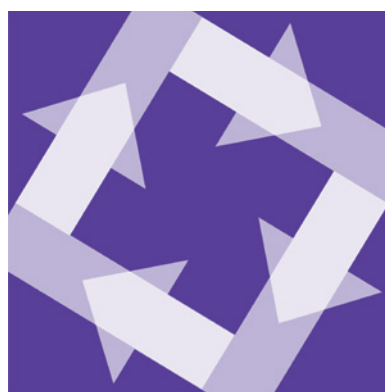


Meeting Report

Expanding HIV Prevention Options for Women

A Satellite Session at IAS 2013, Kuala Lumpur, Malaysia
30 June 2013



Organized by the International AIDS Society's Industry Liaison Forum
and AIDS Vaccine Advocacy Coalition

Acknowledgements

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Expanding HIV Prevention Options for Women

Chairs:

Linda-Gail Bekker, Desmond Tutu HIV Centre, South Africa
Mitchell Warren, AVAC, USA

Introduction

Mitchell Warren opened the session by introducing his Co-Chair, Linda-Gail Bekker, welcoming participants, and noting the enormous data generated from a number of oral and topical tenofovir (respectively, TDF and TFV¹) or TDF/emtricitabine (FTC)-based HIV prevention trials in the past few years. The Centre for the AIDS Programme of Research in South Africa (CAPRISA) 004 trial was the first study of TFV prophylaxis (in a 1% topical gel) to demonstrate efficacy. A number of other studies have since reported results and, given the variable

findings, Warren underscored the need to carefully analyse the data and their implications for expanding HIV prevention options for women. He emphasized that, on balance, the results demonstrated that pre-exposure prophylaxis (PrEP) can be efficacious in preventing HIV infection, but that substantial qualitative, quantitative and post-hoc analyses are required to explore findings from these trials in order to develop a range of ARV-based prevention options tailored to maximize their use and protective benefit among women.

Tenofovir-based PrEP technologies in women: what do we currently know?

Linda-Gail Bekker provided a comprehensive overview of PrEP research, of trial results, including quantitative and qualitative analyses, and of the knowledge we have gained as a result regarding the use and efficacy of ARV-based prevention interventions among women and other at-risk populations. She emphasized the significant unmet need for a female-initiated and controlled prevention intervention, particularly given the significant numbers of young women at risk for HIV infection. She emphasized that effective HIV prevention technologies must incorporate not only biomedical but also structural and behavioural interventions to address the complex risk environment for women and girls.

Why tenofovir and what are the results of trials to date?

She reviewed the rationale for selecting tenofovir as the ARV for the first generation of HIV prevention trials:

- It demonstrated protection in animal models.
- It is enriched in genital fluids.
- It has no interactions with tuberculosis (TB) drugs or hormonal contraception.
- It has a high barrier to developing drug-resistant mutations.
- It was already licensed for the treatment of HIV disease.

1. Tenofovir exists as three different forms. The prodrug (tenofovir disoproxil fumarate or TDF) is hydrolyzed to tenofovir (TFV) which is then phosphorylated to tenofovir diphosphate (TFV-DP), the active form of which intracellular levels are measured clinically. TDF is administered orally while TFV is administered in topical gels.

