# Pre-Exposure Prophylaxis (PrEP) in Thailand :

# Report of the Stakeholder Meeting

December 8-9, 2010

AVAC
Global Advocacy for HIV Prevention

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Princeton Park Suite, Din Daeng, Bangkok



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# Executive Summary

The first participatory HIV Pre-exposure Prophylaxis (PrEP) Stakeholder Meeting in Asia-Pacific and also the first country meeting after the announcement of iPrEx study was held in Thailand in December 2010, bringing together over 80 representatives of government entities, the health sector, a broad range of civil society groups (community-based organizations, ethical committees, community advisory boards and academic institutions) and international organizations. Co-hosted by the Thai Department of Disease Control, Ministry of Public Health (MoPH) and Thai NGO Coalition on AIDS (TNCA), the meeting aimed to provide participants with background information on biomedical HIV prevention - including the history and an update of PrEP trials, identify issues and recommendations for the most effective way forward in implementing PrEP, address community participation in research trial processes and discuss the structures and mechanisms dealing with biomedical HIV prevention in Thailand.

Against the backdrop of various global PrEP studies in different phases, the iPrEx study – Pre-exposure Chemoprophylaxis for HIV Prevention in Men who have Sex with Men (MSM) – involved a total of 2,499 participants (5%, or 114 individuals, were based in Thailand) at eleven sites in six countries (Brazil, Ecuador, Peru, South Africa, Thailand, USA). Positive overall results were released on 23 November 2010, showing that the combination of oral ARV Truvada [Tenofovir (TDF) and Emtricitabine (FTC)] provided additional protection against the acquisition of HIV infection among MSM and transgender women receiving a comprehensive package of prevention services, reducing the risk of infection by 43.8 percent. Advantages of Truvada were its high potency and quick absorption, well-known safety profile and relative ease of use.

Main concerns reflected in the meeting included 'Is 44% efficacy good enough? How big amount of additional resources will be needed? Is the public health system ready to integrate PrEP? What are the understandings of public and related partners?

Three main areas were discussed – the need for further research to build on the outcome of the Thai iPrEx study, preparing the public health care system for inclusion of PrEP into the national comprehensive prevention package, and ensuring civil society and community participation and awareness.

Specific to 'further research', the need to study varying sexual behaviors, hormone use among transgender individuals, alternate dosage regimens, and efficacy rates were highlighted. A combination of qualitative and quantitative research would provide the best understanding of these issues and improve the efficiency and effectiveness of long-term implementation. Researchers, practitioners, PLHIV, policy-makers and others working with HIV and AIDS can learn key lessons from the pre exposure prophylaxis for TB and malaria.

Regarding the Thai public health system, PrEP should be used as a tool to facilitate reviewing the system, in the understanding that any adjustment would take time and experience some difficulties. The overall readiness of the public health system has to be ascertained, with certain areas clearly requiring review: voluntary confidential counseling and testing (VCCT), post-exposure prophylaxis (PEP), gender and sexuality based services, community involvement, decision-making processes for practitioners and particularly the burden on medical personnel. The implementation schedule has to be defined as the financial issues and capacity building plan would be developed accordingly, meanwhile taking advantage of the opportunities around GFATM Round 8 to improve quality of basic package of prevention services with efficient access to target population with high risk behavior.

For the third discussion issue on civil society and community preparation and participation; ensuring appropriate, accurate and timely information, education and communication is crucial. A large-scale, well-coordinated education campaign around PrEP should include curriculum development; capacity building for people working with related issues; the use of peer educators and outreach workers to share prevention options and research outcomes, help reduce stigmatization and increase levels of communication and interaction; and a clear distinction between PrEP and PEP. Awareness and understanding of how stigma and discrimination

affect target populations must be promoted among concerned stakeholders, particularly service providers. A system of coordination among existing programs and entities should be created, and good participatory practice (GPP) applied consistently. Finally, a fundamental shift in perception and attitude is necessary, one where everyone begins to 'think outside the box' when working with new or existing prevention tools. One insight is to consider the emotional impact HIV has had on people's sexuality and sex life, where the message to society could transform accordingly: when discussing condom use, for example, instead of talking exclusively about safety, one could emphasize the happiness and joy which individuals experience related to sex and sexuality.

The main points agreed among stakeholders in the meeting that PrEP is NOT to be regarded as a stand-alone solution, but should only be used as part of a comprehensive HIV prevention package; sustained financing for new programs is to be ensured; and ongoing reminder for people that condoms work and keep using them is emphasized.

Key recommendations for national policy on PrEP implementation emerged as follows:

1. PrEP implementation must occur only as an integral part of a comprehensive HIV prevention package.
2. PrEP implementers must take an integrated approach, bringing together related prevention, treatment and care systems and processes, getting buy-in from policy-makers, working with the media, continuing to use and adapt existing tools and programs, and collaborating actively with community members.
3. The rights of affected people, including key groups with high risk-associated behaviors and people living with HIV/AIDS must be considered during any implementation process. More opinions and information need to be collected from gay men, transgender people and other groups of MSM before an implementation strategy is designed.
4. A clear, efficient public communication strategy to introduce PrEP to the general public is needed in advance to prevent misunderstandings and misinformation within affected communities and society as whole.
5. Thailand must develop and adopt a unified country level mechanism for the implementation of PrEP.
6. Realistic funding requirements must be identified and included in any implementation strategy.
7. A practical way forward is to begin with a small pilot project examining community systems and social strengthening.

# Background

The first participatory HIV Pre-exposure Prophylaxis (PrEP) Stakeholder Meeting in Thailand brought together about 80 participants from government entities, international organizations, the health sector and a broad range of civil society groups, including community-based organizations, ethical committees, community advisory boards and academic institutions. Participants gathered in Bangkok from 8-9 December 2010 to share PrEP-related background information and updates on trials, discuss further research requirements and stakeholder engagement, and identify strategic and programmatic needs and recommendations to integrate PrEP into the comprehensive national HIV prevention package.

Thailand is one of several sites worldwide where a variety of PrEP clinical trials are underway, with results being announced. The initial results of Global iPrEx – the Pre-Exposure Prophylaxis Initiative managing oral PrEP efficacy trials in 6 countries, including Thailand – were announced on 23 November 2010, with results from other trials to follow in 2012 and 2013. Despite the initially successful iPrEx outcomes, the challenges in translating research into effective implementation could be considerable, particularly in terms of delivering PrEP as part of a comprehensive prevention package and ensuring adequate and sustained financing for new programs. Additional studies on certain issues will almost certainly be needed.

Co-hosted by the Thai Department of Disease Control, Ministry of Public Health (MoPH) and Thai NGO Coalition on AIDS (TNCA), sponsored by the World Health Organization (WHO) and AVAC: Global Advocacy for HIV Prevention, this multi-stakeholder meeting on PrEP – the first of its kind in the country and Asia-Pacific region – aimed to foster inclusive dialogue for future national action on PrEP. It links to three other AVAC-supported civil society consultations: two on good participatory practice (GPP) in the context of clinical trials for biomedical HIV prevention, held in Chiang Mai and Bangkok in November 2010; and one PrEP-related meeting for Thai civil society held in November 2010 in Bangkok.

The meeting's main objectives were to

1. *Provide background information for better knowledge and understanding of biomedical HIV prevention including PrEP*
2. *Provide an update of the progress of PrEP trials in the world and in Thailand*
3. *Address direction, plans and concerns of inclusion of PrEP as part of a combination HIV/AIDS prevention package in Thailand*
4. *Address additional PrEP trials and the continuation of ongoing trials in Thailand and community participation in research trial processes*
5. *Address the structure and mechanisms dealing with biomedical HIV prevention in Thailand*

## A national context for PrEP

*Speakers:* *Dr. Somsak Akkasilp, Deputy Director-General, Department of Disease Control, Ministry of Public Health*
*Khun Supatra Nacapew, Chair, Thai NGO Coalition on AIDS (TNCA), and Director of the Foundation for AIDS Rights (FAR)*

For 25 years Thailand has been taking the initiative on creating domestic HIV and AIDS programs, setting up national guidelines for people living with HIV/AIDS (PLHIV) and numerous services based on internationally accepted guidelines. Thailand often moved ahead without external assistance; waiting for official global results and recommendations would have delayed and impacted the effectiveness of interventions. The country regularly seeks to improve its performance in addressing the epidemic and adjusts to changing circumstances. This PrEP stakeholder consultation is another example bringing together not only researchers and government but also civil society representatives to discuss interventions that will eventually benefit all of Thailand's 60 million citizens. Thus the long-term aim domestically is to build on a strong multi-sectoral collaboration, actively supported by the government, and including networks of PLHIV, local administrative units, medical establishments and staff, and academia.

