Meeting Report

Biregional Expert Consultation on Advancing Implementation Research on HIV/AIDS in Asia

29–30 November 2015

Tokyo, Japan

World Health Organization
Western Pacific Region

WORLD HEALTH ORGANIZATION

REGIONAL OFFICE FOR THE WESTERN PACIFIC

English only

MEETING REPORT

BIREGIONAL EXPERT CONSULTATION ON ADVANCING IMPLEMENTATION RESEARCH ON HIV/AIDS IN ASIA

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Convened by:

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NOTE

The views expressed in this report are those of the participants of the Biregional Expert Consultation on Advancing Implementation Research on HIV/AIDS in Asia and do not necessarily reflect the policies of the conveners.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for Member States in the Region and for those who participated in the Biregional Expert Consultation on Advancing Implementation Research on HIV/AIDS in Asia in Tokyo, Japan during 29–30 November 2015.

CONTENTS

Keywords

Acquired immunodeficiency syndrome / HIV infections / Research / Asia

ACRONYMS

amfAR	The Foundation for AIDS Research
ANRS	French National Agency for Research on AIDS and Viral Hepatitis (English)
ART	antiretroviral therapy
ASI	Addiction Severity Index
AUDIT-C	Alcohol Use Disorders Identification Test
BI	brief intervention
CBO	community-based organization
CBT	cognitive behavioural therapy
CDC	(U.S.) Centers for Disease Control and Prevention
CHTC	couples HIV testing and prevention counselling
DSM	Diagnostic and Statistical Manual of Mental Disorders
FHI	Family Health International
FSW	female sex worker
GMT	gay men, other men who have sex with men and transgender individuals
HATI	The HIV Awal (early) Testing & treatment Indonesia (project)
HBV	hepatitis B virus
HCV	hepatitis C virus
HTC	HIV testing and counselling
ICC	integrated care clinic
IGRA	interferon gamma release assay (for TB)
INSERM	French National Institute for Health and Medical Research (English)
IRIS	immune reconstitution inflammatory syndrome
JHBSPH	Johns Hopkins Bloomberg School of Public Health
MAT	medication-assisted treatment
MDR-TB	multidrug-resistant tuberculosis
MET	motivational enhancement therapy
MMT	methadone maintenance therapy
MOPH	Ministry of Public Health (Thailand)
MSM	men who have sex with men
n-PEP	non-occupational post-exposure prophylaxis
NARI	National AIDS Research Institute (India)
NIAID	National Institute of Allergy and Infectious Diseases (USA)
NIDA	National Institute on Drug Abuse (USA)

NIH	National Institutes of Health (USA)
NIHE	National Institute of Hygiene and Epidemiology (Viet Nam)
NIMH	National Institute of Mental Health (India)
OD	operational district
OLE	open-label extension
PEPFAR	U.S. President's Emergency Plan For AIDS Relief
PI	protease inhibitor
PLHIV	people living with HIV
PrEP	pre-exposure prophylaxis
PWID	people who inject drugs
RAB	Risk Assessment Battery
RCT	randomized controlled trial
STI	sexually transmitted infection
SWING	Service Workers In Group (Foundation)
TasP	Treatment as Prevention
TB	tuberculosis
TG	transgender person
TGW	transgender women
TREAT Asia	Therapeutics Research, Education, and AIDS Training in Asia
TUC	Thailand MOPH–U.S. CDC Collaboration
UGM	Universitas Gadjah Mada (Indonesia)
UNSW	University of New South Wales
US	United States
USAID	United States Agency for International Development
VAAC	Viet Nam Authority for HIV/AIDS Control
VCT	voluntary counselling and testing
VL	viral load
WHO	World Health Organization
WSM	women who have sex with men

EXECUTIVE SUMMARY

The World Health Organization (WHO) revised the 2013 *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* in 2015, recommending immediate treatment for all people living with HIV and pre-exposure prophylaxis (PrEP) for people at high risk of HIV infection. Further strengthening of HIV testing, care and treatment services, and implementation of PrEP are major challenges. To overcome them, implementation research is needed to translate clinical findings into real-world public health systems.

The WHO Regional Offices for the Western Pacific and South-East Asia are committed to expanding the implementation research agenda to support the implementation of HIV programmes as stated in the WHO 2015 interim antiretroviral guidelines. Three consultation meetings on this topic have been convened by WHO since 2012 and resulted in a number of ongoing studies. In 2015, the WHO Regional Offices and the AIDS Clinical Center, National Center for Global Health and Medicine, Tokyo organized an expert consultation meeting on advancing implementation research on HIV/AIDS in Asia, held on 29–30 November 2015 in Tokyo, Japan. The aims of the meeting included updating and expanding a prioritized research agenda to support the implementation of HIV programmes, identifying resources and approaches to support this agenda, and discussing ways to ensure that researchers and national programme managers are better connected, and able to share and access resources to improve national efforts at implementation research.

During the meeting, updates on ongoing studies in Asia, implementation experiences, challenges and new research questions were discussed. Means of HIV prevention during exposure (such as PrEP) and after infection (treatment) were reviewed, basic theories of implementation research were introduced, and methods such as molecular phylogenetics, social science research and health systems research to support implementation of prevention interventions were presented. Research topics discussed included scaling up first-time testing and repeat testing, integrating HIV and tuberculosis sites for testing, and the impact of transition from donor funds to national funds. Key research questions on implementing PrEP were highlighted, such as the cost, indication, timing and duration of PrEP, and identifying standardized methods for discontinuing PrEP. Participants were encouraged to discuss the potential for implementing PrEP demonstration projects, and it was agreed that surveillance measures should be strengthened to include quality data at each stage of the prevention and care cascade. The meeting expanded on earlier discussions about a prioritized research agenda focused on implementation research on HIV.

Countries and partners identified a number of action points. These included supporting the implementation of demonstration projects among men who have sex with men (MSM) and other high-risk groups, and studying the cost–effectiveness of PrEP expansion. Innovative ways of scaling up HIV testing services are also needed. Active case management, unique identifier codes, and viral load measurement to strengthen the HIV treatment cascade merit further evaluation. Integrating HIV and chronic disease service delivery could be a potential way forward. Identifying sustainable funding for HIV services including PrEP, strengthening capacity for generating HIV treatment cascades not only at the national level but also at subnational level, compiling HIV-related data from countries, extending existing platforms for sharing information, facilitating collaboration, and building local research capacity are additional actions that will be needed to support programmes in countries.

1. INTRODUCTION

In 2015, the World Health Organization (WHO) revised the 2013 *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* to include two key recommendations *(1, 2)*. First, initiate antiretroviral therapy (ART) for all people living with HIV at any CD4 cell count. Second, people at substantial risk of HIV infection are recommended to use daily oral pre-exposure prophylaxis (PrEP) as part of combination prevention approaches. In addition, in July 2015, the *Consolidated guidelines on HIV testing services (3)* were launched. These guidelines encourage scaling up of quality HIV testing services (HTS) in a variety of settings to achieve the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90–90–90 targets *(4)*. HIV-related morbidity, mortality and incidence should decline if the new guidelines are fully implemented.

However, significant leakages along the cascade of HIV care were reported in many countries in the Asia–Pacific region, even though most of them have adopted or are adopting the recommendations of the WHO 2013 *Consolidated guidelines on the use of antiretroviral drugs (1)*. Substantial challenges have been faced during the implementation of HIV testing and treatment programmes. Implementation research is needed to identify problems, pilot new interventions to inform introduction and scale up, and assess the effectiveness and feasibility of new policies. HIV implementation research projects have started in Australia, Cambodia, China, India, Indonesia, Mongolia, Thailand and Viet Nam, focusing on early diagnosis and treatment among key populations. An ongoing dialogue between policy-makers and researchers to enhance the use of implementation research could help address the stagnating number of new HIV infections and deaths overall and the sharp increase in new infections among key populations during the past eight years. Implementation research that focuses on scaling up PrEP and HTS, and improving the treatment cascade is urgently needed in the region. Some studies have started in Thailand, a relatively well-resourced setting.

The "Biregional Expert Consultation on Advancing Implementation Research on HIV/AIDS in Asia" was organized by the WHO Regional Offices for South-East Asia and the Western Pacific, and the AIDS Clinical Center, National Center for Global Health and Medicine (NCGM), Tokyo, Japan during 29–30 November 2015.

1.1 Meeting organization

The "Biregional Expert Consultation on Advancing Implementation Research on HIV/AIDS in Asia" was organized by the WHO Regional Offices for South-East Asia and the Western Pacific, and the AIDS Clinical Center, National Center for Global Health and Medicine (NCGM), Tokyo, Japan during 29–30 November 2015. The meeting was attended by 63 participants from 14 countries. It was held in conjunction with the 29th Annual Meeting of the Japanese Society for AIDS Research, 23 November to 1 December 2015 in Tokyo, Japan..

1.2 Meeting objectives

The objectives of the meeting were:

1) to update and expand a prioritized research agenda to support implementation of HIV programmes;
2) to identify resources and approaches to support the research agenda; and
3) to discuss ways to ensure that researchers and national programme managers are better connected, and able to share and access resources to improve national research efforts.

2. PROCEEDINGS

2.1 Regional situation of the HIV epidemic in the Asia–Pacific region

Based on the Global AIDS Response Progress Reporting of UNAIDS *(5)*, there were 4.9 million people living with HIV in Asia and the Pacific region in 2014. Of these people, about 74% were in three countries: India (43%), China (17%) and Indonesia (14%). In addition, an estimated 321 000 new HIV infections occurred in 2014 (Fig. 1). There was no decline in new HIV infections since 2007, even though there was an overall decline compared to 2001. This contrasts with the trends in sub-Saharan Africa, where the estimated incidence and number of new adult HIV infections continued to decline since 2007[1]. In most countries in the Asia–Pacific, HIV is concentrated among key populations, including men who have sex with men (MSM), transgender people, sex workers, and people who inject drugs (PWID) *(6)*. Further, with the increase in HIV testing in some communities (e.g. MSM in China), an increasing number of new cases were identified, suggesting that HIV testing rates among key populations are very low. The failure to diagnose people with HIV is the most critical barrier for the prevention and control of HIV in this region *(7)*. Effective intervention programmes are urgently needed to further expand HIV testing.

In 2015, WHO released an updated treatment guideline, moving HIV into the era of universal treatment *(8)*. Some countries have started to change their national guidelines by adopting the 2015 WHO interim antiretroviral (ARV) guidelines. However, in 2014, only 36% of 4.9 million people living with HIV in the Asia–Pacific region were receiving ART *(5)*, which is far short of the UNAIDS 90–90–90 targets and lower than that in South and East Africa (47%)[2]. WHO is developing a global health sector strategy for moving from HIV prevention and control to elimination. However, how elimination will be operationalized and measured remains unclear. Amid shifting donor priorities and decreased international support for HIV services, implementation research in the region is necessary to help inform countries how to achieve these ambitious goals and targets.

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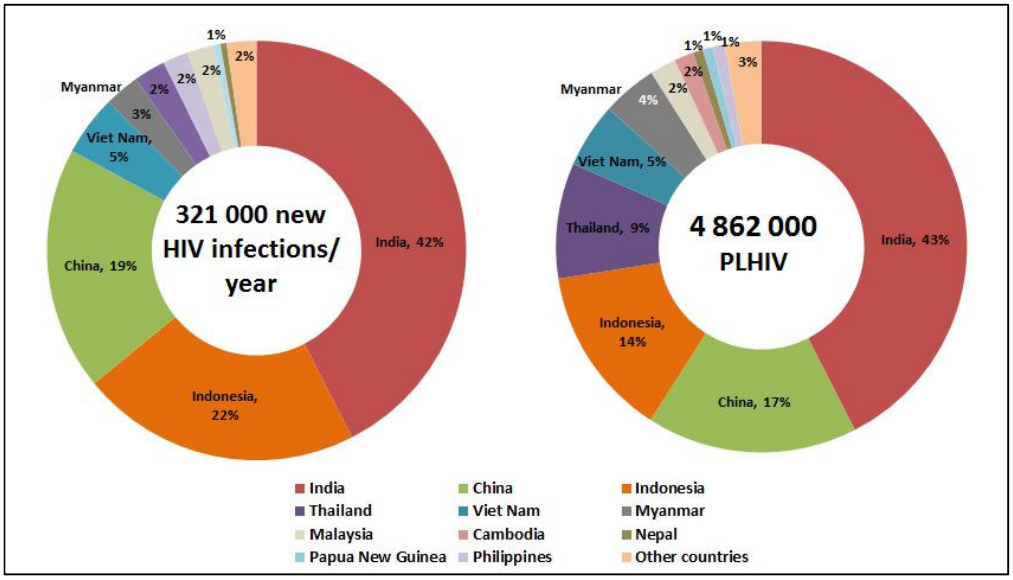
[1] HIV estimates with uncertainty bounds 1990–2014.

(http://www.unaids.org/en/resources/documents/2015/HIV_estimates_with_uncertainty_bounds_1990-2014 , accessed 11 February 2016)

[2] AIDS Info (http://aidsinfo.unaids.org/, accessed 11 February 2016).