Tenofovir-based prevention results, as of June 2013

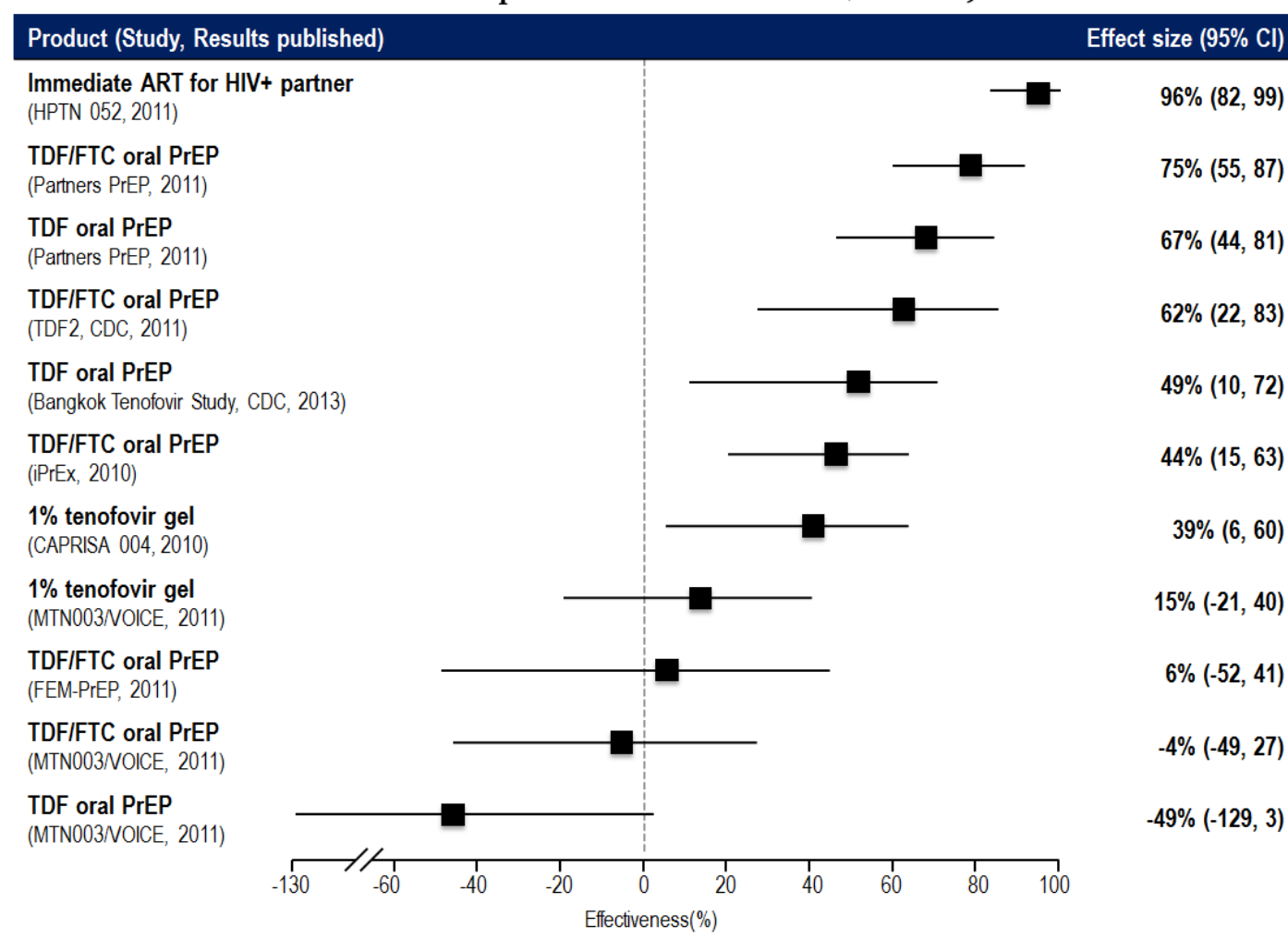


Figure 1. Tenofovir-based prevention results, as of June 2013 (Bekker L-G, Tenofovir based PrEP technologies in women: what do we currently know? IAS 2013, Kuala Lumpur, Malaysia)

To date, four randomized controlled trials (RCTs) of systemic (oral) PrEP have been conducted: (1) the Pre-exposure Prophylaxis Initiative (iPrEx) among populations of men who have sex with men (MSM); (2) the Partners PrEP study among serodiscordant heterosexual couples (which evaluated both TDF and TDF/FTC against placebo); (3) the Centers for Disease Control and Prevention (CDC) 4940 (TDF2), which evaluated efficacy among young HIV-negative heterosexual males and females; and (4) CDC 4370 (the Bangkok Tenofovir study) among people who inject drugs (injecting drugs users, or IDUs). These studies have involved more than 10,000 HIV-negative individuals and resulted in point efficacy ranges from 44% to 75%.