People working with HIV and AIDS in Thailand need to consider three main areas: prevention, treatment and care of the 600,000 HIV-positive Thai people and mitigation of the impact of HIV, acknowledging that HIV/AIDS is more than simply a

disease, as it concerns many other dimensions in people's lives and society as a whole. Efforts around prevention technology and tools, including condoms, have produced hopeful outcomes, also requiring an increased responsibility to provide correct information to and educate the public. Engagement and involvement of community members is essential, improving project efficacy and smoothness: local networks of PLHIV actively participated in treatment and care programs, and deserve much credit for the praise Thailand has received internationally. Human rights, equality and risk are important particularly with regard to identifying risk-associated behaviors rather than 'risky groups' and going beyond sexual, racial, religious differences to see all people as human beings. Universal access is another key issue, remaining on the agenda of the International AIDS Conference. The upcoming National AIDS Conference will focus on human rights in terms of ensuring that everyone will have equal access to new prevention-, treatment- and care-related tools and technology when these are available. This links to Thailand's universal health care system, which still does not ensure equal access to public health care for everyone living in Thailand, as it excludes undocumented migrants and displaced people.

## History, evolution and status of HIV prevention trials

### The big picture: Global biomedical HIV prevention research

*Speakers:* *Ms. Lori Miller, AVAC, USA*
*Dr. Kevin O'Reilly, World Health Organization (WHO), Geneva, Switzerland*

Any **comprehensive response to HIV/AIDS** must include the following elements:

1. Prevention: behavior change, voluntary confidential counseling and testing (VCCT), clean needles, prevention of mother-to-child transmission (PMTCT), condoms, sexually transmitted disease (STI) screening and treatment, male circumcision, etc.
2. Social justice: addressing the relationship between equality and poverty with the HIV/AIDS epidemic; understanding the behavior rather than blaming the group or individual, as these may not always have the power to change their situation

3. Testing: free and accessible voluntary counseling and testing
4. Treatment & Care: treatment of opportunistic infections (OIs), food security, nutrition, affordable and accessible ARV therapy
5. Research: vaccines, microbicides, PrEP and other interventions

**Strategies** for responding are based on **three phases – before, during and after exposure to HIV** – in line with the above-mentioned options. Still being researched are preventive vaccines and pre-exposure prophylaxis, 'under point of transmission' tools like topically applied vaginal and rectal microbicides, and vaccines for treatment. Rigorous biomedical prevention research processes can take ten or more years to complete and follow a systematic set of three main steps, from the conceptual idea formulation stage and laboratory-based development via pre-clinical trials in animals to three-stage clinical trials in humans that aim to ensure the drug is both safe and effective. There are currently over 50 clinical trials for HIV prevention methods being implemented globally including research in vaccines, microbicides, PrEP and partner treatment.

## The small(er) picture: HIV Prevention in Thailand – Adding to the tool box

*Moderator: Dr.Tanarak Plipat, Thailand MoPH – US CDC Collaboration (TUC)*
*Speaker: Joseph Chiu Armed Forces Research Institute of Medical Sciences (AFRIMS)*

Thailand's efforts to curb the epidemic have been slowed down by limited access to inefficient tools, evidenced by the occurrence of daily new infections that existing data (based on estimates and surveillance systems) has underestimated. New tools are useful, though it is the users who make a difference with regard to decisions around when and how to apply them.

### *HIV Vaccine Research – RV144*

The Thailand-based US Army Medical Component, Armed Forces Research Institute of Medical Sciences (USAMC-AFRIMS) is doing research on three promising prevention approaches in the effort to develop a globally effective HIV vaccine. Despite the promise, many questions remain. The ideal PrEP would be a vaccine, because with a vaccine there is, has been or tends to be

- ✓ Proven success in other fields: e.g. human papilloma virus (HPV) prevention in adolescents and also H1N1
- ✓ Better adherence: Vaccines are easier to administer, better than relying on someone to take a drug every day
- ✓ Less danger of resistance: The long-term effects of ARVs in the PrEP context are not clear yet.
- ✓ The option of integrating into existing vaccination programs: Many countries implement good immunization programs
- ✓ A cost-effective prevention of infectious diseases

AFRIMS covers three areas in developing an effective HIV vaccine: conducting human phase 1-3 trials (announced in 2003 and working with the Faculty of Medicine, Siriraj Hospital, Mahidol University and the medical research unit of the Thai Army to select vaccine candidates); investigating human immune responses to HIV infection and HIV vaccines (e.g. hepatitis – if people display antibodies, they can be protected); and characterizing the HIV epidemic and HIV viral diversity among high risk populations.

The **key findings** of the Phase 3 RV144 clinical trial (administered to 8,000 people) concluded the vaccine regimen was safe; offered modest protection with an efficacy rate of 31.2%; could not control the virus after infection; and resulted in higher efficacy early on and within low risk populations. **Key questions** include whether efficacy could be sustained with a booster dose at 12 months; whether a vaccine can protect those at higher risk; and what the correlates of protection are. Thirty scientists who submitted proposals from across the world – including Thailand – are examining the latter, to be reviewed by a scientific steering committee, and they will have the first answers by mid-2011. Another question is whether RV144 will also work against HIV subtypes A, B, and C, as Thailand mostly has subtypes B and E. Work on developing a vaccine that would cover all subtypes is beginning, mostly in Phase 1 trials in affiliated African sites.

The HIV/AIDS research field has progressed dramatically, with tests being done now that were not available even three years ago, and requiring ongoing studies. **Three follow-on laboratory studies of RV144** – all due in 2011 – aim to

evaluate immunogenicity instead of the efficacy rate. This includes AIDSVAX (RV 328), RV 144 extended boost study (RV 305) (focusing on uninfected RV144 recipients), and an intensive immunogenicity study (RV 306) (vaccinating new volunteers). Researchers want to find out whether the vaccine can reduce immune response in those important populations. Once the vaccine has been improved on, a trial is planned in high risk populations, among them MSM. Non-vaccine AFRIMS research focuses on immune responses, studying people with acute infections.

## Pre-exposure Prophylaxis (PrEP)

*Speakers:* *Ms. Lori Miller, AVAC, USA*
*Dr. Kevin O'Reilly, World Health Organization (WHO), Geneva, Switzerland*

***What is PrEP and how does it work?***

PrEP is an experimental HIV prevention strategy using anti-retroviral drugs (ARVs) for HIV prevention in HIV negative people. It involves taking a single drug or combination of drugs before exposure to HIV to prevent infection from occurring. Examples of different possibilities are gels, sponges, pills, vaginal rings and injections that could be used daily, intermittently, once a week, every two weeks, once a month and episodically (e.g. before having sex). Most effectiveness trials involve daily oral PrEP or microbicides; agents used are Tenofovir Disoproxil Fumarate (TDF) and Tenofovir plus Emtricitabine (TDF/FTC - Truvada), and Tenofovir (TVF) gel. Initial results from oral PrEP clinical trials are good, but the research process for other PrEP technologies is ongoing. Some ARV-based prevention strategies are already applied widely in PMTCT and PEP (Post-exposure Prophylaxis).

***Why PrEP?***

Evidence that PrEP already works can be found in the use of ARVs in preventing mother-to-child transmission (Nevirapine and Zidovudine can block transmission that could happen during breast feeding), animal tests, post-exposure prophylaxis (PEP), and now the iPrEx study as well. The rationale is thus clear: **an HIV uninfected individual takes antiretroviral medication(s) and by having these**

**medications in the blood stream, HIV may be unable to establish infection.** Preclinical trials of TDF and TDF/FTC in macaque monkeys showed 70-100% effectiveness in protecting from infection. Truvada is appropriate because of its

- ✓ **High potency & quick absorption:** increases potential for intermittent use; broad antiretroviral activity; blocks initial infection because acts early in life-cycle of HIV.
- ✓ **Well-known safety profile:** difference in tolerance of sick people taking them for treatment versus well people taking them for prevention; high barrier to resistance.
- ✓ **Relative ease of use:** 1 pill per day, no complications with other medication or food.

