

PrEP Use among Sexually Active Older Adolescents

Vancouver Canada | 17-18 July 2015



Consultation on Clinical, Ethical and Operational Considerations for the implementation of Oral Pre-Exposure Prophylaxis (PrEP) in Sexually Active Older Adolescents (15 – 19) at High Risk of HIV Infection

Meeting Report

HIV Section, UNICEF New York

UNICEF consultation on clinical, ethical and operational considerations for the implementation of Oral Pre-Exposure Prophylaxis (PrEP) in sexually active older adolescents (15-19) at high risk of HIV infection: meeting report, July 2015.

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Acknowledgements

We would like to give special thanks to the presenters, speakers and all the meeting participants for their contributions at the meeting. Special thanks go to the youth panellists who shared current adolescent and youth perspectives, experiences and realities at the meeting.

The consultation was organized by UNICEF as an affiliated event during the 8th International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention with support from a steering team comprised of Craig McClure (UNICEF, New York), Bill Kapogiannis (NIH, USA), Peter Godfrey-Faussett (UNAIDS, Geneva), Chris Collins (UNAIDS, Geneva), Rachel Baggaley (WHO, Geneva), Mitchell Warren (AVAC, USA) and Linda-Gail Bekker (Desmond Tutu Centre, University of Cape Town, South Africa).

This meeting was organized by Catherine Richey and Tajudeen Oyewale with support from Chewe Luo, Susan Kasedde and Ken Legins.

This report was prepared by Tajudeen Oyewale (UNICEF, New York) with support from Susan Kasedde and Catherine Richey. The report benefitted from review by members of the steering committee and John Stover (Avenir Health, USA). Meeting notes were taken by Catherine Richey (UNICEF, New York), Tajudeen Oyewale (UNICEF, New York), Deirdre Grant (AVAC, USA), Tim Sladden (UNFPA, New York), Olusoji Akinyele (UNICEF Nigeria) and Charles van der Horst (independent consultant).

Executive Summary

The efficacy of oral tenofovir-based antiretroviral (ARV) formulations as pre-exposure prophylaxis (PrEP) for HIV is now well established based on trial experience from multiple regions and in different population groups. Oral PrEP significantly reduces the risk of HIV acquisition when taken as prescribed. Making this new bio-medical tool available as an additional prevention option to sexually active older adolescents at high risk of HIV infection may have a significant impact on the HIV epidemic if individuals are able to adhere to PrEP and if the right combination of other behavioural, structural and biomedical interventions are provided in tandem. If delivered effectively, PrEP, as an innovative new HIV prevention approach, can contribute to achieving the targets of ALL IN towards ending AIDS among adolescents and the broader SDG goal of ending AIDS as a public health threat by 2030.

“PrEP provides an opportunity for empowering adolescents to take control of their sexual health”. **Niluka Perera**, 26, Youth Voices Count, Thailand

A global consultation of 58 scientists, researchers, government, community and development partners, and youth advocates was convened by UNICEF to consider the clinical, ethical and operational issues associated with implementing oral PrEP among sexually active older adolescents aged 15-19 in populations at high risk of HIV infection.

Prioritizing individuals who are at “substantial risk” of HIV infection and willing to take PrEP will have significant cost-savings on national HIV responses. “Substantial risk” has no strict definition and depends on national HIV epidemic priorities. Some groups of men who have sex with men and transgender people, sex workers in higher-incidence locations, young women and girls and men in very-high-incidence settings and the sex partners of people living with HIV have exceptionally high incidence of HIV, such as 2–3%. For individuals within these populations, markers of substantial risk can include frequent condomless sex, repeat sexually transmitted infections (STI) and repeated use of post-exposure prophylaxis.

The delivery of PrEP in a safe space for older adolescents, as part of a combination HIV prevention package that includes biomedical, behavioural and structural interventions, will be key to maximizing success. Entry points such as sexual and reproductive health (SRH) clinics, family planning services, and youth centres offer strategic sites to identify and initiate eligible adolescents on PrEP. Task shifting among healthcare providers and community linkages along the continuum of HIV testing, PrEP (ARV) dispensing and follow up care will limit additional burden on the health system.

In building demand, programs should consider the diversity of adolescents eligible for PrEP. The development of communication strategies should engage appropriate stakeholders especially adolescent and youth groups and prioritize social marketing of PrEP as a positive health choice. Multiple and innovative adherence support strategies will be important for better PrEP effectiveness among adolescents. Legal, ethical and policy issues, such as age of consent to HIV and SRH services for adolescents less than 18 years, gender based violence, and criminalizing of sexual behaviours remains a challenge in some countries. In addition, mechanisms to assure confidentiality and protect adolescents from harm which may result from negative effects of disclosure obligations intended to safeguard their well-being may be required for the success of PrEP among adolescents. Finally,

knowledge gaps for PrEP use in adolescents should be addressed as appropriate and in parallel to ongoing implementation activities.

The development of PrEP implementation guidelines by the World Health Organization (WHO) should incorporate these considerations to enable PrEP implementation for eligible adolescents.

Acronyms and Abbreviations

AIDS	acquired immune deficiency syndrome
ALT	alanine aminotransferase
ARV	Antiretroviral medications
FTC	Emtricitabine
GFATM	Global fund to fight AIDS, tuberculosis and malaria
HIV	human immunodeficiency virus
IAS	International AIDS society
NIH	National institutes of health
MSM	men who have sex with men
PEP	post-exposure prophylaxis
PEPFAR	US president's emergency plan For AIDS relief
PrEP	pre-exposure prophylaxis
RCT	randomized clinical trial
SRH	sexual and reproductive health
STI	sexually transmitted infections
TDF	Tenofovir disoproxil fumarate
TGW	Transgender women
UNAIDS	Joint United Nations Programme on HIV and AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
WHO	World Health Organization

Introduction

Oral pre-exposure prophylaxis (PrEP) involves the use of antiretroviral (ARV) medications by HIV-uninfected persons to prevent the acquisition of HIV. Making this new bio-medical tool available as an additional prevention option to sexually active older adolescents (aged 15-19) at substantial risk of HIV acquisition with appropriately tailored combination prevention interventions may significantly impact the HIV epidemic among adolescents and contribute towards ending AIDS as a public health threat by 2030.

UNICEF convened a global consultation of 58 scientists, researchers, donors, government, community and development partners, and youth advocates (see annex 1 for participant list) to consider the clinical, ethical and operational issues required to implement oral PrEP among sexually active older adolescents aged 15-19 in populations at high risk of HIV infection. This consultation was held as an affiliated independent event of during the 8th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention in Vancouver, Canada on 17-18 July 2015.

Opening session

Dr Chris Beyrer, the President of the International AIDS Society (IAS), opened the consultation, urging the inclusion of older adolescents at substantially high risk of HIV acquisition in PrEP demonstration projects as part of targeted combination HIV prevention strategies. Without greater focus and innovation in preventing HIV among young people, he said, ‘the world could not end the AIDS pandemic’. The consultation on PrEP use in adolescents, he added, would provide a solid basis to inform the upcoming World Health Organization (WHO) PrEP implementation guidelines and provide recommendations.