The CAPRISA 004 trial of a topical 1% TFV gel formulation demonstrated a point efficacy of 39% and led to a second confirmatory study. However, two other RCTs, the Pre-exposure Prophylaxis Trial for HIV Prevention among African Women (FEM-PrEP) and the Vaginal and Oral Interventions to

Control the Epidemic (VOICE) trials were both stopped by their respective data and safety monitoring boards due to futility (non-efficacy). What has emerged from post-trial analyses is a strong dose-response curve; objective adherence measures from trials show high levels of protective benefit (92% of iPrEx participants and 90% of Partners PrEP participants) among individuals with detectable tenofovir in blood plasma. In the Bangkok IDU study, efficacy increased from 46% to 56% in the per-protocol analysis based on observed adherence and increased to 74% when limited to participants with detectable TFV-DP concentrations. Figures 1 and 2 summarize the effectiveness of the different studies to date, as well as the correlation between effectiveness and adherence.

RCTs have also demonstrated that TDF and TDF/FTC are well tolerated; gastrointestinal side effects (e.g., nausea) were prevalent in a minority (approximately 10%) of trial subjects and generally disappeared after the first month following initiation.



Despite concerns regarding the potential for the development of drug resistance among seroconverters, in the four studies mentioned here, there were almost no documented cases of drug resistance (and none among participants in topical PrEP trials). However, resistance risk increases if PrEP is started during unrecognized acute HIV infection, although the number of documented cases remains small. Of note is the difference in demographics between participants in different trials (particularly the median age of women); this may be significant in determining adherence levels and, ultimately, efficacy. Concerns regarding the impact of TDF on renal function impairment have also not materialized (in the five cases where patients had elevated creatinine levels, these resolved when the drug was stopped and four resumed the study drug without adverse effect). Studies report a modest 1% reduction in bone mineral density and no associated increase in bone fractures following initiation of the study drug. In qualitative research, factors associated with increased adherence among women included support from their HIV-infected partner, as well as external support from research staff, family members and friends. Of concern was the perception of low HIV risk among study participants (70% of women among the Partners PrEP trial participants reported that they felt at little risk for acquiring HIV) despite an annualized incidence rate of 5%.

In VOICE, adherence was lower among younger women in the trial, who also had the highest HIV incidence in the trial.

In summary, the key issue after a number of RCTs have reported results is less a question of the potential efficacy of this intervention, but rather on the acceptability of this intervention among women and whether different approaches or delivery mechanisms, such as intermittent PrEP dosing (iPrEP, time- or event-driven dosing), might provide answers to the adherence challenges of daily PrEP. Concerns were also documented among HIV-negative women regarding being labelled as HIV infected due to the association of tenofovir with HIV infection, an important consideration in understanding study results and rethinking approaches to delivering this intervention. Of note, male participants were more likely to be able to predict when they were going to have sex compared with women. The level of adherence to achieve the HIV prevention benefit is also not clear. In the iPrEx study, statistical modelling combining pharmacokinetics and drug data estimated that two PrEP doses per week might achieve a 76% reduction in the risk of HIV acquisition; this rose to greater than a 95% protective benefit with more than four doses per week, but there are currently no data available to guide less than daily dosing of oral TDF/FTC as PrEP.