*The current state of PrEP research*

There are numerous studies at different stages taking place in the world, with two PrEP trials in Thailand, iPrEx (the completed 2007-2012 trial using Truvada with MSM and transgender women) and CDC 4370 (the Bangkok study using Tenofovir with injecting drug users, to be finished 2012). The CAPRISA 004 trials using a vaginal 1% Tenofovir gel, announced in Vienna 2010 showed HIV infection reduced by 39% among heterosexual women participants from South Africa; the gel also helped reduce infection of Herpes Simplex Virus 2.

PrEP remains an exciting research topic, although without clear answers. Discussions and decisions on how to move forward must happen at the country level, with international entities like the WHO or AVAC offering guidance. Setting appropriate parameters for the possible format of the discussion to take place is not easy; it is essential, however, that everyone fully understands the practical aspects of PrEP and its possible social, political, and economic implications.

## iPrEx Revealed - Outcome of the iPrEx study in Men Who Have Sex with Men

*Moderator: Khun Supatra Nacapew, Chair, Thai NGO Coalition on AIDS, and Director of the Foundation for AIDS Rights*

*Speaker: Dr. Suwat Chariyalertsak, Director, Research Institute for Health Sciences (RIHES), Chiang Mai University*

> ***"Oral FTC/TDF PrEP provided additional protection against the acquisition of HIV infection among MSM receiving a comprehensive package of prevention services."***

News about iPrEx results was disseminated via local and international media. Some English-language documents were translated, shared with the Thai press and posted on the Research Institute for Health Sciences (RIHES) and iPrEx websites. Misunderstandings and misinformation occurred, such as misquoting the source piece (calling iPrEx "ITECH"), and most of the photos included were unrelated and could give readers a wrong impression (file photos of the first-line ARV combination therapy GPO-VIR might lead readers to assume that taking it would prevent infection). Dr. Suwat was interviewed on Thai TV and a Chinese film crew made a documentary for Chinese TV, anticipating 70 million viewers. There is also the official iPrEx clip "Even stronger" on YouTube, which introduces global results.

The global iPrEx study – **Pre-exposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men, and focusing on 'Safety, Efficacy, Behavior, and Biology'** – was sponsored by NIH/NIAID/DAIDS, co-funded by the Bill &Melinda Gates Foundation, with drugs donated by Gilead Sciences. The trials used the ARV combination Truvada [Tenofovir (TDF) and Emtricitabine (FTC)], included a total of 2,499 participants (5%, or a total of 114, were based in Thailand) and were conducted in eleven trial sites in six countries (Brazil, Ecuador, Peru, South Africa, Thailand, USA). Positive results were released on 23 November 2010. In Thailand, RIHES managed the trial and Ban Piman Center in Chiang Mai was the main implementation site.

Thailand is one site of the iPrEx study on PrEP focusing on MSM. Key results: **oral FTC/TDF PrEP provided additional protection against the acquisition of HIV infection among MSM receiving a comprehensive package of prevention services,** and detectable drug in the blood stream strongly correlated with the prophylactic effect. Among 100 HIV incident cases (plus 10 cases at baseline), 36 were recorded among the 1,251 participants given Truvada, and 64 among the 1,248 who had been given a placebo. This showed that the drug reduced the risk of infection by 43.8 percent. Data indicated that efficacy was clearly related to drug adherence: if adherence was over 50%, data indicated that risk of HIV infection was reduced by 50.2%, if adherence exceeded 90%, data indicated risk of HIV infection was reduced by 72.8%. In terms of drug safety and resistance, there was no severe toxicity, and few side effects like nausea and weight loss occurred. Drug resistance did not occur among those infected after PrEP started; the three cases of drug resistance occurred in people who had been tested HIV positive at enrollment.

Some issues were raised in the course of the study, including around **participants' reactions to side effects** when using either the drug or the placebo. In the context of safety, bone mass studies will continue assess impact in participants taking the drug. Also, a death was reported during the study, though this was a motor cycle accident and not related to the trial proceedings in any way, which pointed to the importance of careful, monitored communication with media.

The next phase, iPrEx 2: Open Label Extension' will involve giving Truvada to the HIV-negative participants of both arms (treatment and placebo) of the first trial and observing their sexual and pill taking behaviors, which are significant determinants of PrEP effects in practice. Information about PrEP safety and efficacy could affect this behavior.

## iPrEx Thailand – Involving the community

*Speaker: Khun Thitiyanant Nakpoh, Ban Piman Community Advisory Board (CAB) and M plus member*

**Community engagement** throughout the iPrEx trials was active in Thailand. The non-governmental organization (NGO) M plus, the Chiang Mai Provincial Public Health Office and RIHES coordinated this work together, because M plus is rooted in the locality and people know the organization. She joined community activities in Phase 1, mainly talking to people in the field, building rapport and simultaneously campaigning on HIV/AIDS through trainings, handing out IEC materials at events and referring individuals for VCT.

In terms of **pre-study selection**, the team targeted several groups in the Ban Piman Center in Chiang Mai, including sex workers, transgender people and transvestites. The iPrEx team searched in various establishments such as pubs, bars and other communities where MSM and transgender people met. In Chiang Mai there were few gathering places except M plus and Purple House (a community-based support group for HIV infected MSM). Most of the transgender individuals were university students who tended to live sedentary lives together with their partners. One study-related benefit was that recruits, and also participants, received free medical checkups for blood, kidney, liver, internal organ function, especially the regular blood tests were useful, as some of them expressed initial fear of blood tests.

## iPrEx implications for Thailand or 'The unfinished white temple'

*Speaker: Dr Frits van Griensven, Thailand MoPH – U.S. CDC Collaboration (TUC)*

> ***"There is a beautiful white temple in northern Thailand which was started years ago and never seems to be completed, because the architect always finds something new and special to add. PrEP is very similar, and if we can be satisfied with something beautiful that is never finished, we will be able to do a god job."***

**The Thailand MoPH– U.S. CDC Collaboration (TUC)** had plans for future programmatic intervention focusing on men who have sex with men, working at the Silom Community Clinic. TUC's MSM cohort study focused on the willingness to participate, sex planning and spacing of the participants (how often people will have sex, if they know in advance etc.) and pharmaco-economics (cost of the drug).

**Sex planning and spacing for MSM** is relevant as it can affect how often people need to take a pill. The daily regimen is relatively easy for most to follow, but would only make sense for the small percentage of MSM who have sex more than once a week. For the majority, an alternative regimen makes more sense as they have sex less often and therefore low exposure to infection. Another consideration is the spacing of sexual activity (i.e. three times in one day or more on the weekends). Currently three main alternative dosage regimens are being looked at: **daily dosing (time driven), pre-post sexual exposure dosing (exposure/event-driven), and bi-weekly standing plus post exposure dosing (hybrid dosing).** Economics becomes important because of the three options the exposure driven regimen is the cheapest, as it requires the least amount of drugs, while the time driven regimen is tied to daily intake and therefore most expensive.

In a study on intermittent adherence in Kenya, overall adherence was 68%, though post-coital intake very low. Monitoring is also controversial due to the frequent inconsistencies of self-reporting. A new study called ADAPT (HPTN 67) to

start in 2011 will research the above-mentioned alternative dosing options using different ARVs and focusing on high risk MSM in Bangkok and high risk heterosexual women in Capetown. It is anticipated that the findings will show daily dosing is the most effective in protecting from infection. The recently concluded CAPRISA study of vaginal gel the use before and after vaginal sex showed 39% difference in infection rate between the gel and placebo arms. This may be of significance for transgender women with vaginas and also raises the possibility of applying it rectally for MSM. The microbicide could then be used in combination with the oral pill.

**A very high percentage of young MSM– 30% - were infected** by the end of a Silom Community Clinic cohort study from 2006-2010. With MSM it has been shown that when they do not get infected when young, then the likelihood that they get infected later decreases. Thus, any programmatic interventions should focus on those with the highest behavioral risk: young MSM experimenting sensuality/sexuality and young entering male sex workers.