Fig. 1. Estimated number of people living with HIV and new infections by selected high HIV burden countries, Asia and the Pacific, 2014



Source: Global AIDS Response Progress Reporting 2015*(5)*

2.2 Implementation research and improving the HIV treatment cascade

When implemented in a real-world context, optimizing HIV prevention, treatment programmes, PrEP and related services poses a huge challenge *(9)*. To meet this challenge, implementation research is urgently needed, particularly in resource-limited settings *(10)*. The basic intent of implementation research is to understand not only what is and is not working, but also how and why implementation is going as planned or not, and iteratively testing interventions to improve them. In this meeting, the definition, principles, measures and methods of implementation research were discussed, and successful examples of implementation research conducted in the Asia–Pacific region were presented.

Implementation research is a multidisciplinary field that seeks generalizable knowledge about the behaviour of stakeholders, organizations, communities and individuals to understand the magnitude, reasons for and strategies to close the gap between evidence and routine practice for health in real-world contexts *(11)*. By using the research disciplines of epidemiology, biostatistics, health policy and health economics, implementation research identifies, develops and measures the impact of innovative strategies to close the "research-to-policy" gaps and "research-to-programme" gaps *(11, 12)*. Specifically, implementation research – including impact evaluation – can be conducted to identify and solve problems in a timely fashion, inform policy-makers and implementers to make evidence-based programme decisions, and improve programme quality and performance using scientific methods.

Besides answering questions on what is and is not working, implementation research can also help implementers foresee and anticipate problems and, in turn, answer questions on how to deliver interventions effectively *(13)*. To inform the implementation of health policies and programmes, and to ensure that needed interventions are made widely available within health systems through effective scaling up, WHO released its guideline on *Implementation research in health (13)*. This guideline may facilitate and scale up implementation research on HIV in Asia, and achieve the goal of HIV control and ultimately elimination.

Implementation research measures the acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration and sustainability of a programme. There is a range of trial designs, from explanatory to pragmatic: (i) explanatory (traditional gold standard, not implementation research),

which is used to understand and explain the benefit of an intervention under controlled conditions, and maximize internal validity; (ii) adaptive designs (one form of implementation research) that include potential predetermined changes and an attempt to balance internal and external validity; and (iii) pragmatic trials (another form of implementation research), which focus on the intervention in routine practice, maximizing the variability in how a programme is implemented, and maximizing external validity.

The stepped-wedge design is another implementation research method that has become common in recent years. This design allows staggered introduction of a new intervention, randomizing the timing of introduction in multiple communities. Publications resulting from stepped-wedge design studies have increased markedly in recent years.

Standard measures should be used when reporting implementation research projects. A form of such measures has been published and may be helpful for groups organizing implementation research *(14)*.

To enhance the response to HIV/AIDS and improve the efficacy of prevention studies, several key research questions for future implementation research in the Asia–Pacific region need to be answered. Some of them are listed in Table 1.

Table 1. Key research questions for future implementation research in the Asia–Pacific region

Cascade step	Key research questions/topics	
Prevention	**PrEP**	The management of PrEP (spacing visits, cost, demand creation by clients and providers, minimum service package)
		How to use crowdsourcing and innovation contests to improve PrEP uptake
		Community and facility-based PrEP
		Cost of PrEP and different strategies for co-payment
		Indication, timing, and duration of PrEP
		Standardized methods for stopping PrEP
		Influence of PrEP roll-out on condomless sex, STI transmission and HIV acquisition
		Will routine PrEP implementation lead to an increase in STIs and genital inflammation that could inadvertently offset the HIV prevention benefits of PrEP?
		Ruling out acute HIV infection before administering PrEP
		Metrics for evaluating PrEP and their integration with continuum-of-care metrics
Screening and diagnosis	**Lay provider rapid HIV testing**	The minimum package of training (counselling, sample collection, testing) for the lay provider to implement quality HTS
		Assurance of HTS quality by the lay provider
		Willingness of clients to pay for HTS
	Innovative strategies to increase uptake of HIV testing	Strategies to encourage key populations to access HTS
		Effectiveness of media/dating sites and mobile phone technologies
		Self-testing, home testing and internet-based testing, including willingness to pay
		Community-based testing approaches for key populations
		Strategies for linking those with a positive self-test to the nearest testing centre
		How to best reach “hard-to-reach” high-risk populations, e.g. MSM, PWID, sex workers
		How do we better engage first-time testers?

Cascade step	Key research questions/topics	
		How to enhance partner services (e.g. notification, testing)
		Will offering STI testing increase HTS uptake? Can STI testing be the entry point for HTS (and vice versa)?
		How frequently do people need to be tested among subpopulations, delineated by risk behaviour, key population or other standard?
		What are appropriate/effective forms of HTS incentives? (financial vs non-financial; patient/client vs referring individual; participation in innovation contests)
		How to use crowdsourcing and innovation contests to improve HIV testing uptake
		Integration between HIV, TB and maternal care sites for HIV testing
		Can the private health-care sector (e.g. pharmacists) supplement HTS? How would this impact the health-care costs?
Enrolment in care	**Strategy to increase uptake of care and treatment**	Does community-based testing and immediate referral to an ART centre on the first positive test increase the uptake of ART?
	Laboratory assessment	What is the impact of removing the necessity to test for CD4 count as a prerequisite to enrolling in ART programmes?
	Opportunistic infections	How to enhance integrated care for those seeking TB or HIV or drug dependence treatment
Treatment	**Treatment uptake and retention**	Does integrating testing and treatment + laboratory testing (e.g. CD4 count, TB, hepatitis B/C, etc.) at primary health-care facilities facilitate early uptake of and retention in treatment?
		Strategies to engage families and strengthen social support systems to improve uptake of and adherence to immediate ART
		Interventions to increase adherence among populations for whom adherence is a particular challenge, e.g. adolescents
		Will reducing the frequency of health-care contacts improve long-term retention? Does this vary by population?
		How do we improve/integrate treatment services within health systems?
		How does task-shifting impact treatment uptake and retention? (from specialist to primary care provider; doctor to nurse; professional to lay provider; community-based ART distribution)
		How do we better focus resources on those who need more support for adherence and retention?
		Does parallel linkage to opioid substitution therapy or harm reduction improve ART uptake and retention among people who use drugs?
		In what settings/populations should we promote community-led provision of ART?
		In the context of decreasing external funding and increasing domestic funding, what will be the impact of provider and payer transitions on treatment interruption?

Cascade step	Key research questions/topics	
		Change of care and adherence of patients during the transition from adolescence to adult
	HIV drug resistance (HIVDR)	How will retention in the context of early ART impact the incidence and prevalence of HIVDR (pretreatment/acquired HIVDR)?
		Mathematical models to assess how frequently HIVDR surveys should be carried out in resource-limited settings
		Utility and predictability of early warning indicators (EWIs) for HIVDR surveillance
		What is the most cost–effective – monitoring multiple EWIs for HIVDR or implementing viral load (VL) monitoring with/without resistance surveys?
		Assess the utility of routine data for HIVDR or case surveillance in low and concentrated epidemics
Outcome	**Treatment outcome**	Does decentralization of novel point-of-care VL tests (e.g. GeneXpert machines at primary health clinics) improve the uptake of VL testing?
		Can the use of dried blood spots for blood specimen collection improve access to and quality of VL monitoring?
		How can we raise patients' awareness on the importance of VL monitoring?
		What is the impact of VL estimation on patient adherence and retention?
		How can we optimize VL tests and implementation of testing in our contexts?
	Implementation research outcome	Type of surveillance and routine programme data needed for outcome evaluation
	Surveillance	Phylogenetic analysis as a new method for measuring incidence
Others	**Strategic information**	Use of unique identifier codes to transform programme data into cohort data to track patients across the continuum/cascade
		Need a way to transform programme data into cohort data to track patients across the continuum/cascade (e.g. unique identifier codes, master patient index, mother tracking system)
		How to best integrate HIV treatment data with TB, PPTCT and laboratory services?
	Addressing cascade gaps	Determine how HIV health systems integration can improve HIV service delivery along the cascade
	Funding	What are the impacts of shifting donor funds to national funds on HIV service delivery?

ART: antiretroviral therapy; HIVDR: HIV drug resistance; HTS: HIV testing services; PPTCT: prevention of parent-to-child transmission; PrEP: pre-exposure prophylaxis; STI: sexually transmitted infection; TB: tuberculosis; VL: viral load.

2.3 Ongoing research on test and treat

Policy-makers and researchers from China, India, Indonesia, Japan (for projects in Mongolia), Thailand, Viet Nam and the United States of America discussed their ongoing or planned implementation research projects (Annex 3).

One of the largest test-and-treat studies in the region demonstrated that early ART was associated with decreased mortality among MSM in China *(15)*. Other pilot data from the Chinese MSM crowdsourcing studies *(16, 17)* and one Thai MSM/transgender persons test-and-treat study *(18)* highlighted that community engagement before implementation of HIV programmes is a key strategy for the success of these programmes (Annex 3). A pilot test-and-treat study was conducted in 2012–2015 among 810 MSM and transgender women in Bangkok, Ubonratchathani, Lampang and Mahasarakam. HIV testing with same-day results was provided at baseline and every 6 months for 2 years for HIV-negative participants. Immediate ART was offered to all HIV-positive participants. In 2015, a community-based test-and-treat study was started in six community-based organizations (CBOs) in Bangkok, Pattaya, Chiang Mai and Hat Yai, which aimed at enrolling 6000 MSM and transgender women for 1.5 years of follow up. A parallel facility-based test-and-treat study also started at the same time, which planned to enrol 2000 MSM and transgender women through five hospitals in Bangkok, Pathumthani, Khon Khaen and Udonthani.

The purpose of smaller studies in Viet Nam is to inform national guidelines and policies, such as a pilot project conducted by the Vietnam Authority of HIV/AIDS Control (VAAC) with the support of WHO to assess the feasibility and durability of couples HIV testing and counselling, and immediate ART for serodiscordant couples in Dien Bien and Can Tho provinces. Another study assessed the feasibility and acceptability of periodic HIV testing and immediate ART among PWID in Thai Nguyen and Thanh Hoa provinces. A pilot project to decentralize HIV testing is ongoing. Preliminary results show that immediate treatment among key populations is feasible, irrespective of population and geographical area, and decentralization can enhance the uptake of early HIV testing and immediate treatment *(19)*. Preliminary results have informed revision of the national treatment guidelines in 2015.

The importance of improved uptake of testing for the success of test-and-treat interventions was particularly emphasized during the discussions. Implementation research is needed to identify best testing strategies in low-prevalence settings, engage the private sector in monitoring the HIV cascade of care, and move towards task-shifting and community-based models. There is a need for (i) better methods/assays to measure HIV incidence at a population level, and (ii) innovative strategies to create a demand for HIV testing among key populations.

During the meeting, the final results of the HPTN 052 study were presented *(20)* showing a 93% reduction in the earlier treatment arm compared to the standard treatment arm.

2.4 Strengthening the cascade of HIV testing, care and treatment services

A number of ongoing studies on HIV testing conducted in Asia, especially among key populations, were presented and discussed (*see* Annex 3). These studies were divided into two groups: studies focusing on scaling up HTS, and studies focusing on improving linkages to care.

2.4.1 Scaling up HIV testing services

An online test-and-treat study on 600 MSM and transgender women began in Bangkok and Pattaya in late 2015. There are three different arms: (i) conventional offline HIV testing at the clinic; (ii) combined online counselling with offline HIV testing; and (iii) online, supervised, blood-based HIV self-testing through real-time video chatting platform with a counsellor (*see* Annex 3). Another oral fluid HIV testing study is in the development phase. Participants can select to participate in any of the three different arms: (i) peer-mediated oral fluid testing on participants during outreach; (ii) oral fluid self-testing accessed by providing a test kit to participants; and (iii) referral to a CBO for conventional blood-based HIV testing.

In Guangzhou, China, an ongoing study supported by the US National Institutes of Health (NIH NIAID 1R01AI114310) will test crowdsourcing as a means to expand HIV testing and linkage to care among MSM. In addition, to collect preliminary data for the study, a pilot randomized controlled trial was conducted in 2014 among MSM and transgender persons. Multiple screening strategies, including home testing, are also in progress in China. For instance, by collaborating with a local CBO in

Guangzhou, the Centers for Disease Control and Prevention (CDC) has built a social entrepreneurship model to promote HIV self-testing and linkage to care among Chinese MSM by providing HIV self-testing kits online.

In summary, some countries have applied implementation research and methods of social science research in their studies to increase access to and uptake of HTS for key populations, linkages to care and treatment, and PrEP. Some countries have piloted HTS by lay providers. Several concerns were identified during the implementation of HIV testing models and approaches. These included, but were not limited to, scaling up first-time testing and repeat testing, and the way to integrate HIV and TB sites for testing. More implementation research for HTS is needed to overcome these challenges.

2.4.2 Improving linkage to care

An MSM cohort study (2013–2015) in Mongolia was conducted collaboratively by Together Center Youth for Health Center and Human Right Health Support Center, National Centre for Communicable Diseases (NCCD), Hepatitis Center of NCGM, and AIDS Clinical Center of NCGM (*see* Annex 3). The study used a treat-all strategy as an intervention in Mongolia. The finger vein authentication system was used for data management and participants were tested for HIV, hepatitis B, hepatitis C and syphilis by *Treponema pallidum* haemagglutination assay (TPHA). Phylogenetic analysis was performed to identify the clusters and illustrate the possible spread of HIV in clusters. Early data suggest that a treat-all strategy is associated with a decrease in the incidence of HIV.