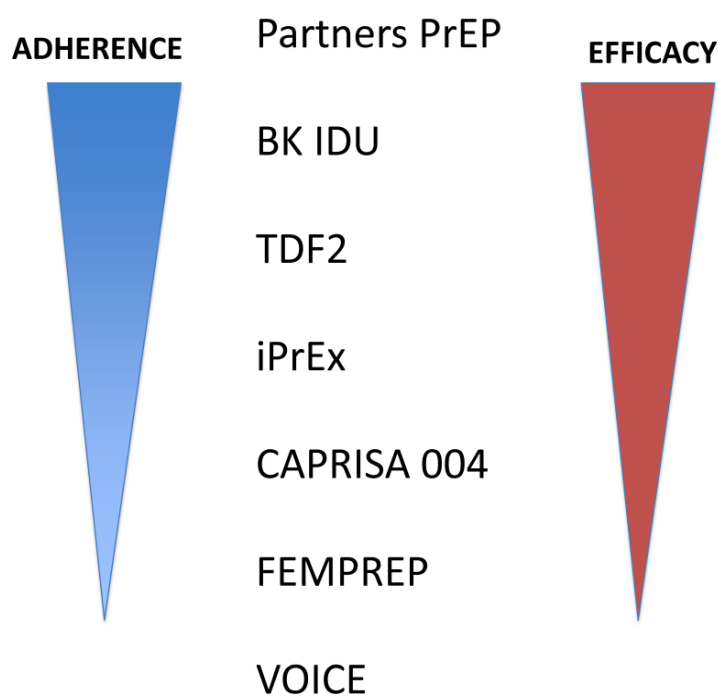


Figure 2. Adherence vs. efficacy in PrEP trials (Bekker L-G, Tenofovir based PrEP technologies in women: what do we currently know? IAS 2013, Kuala Lumpur, Malaysia)

The next generation: what to do with what we've learned

The HIV Prevention Trials Network (HPTN) 067 Alternative Dosing to Augment PrEP Pill Taking (ADAPT) Phase II study is a randomized, open-label pharmacokinetic and behavioural study on the use of intermittent oral TDF/FTC (with daily, time-driven and event-driven intervention arms) and could provide important data on the efficacy of intermittent versus daily PrEP strategies. HPTN 067 also has a qualitative research component, which is exploring women's perceptions of PrEP, practical considerations (such as the feasibility of carrying pills with them or their motives in participating in PrEP clinical trials) and other factors that might affect their use of PrEP. An Open Label Extension (OLE) of the iPrEx trial (iPrEx OLE) is also enrolling participants to assess long-term safety and efficacy, adherence, changes in participants' sexual behaviour and drug resistance and toxicities.

The pipeline of potential PrEP interventions (see Figure 3) that could proceed to trial includes a range of delivery mechanisms (such as vaginal rings, gels and rectal microbicides), different active pharmaceutical ingredients (such as rilpivirine [RPV] and maraviroc [MVC]) and formulations (including combination formulations) for use in a range of populations, including heterosexual women and men, young MSM and IDUs. A number of Phase III studies, including study extensions and rollovers, are underway, as are a number of demonstration projects and Phase II studies, including several studies focusing on adolescent at-risk populations. Linda-Gail Bekker closed her presentation by noting that the question of whether an HIV prevention package for women will include ARV-based interventions will be most likely if multiple options, tailored to the preferences of at-risk populations, are delivered in ways that fit the reality of women's lives in diverse settings.

