

AUGUST  
2017

# Summary of Expected Insights from Oral PrEP Projects in Zimbabwe

---

*PZAT in partnership with FSG and AVAC*



# Introduction

- A number of questions remain around how best to provide PrEP for target populations, such as MSM, FSW, sero-discordant couples, and AGYW in Zimbabwe
- Over the next several years, there will be a number of projects that aim to deliver oral PrEP to these populations
- This analysis aims to explore two topics:
  1. Investigate which questions will / will not be addressed by the current slate of ongoing or planned projects. This will be used to make decisions about investments in additional research (if needed)
  2. Provide an understanding of when insights across key questions will become available, to help inform PrEP rollout planning in Zimbabwe
- This research was compiled through a survey circulated by PZAT and a series of interviews with project leaders in Zimbabwe. Research was compiled by PZAT and AVAC, and the development of this analysis was supported by FSG.
- Please contact Definate Nhamo ([dnhamo@pzat.org](mailto:dnhamo@pzat.org)) at PZAT with questions or additional information

# Seven ongoing or planned projects on PrEP

Ongoing or planned oral PrEP projects included in this analysis		
Project	Implementing Partners	Description
<b>DREAMS</b>	PSI	Partnership to reduce HIV infections among AGYW; extends beyond health sector to address poverty, gender inequality, sexual violence, lack of education; PrEP implementation component included
<b>EMOTION</b>	IDEO, Abt, RTI, CAPRISA	Project to identify strategies to increase uptake and correct/consistent use of ARV-based prevention products by women at high-risk of HIV infection using an end-user centered strategy
<b>GEMS</b>	FHI 360, BARC South Africa, University College London, SCHARP	Project to inform policies and define programmatic considerations related to use of ARV-based prevention products and resistance risk
<b>HPTN 082</b>	University of Zimbabwe, University of Cape Town, Desmond Tutu HIV Foundation	Project to evaluate daily oral PrEP as a primary prevention strategy for young African women
<b>IMPAACT 2009</b>	IMPAACT	Project to study pharmacokinetics, feasibility, acceptability and safety of oral PrEP for primary HIV prevention during pregnancy and breast feeding in adolescents and young women
<b>IPM 045 / MTN 034</b>	UZ-UCSF	Project to evaluate use of the dapivirine ring and oral PrEP, each for a period of 6 months of use, to collect data on safety, adherence, and acceptability
<b>SAPPH-IRe</b>	CESSHAR, University College London, LSHTM, RTI	Project to enhance HIV treatment and prevention among highway-based sex workers at 7 sites by increasing uptake and frequency of testing, demonstrating the acceptability and feasibility of delivering oral PrEP, and maximizing retention in care.

*Note: Other projects include HPTN 084 (clinical trial for injectable PrEP) and OPTIONS, which supports PrEP rollout but does not include service delivery or delivery of oral PrEP – these projects are not included in this analysis*