Thailand has conducted a pilot project on improving linkage to care. They compared linkage to care rates among those initially tested at hospitals and those initially tested in the community (e.g. bars, saunas and entertainment venues). Unique identifier codes have been developed for integrating study data with the national data system. It is useful for monitoring enrolment and retention along the cascade of HIV care over time *(21)*.

TREAT Asia will conduct a two-year pilot study focused on studying the transition between adolescent and adult HIV care in Thailand and Malaysia in early 2016. The study aims to evaluate transition outcomes and identify weaknesses in the process that could be improved with social, operational and clinical interventions (Annex 3).

In summary, a number of countries presented implementation research for improving the cascade of care. Concerns on the possible impact of shifting from donor funds to national funds on HIV service delivery were raised. Nonetheless, it is encouraging to know that these studies have applied methods of molecular phylogenetics and unique identifier codes. Historical examples suggest that in cases where the research questions have been discussed from the onset with national programmes, the chances are higher that the study results would inform the national guidelines *(22, 23)*.

2.5 Pre-exposure prophylaxis demonstration project

Introduction of PrEP among key populations in the Asia–Pacific region is needed in view of the high incidence of HIV among MSM and in line with the recommendation in the WHO 2014 *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations (6)*. To promote the implementation of PrEP in the Asia–Pacific region, this meeting provided a brief overview of completed PrEP studies, discussed the potential of implementation research to answer questions related to the introduction of and increase in uptake of PrEP, and potential outcomes and study designs of future PrEP demonstration projects.

Several PrEP studies are ongoing and planned in Asia (BTS, iPrex, HPTN 067), notably in India and Thailand (*see* section 3.4 and Annex 3). The India PrEP study is in the design phase and therefore not included in Annex 3. In Thailand, a PrEP substudy of the aforementioned two ongoing test-and-treat studies commenced in 2015, which administered daily tenofovir and emtricitabine to 300 participants in four CBOs in Bangkok and Pattaya, and 300 participants in two hospitals in Bangkok and Pathumthani. In addition, the Princess PrEP Project was launched in January 2016 to accelerate PrEP roll out for 3000 MSM and transgender women over three years through seven CBOs using a community-led PrEP service delivery model (*see* Annex 3).

Previous studies have demonstrated that the effectiveness of PrEP depends on adherence. New prevention research in the pipeline, which addresses adherence issues, was introduced; for example, studies on tenofovir gel, monthly vaginal ring, long-acting PrEP (i.e. injectable GSK126744) and broad neutralizing antibodies. For long-acting PrEP, a phase 2b/3 double-blind, safety and efficacy study of quarterly injectable GSK126744 in HIV-uninfected MSM and transgender women (HPTN083) is pending, and a number of Asian sites are keen to participate.

To enhance the effectiveness of PrEP, multiple levels of barriers to routine PrEP implementation (regulatory, pricing, doctor, patient) need to be considered and addressed. Involving CBOs in PrEP implementation is a key method of dealing with these barriers.

Studies that focus on the indication, timing and duration of PrEP among partners of HIV-infected persons are needed. In addition, social science studies should pay attention to physicians' barriers and facilitators to PrEP prescription. Studies that focus on the cost–effectiveness of PrEP, identification of standardized methods for stopping PrEP, effect of incident STI, risk compensation, and universal test and treat on the real-world effectiveness of PrEP are also needed. From an implementation perspective, creating a demand for PrEP (raising awareness among primary-care doctors/key populations/general population; incentive and other behavioural economic strategies), and interventions to improve adherence are lacking. For example, SMS reminders and smartphone-based applications can be used to increase the adherence to PrEP. Formative research could assess ways of community engagement with CBOs, asking doctors about their level of knowledge on PrEP, and conducting research on how options for financing PrEP (e.g. optimal sliding scale) and the optimal PrEP package of services could help inform introduction of PrEP services.

PrEP pilot/demonstration projects targeting key populations, different models of co-payment and cost–effectiveness analyses are needed for ministries of health to consider introduction of PrEP. In addition, implementation research on demand creation for PrEP (social media and in-person campaigns) and pilots on PrEP among partners of HIV-infected individuals in countries such as China were suggested. Discussions about potential PrEP pilots among MSM have started among CBOs in Ho Chi Minh City, Kuala Lumpur and Manila. However, concerns are paramount about the low coverage of HIV prevention programmes for MSM, regulatory issues and sustainability.

2.6 Using routine surveillance and programme monitoring data and phylogeny to evaluate outcomes

The meeting first discussed the existing indicators/data in routine surveillance systems, including but not limited to the following:

- *In the sentinel surveillance system:* sociodemographics (age, marital status, residence and educational level), behaviour (anal/commercial sex with men, vaginal sex with women and frequency of condom use during these sexual acts, lifetime history of injecting drugs), HIV-related knowledge, and HIV, syphilis and hepatitis C status;
- *In the case report system:* sociodemographics, residential address of case reported, behaviours, possible routes of transmission, whether tested for CD4 count and VL, number of days from diagnosis to first CD4 testing, and CD4 and VL measurements after diagnosis;
- *In the treatment system:* sociodemographics, residential address of case reported if different from the registered address, registered place of residence, risk behaviours, treatment history, routes of transmission, clinical stage (based on WHO classification) at diagnosis, CD4 count and VL measurement at baseline, and frequency of CD4 and VL testing at each follow up, date of treatment initiation, regimen, the time and reason of loss to follow up and death.

The meeting suggested that the following new indicators/data need to be included in or linked with the surveillance system:

- Indicators to monitor and evaluate the HIV treatment cascade: need for denominators at each stage of the cascade(s), particularly the estimated number of people living with HIV at the national and subnational levels, in the overall population and each key population group;

- HIVDR EWI and quality-of-care indicators;
- Indicators to monitor and evaluate the impact of implementing universal treatment (coverage, delay to ART initiation, adherence and loss to follow up) and eventually its impact on the epidemic (for example, number of recently infected people as a proxy for incidence);
- Indicators to monitor and evaluate the implementation and impact of PrEP (e.g. behavioural data, transmission in serodiscordant couples);
- Collecting behavioural data to support PrEP.

The subject of HIV phylogenetic analysis was introduced and discussed during the meeting. It was emphasized how phylogenetic analysis has played a crucial role in increasing our understanding of the dynamics of HIV transmission, including the zoonotic origin of the virus, and the dissemination of viral subtypes across the globe. Phylogenetic analysis also played a key role during epidemic outbreaks among MSM and PWID. Also discussed were the role of disease stage in transmission dynamics and underlying trends in regional epidemics, as well as targeting strategies for prevention interventions to control ongoing transmission (e.g. Rakai community in Uganda). Besides these research applications, phylogenetic analysis can be used in conjunction with cross-sectional incidence testing for the following:

- to identify and investigate unexpected HIV clusters;
- to provide early warning about HIV outbreaks or among recent infections to detect hotspots of transmission;
- to generate new insights into HIV transmission dynamics in generalized epidemics;
- to provide a potential new approach for the evaluation of transmission interventions;
- to evaluate hotspots and frequent transmitters in order to more effectively intervene early in new epidemics (as in the Mongolia MSM study).

Some countries routinely collect data for phylogenetic analysis when testing for HIVDR, as both DR and phylogenetic analysis use similar gene sequences of HIV. For phylogenetic analysis, these sequence data are widely available within global databases, and can be used to monitor the geographical dynamics of HIV transmission. For example, in Uganda, these data have been used to track the role of migration on HIV transmission within and outside the region. In Mongolia, an MSM cohort study has applied molecular phylogenetic analysis to evaluate the effectiveness of a treat-all strategy. Even if scaling up VL testing remains a priority, the meeting participants recommended that WHO could help facilitate capacity-building for phylogenetic analysis in specific situations in the Asia–Pacific region through institutional collaboration.

2.7 Partnership, collaboration and capacity development for implementation research

The value of implementation research was presented along with specific regional partnerships. Expertise and technical support from several groups/institutes is available, including but not limited to the following:

- The Thai Red Cross, and SEARCH, Bangkok, Thailand
- Kirby Institute, University of New South Wales, Australia
- NCGM, Japan and other academic institutions in Japan
- Pasteur Institute, Cambodia and Viet Nam
- TREAT Asia/American Foundation for AIDS Research (amfAR), Thailand
- University of North Carolina and its STD Research Training Project in China.

To ensure capacity building in the region, studies are conducted by horizontal collaboration. For instance, the Thai test-and-treat study in Thailand is collaboratively conducted by the Thai Red Cross, Ministry of Public Health, Thailand, U.S. CDC, United States Agency for International Development (USAID) and WHO (Annex 3). The Mongolia MSM treatment – a prevention cohort study – is a collaborative effort between Mongolia and Japan (Annex 3). Utilizing implementation research to

answer questions of national AIDS programmes to inform national guidelines and policy development has been successful in many countries such as India, Malaysia, Thailand and Viet Nam.

3.8 Group work

Group discussions were held among policy-makers and researchers in the region on three main aspects: (i) ARV PrEP demonstration projects; (ii) improving the treatment cascade; and (iii) use of routine surveillance and programme monitoring data and phylogeny to evaluate outcomes. Each country introduced their ongoing studies of scaling up HTS and treatment coverage. Based on the table of research questions prepared at the 2014 meeting, a number of key research questions were updated (Table 1). The main findings were incorporated into sessions 3.4–3.6 and 4.2.

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

In 2015, WHO released the Consolidated guidelines on the use of antiretroviral therapy for treating and preventing HIV infection (2), and moving HIV treatment to the era of universal testing and treatment. To address the stagnating number of new HIV infections and deaths and the sharp increase of new infections among key populations in past years , implementation research that focuses on scaling up PrEP and HIV testing services, and improving the cascade of care are urgently needed in the Region. This is especially true in the context of decreases in international funding. To evaluate the effectiveness of PrEP and treat-all, routine data collection across the care continuum is needed.

Implementation research helps address challenges by identifying innovative interventions and approaches to improve service delivery and efficiency and reduce cost. Implementation science measures the acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration and sustainability of studies. Asian sites will be increasingly engaged in HIV prevention and treatment trials which could help in building local research capacity.

For example, Continued informal partnership with Asian researchers and policy-makers was established in 2012 in the context of test and treat implementation research. The Asia HIV research network managed by National Center for Global Health and Medicine (NCGM) from 2010 to 2013 and the Japan-US HIV research collaboration could further expand networks such as at the Thai Red Cross, SEARCH, TREAT Asia and the Clinical Trials Units supported by the U.S. NIH.

3.2 Recommendations

Recommendations for WHO and partners

- Prioritize identified research questions further and share these with policy-makers, programme managers and researchers from Member States and supporting partners.
- Continue discussions with countries on applying implementation research to monitor and evaluate the implementation of WHO guidelines for improving programmes and service delivery, and ending AIDS.
- Promote the concept of and support capacity-building on implementation research to improve HIV programmes in Asian countries.
- Engage with national and external donors to address identified research questions.

The following priority actions were identified:

PrEP

1) Countries and partners to implement demonstration projects among MSM and other high-risk groups according to the WHO interim guidelines;
2) Countries and partners to undertake cost–effectiveness analyses focused on expanding PrEP;
3) WHO and countries to work together to identify sustainable funding for PrEP.

HIV treatment cascade

4) Countries and partners to identify ways of scaling up HTS in accordance with the 2015 WHO HIV testing services guidelines (3) and ensure linkages from diagnosis to treatment and achieve VL suppression;
5) Countries and partners to evaluate the use of unique identifier codes to build cohort databases to monitor and evaluate the treatment cascade;
6) Countries and partners to assess models of integrated HIV service delivery with other chronic diseases and TB, and evaluate "active case management" to maximize retention across the treatment cascade.

Surveillance

7) Countries and partners to enhance routine data collection across the continuum of care (including PrEP), drawing on all health service delivery systems and triangulating where possible;
8) WHO to work with countries to strengthen the capacity for generating subnational cascades;
9) WHO to work with countries to compile data from countries on information technology platforms used to collect, store and maintain HIV-related information.

Communication and capacity-building

10) WHO to extend existing platforms to share information across countries and facilitate collaboration between researchers, implementers and policy-makers;
11) Academic institutions to build and strengthen research capacity in countries through collaboration, experience sharing and related measures.