## Issues and challenges around PrEP

> ***"Just like people forget to take their pills, we tend to forget how difficult it is to do things effectively and efficiently in the field that worked well in the ideal conditions of a clinical trial setting."***
>
> *Dr. Kevin O'Reilly, World Health Organization (WHO)*

The iPrEx study results could transform HIV prevention packages worldwide, yet much remains to be discovered from **additional analysis,** and the issues around practical PrEP application deserve a **robust discussion before decisions are made,** especially since there is no obvious or 'right' way to proceed with implementation. With regard to this particular target group – men who have sex with men – it will be a long time before other controlled trials will yield results, so it is imperative to look more closely at the large amount of data emerging from the iPrEx study. Any decisions made will be based on assumption models – and it is already known that the **transition from trials to implementation is always**

**more complicated than hoped and planned for**, in terms of pace, scale and quality; just like people forget to take their pills, we tend to forget how difficult it is to do things effectively and efficiently in the field that worked well in the ideal conditions of a clinical trial setting.

The following **key issues and challenges** for introducing daily oral PrEP standards to expand country-level HIV/AIDS prevention interventions were noted throughout the stakeholder meeting. Everyone agreed that **PrEP is NOT to be regarded as a stand-alone solution, but should only be used as part of a comprehensive HIV Prevention Package.**

- **Limited results:** PrEP is not for every group of individuals with risk-associated behavior, it has been tested only among MSM. Also, there will be no more trials or biomedical data for this population group, and it is difficult and impossible to make decisions based on one trial alone.

- **Cost:** Who will pay for PrEP? What is the cost-effectiveness? In the US there could be a cost of 7-14,000 USD per person per year, with much cheaper costs in developing countries (however, given the potentially high numbers of people using PrEP, the cost even in countries like Thailand could end up being prohibitively high.)

- **Distribution:** Should Truvada be distributed in a controlled process, targeting specific, high risk groups? Or distributed widely to the general public? Another approach is to channel distribution via programmatic interventions. The indication is that PrEP is most effective in highest risk individuals, and that targeted distribution would be most cost-effective, yet this is politically delicate and 'unpopular'. Uniform coverage, by contrast, is the least expensive but also the least effective.

- **Access:** A wider dissemination of iPrEx results can lead to premature access, as more well off people will start requesting Truvada prescriptions from their doctors in private clinics. Medical practitioners have to be trained to provide correct information, educate users about comprehensive prevention package and be able to monitor use. Attempts to find Truvada via grey or black markets may also increase.

- **Adherence:** People do not take pills reliably and 'negative' pill taking is less of an incentive than 'positive' pill-taking. An individual's motivation to ensure consistent PrEP adherence could be affected by any number of circumstances, so implementers need to answer the question of how to simulate the same level of reinforcement in the real world as in the clinical trials. The biggest existing example in terms of daily oral drug intake is oral contraceptives, with trials 99.5% effective and reality showing similar (lower) results as condoms – and the reasons for women not taking the pills regularly varied as much as will probably be the case for PrEP. In the iPrEx study adherence was generally poor, though intermittent dosing may result in better adherence because knowing the drug works could provide stronger motivation. Related questions include: Should intake be stopped when the risk of infection has passed? Should both partners take PrEP or only one? How should adherence be monitored, through blood tests or self-reporting?

- **HIV infection:** It is crucial to keep in mind that someone taking PrEP can still become HIV-infected. How often will blood tests be necessary? Can drug intake be stopped immediately when infection occurs?

- **Political dynamics:** In times of global economic constraints, it is not clear how to use new technology like PrEP without challenging the resources of people and countries already in debt, particularly in light of the disenfranchised target populations: MSM, sex workers, IDU are politically difficult to advocate for as they are not powerful.

- **No 'magic bullet':** Prep is simply "another arrow in the quiver of prevention options." Although people are always looking for the one thing that will prevent the epidemic, so far nothing has been found and it is not likely this will be found, and it would be dangerous if PrEP is used to substitute or remove other methods.

- **Regulatory approval:** These vary from country to country, with some happy to make drugs available by using existing indicators to regulate "off-label use" while some countries require an additional step in the regulation process.

- **Manufacturing capacity:** It is possible that manufacture will not be able to keep pace with demand or need.

- **Behavioral compensation or disinhibition:** The availability of PrEP and the belief that the drug will help may lead to greater risk-taking; people on PrEP may choose more partners, have partners with more risky behaviors, use condoms less etc. It will be crucial to find ways to implement PrEP without undoing the good practices in place so far. In Thailand condom use is a very important part of prevention strategies, so this possible threat must be considered.

- **Safety - complications/side effects:** This includes short and long-term effects, with the latter still unknown due to the limited length of the trial. Possible effects like renal dysfunction and hepatitis B flares are being examined, though the iPrEx results have been somewhat reassuring. The hormone intake of many transgender individuals (who sometimes take 3 pills a day and one injection per week) could also lead to longer-term side effects.

- **Drug resistance:** It is good to remain aware of this possibility and limit the potential by monitoring closely for break-through infections. The interval has not yet been established. Fortunately, iPrEx results have also been somewhat reassuring on this front. Post-project closure follow up with the volunteers is also necessary in case infection occurs after completion of the study.

*Specific challenges for Thailand*

- There are too few local HIV prevention campaigns.
- Adherence is not as high as it should/could be.
- Rates of male circumcision are still low and should/could be increased.
- Negative attitudes and stigmatization in society regarding HIV/AIDS-related issues are still common and should be addressed more consistently.
- There must be an ongoing reminder for people that condoms work and to keep using them.
- More effective prevention tools are needed; existing tools can be used to full capacity, but this could strain the system.

## Discussion on general iPrEx study–related issues

The 43.8 % reduction in HIV infection was the overall figure, not the figure for results from Thailand only even though 4-5% of the participants were Thailand-based. The trial was not designed for analysis of results from each individual site or country.

The iPrEx study results were useful in the context of the Thai public health structure, where the VCT system could be linked to a future daily oral PrEP distribution process. There are similarities to Hepatitis B treatment, because medication also has to be taken every day. The question for decision-makers now is where to allocate the budget – towards general distribution or focusing on vulnerable/high risk groups. A possibility is to initiate a pilot project.

Another observation discussed the greater acceptance and implementation of male circumcision in Thailand, where it is currently less cultural accepted prevention intervention. Since risk behavior and also cultural practices are different here, successful strategies need to address this. There are concerns from some that circumcision coupled with Truvada could increase risk behavior.

The appropriate **education and preparation of study volunteers** was discussed, with RIHES highlighting this as one of the steps to be followed. Volunteers should be well-informed before, during and after the study. RIHES and partners approached and held in-depth interviews with potential volunteers six months before asking them to join the trial process, also screening out unsuitable candidates like university students who did not engage in risky sexual behavior. RIHES also engaged with the CAB members and teachers.

Concerns regarding **target group selection** were voiced, including that other vulnerable groups like women were not being mentioned and that expanding Truvada use beyond MSM to the general heterosexual population could be difficult because of the stigmatization linked to the ‘high risk’ label. Although trials with women were taking place, the target groups in this case were MSM and

transgender people, and a certain level of risk was necessary to ensure the appropriateness of this new tool. PrEP focuses on groups with high risk behavior, because a low incidence rate among the participants would require a longer time to aquire the required endpoints and therefore a longer, more costly study. Of the approximately 20,000 people taking part in PrEP trials worldwide, a small percentage was MSM, and although everyone should receive equal treatment, this group has always been a neglected group in terms of support and research. The iPrEx study does not show for certain whether the results would be the same with heterosexual participants or injecting drug users.

The iPrEx team at Ban Piman Clinic in Thailand used several strategies to ensure a high **retention rate of volunteers**, at closure was about 95% (for a total of 114 members). The first step was the understanding among HIV positive people that they could save their own lives with ART. This tendency was found among sero-discordant couples, who in addition to ART also received marriage counseling. Similarly, gay or transgender individuals liked visiting Ban Piman because it felt like a second home. Staff did not focus on 'educating' members or treating them in some way like 'guinea pigs', instead making sure they were well-informed and also emphasizing that this was something more important and symbolic - they were assisting in finding solutions for larger questions relevant for humanity. Members also knew they could withdraw any time and were encouraged to discuss their needs with staff so that a solution could be found together. On a practical level, the staff expressed interest in members by giving them birthday cards and gifts, or being on call 24 hours for emergencies (domestic violence, drug use issues, and insomnia). Ultimately, members saw themselves as official representatives of one of six countries worldwide and this gave them a sense of purpose.