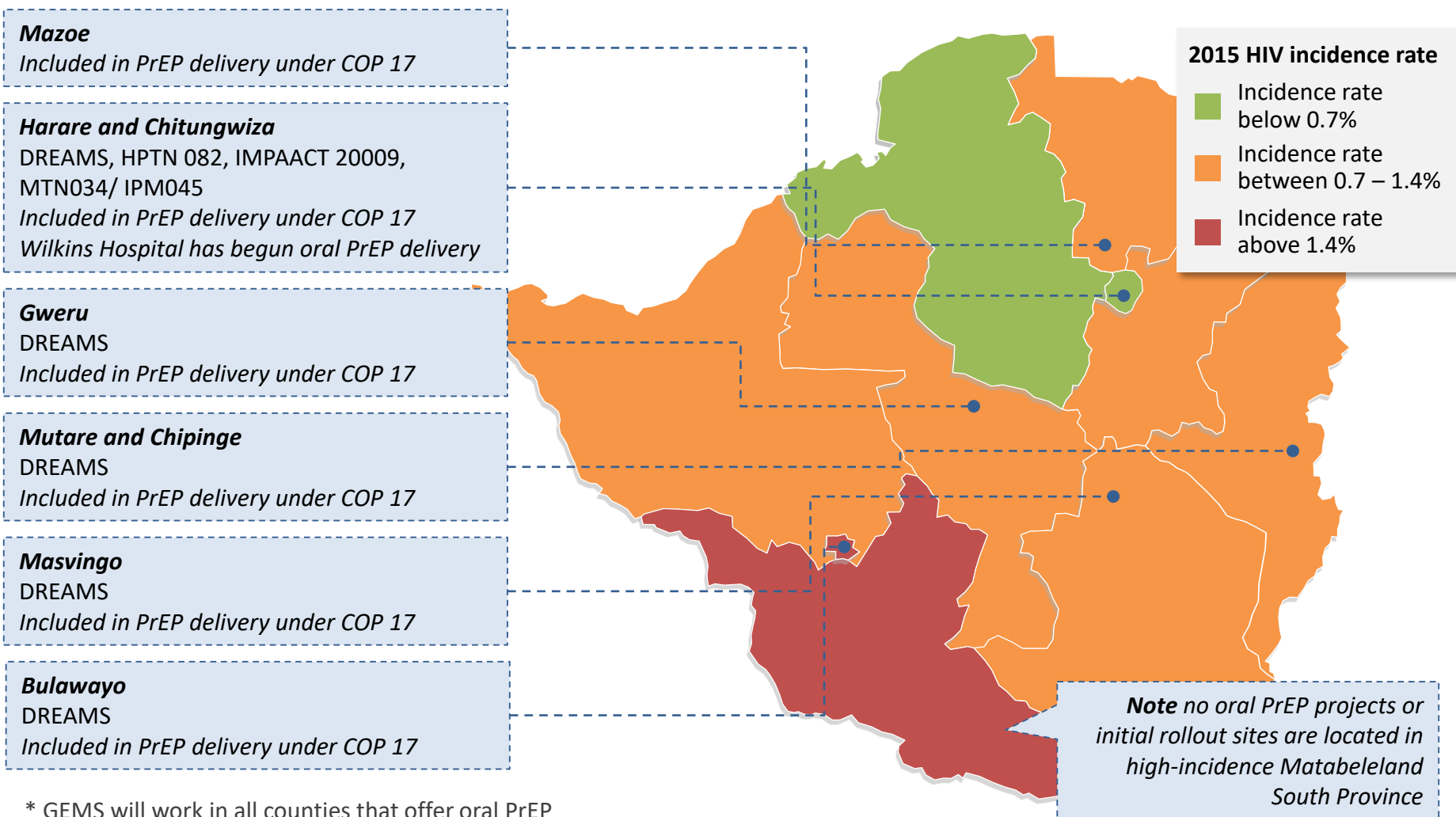
# PrEP projects by target population

	# of target PrEP users	FSW	Serodiscordant couples	AGYW	Women	Men
<b>DREAMS</b>	1,451			Age 18 – 24		
<b>EMOTION</b>	Unknown at this stage					
<b>GEMS*</b>	N/A	General population				
<b>HPTN 082</b>	200			Age 16 - 25		
<b>IMPAACT 2009</b>	40			Age 16 – 24		
<b>IPM 045 / MTN 034</b>	300			Age 16 – 21		
<b>SAPPH-IRe</b>	Unknown at this stage	Completed in 2016		Age 15 - 24		
<b>Wilkins Hospital (public sector delivery)</b>	Ongoing program delivery	General population				

\* General population aged 15+

# Projects are concentrated in Harare, however DREAMS and public rollout sites are more dispersed

## PrEP Projects in Zimbabwe by Province (August 2017)



\* GEMS will work in all counties that offer oral PrEP

# These projects will yield insights over the next several years on effective PrEP strategies

## Timeline of PrEP Projects

	2015				2016				2017				2018				2019				2020			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
DREAMS																								
EMOTION	Planned, but not yet started in Zimbabwe																							
GEMS*																								
HPTN 082																								
IMPAACT 2009																								
IPM 045 / MTN-034																								
SAPPH-IRe																								
Wilkins Public Sector Delivery																								
Public Rollout under COP 17																								

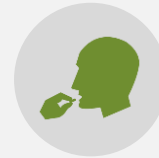
# Input is anticipated on the following key questions



## PLANNING FOR PREP ROLLOUT



## PREP DELIVERY PLATFORMS



## INDIVIDUAL UPTAKE



## EFFECTIVE USE & MONITORING

### Q1

What are the **characteristics of high-risk target populations** and how can PrEP be effectively **targeted** to higher-risk populations?