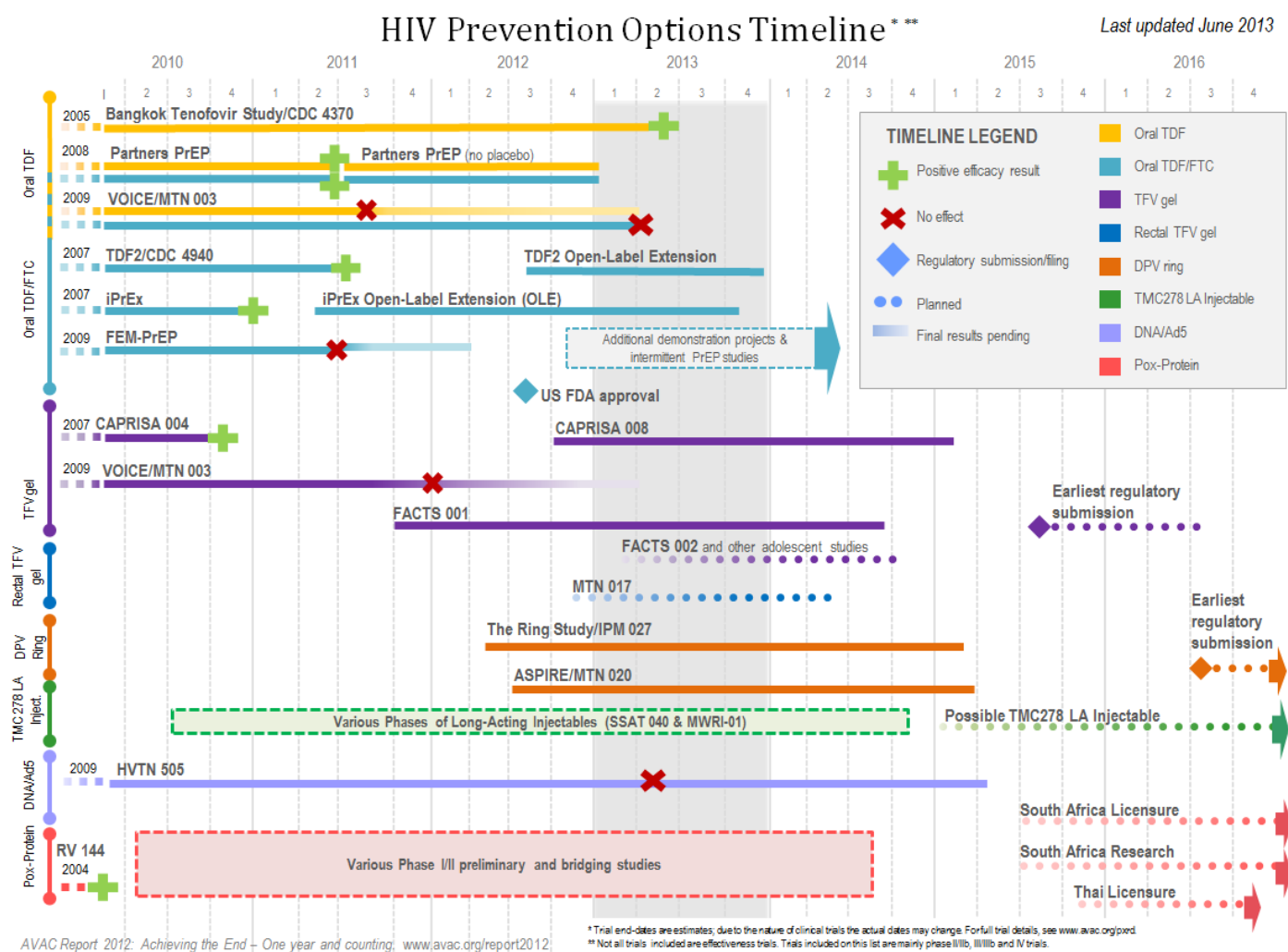


Figure 3. HIV prevention options timeline, last updated June 2013 (Bekker L-G, Tenofovir based PrEP technologies in women: what do we currently know? IAS 2013, Kuala Lumpur, Malaysia)

Next steps in PrEP implementation and additional research

Moderator: Cate Hankins, Amsterdam Institute for Global Health and Development, The Netherlands

Panelists: Beri Hull, International Community of Women Living with HIV, USA
Carl Dieffenbach, Division of AIDS, National Institutes of Health, USA
James Rooney, Gilead Sciences, USA
Judith Auerbach, University of California San Francisco, USA
Roy (Trip) Gulick, Cornell University, USA
Kevin O'Reilly, WHO, Switzerland
John Pottage, ViiV Healthcare, USA

Why the conflicting data from PrEP trials to date?

Judith Auerbach delivered a critique of the way in which the focus on RCTs, which attempt to control for a range of potentially confounding variables, has been part of the problem in the conflicting results reported from trials to date. She noted that the attempts of clinical investigators to control for or remove the “noise” (non-clinical variables) from the trials is problematic in reality and results in a framing narrative that does not reflect the complexity and reality of women’s lives and motivations. She emphasized that it is simply not possible to control for the many different variables, as social scientists often point out, that may affect the use or non-use of the intervention or product. She noted that adherence, as a construct, also needs to be unpacked: i.e., there is an assumption that if we just try harder, we can get women to improve their adherence. The assumption that women will take ARVs for their own preventive health benefit, provided that they have sufficient and accurate information about the product, has proven to be of dubious veracity. She used the example of overweight individuals who continue to engage in eating behaviour that is objectively not in their best health interests as an example that has its corollary in ARV-based prevention trials. The women in the trials are different, not only in age and marital status, but also in cultural background, risk perception and social context. She suggested the starting point should not be where investigators can conduct clinical trials, but to look at high-prevalence settings and conduct ethnographic research in those settings that will illuminate the complex social and cultural environment of women, rather than starting with a product one wants to test.