## From research to implementation – Small group report back and discussion

### 1. Further research to build on the outcome of the iPrEx study in Thailand

A broad range of research-related topics were discussed by small group members, with meeting participants adding other perspectives in plenary; all are summarized here.

*Issues and recommendations*

**Sexual behaviors**

There is need to talk more about varying sexual behaviors and how these affect different regimens. Transgender individuals and gay men display different sexual behaviors, and this was not addressed as part of the iPrEx study.

**Hormone use**

The use of hormones by some transgender people was not examined and more attention to this in the context of Truvada intake could help identify possible long-term side effects.

**Alternate dosage regimens**

The effect of different regimens on dosage levels deserves further research in order to identify the most effective minimum dose and what would happen if volunteers change from daily to before and/or after sex or weekly doses.

**Equality and access**

This is a crucial issue related to stigma and discrimination that needs more attention: a way to ensure that volunteers themselves have access to the drugs they have been taking as members of the trials. In a future roll-out of Truvada it is possible that MSM will not have the same access as other populations and solutions for this obstacle have to be found.

**Social and behavioral research**

More research, focusing not only on bio-medical, but also on social, behavioral aspects, is required to understand the impact of daily Truvada. A combination of qualitative and quantitative research (such as in-depth interviews and focus group discussions) will provide the most comprehensive understanding of these issues and will help improve the efficiency and effectiveness of long-term implementation. Since the iPrEx team already needs to follow up with volunteers for 18 more months, they can study social behavior patterns for these and then design appropriate research questions. Each site also has sub-studies inserted in protocol, which include small focus group discussions where independent researchers talked to participants about happiness and suffering when taking the regimen. In these settings, volunteers shared several reasons why they did/do not always consistently adhere to the given drug regimen, which included the phenomenon of lying to their doctors about drug intake.

This kind of research will allow practitioners and program staff to best prepare for the implementation of PrEP, including decisions around what kind of training medical personnel may need and how the general public should be informed and educated. It is important to make sure that society as a whole is ready for the implementation process, particularly since clinical trials take place in such specific settings, e.g. where counseling is already provided, while implementation may not always include each element.

**Perceptions of risk**

Qualitative research should also focus on behavioral questions about people's perceptions about the risk they are undergoing/exposing themselves to and whether they understand the consequences of their actions. This is different country to country and has changed in the field of HIV in general, where there is a high perception of risk and understanding of consequences because more people have been/are dying. Because treatment is available and HIV/AIDS tends to be considered more of a chronic disease, some stakeholders are concerned that people are shifting to regard HIV with more of a 'low risk approach' in terms of consequences. The possibility of risk compensation increasing or decreasing with inclusion of PrEP should be further examined. Throughout, it is important for

public health officials to make sure people understand the consequences of any medical interventions.

A greater understanding of people's 'lifestyle concepts' and perceptions concerning their own risk would thus be useful in implementing PrEP, including risk behavior reduction and the improvement of future trainings and other interventions on other issues. One study with MSM in Seattle showed 75% taking precautions and reducing risk, while 25% were still engaging in risky behaviors. It was found that the latter were at the time not in stable partnerships; this was an indication that when circumstances are right everyone is capable of risk behavior. PrEP could be seen possible as choice for people in periodic phases of risky behavior.

**Implementation – safety, resistance and adherence**

Effective implementation depends on a clear understanding of the interconnected issues of safety, resistance and adherence. In terms of safety, it is known that Truvada is generally safe, easy to take and longer-acting than other combinations, for example AZT. Results from the first and second trial phases have shown short-term renal dysfunction and Hepatitis B. In the future it is crucial to develop a process that ensures HIV-infected people stop taking the regimen immediately, or as soon as possible.

iPrEx demonstrated that Truvada is relatively safe and efficient, but care is still needed with regard to drug resistance. HIV positive individuals whose sero is converted while on Truvada need to stop with the regimen immediately should they become infected while taking it. Researchers need to study the differences in diverse populations.

A key factor in effectiveness – and also relevant to the context of drug resistance – is adherence. iPrEx showed that the better volunteers adhered to the regimen, the higher the overall efficacy rate. Further research could help identify more ways to monitor adherence and improve people's motivation to take drugs more consistently, e.g. devising a system to monitor bottle opening. A successful example is the prevention of mother-to-child-transmission (PMTCT), where

adherence is better because mothers are responsible for the lives of their children. In this context it is important to keep differences in countries and cultures in mind. It is important and a challenge for people who work closely with patients to think of innovative ways to make sure people adhere, and researchers can assist with more studies. Many possibilities exist with varying degrees of effectiveness: "buddy observed therapy", support from family members (who are often not the best), daily or monthly appointments within the health system, twice daily visits by community health workers (example from Cambodia).

There are lessons that PLHIV, practitioners, policy-makers and others working with HIV and AIDS can learn from the TB and malaria treatment context. Adherence is a crucial issue in drug-resistant TB, yet it is sometimes difficult to define adherence. There have been a number of studies on TB treatment, noting reasons why people do or do not take their medication consistently. Researchers studying PrEP-related adherence should review existing literature and see if the results are comparable. The same applies to prophylactic therapy, providing Isoniazid Preventive Therapy (IPT) via directly observed treatment (DOT) to people infected with TB but who have not yet developed TB disease. It is difficult for people to take pills for a condition they do not yet have, which is similar to preventive treatment for malaria, contraception, breast cancer etc.

**Stigma and discrimination**

If PrEP is provided to different population groups then this could result in stigmatization and/or social ostracism, with others assuming that group members engage in risky behavior. It is important to find effective ways for different populations to be able to be treated equally instead of being discriminated against based on which group they may or may not 'belong' to.

**Community engagement**

Researchers need to find ways to engage more community members. They already have the experience working with members of the community advisory boards (CABs), which is useful for the research teams and in promoting community participation, but broader community involvement is even better.

**Expansion to other population groups**

Truvada can be considered for HIV prevention for the key population of men who have sex with men and in this context only. Thus, researchers should continue expanding studies to include other population groups, focusing on those with similar behavior patterns and roots of infection. What works here for MSM may be different for other groups, for whom the cause of infection may be different; the results of about six additional ongoing trials will produce more data. Identifying and working with specific populations will lead to information necessary to design the most effective interventions. This includes private practitioners who can create more precise surveillance/monitoring systems.

**Efficacy rates and impact**

Data suggest the observed efficacy rate of 43.8% can be increased to around 70% with improved adherence. Results of the Tenofovir gel study – where the efficacy was 39% –are similar (see the CAPRISA study), and US FDA will need data from at least one other trial to confirm results and produce more data on drug resistance. Efficacy rates in the vaccine trials were around 31.2%. Some stakeholders felt that a rate of about 40% was still too low to warrant a broad roll out, and that more results were needed. Researchers need to decide on how to design further studies to find interventions with greater efficacy and also how to improve adherence and measure adherence.

Ultimately, higher efficacy rates are needed to gain 'buy-in' from policy-makers and therefore long-term policy level changes that can positively affect not only PrEP but also the implementation of future HIV prevention methods. Strengthening, promoting and consistently applying a comprehensive HIV prevention package as the foundation for introducing PrEP is also essential – this is a challenge for people working with HIV/AIDS, who need to agree on and maintain the elements of a high quality prevention package and how this can/should be implemented among which groups.

Current efficacy rates may be high enough to trigger immediate demand; with financially well-off people wanting to purchase the drugs and access related services, possibly both within and outside the formal health system. An appropriate communication strategy will be needed to address this probable response.

**Research methodology**

Since the trial was double-blind (i.e. participants did not know whether they were taking the drug or the placebo), volunteers knew they were taking a gamble and responded by generally maintaining lower risk behavior patterns, including demonstrating increased concern about their safety, visiting doctors regularly, protecting themselves. Other research teams will take this in and hopefully apply it in their design of new trials, although everyone needs to remain cautious about disinhibition or risk compensation, because the efficacy rate is still only moderately high.

**Voluntary informed consent**

A community member emphasized that in any research study, it is important that each participant gives his or her voluntary informed consent to be part of the study and knows that withdrawal is possible at any time.