Craig McClure, UNICEF Global Chief of HIV/AIDS, in his opening remarks welcomed the many scientists, researchers, community and development partners and youth advocates from all parts of the world on behalf of UNICEF and committed the organization to help accelerate access to innovations in HIV prevention for adolescents, to “fast track” the AIDS response towards ending AIDS as a public health threat by 2030. He noted that a global movement to end AIDS among adolescents, known as ALL IN, has generated engagement of young people, the attention of policy makers, programmers and researchers, governments and donors, and increased momentum for all of us to do better together for and with adolescents living with and at highest risk of HIV infection. In relation to the consultation, he said ‘we need to better understand how we can tailor the implementation of PrEP to the right adolescent populations in the right place’, and emphasized that doing more of the same things that we have been doing up to now, in the same ways, without success, would likely not help us achieve the results we want.

See annex 2 for the meeting agenda. Other resources from the meeting can be accessed on <https://unicef.sharepoint.com/teams/PD/HIV/PREP>

Background

While major advances have been made in almost every area of the response to HIV, progress for adolescents has fallen behind. AIDS is now the leading cause of death among adolescents (aged 10 – 19) in Africa¹ and the second most common cause of death among adolescents globally². AIDS-related deaths are declining in all age groups, except among 10–19 year olds³. New HIV infections among older adolescents (aged 15-19) are also not declining as quickly as among other age groups (figure 1).

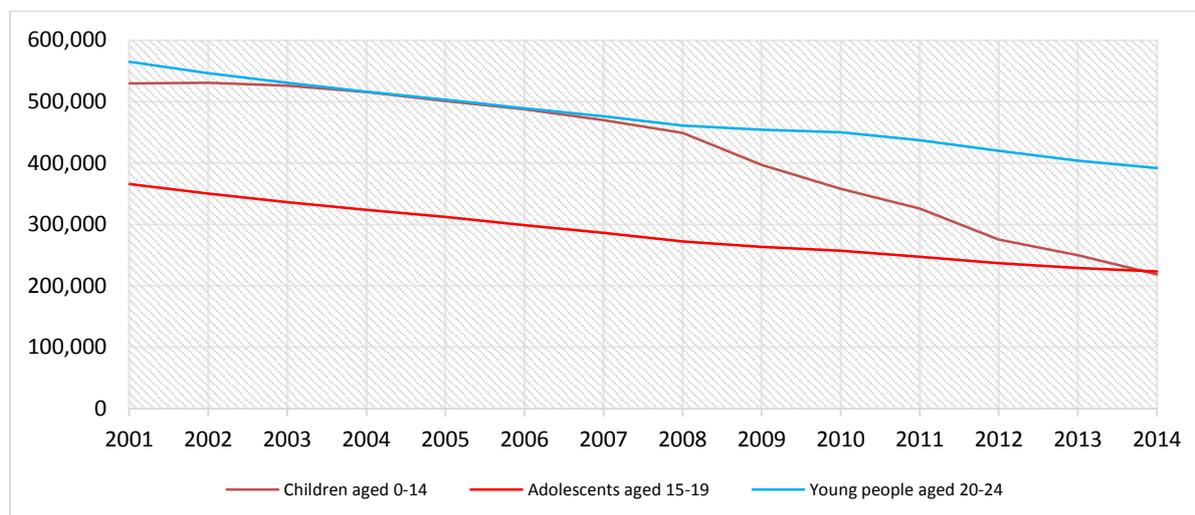


Figure 1: Estimated number of new HIV infections among children (aged 0–14), adolescents (aged 15–19), and young people (aged 20–24), 2001–2014

Source: UNAIDS 2014 HIV and AIDS estimates, July 2015.

In 2014, there were 2.0 million adolescents aged 10–19 living with HIV, and in 2013, an adolescent aged 15–19 years was infected with HIV every two minutes⁴. In addition, HIV incidence and prevalence are disproportionately high among adolescent girls in sub-Saharan Africa and adolescent key populations everywhere⁵.

To address these inequities, a leadership group comprised of United Nations Children’s Fund (UNICEF), the Joint United Nations Programme on HIV/AIDS (UNAIDS), United Nations Population Fund (UNFPA), World Health Organization (WHO), the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM), US President’s Emergency Plan For AIDS Relief (PEPFAR), MTV Staying Alive Foundation and the global youth movement represented by PACT and Y+ launched [ALL IN to #EndAdolescentAIDS](#) - a platform for action and collaboration to inspire and drive better results for adolescents through critical changes in programmes and policy. **ALL IN** seeks to reduce new HIV infections by 75% and AIDS-related deaths by 65% among adolescents globally by 2020.

¹ World Health Organization, ‘Global health observatory data repository’, 2012
<http://apps.who.int/gho/data/view.wrapper.MortAdov?lang=en&menu=hide>

² World Health Organization, ‘Health for the World’s Adolescents: A second chance in the second decade’, 2014.
www.who.int/adolescent/second-decade

³ United Nations Children’s Fund, ‘Analysis of UNAIDS 2014 HIV and AIDS estimates’, July 2015.

⁴ United Nations Children’s Fund and the Joint United Nations Programme on HIV/AIDS. ALL IN to #End AdolescentAIDS: Launch document, 2015. <http://allintoendadolescentaids.org/wp-content/uploads/2015/02/ALL-IN-Launch-Document.pdf>

⁵ Idele, P, Gillespie, A, Porth, T et al., Epidemiology of HIV and AIDS among adolescents: Current status, inequities, and data gaps, *J Acquir Immune Defic Syndr*, 2014;66(2): S144–S153

ALL IN is focused on accelerating the HIV response for adolescents by focusing efforts around four key action areas (figure 2) to:

1. Engage, mobilize and support adolescents as leaders and agents of social change;
2. Sharpen adolescent-specific elements of national AIDS programmes by improving data collection, analysis and use to drive programming and results;
3. Foster innovation in approaches that improve the reach of services for adolescents and increase the impact of prevention, treatment and care programmes;
4. Advocate and communicate at the global, regional and country level to generate political will to invest in the adolescent HIV response and mobilize resources.