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ANNEXES

Annex 1: Programme

Day 1 – Sunday, 29 November 2015

TIME	TOPIC	PRESENTER
08:00–08:30	**REGISTRATION**	
08:30–09:00	**OPENING SESSION** WHO REGIONAL OFFICE FOR THE WESTERN PACIFIC REPRESENTATIVE FROM MINISTRY OF HEALTH JAPAN National Center for Global Health and Medicine *GROUP PHOTO*	SHIN YOUNG-SOO, REGIONAL DIRECTOR, *WHO REGIONAL OFFICE FOR THE WESTERN PACIFIC, TO BE DELIVERED BY YING-RU LO* Ministry of Health Japan SHINICHI OKA, DIRECTOR, *AIDS CLINICAL CENTER, NCGM*
09:00–09:20	OBJECTIVES OF THE MEETING INTRODUCTION OF PARTICIPANTS	YING-RU LO *WHO REGIONAL OFFICE FOR THE WESTERN PACIFIC*
09:20–09:45	*COFFEE/TEA BREAK*	
09:45–10:00	IMPLEMENTATION RESEARCH IN ASIA (2012–2015)	YING-RU LO *WHO REGIONAL OFFICE FOR THE WESTERN PACIFIC*
10:00–10:30	WHAT RESEARCH IS IN THE PIPELINE AND WHAT ARE POTENTIAL QUESTIONS REQUIRING IMPLEMENTATION RESEARCH?	MYRON COHEN, *UNIVERSITY OF NORTH CAROLINA/NIH*
10:30–11:30	IMPLEMENTATION RESEARCH IN HIV: A PRIMER UTILIZATION OF MOLECULAR PHYLOGENETICS IN ASSESSING HIV PREVENTION INTERVENTIONS	STEFAN BARAL *JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH* THOMAS QUINN *JOHNS HOPKINS CENTER FOR GLOBAL HEALTH*
11:30–12:30	SOCIAL SCIENCES RESEARCH TO INFORM HIV PROGRAMMES AND POLICY	JOSEPH TUCKER *SOUTH CHINA-UNC STI*

TIME	TOPIC	PRESENTER
		RESEARCH TRAINING CENTER
	HEALTH SYSTEMS RESEARCH FOR INTEGRATING DISEASE PROGRAMMES IN HEALTH SYSTEMS	ABDUL GHAFFAR *ALLIANCE FOR HEALTH POLICY AND SYSTEMS RESEARCH*
	DISCUSSION	
12:30–13:30	*LUNCH BREAK*	
13:30–14:45	**WORKING GROUPS** *RESEARCH AGENDA AND METHODS TO SUPPORT HIV PROGRAMME IMPROVEMENT* IN ASIA	FACILITATORS
	1. ANTIRETROVIRAL PRE-EXPOSURE PROPHYLAXIS DEMONSTRATION PROJECTS	SUWAT CHARIYALERTSAK MICHAEL MARTIN PRAPHAN PHANUPHAK
	2. IMPROVING THE TREATMENT CASCADE	DAVID COOPER ADEEBA KAMARULZAMAN RAMAN GANGAKHEDKAR STEFAN BARAL BOUNPHENG PHILAVONG WILLIAM MILLER
	3. USE OF ROUTINE SURVEILLANCE AND PROGRAMME MONITORING DATA AND PHYLOGENY TO EVALUATE OUTCOMES	
14:45–15:00	*COFFEE/TEA BREAK*	
15:00–16:00	GROUP WORK CONTINUED	

Day 2 – Monday, 30 November 2015

TIME	TOPIC	PRESENTER
08:30–10:00	FEEDBACK FROM GROUP WORK (10' EACH PRESENTATION)	Joseph Tucker Annette Sohn Weiming Tang
	PANEL DISCUSSION ON GROUP WORK PRESENTATIONS	EMILY ERBELDING, *NIAID, U.S. NIH* PRAPHAN PHANUPHAK, *SEARCH AND INFORM ASIA* MICHAEL CASSEL, *USAID REGIONAL MISSION*

TIME	TOPIC	PRESENTER
		TRISTA BINGHAM, *CDC PEPFAR* ANNETTE SOHN, *TREAT ASIA*
10:00–10:30	FEEDBACK FROM GROUP WORK	
10:30–11:30	OPEN SESSION BETWEEN COUNTRIES AND ACADEMIC INSTITUTIONS TO DISCUSS FUTURE COLLABORATIONS	
11:45–12:00	CONCLUSIONS AND NEXT STEPS	YING-RU LO, *WHO REGIONAL OFFICE FOR THE WESTERN PACIFIC* RAZIA PENDSE, *WHO REGIONAL OFFICE FOR SOUTH-EAST ASIA*
12:00–13:20	*LUNCH BREAK*	

Annex 2: List of participants

1. TEMPORARY ADVISERS

AUSTRALIA

David COOPER, Director, The Kirby Institute, Wallace Wurth Building, Sydney NSW 2052. Tel: (61) 2 9385 0900, Email: dcooper@kirby.unsw.edu.au

CAMBODIA

Chhorvann CHHEA, Director, National Institute of Public Health, #2, St 289, Toul Kork, Phnom Penh. Tel: (855) 12 503 844, Email: cchhorvann@niph.org.kh

Penh Sun LY, Director, National Center for HIV/AIDS, Dermatology and STDs Control, #103, ST 19, Sk Phsa Kandal II, Kh. Daun Penh, Phnom Penh. Tel: (855) 12 850 053, Email: penhsun@nchads.org

CHINA

Jie SHEN, Deputy Director and Secretary General, Chinese Association of STD/AIDS Prevention and Control, Room 405, No 27 Nanwei Road, Xicheng District, Beijing. Tel: (86) 10 6303 7405/13910762236, Email: ngoshenj@126.com

Jiangping SUN, Deputy Director, National Center for AIDS/STD Control, Chinese Center for Disease Control and Prevention, No. 155 Changbai Road, Changping District, Beijing. Tel: (86) 10 5890 0907, Email: jpsun@chinaaids.cn

Joseph D. TUCKER, Director, University of North Carolina Project-China, Assistant Professor of Medicine, UNC Chapel Hill Institute for Global Health & Infectious Diseases, Number 2 Lujing Road, Guangzhou. Tel: (86) 13 5602 94997, Email: jdtucker@med.unc.edu

HONG KONG (CHINA)

William WONG, Clinical Associate Professor and Chief of Research, Department of Family Medicine and Primary Care, The University of Hong Kong, 3rd Floor, Ap Lei Chau Clinic 161 Main Street, Ap Lei Chau, Hong Kong. Tel: (852) 2518 5650, Email: wongwcw@hku.hk

INDIA

Raman R. GANGAKHEDKAR, Director-in-Charge, National AIDS Research Institute, 73, 'G'-Block MIDC Bhosari, Pune, Maharashtra 411026. Tel: (91) 20 2733 1200, Email: rgangakhedkar@nariindia.org

Beena Elizabeth THOMAS, Social Scientist, National Institute for Research in Tuberculosis, No.1, Mayor Sathiyamoorthy Road, Santosham Salai, Chetpet, Chennai, Tamil Nadu 600031, Tel: (91) 44 2836 9525, Email: beenaelli09@gmail.com

INDONESIA

Pande Putu JANURAGA, Study Coordinator, HATI, Indonesia Test and Treat Project, Udayana University. Bali. Tel: (62) 36 1895 6176, Email: januraga@unud.ac.id

Muhammad KARYANA, Head, Clinical Research in Communicable Diseases, National Institute of Health Research and Development, Jakarta. Tel: (62) 218 885 5181, Email: mkaryana@gmail.com

JAPAN

Aikichi IWAMOTO, Science and Technology Advisor, Japan Agency for Medical Research and Development, 21st Floor Yomiuri Shinbun Building, 1-7-1 Otemachi, Chiyoda-ku, Tokyo 100-0004. Tel: (81) 70 6641 2210, Email: aikichi@zj9.so-net.ne.jp

LAO PEOPLE'S DEMOCRATIC REPUBLIC

Bounpheng PHILAVONG, Director, Center for HIV/AIDS and STI, Ministry of Health, Km3 Thadeua Road, Vientiane Capital. Tel: (856) 20 23671175, Email: pbounpheng@gmail.com

Vanphanom SYCHAREUN, Dean, University of Health Sciences, Faculty of Postgraduate Studies Samsenthai Road, Ban Kaognot, Sisattanak District, Vientiane 7322. Tel: (856) 21 222883, Email: vsychareun@gmail.com

MALAYSIA

Adeeba KAMARULZAMAN, Dean, Faculty of Medicine, Infectious Disease Unit, University of Malaya, Jalan Universiti, 50603 Kuala Lumpur, Wilayah Persekutuan, Kuala Lumpur. Tel: (60) 3 7949 2050,Email: adeeba@ummc.edu.my

Ilias Adam YEE, Executive Director, Malaysian AIDS Council, 12, Jalan 13/48a, Sentul Raya Boulevard, 51000 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur. Tel: (60) 3 4047 4300, Email: ilias@mac.org.my

MONGOLIA

Davaalkham JAGDAGSUREN, Head, AIDS/STI Surveillance Research Department, National Center for Communicable Diseases, Nam Yang-Jügiin Street, Bayanzurkh District, Ulaanbaatar. Tel: (976) 11 463971, Email: jdavaalkham@gmail.com

Setsen ZAYASAIKHAN, National Center for Communicable Diseases, Nam Yang-Jügiin Street, Bayanzurkh District, Ulaanbaatar. Tel: (976) 11 463972, Email: setsen_77@yahoo.com

MYANMAR

Aye Moe Moe LWIN, Head of Administration, University of Public Health, 246 Myo Ma Kyaung street, Yangon. Tel: (95) 1 375459, Email: ayemoelwin.dr@gmail.com

Saw SAW, Deputy Director, Health System Research Division, Department of Medical Research, No. 5, Ziwaka Road, Dagon Township, Yangon 11191. Tel: (95) 1 395 210, Email: sawsawsu@gmail.com

PHILIPPINES

Rossana A. DITANGCO, Medical Specialist III, AIDS Research Group, Department of Health Research Institute for Tropical Medicine, 9002, Research Drive, Filinvest Corporate City, Alabang, Muntinlupa City 1781. Tel: (63) 2 8072628/30 local 801, Email: raditangco@yahoo.com

Jodor Rey LIM, Head, STD/AIDS Guidance Intervention and Prevention, Section of Infectious Diseases, University of the Philippines-Philippine General Hospital, Taft Avenue, Manila 1000, Metro Manila. Tel: (63) 2 525 1062, Email: drjodlim@yahoo.com

THAILAND

Suwat CHARIYALERTSAK, Director, Research Institute for Health Sciences, 110 Inthavaroros Road, Tambon Sriphoom, Muang District, Chiang Mai 50202. Tel: (66) 53 214 500, Email: schariya@med.cmu.ac.th

Praphan PHANUPAK, Director, Thai Red Cross Society, 104 Rajdamri Road, Bangkok 10330. Tel: (66) 53 214 500, Email: Praphan.P@chula.ac.th

Panusart Midnight POONKASETWATTANA, Executive Director, Asian Pacific Coalition on Male Sexual Health, 66/1 Sukhumvit 2 Road, Klongtoey, Bangkok 10110. Tel: (66) 22554410, Email: midnightp@apcom.org

Annette H SOHN, Director, TREAT Asia, The Foundation for AIDS Research, 388 Sukhumvit Road, Suite 2104, Klongtoey, Bangkok 10110. Tel: (66) 2 663 7561, Email: annette.sohn@treatasia.org

UNITED STATES OF AMERICA

Stefan BARAL, Director/Associate Professor, Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, 615 N Wolfe St, Baltimore, Maryland 21205. Tel: (1) 4105028975, Email: sbaral@jhu.edu

Myron COHEN, Professor, University of North Carolina, 321 S Columbia St, Chapel Hill, North Carolina 27516. Tel: (1) 919 962 8331, Email: myron_cohen@med.unc.edu

William C. MILLER, Professor, Epidemiology Department, University of North Carolina at Chapel Hill, Gillings School of Global Public Health, 170 Rosenau Hall, CB #7400, 135 Dauer Dr, Chapel Hill, North Carolina 27599. Tel: (1) 9199669407, (1) 9199663526, Email: bill_miller@unc.edu

Thomas C. QUINN, Director, Johns Hopkins Center for Global Health, Johns Hopkins University, and Associate Director for International Research, Division of Intramural Research, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Baltimore. Tel: (1) 410 955 7635, Email: tquinn@jhmi.edu

VIET NAM

Thi Nhan DO, Head, HIV/AIDS Treatment and Care Department, Vietnam Authority of HIV/AIDS Control, Ministry of Health, No 7/117, Lang Trung Lane, Lang Ha commune, Dong Da District, Hanoi. Tel: (84) 91489 3069, Email: dothinhan@gmail.com

Minh Giang LE, Vice Chair, Department of Epidemiology, Deputy Director, Office of Science and Technology Management, Hanoi Medical University, Center for Research and Training on HIV/AIDS (CREATA), Room 601, Building A1, #1 Ton That Tung Street, Hanoi. Tel: (84) 91328 1842, Email: leminhgiang@hmu.edu.vn

2. REPRESENTATIVES AND OBSERVERS

Akta Community Center

Kota IWAHASHI, 301, Dai2Nakano Building, 2-15-13, Shinjuku, Shijuku-ku, Tokyo, 160-0022 Japan. Tel: (81) 3 3226 8998, Email: kohta.felsbrucke@gmail.com

Center for Global Health, Centers for Disease Control and Prevention

Trista BINGHAM, Senior Service Fellow, HIV Prevention Branch, Division of Global HIV and Tuberculosis, 1600 Clifton Road, NE, Mail Stop E-04, Atlanta, Georgia 30333 United States. Tel: (1) 8002324636, Email: tub9@cdc.gov

Centers for Disease Control and Prevention

Michael MARTIN, Senior Technical Advisor for HIV/AIDS care and treatment, Study Director, Centers for Disease Control and Prevention, Thailand MOPH –US CDC Collaboration Center, Building 7, 5th Floor, Department of Disease Control, Ministry of Public Health, Nonthaburi, Thailand 11000. Tel: (66) 404 639 4719, Email: znd9@cdc.gov