*Conclusion*

Theoretical concerns and remaining research needs should not become an obstacle in implementing interventions, particularly since the promise of PrEP is good. However, it is prudent to gather more information, as is being done through the other PrEP studies, and move ahead cautiously. It is premature to advise the creation of a global policy based on the results of one study, though some countries may want to move forward on their own. The CDC, usually the entity in the practice of making recommendations, were cautious about the study, but because HIV prevalence was found to be at 25% among MSM in five major US cities, there is a pressing need for a new, effective tool. The CDC will be looking at this issue over next few months and may release interim guidance for providers and doctors on how to respond to individuals with high risk behaviors.

The way forward must be systematic, and if policy makers are to be convinced, then a superficial approach will not work. Thus the four main issues that need to be studied further include 1) the application of PrEP to groups beyond MSM; 2) a more in-depth understanding risk and context, also for other preventive interventions; 3) effective strategies to increase adherence; and 4) the design and implementation of effective monitoring/surveillance systems. The latter is already relevant with the release of the iPrEx study results: monitoring the situation will help see the impact on society as a whole.

## 2. Concerns and preparation of the public health system for inclusion of PrEP into the national comprehensive prevention package

The public health care system in Thailand has the responsibility to help mitigate the consequences of HIV infection and decrease incidence. Since it is Thailand's national agenda that every person gain access to public health services, the efficiency and effectiveness of overall service provision has to be discussed and reviewed even without the advent of PrEP. At this point it is difficult to say whether the system as a whole is ready or not; certain parts are ready while others lag behind, for example VCT and ART, as well as after- and pre-services are good. The adjustment of the system will take some time either way and will not be easy. PrEP, however, does bring new hope to those working with HIV and AIDS, and it can be used as a tool to help review the Thai public health system.

*Supporting points*

The implementation of PrEP should be considered despite the limitations and concerns mentioned throughout the stakeholder meeting (see also below). Some supporting reasons include:

- There are generally few interventions targeting MSM.
- The HIV prevalence rate among MSM tends to be high (at 13%).
- There are sub-groups of MSM who are vulnerable, such as male sex workers who have low negotiating power (for example in condom use) and would thus benefit from alternative protection).
- The need to acknowledge unbalanced power dynamics in sexual relationships between women and men, where women have much less negotiating power and are thus more vulnerable to infection. PrEP, whether in the form of daily oral pill (as in iPrEx) or as a microbicide gel in the future (about which not much has been commented in Thailand) offers a good addition to the current package elements like male condoms.
- There is a current need for this prevention service among some groups and to ascertain this need, application research is a possibility.
- Related socio-economic impacts could include a potentially high demand for and consumption of Truvada, which would affect the market and distribution systems, and trading of the drug in the black market.

*Issues and concerns*

Four main areas were discussed, along with related concerns.

1. It is not clear whether the iPrEx results (44% lower infection rate) are good enough to inform the general public about PrEP and move ahead with implementation.

2. Additional resource requirements and funding sources must be identified. This is especially relevant in the context of treatment, as there generally tends to be greater willingness to allocate budget for treatment; if this is the case, then perhaps PrEP implementation has to be put on hold. How will PrEP implementation affect – and be affected by the decentralized structure, including budgets? The National Health Security Office (NHSO) is convinced by civil society ideas and although they have begun communicating with the Budget Bureau, it is not sure whether they will indeed allocate the budget necessary for implementation. There is a current trend in allocating more funds to NGOs, where people working in prevention and promotion may be working.

3. The overall readiness of the public health system has to be ascertained. This will probably differ from province to province, yet waiting for each province to be ready is not feasible. Programs could be launched in some localities where specific groups request the services. However, as final research results have yet to emerge, the system should at the very least begin with preparations. This includes educating community members like MSM so they are aware of the new drugs. A number of other areas need to be addressed as well.
   - Everyone has to be very clear about what constitutes the public health system. People tend to automatically think about the MoPH, hospitals, government clinics and related entities, but it is evident that the private and civil society sectors are also involved in the system here in Thailand. From the civil society perspective, the NHSO is the biggest entity within the public health care system. All these agencies and sectors should collaborate in an integrated way, or risk a process of information dissemination, the preparation of access to services and referrals that is not smooth.

- The country's objective is to reduce the HIV incidence rate by half. According to the Global Fund, currently providing funds as part of Round 8, greater community involvement is essential to effective HIV prevention, yet this requires more pro-active efforts by the government to engage key populations like IDU, prisoners, migrant workers etc. through the provision of high quality services including drop in/outreach centers, referral systems etc. The problem of insufficient human resources can be solved by approaching and learning from PLHIV themselves, who do not only receive services but also provide important services, and to invest in capacity building programs for community members where relevant. This would help make the system and interventions more sustainable, as it is not advisable to rely on GF money that will one day no longer be available.
- Implementing PrEP will probably increase the burden on medical personnel, who, though willing and able to offer services to patients as this is part of their responsibility often do not provide very patient-friendly/-centered services.
- The decision-making process for practitioners has to be reviewed as they are in control of service delivery and may take advantage of that power by withholding services. Thus PMTCT is effective, but it is possible that some patients approach the practitioner for support and do not receive it. This will be particularly relevant with regard to PrEP, were someone makes the decision whether a person is at risk and/or whether PrEP might be appropriate for them.
- The existing VCT system needs to be improved in some areas in order to incorporate PrEP appropriately. It is important that the public health system facilitate this process, including the expansion from VCT to VCCT (voluntary confidential counseling and testing), as it both a tool and a frontline service and represents the link between treatment and prevention. This is where the role of civil society can be incorporated, for example ensuring through the appropriate training of outreach workers or volunteers that key communities like MSM and sex workers are reached and that patients going to the hospital already have prior knowledge about VCT, as this will allow them to make informed decisions. The public health system must be made more efficient to enhance VCT, such as offering a same-day results test,

because too great a burden (due to inefficiency) will put pre- or post-test counseling at risk.

- Post-exposure prophylaxis (PEP) needs to be discussed, as it could go hand in hand with PrEP in providing alternate solutions for marginalized groups like CSWs who often do not use condoms. PEP is also relevant in the context of involuntary exposure such as needle sticks or rape.
- Needle exchange programs should be discussed as another good intervention for the public health system to support.
- The Universal Coverage (UC) system under NHSO is at present able to check/test patients bi-annually but it is not certain how this rate of testing could be increased if needed.
- The public health system would need to be ready to deal with and appropriately monitor related issues like side effects, adherence and drug resistance. Strategies to promote higher rates of adherence with the existing mechanisms need to be designed.
- Pre-PrEP HIV testing and regular blood testing during PrEP intake should be offered.
- The related important issues of gender and sexuality must be highlighted and how the public health system addresses them.
- For financially well-off individuals who need to use PrEP, clinical practice guidelines may have to be (re-) examined.

4. Those responsible for roll-out will have to strategize on how to maximize the implementation and use of PrEP (with the repeated reminder that iPrEx is only relevant for MSM, and there are still no results available for other groups), including an implementation program or schedule for different population groups.MSM were chosen as the target population because results were needed quickly and it was already known that incidence rates were high among them.

*Recommendations*

1. The opportunities around GFATM Round 8should be taken advantage of, including the annual national report submitted to the Global Fund. This requires Thailand to proceed very carefully in setting the direction for PrEP.

One goal should be to promote more collaboration between and also to work in tandem with the public and civil society sectors. Government agencies can also cooperate to implement in different areas.

2. A high quality basic package of prevention services–including equal promotion for elements like condoms – should be developed with PrEP forming a part and aimed at a variety of populations that display high-risk behaviors. This package could be prepared for MSM first and could be implemented in the context of Global Fund Round 9 and as a contingency or emergency plan.

3. Before implementation starts, a clear, efficient public communication plan to introduce PrEP to the general public is needed to prevent misunderstandings and misinformation within affected communities and the general public. Negative effects could occur without such a plan, including the misuse of drugs and risk-associated behavior. The plan should be aimed at three different target groups: MSM, practitioners and service providers, and society at large. Methodology should include building an understanding from the grassroots up, producing easy-to-understand information, and building a communication network.

4. The target population for PrEP implementation should be decided on and include MSM as well as various sub-groups that may engage in high risk behavior - young MSM, young male sex workers, and prison inmates. The latter group is frequently neglected, although HIV positive inmates take advantage of their rights as part of UC or NAPHA extension programs, and prison medical staff also provides education around HIV/AIDS. Prisons are high risk environments, including the availability of (injecting) drugs and sexual services gained in exchange for cigarettes or food. Work has been done with female and male inmates in Chiang Mai province, where most of the prison population was convicted on drug charges, and the vast majority continues to use drugs. PrEP would be an appropriate intervention in this setting as clean needle programs are prohibited and condoms only distributed in some prisons.

