhanced community-based intervention compared with current practice, on the following:

(a) Proportion of people from each key population who are virologically suppressed 12 months after HIV diagnosis. Analyses will be conducted separately for each key affected population;
(b) Total number of virologically suppressed individuals from each key affected population

Besides that primary objective, the secondary objective of the study as follow.

a) To quantify and compare other components of the HIV treatment cascade/continuum of care, including:
   - Uptake of HIV testing and retesting
   - Clinical and immunological stage at time of HIV diagnosis
   - Uptake of ART and time to initiation of treatment
   - ART adherence and retention in care

b) To assess the safety and acceptability of early ART initiation, including:
   - ART toxicity
   - Short term incidence of AIDS and mortality in those who do and do not initiate ART
   - Proportion failing on first-line ART by virological criteria
   - Emergence of resistance mutations in those failing first-line ART
   - For those who decline immediate ART, reasons for refusal and barriers to initiation of ART

c) To assess behavioral aspects of a T&T strategy, including:
   - Impact of ART initiation on risk behaviour
   - Impact of enhanced community-based intervention package on risk behavior

Based on the proposal the statistical analysis that planned to each intervention as follow:

1. **Oral Fluid Based Self Testing**
   This intervention will aim to make HIV testing easier and more attractive for MSM in Bali, with the goal of increasing the number of HIV-positive diagnoses.
   Evaluation of this intervention will be limited to MSM in Bali. We will summarize the number of oral HIV self-tests being conducted, and the number of people diagnosed as HIV positive. The effect of this intervention on numbers of HIV-positive diagnoses will be estimated by comparing the pre and post intervention phases. Poisson regression methods will be used to compare the counts of HIV-positive diagnoses, with time duration of the phase as exposure. Number of tests conducted will not be used as the exposure (ie we will not compare the rate of HIV-positive diagnoses from all HIV tests conducted) as the intervention is designed, and expected, to increase the number of HIV tests.

2. **Simplification of ART Initiation**
   This intervention will aim to make it easier and quicker for people diagnosed HIV-positive to commence ART. The intervention will be in MSM, *waria* and FSW in Bali, Bandung and Yogyakarta.
   The effect of the intervention will be assessed by comparing time to starting ART in people diagnosed HIV-positive and recruited to the study who commence ART. Time to ART will be summarized pre and post intervention using Kaplan-Meier survival curves, and formally compared using Cox regression.
The intervention will be evaluated overall, across all sites and key populations, and separately within subgroups defined by site and key population. The consistency of the intervention across these subgroups will be formally assessed using tests for interaction between intervention and subgroup.

3. **CBO and Brothel Based ART Service**

This intervention will aim to make it easier for MSM, *waria*, and FSW to access HIV testing and treatment services by expanding these services into sites at CBOs and brothels. The intervention will be in Yogyakarta.

The intervention is aimed to have two effects. First, it will aim to increase HIV testing and HIV-positive diagnoses. Second, it will aim to make ART uptake easier and quicker.

The effect of the intervention on HIV-positive diagnoses will be evaluated by comparing the number of diagnoses pre and post-intervention using Poisson regression with period duration as exposure. The effect of the intervention on time to starting ART will be assessed using survival analysis methods. The analysis will stratify the post-intervention period into hospital and *puskesmas* sites, and the new CBO and brothel base sites. The hypothesis is that time to ART will decrease in both types of sites in the intervention phase compared with phase I. Hence the effect of this intervention, expanding services to CBOs and brothels, should be able to be evaluated separately from the effect of intervention 2, the simplification of ART services.

4. **SMS Reminders to Increase Treatment Adherence**

This intervention will aim to improve retention on ART and ART adherence. The intervention will be in all key populations and all sites.

The effect of the intervention on retention on ART will be assessed by comparing the proportion of patients who started ART still receiving ART at 12 months. The pre and post-intervention periods will be compared using logistic regression methods.

The effect of the intervention on ART adherence will be assessed in two ways. First, the proportion of patients who started ART with undetectable viral load at 12 months will be compared using logistic regression methods. Second, self-reported adherence will be compared using linear regression methods or non-parametric equivalents.