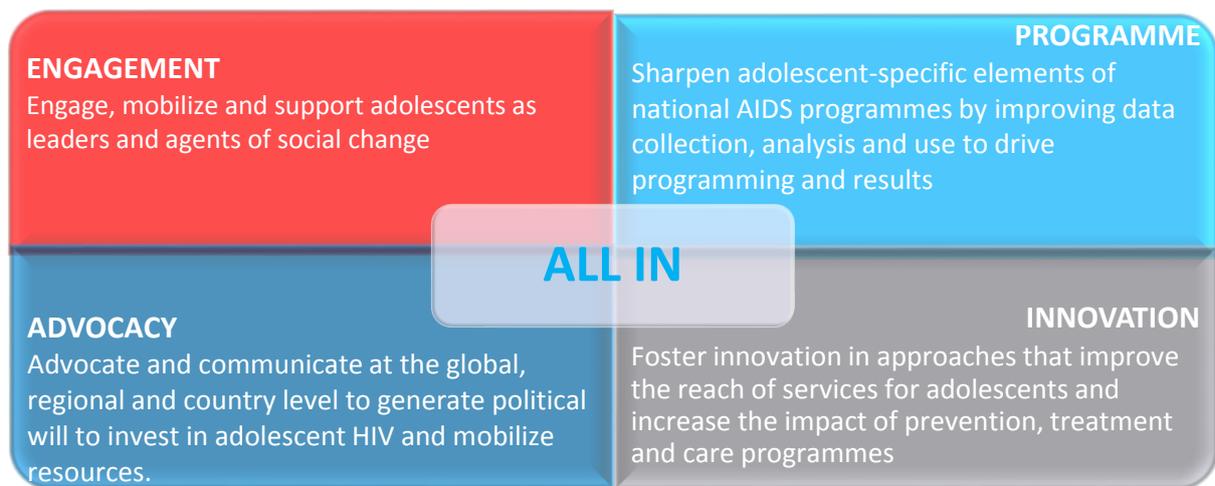


Figure 2: ALL IN: Four work streams to accelerate results

Source: UNICEF and UNIADS, ALL IN to #End AdolescentAIDS: Launch document, 2015

Purpose and objectives of consultation

The purpose of the consultation was to consider the range of clinical, ethical and operational issues required to implement oral PrEP to prevent HIV acquisition among sexually active older adolescents (15-19) in populations at substantially high risk of HIV infection. The consultation was intended to bring perspectives on programming for adolescents into the ongoing WHO-led PrEP implementation guidelines development process.

The main objectives of the consultation were to:

1. Share the current state of the evidence on PrEP and discuss key considerations for the implementation of PrEP among sexually active older adolescents (15-19) as input into the update of WHO implementation guidelines on PrEP use,
2. Discuss potential approaches for enrolling and motivating sexually active older adolescents (15-19) in priority population groups to use PrEP based on current evidence and documented experiences from other initiatives,
3. Identify priority areas for further research (clinical, operational, ethical) regarding PrEP implementation among older adolescents (15-19), and
4. Identify opportunities for advocacy and innovation in PrEP implementation among older adolescents (15-19)

Context for PrEP use among Adolescents

The world will not achieve an AIDS-free generation without addressing the HIV epidemic among adolescents. This will require innovative approaches to prevent new HIV infections and reduce AIDS-related deaths among adolescents. Available evidence (see figure 4 below) on the efficacy of oral tenofovir based PrEP supports including PrEP as an additional effective HIV prevention option for high risk population groups. The evidence together with the perspective of youth panellists at the meeting that PrEP be considered as an additional tool in the combination HIV prevention package provided the context for this consultation on PrEP use in sexually active older adolescents (aged 15 – 19) at high risk of HIV infection.

The Evidence

Oral PrEP is the use of antiretroviral (ARV) drugs by HIV-negative persons to prevent the acquisition of HIV. The use of oral tenofovir based ARV formulations as PrEP has been shown to be highly efficacious when taken consistently in preventing HIV acquisition (Figure 4). Currently, WHO has issued guidance⁶ on the use of combination ARVs – tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) - for use as PrEP, and the US government also released clinical practice guidelines for PrEP in 2014⁷.

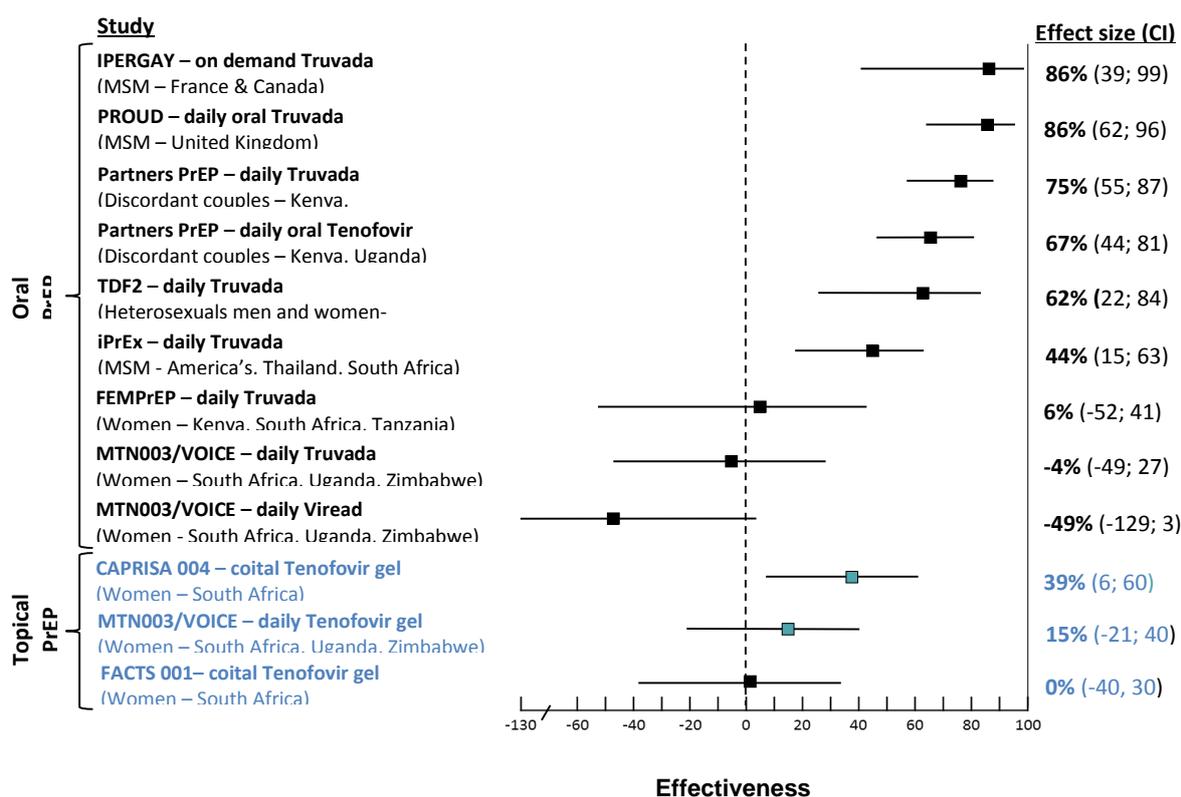


Figure 3: Overall evidence for Pre-Exposure Prophylaxis (PrEP)

Source: Baggaley, R., Pre-Exposure Prophylaxis (PrEP): WHO recommendations and guidance. WHO presentation at PrEP and adolescents consultation, July 2015.

⁶ World Health Organization, Consolidated guidelines for HIV prevention, diagnosis, treatment and care for key populations, 2014.