5. The Thai public health system should be prepared to provide some kind of motivation and/or compensation for volunteers who take part in clinical trials like iPrEx. In the context of implementing PrEP, these individuals who have sacrificed themselves for the sake of improving health conditions for humanity, should receive incentives that could include special benefits, such as health care for life. This would also improve the trial process, possibly decreasing low adherence and/or faulty reporting.

## 3. Preparation of civil society and the community for the inclusion of PrEP into the national system for prevention and care

Two sub-groups discussed the implications for and needs of civil society related to PrEP implementation. This included main issues and concerns, the best conditions for and restrictions on decision-making, possible impact on existing programs, and the requirements for long-term effects and success. Other meeting participants added their perspectives in plenary; all are summarized in the following recommendations.

*Recommendations*

1. Continued awareness and understanding of stigma and discrimination and how they affect target populations are the key to implementing PrEP and all related activities effectively.

2. The impact on existing programs like condom distribution, STIs, unwanted pregnancies, etc., may be great. Any preparations must incorporate clarity on what this could mean for PrEP implementation in the short and longer term. A system of coordination with existing programs and entities should be created. Budgetary requirements would probably increase, for example in VCT programs or to support agencies who would screen individuals for PrEP. Existing treatment schemes may also be affected, with people seeking drugs by themselves and not considering potential effects on their internal organs and how this could impact on future treatment needs.

3. The implementation process should respect the contribution of the volunteer participants in the trial and consider options to compensate them for their involvement, for example by reimbursing them. This could be discussed also in terms of future trials.

4. Any prevention package must be adapted to suit different target groups, as these can be disparate in their needs. PrEP should not only be seen as a new tool but also as an opportunity to expand communication and awareness raising among both key populations and the general public.

5. The monitoring of drug distribution and sales is a process that is often neglected, but for PrEP it is important to record how and where Truvada is sold, including official channels, black or grey market procurement, re-sales, or sale among friends. This also affects the relationship between researchers, implementers/program managers and drug manufacturers and distributors like the Government Pharmaceutical Organization (GPO). A systematic and regular coordination process should be established with support from the government for researchers.

6. Ensuring appropriate, accurate and timely information, education and communication is a crucial aspect of any implementation process. In Thailand, a large-scale, well-coordinated education campaign around PrEP is needed, and it can use existing mechanisms like peer educators and outreach workers to share prevention options and research outcomes, help reduce stigmatization and increase levels of communication and interaction. Thus people working with related issues – school teachers, medical staff and NGO workers – need to keep up with new developments and this will require capacity building in the form of training. Curricula must be tailored to different target groups, including adapting language, and avoiding information overload or excessively technical terminology, which can lead to confusion and possibly misuse of the drug regimen. This includes setting a clear distinction between PrEP and PEP, as perceptions and knowledge among PLHIV about these two prophylaxis methods continues to be an issue, with PLHIV networks equipped with varying levels of information and understanding.

7. As noted several times during the meeting, it is essential to integrate the media into the overall PrEP planning and implementation process. If appropriately informed, media practitioners can become allies and provide excellent public relations. Those working with PrEP need to learn how to use and collaborate effectively with the media, managing the communication process systematically. This includes a long preparation process prior to roll-out, multi-lingual approach, high quality translation, timely release/sharing of accurate, clear information, and providing education and training to media personnel. Three important issues were highlighted: ensure that the source of the information is correct and is communicated in an appropriate manner; understand that journalists are guided by the requirements and limitations of their profession and tend to tailor news to their audiences, who prefer news to be interesting or fun or unusual in some way; understand that the public responds like consumers, and news becomes a product that needs to be 'sold' to them like any other product – and in media, 'good news is no news.'

8. PrEP implementers must take an integrated approach, bringing together related prevention, treatment and care systems and processes, getting buy-in from policy-makers, working with the media, continuing to use and adapting existing tools, and collaborating actively with community members.

9. A variety of areas require further study, including social-behavioral aspects in addition to the clinical focus, dosages and frequency of intake, different types of drugs, intake options (from oral to injection and topical)

10. Incorporating principles of good participatory practice (GPP) is important for the civil society sector and has already been successfully applied in Thailand, where stakeholders were involved before, during and after iPrEx. In November 2010, TNCA organized two consultation forums on GPP to connect with a broad range of stakeholders.

11. Finally, a fundamental shift in perception and attitude is necessary, one where everyone begins to 'think outside the box' when working with new or existing prevention tools in Thai society. One insight is to consider the emotional

impact HIV has had on people's sexuality and sex life - nobody mentions the fact that since the advent of HIV, sex has stopped being fun, and that people's happiness has consequently also been decreasing. The general public may know how HIV is transmitted, but the ongoing occurrence of new incidences clearly indicates that this knowledge is not being translated into action in their daily lives. Thus a more fundamental attitude change becomes necessary; it is no longer useful to maintain old ways of thinking or working, as these are clearly not effective in motivating people to go to hospital or get tested or consistently use condoms or other preventive methods. The message should therefore transform accordingly: when discussing condom use, for example, instead of talking about safety, it is the happiness and joy which individuals experience related to sex and sexuality that should be emphasized. People themselves should have a part in deciding what is most important if they want to maintain or increase happiness.

## Conclusion – A way forward

Participants emphasized that any recommendations made now are preliminary; it is only when final results have been compiled that more concrete ones can be made. The following recommendations seem most relevant for planning and organizing PrEP implementation at the national level, though the recommendations recorded for each of the three key themes (further research, public health system and civil society) must also be considered before any concrete steps are taken.

## National PrEP implementation – Thailand multi-stakeholder recommendations

### Comprehensive HIV prevention package

One of the main issues affecting the way forward in implementing PrEP in Thailand is the ongoing occurrence of new HIV incidences, which the government plans to reduce by half (in 2011 incidence was reduced by 50 %). The most effective way to address this is to ensure that any PrEP treatment should not be seen as a stand-alone solution, but only as an integral part of a comprehensive HIV prevention package. Related questions include how to incorporate PrEP into the existing package in Thailand, and – looking at the larger picture in the future – accepting that drugs are only one option of many and may be more risky due to possible side effects and/or drug resistance. Incidence rates can be reduced if with the integrated approach, because people would have access to VCT and other elements of the package.

### Unified country level mechanism

In Thailand different groups prioritize different issues and in order to successfully implement PrEP a unified, country-level mechanism is necessary. The National AIDS Committee (NAC) has a subcommittee for an HIV vaccine, and at the last NAC meeting an expansion of the committee's scope of work to include other biomedical HIV prevention researches was discussed, as well as the possibility of establishing more subcommittees, which could help in scaling up awareness around the issue.

### Rights of affected people

Implementers must remain aware of and consider the rights of target populations throughout any implementation process, including key group with high risk-associated behaviors and people already living with HIV/AIDS. This includes putting in place mechanisms and capacity building options for practitioners and others that combat stigmatization and discriminatory practices. A clear decision on whether and how to move forward depends on further pre-PrEP implementation research among members of target communities. More opinions and information

need to be collected from gay men, transgender people and other groups of MSM before an implementation strategy is designed. The concept of PrEP and their knowledge around this new opportunity should be tested on them first.

**Communication strategy**

An effective and holistic 'PrEP communication strategy' must be devised, one that does not focus exclusively on HIV prevention. This strategy must include a plan for approaching the media and establishing clear channels for discussion and information dissemination to media personnel. The strategy must ensure a clear message for society to avoid labeling MSM and other key population 'high risk groups', as they are already subject to high levels of stigmatization by the general public. The strategy should raise awareness and understanding of the gender concept in society. Innovative communication methods can be applied to different groups as well. For example, MSM in Thailand, who actively use internet-based, social networking sites like face book. The internet could thus be used to survey MSM, asking them about their adherence and other practices via web-based surveys or interacting with them in chat rooms. M plus could help initiate this connection. Others in the civil society sector should also look into using new media and TNCA could assist in further examining this in the context of creating new surveillance mechanisms, educating society and also motivating greater civil society participation. Some kind of mechanism is needed that will facilitate discussion and engage the general public and people from all walks of life in addition to key populations or people working with HIV/AIDS.