Prin VISAVAKUM, Study Coordinator, Prevention for Special Populations Section, Global AIDS Program, Building 7, 5th Floor, Department of Disease Control, Ministry of Public Health, Nonthaburi, Thailand 11000. Tel: (66) 2 580 0669 Ext. 532, Email: hqa2@cdc.gov

Chinese Center for Disease Control and Prevention

Lv FAN, Director, Division of Policy and Social Sciences Research, 155 Changbai Road, Changping District, Beijing 102206 China. Tel: (86) 10 5890 0240, Email: fanlv@vip.sina.com

Kaohsiung Medical University

Yi-Ming Arthur CHEN, Vice President, 100,Shih-Chuan 1st Road, Kaohsiung,80708,Taiwan (China). Tel: (886) 7 312 1101, Email: arthur@kmu.edu.tw

Ministry of Health, Labour and Welfare, Japan

Kazunari ASANUMA, Director, Tuberculosis and Infectious Diseases Control Division, Health Service Bureau, Ministry of Health, Labour and Welfare, 1-2-2 Kasumigaseki Chiyoda-ku, Tokyo, 100-8916 Japan. Tel: (81) 3 5253 1111, Email: asanuma-kazunari@mhlw.go.jp

Kanako KITAHARA, 1-2-2 Kasumigaseki Chiyoda-ku, Tokyo, 100-8916 Japan. Tel: (81) 3 5253 1111, Email: kitahara-kanako@mhlw.go.jp

National Institute of Infectious Diseases

Tetsuro MATANO, Director, AIDS Research Center, Toyama 1-23-1, Shinjuku-ku, Tokyo 162-8640, Japan. Tel: (81) 352851111, Email: tmatano@nih.go.jp

National Institutes of Health

Emily ERBELDING, Deputy Director, Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID), 5601 Fishers Lane, RM 8D42 MSC 9831, Rockville, Maryland 20852, United States. Tel: (1) 3014353384, Email: emily.erbelding@nih.gov

South China-University of North Carolina STI Research Training Center

Ngai Sze WONG, Researcher, Guangdong Provincial Dermatology, Hospital No.2, Lujing Road, Yuexiu District, Guangzhou, China. Tel: (86) 20 8725 5824, Email: iseewong@gmail.com

Weiming TANG, Assistant Director, University of North Carolina Project-China, No 2 Lujing Road, Guangzhou, China. Tel: (86) 159 205 67132, Email: weimingtangscience@gmail.com

The Alliance for Health Policy and Systems Research

Abdul GHAFFAR, Executive Director, 20 avenue Appia, Geneva 1211, Switzerland. Tel: (41) 22 791 2213, Email: ghaffara@who.int

United States Agency for International Development

Ravipa VANNAKIT, Strategic Information Team Lead, US Agency for International Development, (USAID, Regional Development Mission Asia), Office of Public Health, Athenee Tower, 25th Floor, 63 Wireless Road, Lumpini, Patumwan, Bangkok, Thailand. Tel: (66) 2257 3000, Email: rvannakit@usaid.gov

Michael CASSELL, Regional HIV and TB Advisor, Regional Development Mission for Asia, Athenee Tower, 25th Floor, 63 Wireless Road, Lumpini, Pathumwan, Bangkok 10330 Thailand. Tel: (66) 2257 3000, Email: mcassell@usaid.gov

3. SECRETARIAT

WHO Regional Office for the Western Pacific

Ying-Ru LO, Coordinator, HIV, Hepatitis and STI, WHO Regional Office for the Western Pacific, P.O. Box 2932, 1000 Manila, the Philippines. Tel: (63) 2 528 9714, Email: loy@wpro.who.int

Naoko ISHIKAWA, Scientist (Care and Treatment), HIV, Hepatitis and STI, WHO Regional Office for the Western Pacific, P.O. Box 2932, 1000 Manila, the Philippines. Tel: (63) 2 528 9719, Email: ishikawan@wpro.who.int

Yoshinori NAGAHARA, Volunteer, WHO Regional Office for the Western Pacific, P.O. Box 2932 1000 Manila, the Philippines. Tel: (63) 2 528 8001, Email: nagaharay@wpro.who.int

WHO Regional Office for South-East Asia

Razia PENDSE, Regional Adviser (HIV/AIDS and STI), WHO Regional Office for South-East Asia, World Health House, Indraprastha Estate, Mahatma Gandhi Road, New Delhi 110002, India. Tel: (91) 11 2330 9632, Email: pendsera@who.int

WHO CAMBODIA

Laurent FERRADINI, Medical Officer (HIV, Hepatitis and STI), Office of the WHO Representative in Cambodia, 1st Floor No. 61-64, Preah Norodom Blvd. (corner St. 306), Sangkat Boeung Keng Kang I, Khan Chamkamorn, Phnom Penh, Cambodia. Tel: (855) 23 216 610, Email: ferradinil@wpro.who.int

WHO CHINA

Po-Lin CHAN, Technical Officer (HIV/AIDS), Office of the WHO Representative inthe People's Republic of China, 401, Dongwai Diplomatic Office Building, 23, Dongzhimenwai Dajie, Chaoyang District, Beijing 1000600, China. Tel: (86) 10 6532 7190, Email: chanpo@wpro.who.int

WHO INDIA

Nicole Simone SEGUY, Technical Officer (HIV/AIDS), Office of the WHO Representative to India, 537, A Wing, Nirman Bhawan, Maulana Azad Road, New Delhi 110 011, India. Tel: (91) 11 6656 4800, Email: seguyn@who.int

WHO MYANMAR

Masami FUJITA, Medical Officer (HIV/AIDS), WCO-MMR, Office of the WHO Representative in Myanmar, No. 2, Pyay Road, 7 Miles, Mayangone Township, Yangon 11061 Myanmar. Tel: (95) 9 4306 4734, Email: fujitam@who.int

WHO VIET NAM

Masaya KATO, Communicable Disease Group Coordinator | HIV Team Leader Office of the WHO Representative in Viet Nam, 63 Tran Hung Dao Street, Hoan Kiem District, Hanoi, Viet Nam. Tel: (84) 4 3943 3846, Email: katom@wpro.who.int

National Center for Global Health and Medicine

Shinichi OKA, Director, 1-21-1 Toyama Shinjuku-ku, Tokyo 162-8655 Japan. Tel: (81) 3 3202 7181, Email: oka@acc.ncgm.go.jp

Takeshi NISHIJIMA, 1-21-1 Toyama Shinjuku-ku, Tokyo 162-8655 Japan. Tel: (81) 3 3202 7181, Email: tnishiji@acc.ncgm.go.jp

Daisuke MIZUSHIMA, 1-21-1 Toyama Shinjuku-ku, Tokyo 162-8655 Japan. Tel: (81) 3 3202 7181, Email: dmizushi@acc.ncgm.go.jp

Shoko MATSUMOTO, 1-21-1 Toyama Shinjuku-ku, Tokyo 162-8655 Japan. Tel: (81) 3 3202 7181, Email: smatsumo@acc.ncgm.go.jp

Misao TAKANO, Clinical Research Coordinator, 1-21-1 Toyama Shinjuku-ku, Tokyo 162-8655 Japan. Tel: (81) 3 3202 7181, Email: mtakano@acc.ncgm.go.jp

Noriko WATANABE, Research Coordinator, 1-21-1 Toyama Shinjuku-ku, Tokyo 162-8655 Japan. Tel: (81) 3 3202 7181, Email: nwatanab@acc.ncgm.go.jp

Shinsuke MIYANO, Medical Officer, 1-21-1 Toyama Shinjuku-ku, Tokyo 162-8655 Japan. Tel: (81) 3 3202 7181, Email: s-miyano@it.ncgm.go.jp

Annex 3: List of ongoing and planned implementation research studies in Asia and the Pacific

Selected implementation research studies on HIV prevention, care and treatment in Asia and Australia (last updated 25 April 2016)

Running number	Area	Target population (s)	Study/project	Study type	Focus	Principal interventions	Outcomes	Sample size	Principal investigator	Principal/lead institution	Countries	Study period	Funding source
	Prevention	Gay men, transgender people, HIV-negative partners (in heterosexual serodiscordant couples), people who receive non-occupational post-exposure prophylaxis (n-PEP) on more than two occasions	The Victorian HIV PrEP Demonstration Project: the VicPrEP study	Demonstration project	Determine the effectiveness of pre-exposure prophylaxis (PrEP) in the local setting and the factors contributing to its success	Daily oral TDF/FTC	Adherence, behavioural change, acceptability, safety, and feasibility of use of HIV PrEP	200 men and women at high risk of HIV infection will be enrolled, with 100 taking PrEP for up to 12 months.	Edwina Wright	Alfred Health,Victorial AIDS Council/Gay Men's Health	Australia	July 2014–mid 2019	Department of Health, Victoria
	Prevention	All genders, but mostly men who have sex with men (MSM)	PrELUDE: Implementation of HIV pre-exposure prophylaxis with antiretroviral medications among people at high risk for HIV infection: a demonstration project	Demonstration project	Establish and evaluate PrEP service delivery model in New South Wales (NSW), Australia; evaluate PrEP acceptability, adherence, behaviour, sexually transmitted infection (STI) incidence	Daily oral TDF/FTC	Time to accrual of 300 person-years of follow up on TDF/FTC; seroconversion-free time on PrEP Time to TDF/FTC discontinuation Prescribed doses taken Incidents of HIV seroconversion Incidents of rectal gonorrhoea and chlamydia Serious adverse reactions Adverse events	400	Iryna Zablotska	The Kirby Institute, UNSW Australia	Australia	2014–2016	New South Wales, Ministry of Health
	Prevention	All genders, but mostly MSM	EPIC-NSW – Expanded PrEP Implementation in Communities in NSW	Implementation study	Assess the impact of the rapid expansion of access to PrEP on HIV incidence among those at high risk of acquiring HIV	Daily oral TDF/FTC	Rapid enrolment of eligible people and follow-up of participants for two years while they take PrEP	3700	David Cooper	The Kirby Institute, UNSW Australia	Australia	2016–2018	Awaiting information from Kirby Institute
	Prevention	MSM	QPrEP	Demonstration project	Evaluate PrEP delivery in Queensland health services	Daily oral TDF/FTC	Feasibility of PrEP provision through sexual health clinics and general practice services in Queensland Acceptability of this model of PrEP provision	50 MSM	Daren Russell	Queensland Health	Australia	January 2016, ongoing	Queensland HIV foundation, ACTRN12615000032550
	Prevention	MSM	Fostering resilience of psychosocial and HIV risk in Indian MSM	Randomized controlled trial (RCT), two arms	To reduce HIV, STI and sexual transmission risk through behavioural self-acceptance-based intervention compared to HIV/STI counselling and testing alone	A self-acceptance-based HIV sexual risk reduction intervention and HIV/STI voluntary counselling and testing (VCT) (4 group sessions focused on building self-acceptance, social support and HIV risk reduction skills; 6 individual sessions focused on personalized risk reduction; prevention case management) vs HIV/STI VCT	Primary outcome measures: changes in frequency of condomless sex self-reported insertive or receptive anal sex without the use of a condom), • Number of incident STIs from baseline (chlamydia, gonorrhoea, syphilis and HIV) Secondary outcome measures: changes in psychosocial mediators, • cost–effectiveness of intervention	608	Steven A. Safren, University of Miami; Matthew J. Mimiaga, Brown University; Conall M. O'Cleirigh, Massachusetts General Hospital	Massachusetts General Hospital, National Institute of Mental Health (NIMH), The National Institute for Research in Tuberculosis, Indian Council of Medical Research, Sahodaran, Fenway Community Health	India	September 2015, ongoing	ClinicalTrials.gov Identifier: NCT02556294 RO1.
	Prevention	People who inject drugs (PWID)	Modelling interactions between HIV interventions in key populations in India	Modelling	Use a novel modelling approach to help disentangle multiple dynamic effects of combination interventions in order to inform future large-scale implementation of such combination interventions. (1) Explain differences in prevalence and incidence of HIV in multiple populations of PWID in India using mechanistic transmission models; (2) Estimate the impact of multiple interventions and their interaction using mechanistic transmission models	The intervention is a combination of the nine interventions currently recommended for PWID by the World Health Organization (WHO): including HIV counselling and testing, antiretroviral therapy, opioid substitution therapy, needle–syringe exchange, treatment of sexually transmitted infections, treatment of tuberculosis, education and provision of condoms, delivered in an integrated care centre.	Prevalence and incidence of HIV in multiple populations of PWID Impact of multiple interventions and their interaction	14 450	Gregory M. Lucas, Shruti H. Mehta, Johns Hopkins University	Johns Hopkins University, National Institutes of Health, National Institute of Allergy and Infectious Diseases	India	2015–2017	Project # 1R21AI116296-01. The study is in progress.
	Prevention	PWID	Bangkok Tenofovir Study open-label extension (OLE)	Observational study	Provide additional information about the safety of PrEP and the behaviour of people taking PrEP over a long term. Hypothesis: participants' knowledge that PrEP provides some protection against HIV infection, and the fact that all HIV-negative participants in iPrEx OLE know that they are receiving-PrEP and not a placebo, will lead to increased use of the study drug by participants in iPrEx OLE, and increase protection against HIV infection.	Daily oral TDF/FTC	• Long-term efficacy • Long-term safety • Pill taking and adherence • Any changes in participants' sexual behaviour • Drug resistance • Bone mineral density and fat distribution • Impact on hepatitis infection	2261	Robert M. Grant	U.S. Centers for Disease Control and Prevention (CDC)	Thailand	2012–2013	Division of AIDS (DAIDS) of the National Institutes of Health (NIH) through a grant to the Gladstone Institutes in San Francisco, California
	Prevention	Female sex workers (FSWs)	The effectiveness of Personal Resilience and Enrichment Programme (PREP) for HIV prevention among female sex workers	Randomized controlled trial, two arms	Evaluate the effectiveness of PREP, the resilience-promoting intervention, in enhancing FSWs' overall resilience, reducing their psychological distress, and eventually reducing HIV risk behaviours among FSWs in Hong Kong	FSWs in the intervention group received the 6-session PREP work aimed at promoting their awareness and expression of their emotions and thoughts, management of their emotions, whereas participants in the control group received usual care provided by nongovernmental organizations.	Complex intervention evaluation to evaluate the effectiveness of the programme, mainly questionnaires eliciting sociodemographic information, psychological functioning, sexual health behaviours, and programme feedback.	128	William C.W. Wong, Clinical Associate Professor, Department of Family Medicine and Primary Care, The University of	The University of Hong Kong	China	2014–16	Research Grant Council, Hong Kong Special Administrative Region Government