⁷ US department of health and human service and Center for Disease Control, 2014. Pre- exposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014 Clinical Practice Guideline <http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf>

The latest evidence, presented by WHO, (figure 4 above) indicated that PrEP is efficacious in different population groups at high risk of HIV acquisition i.e. males and females in sero-discordant relationship, men who have sex with men (MSM), people who sell sex, and transgender people.

The WHO presentation included a systematic review⁸ of randomized clinical trials (RCT) that compared PrEP to non-PrEP use among high risk populations. The results of the RCT indicated that PrEP is effective in individuals with a wide range of characteristics when they adhere (table 1). The systematic review showed no evidence of increasing rates of adverse events in PrEP users. However, studies have reported increases in alanine aminotransferase (ALT) a liver blood test^{9,10} and small decreases in bone mineral density related to PrEP^{11,12}, although these changes have not led to an increase in fractures.

Based on the strength of the RCTs, WHO is revising its current guidance and recommendations on PrEP use beyond the current population focus on MSM and individuals in sero-discordant relationships to recommend that countries implement PrEP for any population at high risk of infection, for example with an HIV incidence rate of >3%¹³.

Table 1: Meta-analysis results for HIV Infection across all sub-groups⁸

Analysis	No. of Studies	Sample Size (N)	Risk Ratio (95% CI)	p-value	I ²	P-value (meta-regression)
RCTs comparing PrEP to placebo						
Overall	10	17424	0.49 (0.33-0.73)	0.001	70.9	--
Adherence						
High (>70%)	3	6150	0.30 (0.21-0.45)	<0.0001	0.0	<0.0001
Moderate (41-70%)	2	4912	0.55 (0.39-0.76)	<0.0001	0.0	0.009
Low (≤40%)	2	5033	0.95 (0.74-1.23)	0.70	0.0	ref
Mode of Acquisition						
Rectal	4	3167	0.34 (0.15-0.80)	0.01	29.1	
Vaginal/penile	6	14252	0.54 (0.32-0.90)	0.02	80.1	0.36
Biological sex¹						
Male	7	8706	0.38 (0.25-0.60)	<0.0001	34.5	
Female	6	8716	0.57 (0.34-0.94)	0.03	68.3	0.19
Age²						
18 to 24 years	3	2997	0.71 (0.47-1.06)	0.09	20.5	0.29
≥25 years	3	5129	0.45 (0.22-0.91)	0.03	72.4	
Drug Regimen						
TDF	5	4303 active	0.49 (0.28-0.86)	0.001	63.9	
FTC/TDF	7	5693 active	0.51 (0.31-0.83)	0.007	77.2	0.88
Drug Dosing						
Daily	8	17024	0.54 (0.36-0.81)	0.003	73.6	
Intermittent	1	400	0.14 (0.03-0.63)	0.01	0.0	0.14
RCTs comparing PrEP to no PrEP						
Overall	2	720	0.15 (0.05-0.46)	0.001	0.0	NA

¹ The iPrEx trial included 313 (13%) transgender women. ² Includes only studies that stratified age by <25 and ≥25.

⁸ Fonner et al., Oral pre-exposure prophylaxis (PrEP) for all populations: Review of evidence for effectiveness, safety, and sexual and reproductive health outcomes. Presentation at WHO Guidelines Development Meeting, June 2015, Geneva

⁹ Choopanya K, Martin M, Suntharasamai P, et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet* 2013; 381(9883): 2083-90.

¹⁰ Van Damme L, Corneli A, Ahmed K, et al. Preexposure prophylaxis for HIV infection among African women. *The New England Journal of medicine* 2012; 367(5): 411-22.

¹¹ Kasonde M, Niska RW, Rose C, et al. Bone mineral density changes among HIV-uninfected young adults in a randomised trial of pre-exposure prophylaxis with tenofovir-emtricitabine or placebo in Botswana. *PLoS One* 2014; 9(3): e90111

¹² Liu AY, Vittinghoff E, Sellmeyer DE, et al. Bone mineral density in HIV-negative men participating in a tenofovir pre-exposure prophylaxis randomized clinical trial in San Francisco. *PLoS One* 2011; 6(8): e23688.

¹³ Baggaley, R., Pre-Exposure Prophylaxis (PrEP): WHO recommendations and guidance. WHO presentation at PrEP and adolescents consultation, July 2015

Key Considerations

The operational considerations in the implementation of PrEP among adolescents as discussed at the meeting are presented in this section of the report. Considering the limited number of PrEP demonstration projects thus far that include adolescents, research questions related to clinical considerations on drug resistance, metabolism and toxicity discussed at the meeting are presented in the section on research in this report.

Considerations for public health application

Public health application of PrEP among adolescents requires careful consideration of the estimated population of sexually active adolescents (aged 15 – 19) at high risk of HIV acquisition, and cost implications of delivering PrEP as part of a combination HIV prevention package. The presentation by UNAIDS¹⁵ highlighted the HIV threshold when the cost of PrEP is more beneficial to national programmes than the cost of HIV treatment. If PrEP is very effective in averting new infections and is inexpensive compared to the cost of ART then PrEP would be cost-saving, that is, the costs of implementing PrEP would be less than the future costs of ART if PrEP were not available. The point at which PrEP becomes cost-saving compared to ART depends on the effectiveness of PrEP, the costs of PrEP and ART and the incidence in the target population. The incidence at which PrEP becomes cost-saving can be estimated as:

$$\text{Incidence threshold} = 1 / (\text{LT} / (\text{C}_{\text{PrEP}} / \text{C}_{\text{ART}}) \times e$$

Where:

- LT = life-time cost of ART divided by the annual cost of ART
- C_{PrEP} = Annual cost of PrEP
- C_{ART} = Annual cost of ART
- e = effectiveness of PrEP in reducing susceptibility to HIV infection

For this example, data from the [IeDEA](#) Consortium on survival on ART was used and assumed a new infection occurring at age 20, ART start at a CD4 count of 500, a discount rate of 3% on the future costs of ART and non-AIDS mortality equivalent to a life expectancy of 60 years.

Figure 5 shows the results. Each line represents a different ratio of the annual costs of PrEP compared to ART. Thus, with a cost ratio of 0.3, the orange line, PrEP would be cost saving at 90% effectiveness in a population with incidence of 2.5%, and at 60% effectiveness in a population with incidence of 4.0%. At effectiveness of 70% to 80% and a cost ratio of 0.3 to 0.4, PrEP would be cost-saving in a population with incidence of about 3%, represented by the dashed line.

¹⁵ Godfrey-Faussett, P., Ghys, PD., Stover, J., Mahy, M., Daher, J., Sabin, K., and Dall, J. Estimated population of sexually active adolescents (15-19) at high risk of HIV infection in need of PrEP and cost implications. UNAIDS presentation at PrEP and Adolescent Consultation, July 2015

The following **considerations for public health application of PrEP** were highlighted:

1. Prioritizing individuals who are at substantial risk of HIV infection (for example HIV incidence threshold > 3 per 100 person years in the absence of PrEP) is essential for the intervention to have substantial cost-saving on the national HIV response.
2. Ensure PrEP is offered to individuals who have the desire to use it.