**Funding**

This was an important area mentioned several times that requires more discussion, because without adequate financial support, suggested interventions would not be able to be implemented.

**A pilot project**

Dr. Frits van Griensven of TUC supported the general consensus on proceeding with caution, although he felt it was impossible to wait for conditions to be perfect before a roll out. He therefore recommended action in the form of a small pilot project examining community systems and social strengthening. In this project, Truvada would be used in two short 6-month (weekly for two months, monthly for four months) demonstration pilot projects of daily PrEP at a cost of about 1 million USD, via either dyads (where one person is responsible for the other), or buddy-observed therapy (BOT-PrEP). The pilots would have 500 people per group (250 dyads = 1000 total, 500 MSM, 500 MSW) and include

- weekly visits;
- KAPP adherence assessments;
- monthly pill counts;
- assessments of drug burden;
- possibly pre- and post-study bone density tests; and
- partnerships with different community groups.

Dr. Anupong Chitwarakorn of the Department of Disease Control, and Dr. Tanarak Plipat of TUC had already agreed to establish a research center focusing on MSM together with Dr. van Griensven, also of TUC. There will be more coordination and discussion with Silom Clinic regarding the budget for this new center.

National focal points that would be responsible for following up on related issues were identified. Dr. Petchsri Sirinirund of the National AIDS Management Center would approach colleagues about this situation. Dr. Anupong Chitwarakorn agreed to be the focal point concerning surveillance mechanisms with private practitioners and possibly also the coordination point with the Department of Disease Control (DDC). Dr. Suwat Chariyalertsak of RIHES will continue focusing on the research aspect, while Dr. Timothy Holtz of TUC would be the focal point in TUC for future collaboration with researchers and both the public and private sectors.

# Annex 1 – Agenda

**Pre-exposure Prophylaxis (PrEP) Stakeholder Meeting**
**December 8-9, 2010**
**Princeton Park Suite, Din Daeng, Bangkok**

**Wednesday 8 December 2010**

09:00-09:30 Opening remarks
Moderator: Dr. Petchsri Sirinirund
- Dr. Somsak Akasilp, Deputy Director-General, Department of Disease Control, Ministry of Public Health
- Khun Supatra Nacapew, Chair, Thai NGO Coalition on AIDS, and Director of the Foundation for AIDS Rights

09:30-10:30 History, evolution and status of HIV prevention trials – a global perspective
Moderator: Khun Niwat Suwanphattana
- Ms. Lori Miller, AVAC, USA
- Dr. Kevin O'Reilly, World Health Organization (WHO), Geneva, Switzerland

10:30-10:45 Break

11:00-13:00 Update Bio-medical HIV Prevention research Pre-exposure Prophylaxis
Moderator: Dr. Tanarak Plipat (TUC)
- Joseph Chiu, Armed Forces Research Institute of Medical Sciences, US Army Medical Component (USAMC-AFRIMS)
- Dr Frits van Griensven, Thailand MoPH – U.S. CDC Collaboration (TUC)

11.30-12.00 Discussion

12:00-13:00 Lunch

13:00-14:30 Concerns and responses to PrEP results – stakeholder perspectives
Moderator: Khun Supatra Nacapew

- "Outcome of iPrEx study in Men who have Sex with Men" by Dr. Suwat Chariyalertsak, Director, Research Institute for Health Sciences (RIHES), Chiang Mai University
- "Experience from iPrEx study community engagement" by Khun Thitiyanant Nakpoh, Ban Piman Community Advisory Board

**Discussion**

14:30-16:30 From research to implementation – small group breakout
Mixed: GO, NGO, CAB, researchers, CBO
Moderators: Dr. Suwat Chariyalertsak, Dr. Petchsri Sirinirund (NAMc),
Khun Niwat Suwanphatthana

Group 1: Concerns and preparation of the public health system for inclusion of PrEP into the national comprehensive prevention package
Group 2: Concerns and preparation of civil society and the community for the inclusion of PrEP into the national system for prevention and care
Group 3: Further research to build on the outcome of the iPrEx study in Thailand, including the participation of stakeholders

**Thursday 9 December 2010**

09:00-12:00 Small groups report back and discussion
Summary of important points for

- Preparation of the public health system for inclusion of PrEP into the national comprehensive prevention package
- Preparation of civil society and the community for the inclusion of PrEP into the national system for prevention and care
- Further research to build on the outcome of the iPrEx study in Thailand, including the participation of stakeholders

12:00-12:30 Wrap up and closing remarks

- Dr. Petchsri Sirinirund, Director, National AIDS Management Center, Department of Disease Control, Ministry of Public Health

# Annex 2 – Acronyms

| | |
|---|---|
| AFRIMS | Armed Forces Research Institute of Medical Sciences, US Army Medical Component |
| ARVs | Anti-retroviral drugs |
| CAB | Community Advisory Board |
| CAPRISA | Centre for the AIDS Programme of Research in South Africa |
| CDC | Centers for Disease Control and Prevention (USA) |
| CS | Civil society |
| CSW | Commercial sex workers |
| DDC | Department of Disease Control (Thailand) |
| FDA | Food and Drug Administration (US) |
| GFATM | The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria |
| GPO | Government Pharmaceutical Organization (Thailand) |
| GPP | Good participatory practice |
| HPV | Human papilloma virus |
| IDU | Injecting drug user(s) |
| iPrEx | Iniciativa Prophylaxis Pre-exposición (Pre-Exposure Prophylaxis Initiative) |
| IPT | Isoniazid preventive therapy |
| KAP | Knowledge, Attitude and Practice |
| MoPH | Ministry of Public Health (Thailand) |
| MTCT | Mother-to-child transmission |
| MSM | Men who have sex with men |
| MSW | Male sex workers |
| NAC | National AIDS Committee |
| NAMc | National AIDS Management Center |
| NAPHA | National Access to Antiretroviral Program for People Living with HIV/AIDS |
| NGO | Non-governmental organization |
| NHSO | National Health Security Office (Thailand) |
| NIH | National Institutes of Health |
| OI | Opportunistic infection |
| PEP | Post-exposure prophylaxis |

| | |
|---|---|
| PLHIV | People living with HIV/AIDS |
| PMTCT | Prevention of mother-to-child HIV transmission |
| PrEP | Pre-exposure prophylaxis |
| RIHES | Research Institute for Health Sciences |
| STI | Sexually transmitted disease |
| TB | Tuberculosis |
| TDF | Tenofovir Disoproxil Fumarate |
| TDF/FTC | Tenofovir plus Emtricitabine (Truvada) |
| TNCA | Thai NGO Coalition on AIDS |
| TUC | Thailand MoPH– U.S. CDC Collaboration |
| TVF | Tenofovir |
| UC | Universal Coverage under the National Health Security Office (NHSO) |
| VCCT | Voluntary confidential counseling and testing |
| VCT | Voluntary counseling and testing |
| WHO | World Health Organization |

# Annex 3 – Relevant websites

Armed Forces Research Institute of Medical Sciences, US Army Medical Component (USAMC-AFRIMS) (Thailand) www.afrims.org

Ban Piman Center (Thailand) www.pimancenter.com

Centers for Disease Control and Prevention (CDC) (U.S.A.) www.cdc.gov

Centre for the AIDS Programme of Research in South Africa (CAPRISA) www.caprisa.org

Faculty of Medicine, Siriraj Hospital, Mahidol University (Thailand) www.si.mahidol.ac.th/eng

Global Advocacy for HIV Prevention (AVAC) (U.S.A.) www.avac.org

The Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria (GFATM) www.theglobalfund.org

Government Pharmaceutical Organization (GPO) (Thailand) www.gpo.or.th, www.intergpomed.com

iPrEx [Iniciativa Prophylaxis Pre-exposición (Pre-Exposure Prophylaxis Initiative)] www.globaliprex.com, www.iprexnews.com

Ministry of Public Health (Thailand) www.moph.go.th, http://eng.moph.go.th

National Health Security Office (NHSO) (Thailand) www.nhso.go.th

Research Institute for Health Sciences (RIHES), Chiang Mai University (Thailand) www.rihes.cmu.ac.th

Thailand MoPH– U.S. CDC Collaboration www.tuc.or.th

Thai NGO Coalition on AIDS (TNCA) www.tncathai.org

World Health Organization (WHO) (Switzerland) www.who.int

# Annex 4 – Participant list

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