Running number	Area	Target population (s)	Study/project	Study type	Focus	Principal interventions	Outcomes	Sample size	Principal investigator	Principal/lead institution	Countries	Study period	Funding source
	STI prevention and treatment	Male sex workers between the ages of 16 and 29 years	Implementation of a sexual health intervention for young MSM in two Vietnamese cities	Interventional model: single group assignment	Implement a sexual health promotion intervention for male sex workers in Hanoi and Ho Chi Minh City, Viet Nam. The study hypothesis is that this intervention will increase testing, treatment and vaccination for STIs, including the intention of participants to engage in these services beyond the conclusion of the intervention. At the community level, the study hypothesis is that male sex workers will be more aware of sexual health care and more likely to access these services in the future.	The sexual health promotion intervention is administered in community and clinic settings. The full intervention consists of seven core modules: Sexual health, Sexual diversity, HIV/STI transmission, Behavioural risk and risk reduction, Alcohol and drugs, Stigma, and HIV/STI and Health-seeking practices. In the community, outreach is conducted by health educators to deliver the intervention modules that young men express an interest in, as well as to provide risk reduction materials, including condoms and lubricant. Study interviewers conduct a cross-sectional interview of young male sex workers in community venues (the interviewers and health educators are never present in a venue at the same time), and a random sample of interviewees are invited to a local clinic, where they receive a more detailed interview, the full intervention (delivered one on one by a health educator and including all seven	Acceptance of testing (chlamydia, gonorrhoea, syphilis, HIV, hepatitis B virus [HBV] and hepatitis C virus [HCV]); return for test results; intention to access health services (STI testing, treatment, and vaccination)	1500 male sex workers between the ages of 16 and 29 years	Le M. Giang	Hanoi Medical University; National Development and Research Institutes, Inc.	Viet Nam	May 2013–May 2017	
	Prevention	MSM	HPTN 067/ADAPT Stud	Phase 2, randomized, open-label pharmacokinetic and behavioural study	Evaluate the feasibility of intermittent dosing of a PrEP regimen (alternative dosing to augment PrEP pill-taking)	Daily: one tablet FTC/TDF once a day regardless of sexual activity; Time driven: one tablet FTC/TDF 2 days/week and a post-exposure dose within 2 hours after sexual intercourse; Event driven: one tablet FTC/TDF prior to sexual intercourse and one post-exposure dose within 2 hours of sexual intercourse	Feasibility of intermittent dosing of a PrEP regimen. Recommending intermittent (non-daily) usage of oral FTC/TDF chemoprophylaxis, compared with recommending daily usage, will be associated with: 1) Equivalent coverage of sex events with pre- and post-exposure dosing; 2) Lower number of pills needed for coverage and fewer pills used; and 3) Decreased self-reported symptoms/side-effects (both severity and frequency) during 24 weeks of self-administered use	540 evaluable participants, including 360 MSM/transgender women (TGW) and 180 women who have sex with men (WSM) (180 for Thailand - final enrolment 238)	Robert M. Grant	University of California, San Francisco	Thailand, South	2011–2014	National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases (NIAID), ClinicalTrials.gov ID: NCT01327651
	Prevention	MSM	Effectiveness of combination HIV preventive interventions for young Thai MSM (COPE4YMSM)	Open label	To assess the effectiveness of a combination HIV prevention intervention with and without daily oral PrEP among HIV-uninfected young (18–26-year-old) men who have sex with men (YMSM) in Bangkok with current or recent (in the past 12 months) history of selling or trading sex to other men	The combination intervention includes: regular HIV testing, risk reduction counselling, condom and condom-compatible lubricant distribution STI screening and treatment (which/how), community awareness and mobilization intervention AND open-label offer of daily oral tenofovir/emtricitabine PrEP with mobile phone-based SMS (FrontlineSMS) adherence support	Assessing the effectiveness of combination interventions with and without PrEP and SMS adherence support with an HIV infection end-point; and a costing and cost–effectiveness assessment that will measure the costs associated with the combined intervention, the number of infections averted through PrEP use, discounted treatment costs saved, and assess whether the intervention packages are cost saving, cost–effective, or not cost–effective	1240 young MSM, 620 who choose PrEP and 620 who do not choose PrEP	Chris Beyrer (JHSPH); Co-PI: Tim Holtz (TUC)	Johns Hopkins Bloomberg School of Public Health, Thailand Ministry of Public Health (MOPH)–US CDC Collaboration (TUC) Thailand MOPH, Department of Disease Control, Silom Community Clinic @ Trop Med, Emory University, Mahidol University, SWING Foundation	Thailand	2015–2020	National Institute of Allergy and Infectious Diseases (NIAID) of the NIH
	Prevention	MSM, TG	Thai men who have sex with men and transgender women	Observational study	Uptake of oral PrEP and factors influencing decision-making among HIV-negative MSM and TG who participate in 4 community-based organizations (CBOs) in the community-based Test and Treat project (Bangkok and Pattaya) and in 2 hospitals in the facility-based Test and Treat project (Bangkok and Pathumthani)	Oral TDF/FTC once daily as PrEP offered and prescribed by trained and quality-controlled CBO staff at the CBOs or health-care professionals at the hospitals	PrEP uptake, PrEP adherence, adherence to clinic visits, HIV incidence, STI prevalence and incidence, comparison of outcomes between community-based setting and facility-based setting	600 MSM and TG (300 in the community-based setting and 300 in the facility-based setting)	Cheewanan Lertpiriyasuwat, Department of Disease Control, Thai MOPH	Department of Disease Control, Thai MOPH, and Thailand MOPH–U.S. CDC Collaboration (TUC), Thai Red Cross AIDS Research Centre	Thailand	2015–2018	Thai MOPH, Government Pharmaceutical Organization, Thai Red Cross AIDS Research Centre, U.S. CDC/U.S. President's Emergency Plan For AIDS Relief (PEPFAR), USAID/PEPFAR
	Prevention	MSM, transgender	Princess PrEP Project	Observational study	To expand oral PrEP access among MSM and TG through 7 CBOs in Bangkok, Pattaya, Chiang Mai and Hat Yai, and to study characteristics of these MSM and TG	Oral TDF/FTC once daily as PrEP offered and prescribed by trained and quality-controlled CBO staff at the CBOs	PrEP uptake, PrEP adherence, adherence to clinic visits, HIV incidence	3000 MSM and TG	Praphan Phanuphak, Thai Red Cross AIDS Research Centre	Thai Red Cross AIDS Research Centre, USAID RDMA, FHI360	Thailand	2016–2018	Thai Red Cross Princess Soamsawali Fund for HIV Prevention among Key Populations, USAID/PEPFAR
	Prevention	All sexes	PrEP-30 Project	Observational study	Feasibility of a self-paid oral PrEP programme (clients pay THB 30 per day or US$ 1 per day - this could cover generic TDF/FTC cost, laboratory screening and monitoring cost, and counselling cost) at the Thai Red Cross Anonymous Clinic	Oral TDF/FTC once daily as PrEP	PrEP uptake, PrEP adherence, adverse events, adherence to clinic visits, HIV incidence	200 clients enrolled (95% were men – 91% were MSM) over 12 months, enrolment ongoing	Donn Colby, Thai Red Cross AIDS Research Centre	Thai Red Cross AIDS Research Centre	Thailand	2014 – ongoing	Thai Red Cross AIDS Research Centre
	Prevention	MSM, TG	Acceptability of HIV oral PrEP among MSM and TG "PrEP @ PIMAN"	Prospective implementation research study	Acceptability of daily oral PrEP among MSM and TGW, the factors that influence the decision of taking daily oral PrEP and to assess adherence to PrEP among PrEP users	HIV testing, counselling and oral PrEP	Repeated HIV testing rate, percentage of MSM on oral PrEP, motivating factors to be on PrEP, changes in risk behaviours and rates of STI; uptake, adherence and retention in PrEP, HIV seroconversion rate	200 MSM and TGW in Chiang Mai and surrounding areas	Suwat Chariyalertsak, Research Institute for Health Sciences	Research Institute for Health Sciences (RIHES), Chiang Mai University, Chiang Mai	Thailand	2015–2017	RIHES Fund
	Prevention	Female sex workers (FSWs)	Closing a critical HIV prevention gap: demonstrating safety and effective delivery of daily oral pre-exposure prophylaxis (PrEP) as part of an HIV combination preventive intervention for sex workers in Kolkata and Mysore-Mandya, India	Demonstration project	Acceptability of PrEP among FSWs and evaluation of different service delivery models for the same	Daily oral TDF+FTC	(1) to identify FSWs in need of HIV prevention and willing to take PrEP; (2) to evaluate sustained uptake of and adherence to oral PrEP; (3) assess safe delivery of PrEP; and (4) demonstrate effective delivery of PrEP within the context of the National Programme of Targeted Interventions	400	Dr S Jana and Dr S Reza Paul	University of Manitoba	India	2015–2017	Bill & Melinda Gates Foundation (BMGF)