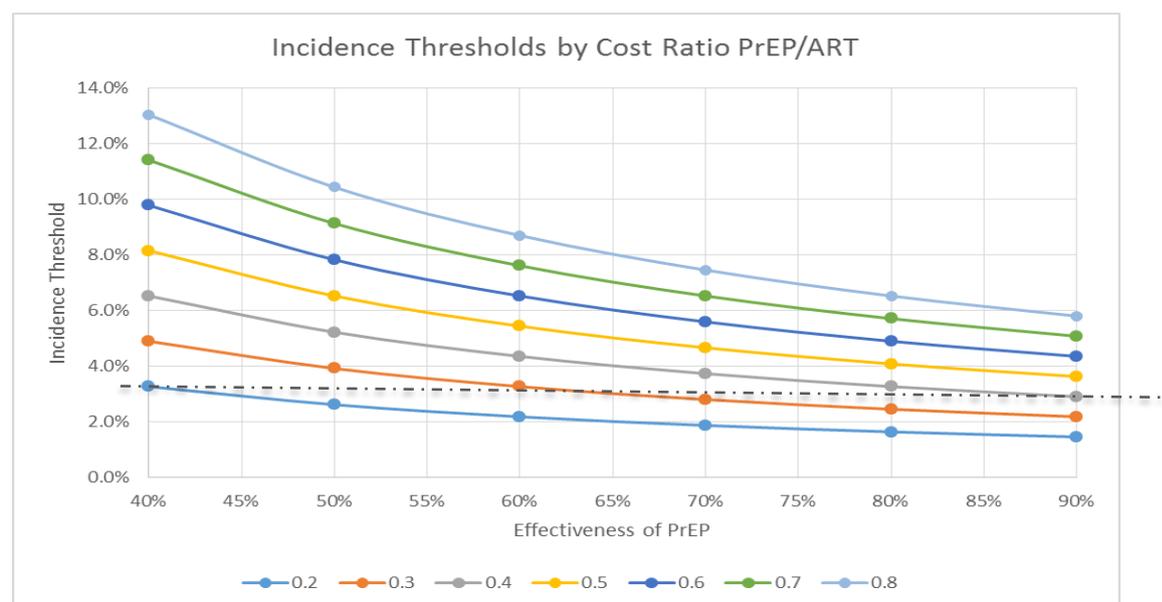


Figure 5: Incidence level at which the cost for PrEP is less than the costs for ART to treat averted infection

Source: Godfrey-Faussett, P., et al. Estimated population of sexually active adolescents (15-19) at high risk of HIV infection in need of PrEP and cost implications. UNAIDS presentation at PrEP and Adolescent Consultation, July 2015

Considerations for market shaping

An understanding of the adolescent population in need of PrEP is required to inform programme planning, drive commodity supply and target demand creation – market shaping. Using the public health considerations above, UNAIDS estimated the population of older adolescents living in areas where the incidence in their own age and gender specific cohort is predicted to be above various thresholds. The calculations used the estimate of age and gender-specific incidence derived from the UNAIDS estimates model (Spectrum) and national surveillance and survey data. Initial findings from the estimation¹⁵ indicated that only a few countries such as Kenya, Lesotho, Mozambique, South Africa, and Swaziland, for example, have areas with HIV incidence $\geq 3\%$ in some age and gender specific cohorts. The size of the estimated population of adolescents and young people in these countries living in areas with age and gender specific HIV incidence $\geq 3\%$ and $\geq 1.5\%$ respectively are presented in table 2. Key populations of older adolescent gay and bisexual boys, adolescent transgender people and adolescents who sell sex may have high HIV incidence rates, particularly in major cities, including outside of sub-Saharan Africa.

The estimates in table 2 (below) should however be interpreted with caution due to lack of precise sub-national level data beyond the first level of analysis; and the fact that age and gender specific HIV incidence used in the estimation were not directly measured.

The following **considerations for market shaping of application of PrEP** was highlighted:

1. Invest in sub-national data on HIV incidence to better estimate the need and to target information campaigns for PrEP implementation among adolescents.
2. Define the characteristics of adolescents at substantial risk of HIV acquisition for better targeting.

Table 2: Estimated number of people in need of PrEP in selected countries¹⁵

Number of people uninfected with HIV and living in sub-national areas with incidence $\geq 3\%$		Number of people uninfected with HIV and living in sub-national areas with incidence $\geq 1.5\%$	
Characteristics	Estimates	Characteristics	Estimates
Women: <ul style="list-style-type: none"> • 15-19 years old • 20-24 years old 	140,000 770,000	Women: <ul style="list-style-type: none"> • 15-19 years old • 20-24 years old 	2.2 Million 2.4 Million
Men: <ul style="list-style-type: none"> • 15-19 years old • 20-24 years old 	0 40,000	Men: <ul style="list-style-type: none"> • 15-19 years old • 20-24 years old 	0 1.2 Million
Countries: Kenya, Lesotho, Mozambique, South Africa, Swaziland.		Countries: Kenya, Lesotho, Mozambique, South Africa, Swaziland, Zimbabwe and Uganda.	

Legal and ethical considerations

The different legal and ethical concerns regarding PrEP use among adolescents especially around age of consent to HIV testing (at initiation and for monitoring), disclosure of HIV status and initiation and use of PrEP in adolescents less than 18 years were discussed. It was highlighted that the legal requirement for age of consent for adolescents below 18 years to access and utilize certain services (e.g. HIV testing, medical male circumcision, surgery, treatment, supply of medication) and participate in research differs in different jurisdictions with implications for linkage to HIV prevention (including PrEP), treatment and care. Two legal and ethical challenges with consent laws were highlighted as needing clarification for providers and adolescents. The first issue was “assent” and the other was the assumption in the law of ready access to an adult to provide consent on behalf of adolescents in need of services.¹⁶

Assent is the expression of approval or willingness, usually by persons who are, by definition, too young to give informed consent but who are old enough to understand expected risks and possible benefits. Assent was highlighted as a concern in situations where there are contradictions in the age limits for complementary HIV and SRH service for adolescents e.g. situation where legal provisions that allow adolescents under the age of 18 years to assent to HIV testing, whereas complementary services like condom provision, PrEP and treatment require adult consent. With regards to the requirement for adult consent, this presumes that the adolescent needing the services has an adult responsible for his/her care and support, which is not reflective of realities faced by vulnerable adolescents. It also presumes that the adolescent is able and willing to disclose her/his interest in and

¹⁶ Singh, JA., Adolescents and PrEP: ethical and legal challenges, presentation at PrEP and Adolescent Consultation, July 2015

need for the medication to the adult, which again is not the case for many adolescents, particularly because the service relates to adolescent sexuality and sexual health.

Ethical concerns raised during the meeting included the breach of the child's rights to confidentiality in settings where the consent of adults / parents is required to access HIV testing and or for initiation of PrEP. The ethical concerns associated with the obligation of service providers to report adolescents who are below the legal age for sexual intercourse presenting for PrEP or to report behaviours of adolescent key populations in settings with restrict legal provisions were highlighted.