### Q2

What are the major **barriers to PrEP uptake** for target populations and how can they be addressed?

### Q3

What service delivery and civil society **channels** will most effectively reach different target populations?

### Q4

What types of **investments** are required to effectively deliver PrEP through these channels? What are the cost implications?

### Q5

How can negative **health care worker attitudes** be effectively mitigated?

### Q6

What are the most effective **messages and strategies** to build awareness and/or generate demand for PrEP amongst target populations?

### Q7

Are participants taking oral PrEP while **pregnant** or breastfeeding?

### Q8

How are “**seasons of risk**” defined? What strategies/tools are effective to support users’ decision-making around on/off decisions for PrEP?

### Q9

To what extent are participants adhering to PrEP? What messages and strategies effectively support **daily adherence** to PrEP?

### Q10

To what extent are participants getting regular **HIV and STI testing**? What messages and strategies effectively support retention in regular testing? What frequency of testing is required?

*Additional detail on each question can be found on the following pages*



# Q1 | What are the characteristics of high-risk target populations and how can PrEP be effectively targeted to those populations?

## PARTICIPANT CHARACTERISTICS

Study	Characteristics
<b>DREAMS</b>	Women aged 18 – 24 Multiple sexual partners Unprotected sex in past 6 months Knowledge of partner's HIV status and inconsistent condom use Recent STI testing Recent experience exchanging sex for money, goods, or services in past 6 months Participation in sex parties in past 6 months
<b>EMOTION</b>	<i>Planned, not yet started</i>
<b>GEMS</b>	N/A
<b>HPTN 082</b>	Areas with annual incidence of 5-6% Women aged 16 – 25 years Sexually active (vaginal or anal intercourse at least once in prior month) Scored 5 or greater in VOICE risk score tool (sexual and substance use behaviors, HIV stigma, social harms and GBV) Aspirations and reasons for PrEP acceptance
<b>IMPAACT 2009</b>	Areas with annual incidence of 5-6% Women aged 16 – 24 years Sexual behavior questionnaire and HIV test done quarterly
<b>IPM 045 / MTN-034</b>	Women aged 16 - 21 History of sexual intercourse (at least one episode in participant's lifetime) or expectation of becoming sexually active during study participation Recent pregnancy or STI test
<b>SAPPH-IRe</b>	<i>Currently inactive</i>
<b>Wilkins Public Sector Delivery</b>	HIV negative and sexual partner with HIV who has not been on effective therapy for the preceding 6 months, vaginal or anal intercourse without condoms with more than one partner, sexual partner with one or more HIV risk factors, history of STI by lab testing or self-report or syndromic STI treatment, use of post-exposure prophylaxis (PEP), requests for PrEP

## Insights expected from projects

- ✓ HPTN 082 is testing a the VOICE risk scoring tool, which could provide insights on how risk scoring tools can be effectively used to identify potential PrEP users
- ✓ DREAMS is using a risk assessment tool to determine appropriateness for PrEP use specifically for AGYW

## Remaining questions about projects

- ? How will other upcoming projects define criteria for AGYW participation?
- ? How can risk assessments be developed or adapted for non-AGYW populations?
- ? What insights will delivery at Wilkins yield about the relationship between self-perceived risk and actual risk? Adherence?



## Q2 | What are the major barriers to PrEP uptake for target populations and how can they be addressed?

### BARRIERS TO UPTAKE

Study	Characteristics
DREAMS	PSI is developing a protocol to understand why some PrEP users do not return for prescription refills
EMOTION	<i>Planned, not yet started</i>
GEMS	N/A
HPTN 082	Will collect data on: partnership characteristics, sexual behaviors, HIV risk perception, and HIV stigma and will specifically collect factors that influence women's decisions to decline PrEP, barriers / facilitations to PrEP pill-taking and PrEP acceptability
IMPAACT 2009	<i>Planned, not yet started</i>
IPM 045 / MTN 034	Will regularly assess adherence, product acceptability, and gather insights into product use, including patterns of use, motivators and barriers for both the oral pill and the vaginal ring products
SAPPH-IRe	<i>Currently inactive</i>
Wilkins Public Sector Delivery	