Carl Dieffenbach agreed that the study findings have been conflicting and humbling, and suggested a reset button to re-examine what prevention looks like from the perspective of (for example) a woman who lives in KwaZulu-Natal, South

Africa, who may be surrounded by risk given the social milieu she lives in. He also noted that the focus on point efficacy must be considered in the context of the confidence intervals of each reported point efficacy reported by investigators (confidence intervals of some data indicating statistical non-efficacy actually overlap with confidence intervals of data in studies demonstrating statistical efficacy, see Figure 1). The priority should be on building something that will be useful in addressing the needs of the population, including contexts where risk perception might be quite low.

Roy Gulick underscored the pharmacokinetic (PK) reasons why tenofovir was chosen, particularly its safety, tolerability and ability to penetrate compartments (such as vaginal and rectal mucosa) that provide the first line of defence against HIV infection. Gulick suggested that scientists should look more closely not only at which drugs reach these compartments, but also in what concentrations. TDF is able to reach much higher drug concentrations in rectal tissue compared with genital tract/vaginal tissue, which may provide part of the explanation regarding the higher levels of efficacy demonstrated in the iPrEx trial (which focused on MSM) compared with trials among women (i.e., FEM-PrEP and VOICE). He emphasized considering both PK issues, as well as adherence issues in moving forward, including the need to consider additional drugs that are safe and effective at penetrating key compartments in high concentrations when considering possible PrEP agents.

What women want: the package of HIV prevention interventions

Beri Hull emphasized the need to develop as many options as possible (both PrEP and non-ARV interventions) to ensure multiple prevention options for women tailored to individual preferences that are context appropriate. There is unlikely to

be a single ARV-based intervention or delivery mechanism that will be relevant to all or most of the women at risk for acquiring HIV. She noted that many women will not want to take ARVs and (as some of the qualitative research has confirmed) may not perceive themselves to be at risk. They may also be considering pregnancy and have concerns regarding potential drug-related toxicities for both themselves and their infants. She raised the question of why HIV-negative women would want to take this product if what they are doing already has been effective in preventing HIV acquisition. She also raised the possibility of HIV-positive women using PrEP products (such as a TFV-based vaginal gel) to help protect sexual partners from HIV acquisition. There has been a small study among HIV-positive women on the use of the 1% TFV gel, but the results have been inconclusive and a

larger study would be required to determine both acceptability and efficacy of this product among HIV-positive women.

Judith Auerbach reinforced Hull's concerns, pointing out that the qualitative data from the VOICE sub-study indicated that the women were not adherent because they associated ARVs with HIV (partly because of how the product they were using was labelled).



Regulatory pathways to approval and new compounds: safety and efficacy issues

James Rooney noted that tenofovir was chosen, at least partly, because of the characteristics outlined by previous speakers and because it had been approved and was in wide use as part of antiretroviral therapy (ART) to treat HIV disease. There are other approved compounds that could prove promising, but it is important to note that changing the indication for a drug requires substantial investments in studies to demonstrate preventive efficacy and safety among different (HIV-negative) populations. Also, going forward, it might be difficult to do placebo-controlled studies since there is already an approved ARV-based prevention intervention available. Industry, public health, clinicians, civil society and regulators must look carefully at what evidence and regulatory pathways will be required to develop and approve a new ARV-based HIV prevention agent. Determination of the minimal amount of preventive efficacy required for approval is important, as is the required safety profile with newer agents (unlike tenofovir, with which clinicians have had substantial experience, newer agents have had more limited use by clinicians).

John Pottage noted that MVC merits study as a PrEP intervention, given its bioavailability in key compartments, and it is also not widely used, which may be more advantageous than TDF (given that there is less danger of resistance development that would preclude standard TDF-based first-line ART regimens among seroconverters using TDF as a prevention modality). ViiV Healthcare is also looking at MVC in gels and other formulations, and some of these studies should be reporting data soon. In terms of going forward, there is a long-acting integrase inhibitor (S/GSK1265744 developed by Shionogi, ViiV Healthcare and GSK, aka 744), which has a long half-life and may only need to be injected once every three months. However, developing a new agent requires demonstrating efficacy, and there is no consensus on what the minimal amount of evidence for efficacy is required for approval. Pottage also reinforced the need to consider safety data when bringing a new agent forward, including its existing adverse event profile in populations when used as a treatment modality.