Running number	Area	Target population (s)	Study/project	Study type	Focus	Principal interventions	Outcomes	Sample size	Principal investigator	Principal/lead institution	Countries	Study period	Funding source
	Diagnosis	PWID	Integrated care clinics for PWID in India: a cluster randomized trial	Randomized controlled trial	Effectiveness of PWID-oriented integrated care clinics (ICCs) for improving outcomes along the seek, test, treat and retain continuum	VCT; condom distribution; counselling and education; needle exchange programmes; opioid substitution therapy; management of STIs, tuberculosis (TB), and viral hepatitis; and ART vs standard of care	Access to VCT; HIV transmission risk behaviours; access to clinical care; use of ART; community viral load	10 communities	Gregory M. Lucas, Shruti H. Mehta	Johns Hopkins University, National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA)	India	2011–15	5R01DA032059-04.
	Diagnosis	MSM	Spurring innovation in HIV testing and linkage: a crowdsourcing approach	Quasi-experimental trial	Effectiveness of a crowdsourced intervention and a social marketing intervention on HIV testing and linkage among young MSM	Crowdsourced intervention and social marketing intervention	Access to HIV testing, linkage to care, HIV transmission	2000	Joseph D. Tucker, Chongyi Wei	School of Medicine, University of North Carolina Chapel Hill;UCSF	China	2014–19	National Institute of Allergy and Infectious Diseases (NIAID) of the NIH, 1R01AI114310
	HIV testing	MSM and transgender women (TGW)	Innovative strategy to offer online test and treat services	Observational study	Feasibility of using online platform to provide HIV counselling and testing services, and factors associated with the preferences for the online option of HIV pre-test counselling, HIV testing and post-test counselling, referral for HIV treatment, and retention in services among MSM and TG	3 study groups that participants can choose to join. In Group A, participants will receive offline HIV testing and counselling and conventional retention strategies. In Groups B1 and B2, participants will access the "Adam's Love Online Clinic" and receive online pre-test counselling. Group B1 participants are those who choose to come to receive services offline. Group B2 participants are those who choose to continue the services online. All participants in Groups B1 and B2 will receive an online retention strategy.	First-time HIV testing rate, successful referral to HIV treatment, and retention in HIV testing and treatment programme among 3 different study groups	600 MSM and TG	Nittaya Phanuphak, Thai Red Cross AIDS Research Centre	Thai Red Cross AIDS Research Centre	Thailand	2015–2017	amfAR
	Testing/treatment	MSM/TGW	Continuum of care innovations for gay men, other men who have sex with men and transgender women (GMT) in Burma/Myanmar	Implementation research study	Measure and overcome barriers to HIV testing and access to care through a series of three primary innovations GMT in Myanmar	A three-step cascade intervention study. Specific aims and hypotheses are dedicated to each step along the cascade from evaluating self-testing (Aim 1); to the utility of CD4 point-of-care (POC) staging (Aim 2); to benefits associated with peer navigation for treatment initiation and adherence support (Aim 3).	Uptake and acceptability of assigned testing method Uptake of CD4 POC AIM 3:Changes in viral load, uptake of peer navigation, treatment adherence, clinical outcomes	420	Chris Beyrer	Johns Hopkins Bloomberg School of Public Health, Department of Medical Research, Lower Myanmar; National AIDS Program, Myanmar; International HIV/AIDS Alliance Myanmar; Lotus MSM Project; Phoenix Association; Aye Nyien Myitta	Myanmar	2015–2017	amfAR gay men, other men who have sex with men, and transgender (GMT) Initiative Research Grants
	Enrolment in care	MSM/TG	Feasibility/acceptability/ willingness to pay for oral fluid HIV screening among MSM in Thailand	Cohort study	Assess acceptance of oral fluid screening among MSM	HIV testing, linkage to care	Use of oral fluid HIV screening to increase HIV testing uptake among MSM	1800	Ravipa Vannakit	Family Health International (FHI)360/United States Agency for International Development (USAID)	Thailand, Lao People's Democratic Republic	2 years	USAID/PEPFAR
	Antiretroviral therapy (ART)	MSM, TG	Innovative strategy to offer online test and treat services	Observational study	MSM and TG participants self-select to participate in one of the 3 different study groups, which provide various degrees of integrated online interventions and offline interventions for the recruit–test–treat–retain cascade for HIV prevention and care	Group A – offline HIV testing and counselling and conventional retention strategy; Group B1 – online pre-test counselling, offline HIV testing, and online retention through the electronic health record platform; Group B2 – online pre-test counselling, online supervised HIV self-testing, and online retention	First-time HIV testing rate, successful referral to HIV treatment, retention in HIV testing and treatment programme, and characteristics of MSM and TG who prefer to be in each of the 3 groups	600 MSM and TG	Nittaya Phanuphak, Thai Red Cross AIDS Research Centre	Thai Red Cross AIDS Research Centre, SWING Foundation, Rainbow Sky Association of Thailand, Sisters Foundation	Thailand	2015–2017	amfAR
	Enrolment in care	HIV-positive women and men	Active Treatment pilot project in China	Observational study	Impact of early linkage to ART on mortality	One-stop shop for HIV antibody and CD4 testing and linkage to HIV care	Mortality of newly diagnosed HIV/AIDS cases	1034	Zunyou Wu	China CDC	China	2012 onwards	China CDC and National Centre for AIDS/STD Control and Prevention
	Enrolment in care	HIV-positive women and men and their negative spouses	Feasibility of operationalization of early or immediate ART to HIV-infected partner as a combination intervention among HIV-serodiscordant couples	Observational study using mixed methods	Feasibility of and barriers to couples HIV testing and prevention counselling (CHTC), and early or immediate initiation of ART	CHTC, referral of spouse for testing, disclosure of status, linkage to ART centres, retesting, early/immediate ART vs standard of care	Implementation outcomes: feasibility, provider acceptability and adoption fidelity, sustainability of the early ART intervention. Service outcomes: partner referral, HIV testing rates among negative partners Client outcomes :spousal testing acceptability acceptability of early ART, serious adverse events (social and medical), satisfaction with services. Clinical and transmission outcomes (partner seroconversion and viral supression)	4 ART centres (3 in Maharashtra and one in Gujarat) and the Integrated Counselling and Testing Centre and ART Link Centres attached to these ART centers	Sheela Godbole and B B Rewari (co-PI)	National AIDS Research Institute (NARI), Pune	India	2 years	National AIDS Control Organization, Government of India (approved for funding).
	Testing, enrolment in care and antiretroviral therapy (ART)	PWID	HIV Awal (early) Testing & treatment Indonesia for People Who Inject Drugs (HATI-Inject) Project	Prospective implementation research study	a) To evaluate interventions aimed at increasing HIV testing and immediate ART in PWID in Indonesia b) To develop capacity in implementation research in Indonesia through training and	Interventions to be developed by a qualitative study, systematic review and community consultations	Primary outcome - the number and percentage of those virologically suppressed before and after interventions. Secondary outcomes include evaluating each step of the HIV care cascade.	280 newly diagnosed PWID, 120 previously diagnosed ART-naive PWID	Rudi Wisaksana	Kirby Institute, WHO, UNSW, Atma Jaya, Padjajaran	Indonesia	2015–2019	World Health Organization (WHO) Regional Office for South-East Asia Ministry of Health Indonesia Kirby Institute, UNSW Australia
	Enrolment in care	MSM, FSW, *waria* (TG), PWID	The HIV Awal (early) Testing & treatment Indonesia (HATI) Project	Prospective implementation research study	Assess the impact of enhanced community-based interventions	ART irrespective of CD4 count for MSM, FSW, *waria* (TG), PWID.	Primary outcome: number and percentage of people who are virologically suppressed at 12 months after HIV diagnosis. Secondary outcomes: entire cascade of HIV care	600 HIV-positive MSM, 600 HIV-positive FSW	Yanri Wijayanti Subronto	WHO, Kirby Institute, Universitas Gadjah Mada (UGM), Padjajaran, Udayana	Indonesia	2015–19	Department of Foreign Affairs and Trade Australia, Ministry of Health Indonesia, WHO Regional Office for South-East Asia, Kirby Institute
	Antiretroviral therapy	HIV-positive women and men	National evaluation of efficacy of protease inhibitor (PI)-based second-line regimen in Cambodia	Observational study	Assess the PI-based second-line antiretroviral regimen of the national programme (individual and structural factors, and virological efficacy)	Structural and individual factors (questionnaires) associated with second-line treatment failure. HIV-RNA viral load (VL), CD4 count and drug resistance genotyping for patients with detectable VL. Adherence support and control of VL	Proportion of patients with virological failure after adherence support	1350	Vonthanak Saphonn, Bruno Spire, Eric Nerrienet	French National Institute for Health and Medical Research-French National Agency for Research on AIDS and Viral Hepatitis (INSERM-ANRS)	Cambodia	2012–2015	NCT01801618, ANRS12276 2PICAM

Running number	Area	Target population (s)	Study/project	Study type	Focus	Principal interventions	Outcomes	Sample size	Principal investigator	Principal/lead institution	Countries	Study period	Funding source
	Antiretroviral therapy	PWID	Integrated treatment and prevention for people who inject drugs: a vanguard study for a network-based randomized HIV prevention trial comparing an integrated Intervention Including supported antiretroviral therapy to the standard of sare	A multi-site, two-arm, randomized, vanguard study	Determine the feasibility of a future trial that will assess whether an integrated intervention combining psychosocial counselling and supported referrals for ART at any CD4 cell count and substance use treatment for HIV-infected PWID will reduce HIV transmission to HIV-uninfected injection partners, as compared to routine care dictated by national guidelines for HIV-infected PWID.	Standard of care and standard of harm reduction package	Estimating the HIV incidence among network injection partners of index participants in the standard of care arm; enrolment and retention of HIV-infected PWID and their HIV-uninfected network injection partners over a period of 12–24 months; feasibility, barriers and uptake of an integrated intervention for prevention of HIV transmission among HIV-infected index participants	At least 500 network units (1 index and 1 partner)	William Miller, Irving Hoffmann	University of North Carolina	Indonesia, Ukraine, Viet Nam	2014–2017	Division of AIDS, US National Institute of Allergy and Infectious Diseases, US National Institute on Drug Abuse, US National Institutes of Health
	Antiretroviral therapy	MSM	Treatment as Prevention	Cohort study	Assess HIV incidence among MSM cohort and impact of immediate treatment	ART irrespective of CD4 count for MSM	HIV incidence, treatment outcomes	458 MSM	Shinichi Oka	AIDS Clinical Center, National Center for Global Health and Medicine, Tokyo	Mongolia	2013–2015	Grant for National Center for Global Health and Medicine
	Antiretroviral therapy	MSM, transgender women (TGW)	Study to evaluate the feasibility of universal HIV testing and ART regardless of CD4 count using the test-and-treat strategy among MSM and TGW in Thailand	Observational study	Acceptance of regular HIV testing and immediate ART regardless of CD4 count among MSM/TG in 4 provinces (Bangkok, Ubonratchathani, Lampang and Mahasarakam)	HIV testing and ART counselling (if tested HIV-positive, regardless of CD4 count). Participants are randomized 4:1 to receive intensive retention strategy (regular communication via social networking tools) or standard retention strategy (telephone call reminder)	Repeated HIV testing rate and immediate ART acceptance rate; retention rate in the intensive and standard retention arms; adherence to ART and HIV RNA suppression in blood and anogenital compartment; changes in risk behaviours and rates of STI	810 MSM and TG	Praphan Phanuphak, Thai Red Cross AIDS Research Centre	Thai Red Cross AIDS Research Centre and Department of Disease Control, Thai MOPH	Thailand	2012–2015	National Research Council, National Health Security Office programme, Government Pharmaceutical Organization, WHO, Aids Funds, TREAT Asia
	Antiretroviral therapy	MSM, TG	Study to evaluate the feasibility of community-based test-and-treat strategies among MSM and TGW to increase the uptake of HIV	Observational study	Feasibility of a community-based test-and-treat approach that targets MSM and TG populations in 6 CBOs in 4 major cities (Bangkok, Pattaya, Chiang Mai and Hat Yai)	The model involves two linked strategies: (1) community-based HIV/STI service delivery by trained and quality-controlled CBO staff; and (2) enhanced community-based outreach interventions for increasing uptake of services	HIV prevalence, HIV incidence, first-time tester rate, repeated testing rate, immediate ART acceptance rate, median CD4 count at diagnosis, viral load suppression at 6 and 18 months, retention in care for both HIV-positive and HIV-negative groups	6000 MSM and TG	Nittaya Phanuphak, Thai Red Cross AIDS Research Centre	Thai Red Cross AIDS Research Centre, USAID RDMA, FHI360	Thailand	2015–2018	USAID/PEPFAR
	Antiretroviral therapy	MSM, TG	Thai facility-based MSM and TG test, treat, and prevent HIV study	Observational study	Feasibility of a facility-based test-and-treat approach that targets MSM and TG populations in 5 hospitals in 4 provinces (Bangkok, Pathumthani, Khon Khaen and Udonthani)	HIV testing, ART counselling, and immediate ART provided by a team of health-care professionals within the same hospital	HIV prevalence, HIV incidence, first-time tester rate, repeated testing rate, immediate ART acceptance rate, median CD4 count at diagnosis, viral load suppression at 6 and 18 months, retention in care for both HIV-positive and HIV-negative groups	2000 MSM and TG	Sumet Ongwandee, Cheewanan Lertpiriyasuwat, Department of Disease Control, Ministry of Public Health (MOPH) Thailand	Department of Disease Control, Thai MOPH, and Thailand MOPH-U.S. CDC Collaboration (TUC)	Thailand	2015–2018	U.S. CDC/PEPFAR
	Antiretroviral therapy	MSM, TG	Feasibility of universal HIV testing and ART regardless of CD4 count using the test-and-treat strategy among MSM/TG in Thailand	Observational study (randomization of retention strategies)	Acceptance of regular HIV testing and immediate ART regardless of CD4 count among MSM/TG. Enrolment of 2000 MSM and TG at 5 hospitals in 4 provinces of Thailand, follow up for 18 months, ART regardless of CD4 count and enrolment of 300 participants on PrEP at 2 sites companion study in community sites	HIV testing and ART counselling (if tested HIV-positive, regardless of CD4 count). Participants are randomized 4:1 to receive intensive retention strategy (regular communication via social networking tools) or standard retention strategy (telephone call reminder)	Repeated HIV testing rate and immediate ART acceptance rate; retention rate in the intensive and standard retention arms; adherence to ART and HIV RNA suppression in blood and anogenital compartment; changes in risk behaviours and rates of STI	2000	Nittaya Phanuphak, Thai Red Cross AIDS Research Center	Thai Red Cross AIDS Research Centre	Thailand	2015	GMT Initiative Research Grants, Thai Red Cross AIDS Research Centre
	Antiretroviral therapy	MSM, TG	Thai facility-based MSM and TG test, treat, and prevent HIV study	Observational study	Acceptance of regular HIV testing and immediate ART regardless of CD4 count among MSM/TG	HIV testing and ART counselling, immediate ART, PrEP	Repeated HIV testing rate and immediate ART acceptance rate; retention rate in the intensive and standard retention arms; adherence to ART and HIV RNA suppression in blood and anogenital compartment; changes in risk behaviours and rates of STI; uptake, adherence and retention in PrEP	Enrol 2000 MSM and TG at 5 hospitals in 4 provinces of Thailand, follow up for 18 months	Sumet Ongwandee, Cheewanan Lertpiriyasuwat, Ministry of Public Health Thailand	U.S. CDC	Thailand	2014–16	U.S. CDC
	Antiretroviral therapy (HIV cascade)	Serodiscordant couples	Couples HIV testing and immediate ART among serodiscordant couples in Viet Nam	Observational cohort study	Assess feasibility of couples HTC and immediate ART for HIV-positive partners in serodiscordant relationships in Viet Nam's programme	Couples HIV testing and counselling; ART regardless of CD4 count for the HIV-positive partner; promotion of other e-prevention methods	CD4 count at diagnosis; couples HTC uptake; linkage to care; ART retention; viral suppression at 12 months; self-reported risk behaviours; adverse events due to antiretrovirals (ARVs)	134 couples (123 index cases with baseline viral load)	Nguyen Thanh Long (Viet Nam Ministry of Health); Masaya Kato (WHO Viet Nam)	Viet Nam Authority for HIV/AIDS Control, Ministry of Health; Hanoi School of Public Health; WHO; U.S. CDC	Viet Nam	2013–2014	MAC AIDS Foundation, One Plan Fund/WHO, PEPFAR/CDC, Global Fund to Fight AIDS, Tuberculosis and Malaria
	Antiretroviral therapy (HIV cascade)	People who inject drugs (PWID)	Periodic HIV testing and immediate ART among PWID in Viet Nam	Observational cohort study	Assess feasibility and acceptability of periodic offer of voluntary HIV testing and immediate ART among PWID	Voluntary HIV testing and counselling every six months, and immediate ART irrespective of CD4 count; promotion of other e-prevention methods	CD4 count at diagnosis; HTC uptake; linkage to care; retention in care and on ART; viral suppression at 12 months; self-reported risk behaviour; feasibility and acceptability	300	Bui Duc Duong (Viet Nam Ministry of Health); Masaya Kato (WHO Viet Nam)	Viet Nam Authority for HIV/AIDS Control (VAAC), Ministry of Health; Hanoi Medical University; National Institute of Hygiene and Epidemiology, WHO	Viet Nam	2014–16	MAC AIDS Foundation, One Plan Fund/WHO, Global Fund to Fight AIDS, Tuberculosis and Malaria
	Antiretroviral therapy	Key populations, their partners and pregnant women	Integrating HIV services into primary health care (Treatment 2.0 pilot)	Observational study	Assess feasibility of service delivery model to enhance access, retention and sustainability	Decentralization of HIV testing and treatment services into subdistrict primary health-care services, point-of-care HIV diagnosis and CD4 count, once-daily fixed-dose combination, community mobilization	Earlier treatment initiation, improved testing uptake, timeliness of services, acceptability	Not applicable	Bui Duc Duong (Viet Nam Ministry of Health); Masaya Kato (WHO Viet Nam)	Viet Nam Authority for HIV/AIDS Control (VAAC), WHO	Viet Nam	2012–2015	MAC AIDS Foundation, One Plan Fund/WHO, Global Fund to Fight AIDS, Tuberculosis and Malaria
	TB/HIV	HIV-positive children	Improving diagnosis of tuberculosis in HIV-infected children in Asia (Cambodia, Viet Nam) and in Africa (Burkina Faso, Cameroon)	Interventional study	Develop a diagnostic algorithm to improve the diagnosis of tuberculosis in HIV-infected children in the context of developing countries with high burden of tuberculosis	Evaluate the sensitivity, specificity, positive and negative predictive values of an in-vitro interferon gamma release assay (IGRA): the QuantiFERON®-TB Gold In-Tube, for the diagnosis of TB in HIV-infected children. • Evaluate the performance and feasibility of the string test, nasopharyngeal aspirate and stool sample as alternative bacteriological specimen collection methods	Tuberculosis diagnostic algorithm; evaluation of the QuantiFERON(R)-TB Gold In-Tube; comparison of two in-vitro IGRAs; percentage of TB diagnosis sampling procedures actually performed; evaluation of the morbidity (immune reconstitution inflammatory syndrome [IRIS], drug toxicity and other opportunistic infections) and mortality in TB–HIV-coinfected children; specificity and sensitivity of TB diagnosis sampling procedures compared to TB diagnosis gold standard; evaluation of the Xpert MTB/RIF assay	420	Olivier Marcy, UNG Vibol	Agence Nationale de Recherche sur le Sida (ANRS)	Cambodia, Viet Nam	2010–2015	NCT01331811, French National Institute for Health and Medical Research–French National Agency for Research on AIDS and Viral Hepatitis (INSERM-ANRS)