The following **legal and ethical considerations** for the implementation of PrEP were highlighted:

1. Review of national / sub-national provisions on informed consent for (i) HIV testing, (ii) access to PrEP and (iii) treatment of other consequences of PrEP as part of the feasibility phase for the initiation of PrEP among adolescents.
2. Establish / strengthen mechanisms to assure confidentiality in (i) HIV testing vis-a-vis age of consent and (ii) PrEP initiation especially where the cost of PrEP is borne by parents / adult guardians.
3. Develop clearer operational guidance on the issue of disclosure for adolescents under the age of sexual consent to enable service providers to manage their obligations for protection and confidentiality. The guidance should also address restrictive legal positions where behaviors of adolescent key populations are classified as 'unlawful'.

Policy considerations

Positioning PrEP as part of a combination HIV prevention package requires considerations around cost and cost-effectiveness, especially in resource-constrained settings. The importance of cultural acceptability of using ARVs by people not infected with HIV was highlighted. These considerations are important for the sustainability of PrEP programmes in the national HIV response¹⁷.

The following **policy considerations** for the implementation of PrEP were highlighted:

1. Provide policy makers with information on the evidence, cost analysis and modelled impact of PrEP on the HIV epidemic among adolescents to assist with decision making. Community engagement tools to address societal concerns related to PrEP should also be offered to policy makers and programme managers.
2. Support policy discussion on PrEP with human rights principles of equity, non-discrimination and inter-dependence of rights to ensure inclusive and integrated implementation of PrEP with other HIV prevention and social services for eligible adolescent populations.
3. Track and closely evaluate PrEP implementation across countries and epidemic settings and provide information on efficiencies, affordability and sustainability to maintain policy interest.

¹⁷ Mabuza, K., Legal, Policy and Rights for the use of Pre-exposure Prophylaxis (PrEP)Supporting National Efforts to Ending AIDS, presentation at PrEP and Adolescent Consultation, July 2015

Service delivery considerations

Field experience of service providers from Kenya, Thailand, South Africa and the United States reinforced the importance of delivering PrEP as part of the HIV testing, prevention and care continuum. They argued that better understanding of the drivers of new HIV infections and pockets of risk e.g. sexual networks within geographic settings, will be important in the identification of eligible adolescent populations for PrEP. Service providers at the meeting described a variety of approaches to client enrolment. The adolescent PrEP demonstration project in South Africa¹⁸ weighs client motivation heavily in the enrolment decision and requires clients to demonstrate a desire to take PrEP before they are enrolled. In Thailand and Vietnam, a 'PrEP readiness index'¹⁹ is used to determine enrolment. The index tests (i) awareness that PrEP exist, (ii) belief that PrEP is effective and (iii) willingness to take PrEP and was used in the enrollment of MSM and transgender women (TGW) on PrEP.

Several delivery models for PrEP implementation were discussed. These include integration of PrEP services into youth centres¹⁸ and mainstreaming within health facilities²⁰ that offer primary health care, obstetrics and gynecology service, podiatry, dermatology, eye, dental and nutritional care, behavioral health and addiction services etc. Other delivery approaches include the use of stand-alone sites while others apply a combination of the approaches.

Community engagement is a critical component of service delivery and examples include mobile trucks for outreach in South Africa and 'health navigators' in the United States who reach out to youth and help them navigate the health system. Individuals initiating PrEP sometimes present with multiple structural vulnerabilities such as hunger, homelessness, school dropout etc. which are not easy to address. Anticipating these needs, services need to be positioned in such a way that complementary support is readily accessible through staff development, service integration, effective referral and/or strategic partnerships.²¹

Experience has revealed that the risk of HIV infection is not constant but varies with behaviour which itself varies over time. Clients therefore need to be guided on safe interruption and re-initiation of PrEP to effectively meet the needs for prevention given the seasonality of risk.

¹⁸ Bekker, LG., Oral PrEP for YOUTH: Who? When? How?, presentation at PrEP and Adolescent Consultation, July 2015

¹⁹ Colby, D., PrEP Demand Creation and Monitoring: the perspective from South East Asia, presentation at PrEP and Adolescent Consultation, July 2015

²⁰ Mayer, KH., Adolescents and PrEP: service delivery experience, presentation at PrEP and Adolescent Consultation, July 2015

²¹ Mugo, NR., What are the key consideration in integrated delivery of PrEP as part of comprehensive SRH and HIV package/program, presentation at PrEP and Adolescent Consultation, July 2015

The following **services delivery considerations** for the implementation of PrEP were highlighted:

Integrated Service delivery

1. Deliver PrEP services as part of a combination HIV prevention package and consider the drivers of HIV vulnerabilities like early marriage, transactional sex, and hostile environment to adolescent key populations etc. as part of the programme.
2. Prioritize entry points such as SRH services, post-exposure prophylaxis (PEP) services and family planning clinics, pharmacies, community distribution points and youth centres as strategic sites to identify and initiate eligible adolescents on PrEP.
3. Ensure community engagement – facility linkage as part of continuum of HIV testing, PrEP use and follow up support.
4. Link PrEP services with complementary health, protection, care and support services to provide risk reduction, optimize adherence and improve wellbeing.

Service organization

5. Where feasible, ensure same-day initiation of PrEP to eligible adolescents.
6. Task shifting among healthcare providers along the continuum of HIV testing, PrEP dispensing and follow up care will avoid additional burden on the health system.
7. Ensure PrEP is delivered in friendly and safe spaces by providers with the right attitude and capacities.

Service Delivery Tools

8. Standardize risk-assessment tools for use in determining eligibility of adolescents for PrEP. The tools should be available to both care providers and adolescents.
9. Develop operational guidance on the use of HIV self-testing²² as a tool to simplify initiation and monitoring of PrEP use among eligible adolescents.
10. Outline protocols for follow up support to adolescents who start and stop PrEP due to the seasonality of risk of HIV acquisition.

Considerations for demand creation and adherence support

Accessing services remains a major concern for the most vulnerable and marginalized population groups. In the context of PrEP implementation, it was noted that adolescents at substantial risk of HIV infection are a diverse population. These populations are excluded from services for multiple reasons including their age, lack of information, discriminatory attitudes of service providers, gender based discrimination and societal norms. Factors contributing to their vulnerability include imbalance in power to negotiate safer sex, criminalization and exploitation by both the community and law enforcement agents²³.

Adherence to PrEP is critical for its effectiveness²⁴ in HIV prevention and as such, several adherence support strategies were discussed. These included the use of a combination of blood level measurement results of TDF, community mobilization, peer based support ('adherence sisters') and

²² World Health Organization (WHO), Consolidated guidelines on HIV testing: 5Cs: consent, confidentiality, counselling, correct results and connections, Geneva, July 2015 http://apps.who.int/iris/bitstream/10665/179870/1/9789241508926_eng.pdf?ua=1

²³ Cowan, FM., Demand Creation, Adherence and Monitoring of PrEP use among young women who sell sex, presentation at PrEP and Adolescent Consultation, July 2015

²⁴ World Health Organization, WHO consultation on PrEP adherence: meeting report, June 2014.

use of SMS mobile reminders²³. A successful PrEP programme must therefore incorporate communication strategies and approaches to support adolescents to initiate and adhere to PrEP responsibly²⁵.