### Insights expected from projects

- ✓ HPTN 082 and DREAMS are specifically collecting data on barriers to PrEP uptake and ongoing use
- ✓ IPM 045 / MTN 034 will yield comparative results for the daily pill and the vaginal ring across a number of factors related to PrEP use

### Remaining questions about projects

- ? What data will other projects collect about barriers to uptake? Is all data self-reported? What types of factors will they include and how will they gather the information?
- ? What is already known from completed projects, such as SAPPH-IRe?
- ? Can initial public sector delivery (at Wilkins) collect information on PrEP decliners?



## Q3 | What service delivery and civil society **channels** will most effectively reach target populations?

DELIVERY CHANNELS	
Study	Characteristics
DREAMS	New Start Centres
EMOTION	<i>Planned, not yet started</i>
GEMS	N/A
HPTN 082	Clinical research sites PrEP delivery by pharmacists
IMPAACT 2009	Urban research clinic PrEP delivery by pharmacists
IPM 045 / MTN 034	
SAPPH-IRe	<i>Currently inactive</i>
Wilkins Public Sector Delivery	Key population clinic at Wilkins Hospital PrEP delivery by pharmacists

### *Insights expected from projects*

- ✓ Projects will deliver PrEP across a range of different health facilities, including NGO-run New Start Centres, clinics, and key population-focused clinics
- ✓ Comparison across delivery channels can yield insights on effective reach, user populations, and operational / cost considerations

### *Remaining questions about projects*

- ? What are the cost / investment implications across different types of sites?
- ? Which types of sites most effectively reached likely PrEP users?



## Q4 | What types of **investments** are required to effectively deliver PrEP through these channels? What are the cost implications?

INVESTMENTS	
Study	Characteristics
DREAMS	DREAMS will include a costing component
EMOTION	<i>Planned, not yet started</i>
GEMS	GEMS will provide insights on cost-effective approaches to ongoing testing based on risk of resistance
HPTN 082	
IMPAACT 2009	
IPM 045 / MTN 034	
SAPPH-IRe	<i>Currently inactive</i>
Wilkins Public Sector Delivery	

### *Insights expected from projects*

- ✓ Currently, DREAMS is the only project planning a costing component for PrEP delivery
- ✓ GEMS will provide a cost-effectiveness assessment of testing regimens based on risk of resistance development

### *Remaining questions about projects*

- ? What will be included in the DREAMS costing analysis?
- ? To what extent can costing components be added to ongoing or planned projects?
- ? How will costing data be collected and compared across projects to inform national planning?



## Q5 | How do health care worker attitudes and practices be effectively mitigated?

HEALTHCARE WORKERS	
Study	Characteristics
DREAMS	
EMOTION	<i>Planned, not yet started</i>
GEMS	N/A
HPTN 082	
IMPAACT 2009	
IPM 045 / MTN 034	
SAPPH-IRe	<i>Currently inactive</i>
Wilkins Public Sector Delivery	PrEP will be delivered by doctors and nurses trained in ARV management

### *Insights expected from projects*

- ✓ To be determined

### *Remaining questions about projects*

- ? Is any ongoing or planned project studying healthcare workers and their interactions with target populations and PrEP users more broadly?
- ? How will ongoing or planned PrEP delivery monitor the physicians, nurses, pharmacists and others who come into contact with PrEP users? Can this monitoring yield insights on effective vs. ineffective interactions between users and healthcare workers?



## Q6 | What are the most effective messages and strategies to **build awareness and generate demand** for PrEP with target populations?