The intervention will be evaluated overall, across all sites and key populations, and separately within subgroups defined by site and key population. The consistency of the intervention across these subgroups will be formally assessed using tests for interaction between intervention and subgroup.

5. **Motivational Interviewing**

The aim of this intervention will be to increase ART uptake, retention in care and ART adherence in PWIDS in Jakarta and Bandung.

The intervention will be implemented at a subset of the sites in Jakarta and Bandung. Hence the intervention can be assessed by comparing sites with and without the intervention. We believe this is the appropriate way to evaluate this intervention due to the small numbers of PWIDs recruited to HATI in phase I, and some of the changes in sites and eligibility criteria that have been made to increase these numbers.

Time to ART uptake will be compared using survival analysis methods. Retention and care and proportion undetectable viral load compared using logistic regression. Questionnaire data on self-reported adherence and psychological well-being will also be compared between intervention and non-intervention sites using linear regression or non-parametric equivalents.
Increasing capacity of the research staffs, provincial and district health office including ministry of health to understand the data that has been collected, including the analysis that has to be done to provide evidence on effectiveness the intervention that has been done in HATI Study, there is a need to seek the partner that can conduct the data analysis workshop and manuscript training so each site has the capability and be able to produce one research paper to reveal the advantages of the test and treat research.

One of the most critical key components of the training will be done through exercises (practice). Each group will work and analyze the data that has been collected and produce a manuscript on each intervention. To ensure the most relevant and practical discussion, the group materials will use data from all sites. Therefore, an expert with knowledge on understanding research context and data that has been collected is required.

B. Objective
To facilitate participants with the practical skills needed to perform research data analysis and enhance their skill in the use and interpretation of cohort data of HIV early testing and treatment.

C. Outcome
Manuscript and study report for each intervention ready to be submitted to international journal

D. Method
- Workshop in Semarang, Yogyakarta, and Batam. Workshop venue was selected based on coordination with HATI Study team considering value for money.
- Five months mentorship to four sites until manuscript submitted to International Journal. The contractual partner shall be responsive for any consultation (any communication regarding the manuscript should be responded within five days)
- Review and give recommendation for corrective action.

E. Target Audience
- Research staffs
  - Jakarta (3)
  - Yogyakarta (3)
  - Bali (2)
  - Bandung (3)
  - Denpasar (1)
  - Bandung (1)

- Provincial Health Office
  - Jakarta (1)
  - Yogyakarta (1)
  - Bali (1)
  - West Java (1)

- District Health Office
  - Yogyakarta (1)

- Ministry of Health Office
  - Jakarta (2)

- WHO and Field Coordinator of HATI Study
  - Jakarta (2)
  - Yogyakarta (1)
F. Activities & Timeline

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<td>1</td>
<td>Data Management Workshop</td>
<td>April-19</td>
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<td>- cleaning data</td>
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<td>- Understanding the data</td>
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<td>Data Analysis Workshop</td>
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<td>- Survival Analysis</td>
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<td>3</td>
<td>Manuscript Writing Workshop</td>
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<td>- Journal submission</td>
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<tr>
<td>4</td>
<td>Mentoring for Data Analysis and Manuscript Writing</td>
<td>May – Sept 2019</td>
<td>5 months</td>
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G. Technical Report

A technical report covering all aspects of training course, including preparation, learning process as well as the key findings and recommendations to improve HIV data use and programme evaluation in Indonesia. Participants will receive training course certificate and training materials.

H. Budget

The budget will consist of:

1. Trainer/Facilitator for the Workshop
2. Meeting Package for Workshop for 21 participants and additional for trainers and facilitators.
3. Transport (airfare and land transport), daily allowance, accommodation for participants HATI Study team and MOH/PHO/DHO (Jakarta (6), Bandung (5), Bali (4), Yogyakarta (5))
4. Meeting Material

WHO will provide the budget, and consultant will be selected based on suitable expectation and value for money.

Annex 1.
Technical Guideline Document for the Implementation of Phase Two HATI Study in Bandung, Yogyakarta, Denpasar and Jakarta

Annex 2:
Budget Breakdown