The following **considerations in relation to demand creation and adherence support** in the implementation of PrEP were highlighted:

1. Prioritize social marketing of PrEP to reframe messaging towards positive health choices and helping adolescents achieve good sexual health and overall health without excessive focus on negative health messages like avoiding diseases or infections.
2. Develop communication strategies that target different groups of adolescents and take into account networks and well-being of the diverse adolescent populations at substantial risk of HIV acquisition.
3. Engage adolescents and young people at substantial risk of HIV infection in the design of social marketing messages & communication materials on PrEP initiation, use and adherence.
4. Standardize context-appropriate tools to monitor PrEP readiness among adolescents.
5. Incorporate multiple and innovative adherence support strategies into programme design and build capacities for implementation and tracking of PrEP adherence.

²⁵ Celum, C., A key problem we are trying to address: One third of new HIV infections globally occur in young African women, presentation at PrEP and Adolescent Consultation, July 2015

Clinical Research and Implementation Science Agenda

Optimizing the benefits of PrEP as part of combination HIV prevention is relatively new, especially in adolescents. Building the knowledge base in clinical research and implementation science is a priority. The meeting explored the current state of evidence on ARV drug resistance, metabolism and toxicity, as well as the outstanding priorities for an implementation science agenda.

Regarding drug resistance, the meeting discussed two temporal points of developing ARV resistance in individuals taking PrEP²⁶. The first is the case of starting PrEP with undetected HIV infection, and the second is in the case of HIV infection while being non-adherent on PrEP. These concerns reinforce the need for quality assurance in HIV testing at initiation of PrEP and as part of monitoring. It was recommended that, where feasible, fourth generation HIV testing or HIV-RNA screening be considered at initiation, and that drug resistance testing be done on sero-converters.

Available evidence⁸ indicate no gender, racial or age differentials in the metabolism of ARV drugs used for PrEP. Tenofovir is, however, associated with mild nausea and gastrointestinal symptoms, weight loss, renal impairment (glomerulopathy and tubulopathy) and decrease in bone density²⁶. Renal monitoring and dose modification is recommended in those with renal impairment²⁶. Quality communication to adolescent clients in advance about these rare but potential side effects will contribute to better adherence and use outcomes.

In relation to implementation science, there exist knowledge gaps in PrEP implementation in adolescent girls and young women (AGYW) that are at substantial risk of HIV infection, especially in sub-Saharan Africa²⁷. Specific reference was made to further understand the acceptability and use of PrEP by male partners; and cultural norms and stigma associated with taking ARV when not infected with HIV. Other areas for exploration include attitude of care providers; the most effective entry points; and cost implication of rolling out PrEP for adolescent girls and young women at high risk of HIV infection.

Considering the programme and cost benefit of averting new HIV infections through PrEP, the meeting resolved to advocate for an **implementation science agenda around PrEP for adolescents** as part of current efforts and initiatives to reduce HIV infection and to focus research efforts on the following:

1. Drug safety, acceptability and patterns of use in adolescents less than 18 years who are still growing and use PrEP through on-going clinical trials and demonstration projects.
2. Evaluate long term impact of TDF-based regimens on adolescents who undergo multiple cycles of starting and stopping PrEP.
3. Document strategies for PrEP implementation in the different sub-populations of AGYW who are eligible for PrEP e.g. adolescent girls who sell sex and AGYW in different settings.
4. Continue critical work on the review of ethical / legal and regulatory barriers to implementation of PrEP and involvement of adolescents less than 18 years in research

²⁶ Wilson, CM., PrEP Implementation in Older Adolescents: Drug Toxicity, Metabolism and Resistance, presentation at PrEP and Adolescent Consultation, July 2015

²⁷ Pulerwitz, J., PrEP for adolescent girls and young women (AGYW) in sub-Saharan Africa: implementation Science issues, presentation at PrEP and Adolescent Consultation, July 2015

Advocacy Agenda

Next year, the International AIDS Conference will be held in Durban, South Africa. The conference will provide a unique opportunity to take stock of progress made on HIV and adolescents, including PrEP implementation. To maintain the momentum on PrEP implementation, especially among older adolescents, the following advocacy milestones²⁸ were agreed to ahead of Durban, 2016:

1. Increase awareness of PrEP among (i) sexually active older adolescents at substantial risk of HIV infection – “the potential target users”, (ii) service providers – “PrEP providers” and (iii) policy makers responsible for adolescent HIV and SRH programmes
2. Develop a simple language and information brief on “What do adolescents want and need?” to support the implementation of and communication on PrEP with adolescents.
3. Identify and promote adolescent experience in the marketing and demand for PrEP
4. Highlight adolescent PrEP champions among policy makers, service providers and adolescents themselves to mobilize broader acceptability for implementation

Conclusions and Next Steps

The following activities were suggested to continue to move forward to learn more about PrEP implementation among sexually active older adolescents:

1. Clarify what are the “PrEP issues for all eligible populations” and what are “adolescent-specific PrEP issues”.
2. Integrate considerations for adolescents in the WHO PrEP implementation guidelines currently under development.
3. Advocate for and implement PrEP demonstration projects for eligible adolescents to contribute to the global knowledge base on how to promote innovative bio-medical technology to reduce new HIV infections among adolescents.
4. Facilitate adolescent participation and community engagement in the global discussion on PrEP use.

²⁸ Warren, M., PrEP: Embracing the Opportunities for Sexually Active Older Adolescents, presentation at PrEP and Adolescent Consultation, July 2015

Annexes

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Consultation on the Clinical and Operational Considerations for the Implementation of Pre-Exposure Oral Prophylaxis (PrEP) in Sexually Active Older Adolescents (15-19): Vancouver, Canada – Coast Coal Hotel