DEMAND GENERATION	
Study	Characteristics
DREAMS	
EMOTION	<i>Planned, not yet started</i>
GEMS	N/A
HPTN 082	
IMPAACT 2009	
IPM 045 / MTN 034	Recruitment will occur from variety of sources, including: adolescent and primary care health clinics, family planning clinics, HIV testing facilities, gynecology clinics, community based youth centers, schools, and other community-based locations
SAPPH-IRe	<i>Currently inactive</i>
Wilkins Public Sector Delivery	Recruitment strategies include: messaging to existing patients in the key population clinic, GBSRH clinics, peer referrals and word of mouth

### *Insights expected from projects*

- ✓ For now, we do not have much information on how different projects are attracting PrEP users and/or building demand for PrEP
- ✓ The IPM 045 study will yield insights across a number of different recruitment site types and can help inform how best to target demand generation activities

### *Remaining questions*

- ? How are projects recruiting PrEP users? What strategies are working for different populations?
- ? How can we best understand the efficacy of the methods in the projects?
- ? What is the content of the messaging and how does that differ across projects (e.g., messages of safety vs. empowerment)?



## Q7 | Are participants taking oral PrEP while pregnant or breastfeeding?

USE IN PREGNANCY	
Study	Characteristics
DREAMS	PrEP is not offered to pregnant women
EMOTION	<i>Planned, not yet started</i>
GEMS	N/A
HPTN 082	PrEP is not offered to pregnant women
IMPAACT 2009	PrEP offered to women who get pregnant during the project
IPM 045 / MTN 034	PrEP is not offered to pregnant women
SAPPH-IRe	<i>Currently inactive</i>
Wilkins Public Sector Delivery	PrEP offered to women who get pregnant during the project

### *Insights expected from projects*

- ✓ IMPAACT 2009 and delivery through Wilkins Hospital will offer PrEP to women who get pregnant, in comparison to DREAMS, HPTN 082, and IPM 045 which will stop PrEP provision to pregnant women
- ✓ A comparison across these projects – and in particular a study of those women who do become pregnant – could inform future guidelines

### *Remaining questions about projects*

- ? Are any other ongoing or planned projects studying this issue?
- ? How will information be collected on the women who become pregnant when they are no longer taking PrEP?



## Q8 | How are “periods of risk” being defined? What strategies / tools support users’ decision-making around on/off decisions for PrEP?

PERIODS OF RISK / PrEP CYCLING	
Study	Characteristics
DREAMS	
EMOTION	<i>Planned, not yet started</i>
GEMS	N/A
HPTN 082	
IMPAACT 2009	
IPM 045 / MTN 034	
SAPPH-IRe	<i>Currently inactive</i>
Wilkins Public Sector Delivery	

### *Insights expected from projects*

- ✓ To be determined

### *Remaining questions about projects*

- ? What other projects will explicitly collect information on PrEP cycling?
- ? How are “seasons of risk” and on/off periods for PrEP being communicated to study participants in projects currently? To the extent that different projects are using different practices, this could create a good comparison opportunity



## Q9 | To what extent are participants adhering to PrEP? What messages and strategies effectively support **daily adherence** to PrEP?

### ADHERENCE SUPPORT STRATEGIES

Study	Characteristics
<b>DREAMS</b>	Will collect adherence patterns through pill counts and self-reports as well as data on number of partners and condom use
<b>EMOTION</b>	<i>Planned, not yet started</i>
<b>GEMS</b>	N/A
<b>HPTN 082</b>	Will collect qualitative data on what factors enable women to adhere to PrEP
<b>IMPAACT 2009</b>	Will collect data on adherence challenges by ACASI Daily contact with PrEP users for first 12 weeks
<b>IPM 045 / MTN 034</b>	Includes an adherence support program based on self-reported data as well as PK levels, residue in rings, and possibly hair samples to confirm adherence
<b>SAPPH-IRe</b>	<i>Currently inactive</i>
<b>Wilkins Public Sector Delivery</b>	Will collect data on patterns of PrEP use

### *Insights expected from projects*

- ✓ Several methods for tracking and testing adherence will be deployed across the projects and can be compared to develop guidelines for broader implementation

### *Remaining questions about projects*

- ? To what extent are adherence strategies similar or different between different target populations?
- ? To what extent are these strategies realistic in a non-project setting?
- ? What investments or costs are involved in implementing these adherence strategies? To what extent will these be included in costing analyses?



## Q10 | To what extent are participants getting regular **HIV and STI testing**? What messages and strategies effectively support retention?