James Rooney raised an important question: what if an infection occurs and the drugs used to treat it are contraindicated with a previously administered injectable drug? These issues are not insurmountable, however, and regulatory agencies have demonstrated a willingness to work with industry to move forward on such interventions. He noted that the experience with TDF provided an important example of public-private partnerships in evaluating and submitting the drug for approval as an HIV prevention intervention, but cautioned that it may be more difficult to repeat this going forward (e.g., given acceptable safety risk profiles). He added that we may collectively need to discuss alternative approaches to regulation.

Normative agency considerations: guidance on PrEP

Following up on the issue of safety, Kevin O'Reilly noted that the acceptable safety profile for these compounds in HIV-negative populations is very different to what it is for someone with HIV (where treatment is for a life-threatening infection), and this is something regulators must take into consideration. In response to a query from Cate Hankins regarding how WHO is looking at the evidence for PrEP as it relates to women, given the mixed results of trials to date, he noted that WHO had released guidelines on the use of ARVs to prevention of HIV transmission among serodiscordant couples in 2012², and this was based on a careful review and categorization of the available scientific evidence (in terms of high-, moderate- and low-quality evidence, based on WHO's GRADE system). Both HPTN 052 and iPrEx were considered to be high-quality evidence of the preventive efficacy of ARVs, whereas the TDF2 data was considered to be lower-quality evidence.

2. Guidance on Couples HIV Testing and Counselling Including Antiretroviral Therapy for Treatment and Prevention in Serodiscordant Couples: Recommendations for a Public Health Approach. WHO, Geneva (Switzerland), 2012.

He cautioned that WHO must look at broader considerations, as well as the quality of clinical evidence, including how these interventions will be implemented and used by populations at risk. Countries are showing interest in doing PrEP pilot and demonstration projects, but have not demonstrated an interest in rolling out PrEP widely. He also reinforced comments by other panellists regarding the need to temper our expectations of what women want, given their quotidian priorities. The risk of HIV infection is likely not their most important concern.

James Rooney noted that we can now evaluate relatively quickly, through blood level monitoring, whether individuals are using a product, and this is something we did not know before undertaking these trials. This kind of preliminary research with a small group of potential users should be undertaken before larger-scale trials begin; otherwise it would be pointless to mount a large-scale trial.

John Pottage noted that the PrEP world should borrow a page



from the activism around treatment adherence: when regimens are simple, tolerable and easy to use, people are more likely to be adherent. Carl Dieffenbach cautioned that people interested in enrolling in clinical trials represent a fraction of the population that we are interested in providing this product to. In the real-world context of potential users, efficacy may

be significantly lower than those reported in trials, and this is something that we must keep in mind in evaluating the findings from clinical trials.

Finally, panellists emphasized that we must also be very cognizant of how products are packaged and marketed and how target populations perceive these products over time, particularly if the basic idea of the efficacy of ARV-based interventions has been accepted. This is also an important opportunity for social scientists and marketing professionals to work with populations to determine their needs and then tailor the promotion and marketing of these products as an important health intervention relevant to the lives of young men and women.



Audience interventions and discussion

Interventions from the audience underscored the need to consider differences between treatment and prevention populations involved in clinical trials. One participant reminded the panel that HIV incidence in prevention trials is very low, given the counselling, condom provision and other interventions ethically required of research studies; studies must therefore be very large in order to be adequately powered to demonstrate intervention efficacy or non-efficacy. As mentioned by one of the panellists, HIV prevention trials are increasing in complexity and future trials will likely be ethically required to provide oral TDF as a control to test other prevention products.

Audience members also picked up on the need for a different approach to marketing ARV-based prevention products that require a better social understanding of the target population, emphasizing the need to engage social scientists and marketing professionals in undertaking research with relevant populations to identify approaches to marketing and labelling ARV-based prevention interventions to increase uptake and adherence.