AGENDA

Day 1: Friday, 17 July

Time	Agenda Item	Presenters	Chair
8:30-9:00	Registration		
9:00-9:10	Opening and Overview	Craig McClure , UNICEF, New York	
9:10-9:15	Welcome	Chris Beyrer , IAS President and Conference Co-Chair	
Session 1: Setting the Stage for PrEP among Sexually Active Older Adolescents (15-19) at High Risk of HIV Infection			
9:15-10:15	<p>Panel Discussion: Perspectives on engagement of adolescents (15-19) in PrEP programmes</p> <p>Objective: to reflect on the personal experience and concerns of young people who have used PrEP or are advocates for PrEP among sexually active older adolescents at high risk of HIV infection</p> <p>Methodology: 5 minutes opening by moderator followed by 5 minutes speech by each discussant (total 30 minutes) + 30 minutes discussion</p>	<p><i>Panel:</i></p> <p>Niluka Perera, Thailand (video: introduced by Midnight Poonkasetwattana)</p> <p>Joelle Reid, Uganda</p> <p>Carlo Oliveras Rodriguez, Puerto Rico</p> <p>Cassie Warren, USA</p>	Mitchell Warren , AVAC, USA
10:15-10:35	<p>Presentation on the WHO Guidelines on PrEP and on-going review process</p> <p>Objective: to provide an overview of the current WHO guidelines on PrEP and the on-going review process</p>	Rachel Baggaley , WHO, Geneva	Sybil Hosek , Stroger Hospital of Cook County, Chicago, USA
10:35-10:50	Tea Break		
Session 2: Delivery and Access to PrEP among Sexually Active Adolescents (15-19)			
10:50-11:10	<p>Presentation: Overview of PrEP demonstration projects and trials and implications for adolescents</p> <p>Objective: to frame the key questions in PrEP delivery for sexually active adolescents (15-19) based on a review of on-going trials and demonstration projects</p>	Robert Grant , University of California, San Francisco (UCSF), USA	Sybil Hosek , Stroger Hospital of Cook County, Chicago, USA

11:10 – 12:20	<p>Panel Discussion: Adolescents and PrEP Use: Service delivery experience to date</p> <p>Objectives: to share real-world experience in the delivery of PrEP among adolescents and young people.</p> <p>Key Questions for the panelists</p> <ol style="list-style-type: none"> What are the key consideration in integrated delivery of PrEP as part of comprehensive SRH and HIV package / programme? What are the key considerations in the screening and identification of adolescents in need of PrEP? What are the settings (organization of services) for delivery PrEP to different adolescent population groups? <p>Methodology: 15 min presentation by each discussant, followed by 30 minutes of discussion + 10 minutes of wrap up of key conclusions by the chair</p>	<p><i>Panel:</i> Nelly Mugo, Kenya Medical Research Institute, Kenya Ken Mayer, Harvard University and Fenway Health, USA</p> <p><i>Country Programme Respondent:</i> Fabio Mesquita, Brazil</p>	<p>Sybil Hosek, Stroger Hospital of Cook County, Chicago, USA</p>
12:20-12:40	<p>Presentation: Estimated population of sexually active adolescents (15-19) at high risk of HIV infection in need of PrEP and cost implications</p> <p>Objective: to shape the demand and cost implication for rolling out PrEP among sexually active older adolescents (15-19) in the context of broader comprehensive HIV prevention</p>	<p>Peter Godfrey-Faussett, UNAIDS, Geneva John Stover, Avenir Health, USA</p>	
12:40-13:00	Q&A, Discussion		
13:00-14:00	Lunch		
Session 3: Legal, Human Rights and Ethical Issues in PrEP delivery among Adolescents			
14:00 – 15:10	<p>Panel Discussion on legal, human rights and ethical considerations in PrEP use among adolescents</p> <p>Objectives: to review and discuss legal, human rights and ethical considerations that are relevant to the implementation of PrEP among adolescents</p> <p>Key Questions for the panelists</p> <ol style="list-style-type: none"> What are the different legal and ethical considerations in PrEP use among adolescents especially around age of consent and informed consent to HIV testing (initiation and monitoring), disclosure of HIV status and initiation and use of PrEP in adolescents less than 18 years? 	<p><i>Panel:</i> Jerome Singh, CAPRISA, South Africa Jonathan Gunthorp, Southern African AIDS Trust, South Africa</p> <p><i>Country Programme Respondent:</i> Khanya Mabuza, Swaziland</p>	<p>Douglas Shaffer, OGAC, USA</p>

	<ul style="list-style-type: none"> ii. What are the considerations related to confidentiality, availability, accessibility, acceptability, adherence and quality of HIV testing and linkage to prevention, treatment and care in the delivery of PrEP for adolescents iii. What are the social barriers and constructs; laws, policies and practices that contribute to the vulnerability of adolescents, especially adolescent key populations to HIV and hinder their access to HIV services? <p>Methodology: 10 min presentation by each discussant followed by 30 minutes discussion + 10 minutes of wrap up of key conclusions by the moderator</p>		
15:15–15:45	Tea Break		
Session 4: Demand Creation, Adherence and Monitoring of PrEP use among Adolescents			
15:45 -17:00	<p>Panel Discussion: Demand creation, adherence and monitoring of PrEP use among adolescents</p> <p>Objectives: to discuss key issues in demand creation, adherence and monitoring of the implementation of PrEP among adolescents</p> <p>Key Questions for the panelists</p> <ul style="list-style-type: none"> i. What are the approaches and key messages to drive demand for PrEP use among adolescents ii. What programme approaches and innovative strategies motivate and support individuals (e.g. personal, support from partners and community etc.) to initiate and use PrEP correctly and consistently? iii. How can PrEP initiation / uptake, use and discontinuation, as well as use of other prevention methods be monitored? <p>Methodology: 10 min presentation by each discussant followed by 30 minutes of discussion + 10 minutes of wrap up of key conclusions by the moderator</p>	<p><i>Panel:</i></p> <p>Frances Cowan, CeSHHAR, Zimbabwe</p> <p>Connie Celum, University of Washington, USA</p> <p>Donn Colby, Thai Red Cross AIDS Research Centre, Thailand</p>	<p>Douglas Shaffer, OGAC, USA</p>
17:00-17:15	Overview of PrEP Trial Involving Adolescents in South Africa	Linda-Gail Bekker , Desmond Tutu HIV Foundation, South Africa	
17:15–17:20	Wrap up		

Day 2: Saturday, 18 July

Time	Agenda Item	Presenters	Chair
9:00-9:30	Recap of Day 1, Objectives of Day 2	Katie Richey , UNICEF, NY	
Session 5: Research Gaps and Next Steps			
9:30-11:00	<p>Panel on Research Gaps (clinical and operational) in the delivery of PrEP among adolescents</p> <p>Objective: to highlight key areas of knowledge gaps in clinical and operational issues related to implementation of PrEP among adolescents:</p> <ol style="list-style-type: none"> i. Drug toxicity, metabolism, resistance ii. Service delivery models and monitoring iii. Social science research gaps <p>Methodology: 10 min presentation by each discussant followed by 20 minutes of discussion + wrap up of key conclusions by the moderator</p>	<p><i>Panel:</i></p> <p>Craig Wilson, University of Alabama, USA</p> <p>Julie Pulerwitz, Population Council, USA</p> <p>Julie Fox, NHS Foundation Trust, UK</p> <p>Carlos Caceres, Universidad Peruana Cayetano Heredia, Peru</p>	Bill Kapogiannis , NIH, USA
11:00-11.30	Tea Break		
11:30-12:15	Moving the agenda forward: Advocacy, Knowledge Management and Communications	Mitchell Warren , AVAC, USA	
12:15-12:45	Presentation of summary recommendations	Tajudeen Oyewale , UNICEF, NY	
12:45-1:00	Closing remarks	Craig McClure , UNICEF, NY	
1:00-2:00	Lunch		