TESTING	
Study	Characteristics
DREAMS	Monthly visits for first 3 months and one visit every 3 months after that Testing includes Hep B and creatinine clearance
EMOTION	<i>Planned, not yet started</i>
GEMS	GEMS will provide insights on cost-effective approaches to ongoing testing based on risk of resistance
HPTN 082	
IMPAACT 2009	
IPM 045 / MTN 034	Weekly visits for first 4 weeks, then monthly visits through end of study; each visit includes HIV and STI testing, creatinine test, and other laboratory tests (e.g., HSV-2 antibody, CBC with platelets, plasma storage, dried blood spot for biomarkers, cervical swab, etc.)
SAPPH-IRe	<i>Currently inactive</i>
Wilkins Public Sector Delivery	Visit schedule: Initiation, 1 week, 2 weeks, monthly for 3 months, two monthly up to 9 months, then once every 3 months thereafter

### *Insights expected from projects*

- ✓ Several projects have different protocols for frequency of visits and testing – comparisons across them will be informative
- ✓ GEMS will also provide insights and recommendations on effective testing protocols based on resistance risk

### *Remaining questions about projects*

- ? How are visits configured? Is HIV testing done at every visit?
- ? To what extent are these practices replicable in “real-world” implementation situations?
- ? What investments or costs are involved in implementing ongoing testing? To what extent will these be included in costing analyses?

# Tools to be developed by projects

Expected Tool Development	
Project	Tools
DREAMS	IEC materials, AGYW risk assessment algorithm
EMOTION	
GEMS	
HPTN 082	Videos about PrEP
IMPAACT 2009	Adherence support tool
IPM 045 / MTN-034	
SAPPH-IRe	<i>Currently inactive</i>
Wilkins Public Sector Delivery	PrEP delivery guidelines, PrEP screening form

# Status of research agenda on effective practices to target and deliver PrEP

■ Significant coverage in projects  
■ Some projects address topic  
■ No projects address topic

	Question	Status	Notes
Q1	What are the <b>characteristics of high-risk target populations</b> and how can PrEP be effectively <b>targeted</b> to them?		Projects use differing “risk factors” to identify project participants; a comparison across them will be informative
Q2	What are the major <b>barriers to PrEP uptake</b> for target populations and how can they be addressed?		Some will collect data from PrEP decliners and collect information on barriers and enablers to PrEP-taking
Q3	What service delivery and civil society <b>channels</b> will most effectively reach different target populations?		Coverage across different types of delivery channels (e.g., clinics, NGO sites)
Q4	What types of <b>investments</b> are required to effectively deliver PrEP through these channels?		DREAMS will include a costing component
Q5	How can negative <b>health care worker attitudes</b> be effectively mitigated?		No awareness of current plans to study this aspect
Q6	What are the most effective strategies to <b>build awareness and generate demand</b> for PrEP amongst target populations?		Some insights specifically for AGYW from the DREAMS and IPM 045 studies
Q7	Are participants taking oral PrEP while <b>pregnant</b> or breastfeeding?		Projects differ on approach to pregnancy
Q8	How are “ <b>periods of risk</b> ” defined? What strategies / tools support users’ decision-making around on/off decisions?		Some projects allow participants to start / stop taking PrEP and remain in study; plans to study “cycling” are unknown
Q9	To what extent are participants adhering to PrEP? What messages and strategies effectively support <b>adherence</b> ?		Significant focus on monitoring adherence, but little is known about adherence strategies that will be used in projects
Q10	Are participants getting regular <b>HIV/STI testing</b> ? What strategies effectively support retention in regular testing?		Projects have different testing protocols and comparisons across them will be useful; GEMS will provide insights on cost-effectiveness of different testing protocols

# Additional questions critical for PrEP rollout not included in this analysis due to lack of data

- ? To what extent are those **users that self-select** to initiate PrEP those that are at highest need of PrEP?
- ? What do **target populations need** in delivery channels (e.g., hours that fit their schedules, friendly staff)?
- ? How are PrEP users communicating about PrEP use to **partners / family members**?
- ? What are effective strategies to reach **rural populations**?
- ? What are effective strategies to proactively **combat “myths”** around PrEP and PrEP use?
- ? What **information** do health care facilities need to **collect and report** to MOH?