Beri Hull emphasized the need for consultation with potential participants before considering enrolling participants into trials, including asking candid questions about why women would not take PrEP if offered. Picking up on this point, Judith Auerbach noted that the trials themselves are interventions and that there are many different reasons why people participate in trials (including access to health care, financial incentives and other supports) when they may have no intention of using the product. Cate Hankins noted that co-enrolment (in two or more trials) emerged as a problem in some South Africa studies, where it was clear that individuals were registering for multiple trials because of the benefits and interventions available through them. In response, Judith Auerbach agreed that we need to look more carefully at the complexities of risk in heterosexual transmission.

In response to a query from the audience, Linda-Gail Bekker and other panellists indicated that they offered post-exposure prophylaxis (PEP) to study participants who requested it. They also noted that there is very little data supporting the use of PEP as an efficacious product to prevent HIV infection (there is only one study in the peer-reviewed literature of health care workers who accessed post-exposure prophylaxis following possible HIV

exposure, and ultimately there were insufficient numbers in the study to provide clear evidence of efficacy³).

Kevin O'Reilly also noted that there are a number of individuals in the trials who had sexual partners outside the partnership, which adds complexity in terms of the potential for unlinked transmission. Another issue that emerged in discussion is migration, which affects the extent to which we know where the virus exists in the community. Audience members also reminded session attendees that acute infection is the source of up to 50% of infections.

Another question was raised regarding whether too many resources were being allocated to clinical interventions versus addressing the structural drivers of the epidemic and the risk

environment for women and girls. This intervener noted the strong correlation between a country that has a high gender inequity index and large, heterosexually driven epidemics. Judith Auerbach noted that genito-anal violence in the context of intimate partner violence among heterosexual couples must also be considered in the context of its contribution to HIV transmission in heterosexual epidemics.

Audience members strongly thanked the panellists for an engaging, informative and important discussion across cross-disciplinary approaches to move beyond the current

juncture in research. Judith Auerbach agreed that scientists must find ways to better communicate their perspectives across scientific disciplines. This has sometimes been difficult in the past, as it relates to who defines the terms of the conversation in the HIV research agenda. She argued that the first step is understanding community and culture, and then looking at what options are relevant for the specific contexts for women within these settings.

Closing comments by the panellists reinforced the message that PrEP works if used correctly, but that creating multiple choices and options for women (and other populations) and addressing adherence through more cross-disciplinary research (including sociological and ethnographic research) are needed.



3. Cardo DM, Culver DH, Ciesielski CA, Srivastava PU, Marcus R, Abiteboul D, Heptonstall J, Ippolito G, Lot F, McKibben PS, Bell DM and the Centers for Disease Control and Prevention Needlestick Surveillance Group. A Case-Control Study of HIV Seroconversion in Health Care Workers After Percutaneous Exposure. *N. Engl. J. Med.* 1997; 337:1485-1490.

Closing remarks

Co-Chair Linda-Gail Bekker noted that the HIV incidence seen, even in trials, emphasizes the urgency with which we must pursue answers to the many questions regarding expanding PrEP options for women.

Co-Chair Mitchell Warren closed the session by underscoring that PrEP can work for women and men, contrary to the feeling among some scientists following the VOICE trial results at the Conference on Retroviruses and Opportunistic Infections (CROI) 2013. However, researchers must understand how to work with existing health and community systems to support these individuals and deliver the interventions that are appropriate. He outlined a few key messages from the session:

1. The need to better understand and improve adherence in RCTs (and beyond)
2. The need to give people better choices that will make it easier to take the product via a range of delivery mechanisms
3. The need to re-examine how we market the PrEP products we have now in order to better enable their use among at-risk populations
4. The need to develop more and better products in future research on PrEP.

He closed by noting the success of hormonal contraception in Africa, which has demonstrated how effective uptake in an important sexual and reproductive prevention health product can be if it is marketed, labelled and available to relevant populations.



IAS-ILF Mission

The mission of the Industry Liaison Forum is to accelerate scientifically promising, ethical HIV research in resource-limited countries, with a particular focus on the role and responsibilities of industry, namely pharmaceutical and diagnostic companies, as sponsors and supporters of research.

The IAS-ILF fulfills its mission by:
identifying research gaps; promoting targeted research; identifying challenges and best practices; analyzing available data and evidence; disseminating information; consulting and convening stakeholders; providing industry expertise; and supporting capacity building for research and health delivery.

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