Running number	Area	Target population (s)	Study/project	Study type	Focus	Principal interventions	Outcomes	Sample size	Principal investigator	Principal/lead institution	Countries	Study period	Funding source
	TB/HIV	HIV-positive women and men with CD4 <100/mm³	Systematic empirical vs test-guided antituberculosis treatment impact in severely immunosuppressed HIV-infected adults initiating antiretroviral therapy with CD4 cell counts <100/mm³	Multicentre, two-arm, unblinded randomized controlled superiority trial	Compare the 24-week risk of death and occurrence of invasive bacterial infection between two experimental strategies in HIV-1 infected adults who initiate ART with a CD4 count <100/mm³: (i) continuous extensive TB screening during follow up each time the patient presents with symptoms (using chest X-ray, Xpert MTB/RIF® and urine lipoarabinomannan (LAM)), versus (ii) systematic empirical TB treatment started 2 weeks before ART initiation	At inclusion, participants are randomized 1:1 in the two strategies of TB testing and treatment: extensive TB screening (arm 1), or systematic empirical TB treatment (arm 2). Patients who do not start TB treatment because of negative point-of-care tests will start ART immediately, while those who start TB treatment either because of a positive test or randomization in the systematic TB treatment arm will start ART 2 weeks later. ART regimen will be TDF-3TC + efavirenz or TDF-XTC + efavirenz or AZT-3TC + efavirenz	All-cause mortality and incidence of invasive bacterial infections, incidence of confirmed/probable/possible TB, Incidence of grade 3 or 4 adverse events	1050	Francois-Xavier Blanc, Kouao Medard, Serge Domoua	ANRS	Cambodia, Viet Nam	2013–2017	NCT02057796, French National Institute for Health and Medical Research-French National Agency for Research on AIDS and Viral Hepatitis (INSERM-ANRS)
	TB/HIV	TB and HIV patients	A programmatic evaluation of TB diagnosis in Cambodia among people living with HIV and people suspected of having multidrug-resistant TB (MDR-TB)	Multicentre, cross-sectional study	To derive a clinical algorithm for screening and diagnosis of TB disease in HIV-infected persons	Periodic offer of HIV testing and counselling; immediate ART regardless of CD4 count	A clinical algorithm – all persons newly diagnosed with HIV and all HIV-infected persons are screened at regular intervals to improve TB case detection and reduce TB-related mortality	802	Dr Kevin P. Cain, U.S. CDC; Dr Jordan W. Tappero, U.S. CDC; Dr Jay K. Varma, U.S. CDC; Dr Tom M. Shinnick, U.S. CDC; Dr Charles D. Wells, U.S. CDC; Dr Mao Tan Eang, National Center for TB and Leprosy Control, Ministry of Health, Cambodia; Dr. Michael Kimerling, Univ. of Alabama, Birmingham; Dr Kanara Nong,	CDC	Cambodia, Thailand and Viet Nam	2011–2016	CDC
	Prevention of mother-to-child transmission (PMTCT)	HIV-infected pregnant women	Evaluation of the prevention of mother-to-child transmission of HIV cascade and testing strategies in Cambodia	Retrospective, two-stage, nested sampling strategy	1. Identify steps within the PMTCT cascade for programmatic improvement. 2. Determine the diagnostic yield and cost of targeted versus universal strategies for identifying HIV-infected pregnant women for PMTCT services in Cambodia, to achieve the goal of reducing the vertical transmission rate to below 2%.	PMTCT intervention package	Improved PMTCT programme/targeted intervention strategies that can identify factors that influence the likelihood of a woman completing the PMTCT cascade and to address losses along the cascade	522	Tung Rathavy, Director, National Maternal and Child Health Center; Mean Chhi Vun, Director, National Center for HIV AIDS Dermatology and STIs; Wm. Perry Killam, CDC/CGH/DGHA	CDC	Cambodia	2013–2016	CDC
	TB/HIV	TB and HIV patients	Barrier and enablers affecting utilization of Xpert MTB/RIF testing for TB in Cambodia	Concurrent mixed method design (Creswell and Plano Clark 2011) that combines quantitative and qualitative methods	To identify the barriers and enablers among the TB clinicians, HIV clinicians, and operational district (OD) TB supervisors to using Xpert testing for TB diagnosis and rifampicin resistance for target populations: MDR-TB suspects and TB symptom screen-positive people living with HIV (PLHIV)	Speedy and accurate TB testing among target populations	Higher uptake of Xpert testing	Survey among TB and HIV clinicians and TB supervisors, $N = 62$), 6 focus groups ($N = 37$), and in-depth interviews ($N = 18$)	Eng Bunthoeun, Brittany Moore	CDC	Cambodia	2014–2016	CDC
	TB/HIV	TB and HIV patients	Cost–effectiveness analysis of Xpert MTB/RIF use for TB diagnosis in Cambodia among people living with HIV and people suspected of having MDR-TB	A retrospective, ingredients-based costing approach	To assess the incremental cost–effectiveness of using new diagnostic algorithms that incorporate the Xpert® MTB/RIF test compared to the base case algorithms without Xpert® for people living with HIV and individuals suspected of having MDR-TB in Cambodia	TB diagnostic, treatment and care package	Cost–effective TB diagnostic methods	Primary cost data were collected at four sites (2 provincial hospitals, 1 district hospital, 1 national lab), including the costs of personnel, equipment, maintenance, supplies and specimen transport. Data sources included consultation with clinical and laboratory staff, national TB programme managers, and private sector vendors, as well as observation of diagnostic procedures	Sarah Pallas, Marissa Courey, Chhaily Hy, Wm. Perry Killam, Brittany Moore	CDC	Cambodia	May–July 2014	CDC

Running number	Area	Target population (s)	Study/project	Study type	Focus	Principal interventions	Outcomes	Sample size	Principal investigator	Principal/lead institution	Countries	Study period	Funding source
	Substance use and HIV treatment	Injection drug users 18 years or older	A pilot implementation project of methadone and suboxone for injecting drug users in Ho Chi Minh City, Viet Nam	Open-label follow-up study	Demonstrate feasibility and evaluate participant, clinic and community factors that promote or inhibit the implementation of a medication-assisted treatment (MAT) programme (both methadone and buprenorphine/naxolone) integrated within an HIV treatment setting	Medication-assisted treatment (MAT) programme (both methadone and buprenorphine/naxolone) integrated within an HIV treatment setting	Qualitative assessment: acceptability, barriers and facilitators to implement MAT for opiate addiction within an HIV treatment setting; treatment retention at 6- and 12-month follow up; treatment adherence: methadone, suboxone, HIV treatment, counselling sessions; cost–effectiveness ratios calculated at the end of the study; drug use and severity of addiction assessed by the Addiction Severity Index (ASI) scores; risk-taking behaviours: scores from the Risk Assessment Battery (RAB) at 6- and 12-month follow ups	500 opiate-dependent individuals who are 18 or more years of age	Charles O'Brien; Le Truong Giang	University of Pennsylvania, PA, USA	Viet Nam	01 Aug 2012–31 July 2017	National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), R01-DA033671-01
	HIV and substance use-related disorders	HIV-positive individuals 18 years or older with moderate or severe opioid dependence (Diagnostic and Statistical Manual of Mental Disorders [DSM]-V)	Buprenorphine to Improve HIV Care Engagement and Outcomes (BRAVO)	Interventional; randomized allocation	To compare two models of substance abuse treatment in Viet Nam, and how they each affect HIV care. In Viet Nam, the current model for treating people with HIV who are also dependent on opioids is to refer them to methadone maintenance treatment centres. The new model the protocol will study is treatment of HIV and opioid dependence with buprenorphine/naloxone and counselling in the HIV clinic.	Experimental intervention: buprenorphine/naloxone; active comparator: methadone maintenance therapy (MMT)	HIV viral suppression; receipt of ART; retention in HIV care; heroin use	450 opioid-dependent individuals 18 years or older	Philip T. Korthuis	Oregon Health and Science University	Viet Nam	July 2015–April 2018	National Institute on Drug Abuse (NIDA)
	Alcohol use and ART adherence	HIV-infected ART clinic patients with hazardous or heavy alcohol use	Reducing hazardous alcohol use and HIV viral load: an RCT in ART clinics in Viet Nam (REDART)	Three-arm randomized controlled trial (RCT)	Compare the effects of two evidence-based interventions: a brief intervention (BI) vs a combined intervention which draws from motivational enhancement therapy (MET) and cognitive behavioural therapy (CBT,) both against each other and compared with an assessment-only (standard of care) control	1) Brief intervention (BI) - the brief intervention comprises a total of 2 individual face-to-face sessions and 2 individual booster phone sessions for each participant assigned to this arm. The face-to-face sessions will occur approximately 1 month apart, and a phone session will take place 2–3 weeks after each face-to-face session. 2) The combined intervention - the combined intervention derives from both motivational enhancement therapy (MET) and cognitive behavioural therapy (CBT). The combined intervention comprises a total of 6 individual face-to-face sessions for each participant assigned to this arm, with each session occurring approximately 1 week apart.	Alcohol use; viral load; costs; health utility; client's attitudes and perceptions about drinking; and perceived barriers and facilitators to changing alcohol patterns	For the RCT phase, 441 hazardous drinkers (use Alcohol Use Disorders Identification Test [AUDIT-C] score ≥4 for men; AUDIT-C score ≥3 for women) who are 18 years of age or older	Vivian F. Go	University of North Carolina-Chapel Hill, Chapel Hill, USA	Viet Nam	2015–2019	Sponsor: University of North Carolina, Chapel Hill Collaborator: National Institute on Drug Abuse (NIDA); NCT02153216

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