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Summary of Expected Insights on Oral PrEP for AGYW from Demo Projects in South Africa

Wits RHI in partnership with FSG and AVAC



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OPTIONS
OPTIMIZING PREVENTION TECHNOLOGY INTRODUCTION ON SCHEDULE

Introduction

- A number of questions remain around how best to provide AGYW with PrEP in South Africa
- Over the next several years, there will be a number of demonstration projects that aim to deliver PrEP to AGYW
- This analysis aims to explore two topics:
 1. Investigate which questions will / will not be addressed by the current slate of ongoing or planned demonstration 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 South Africa
- This research was compiled through a survey and a series of interviews with project leaders in South Africa.
- Please contact Dawn Greensides (DGreensides@wrhi.ac.za) or Alison Stretton-Downes (AStretton-Downes@wrhi.ac.za) at Wits RHI with questions or additional information

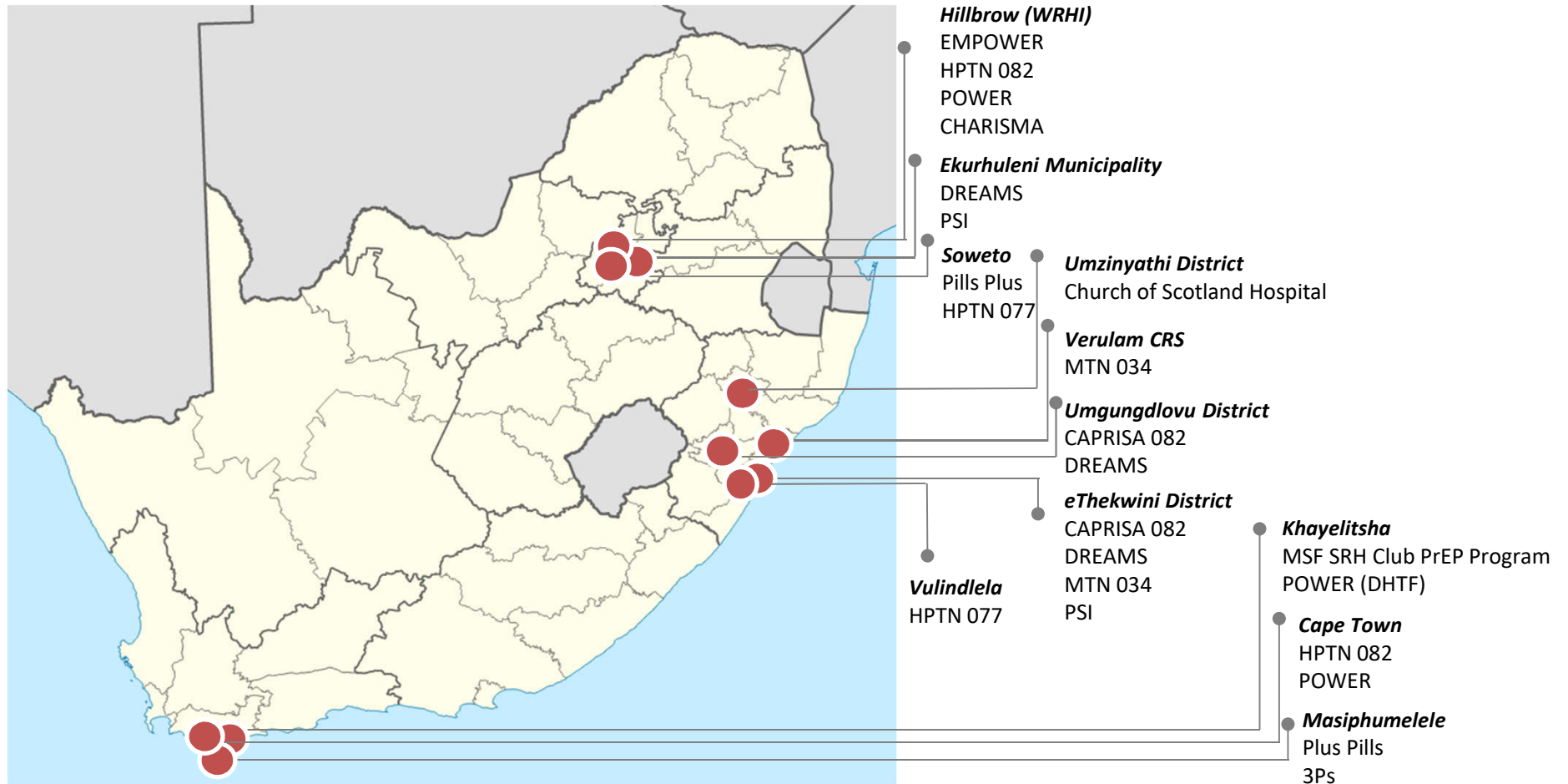
18 ongoing or planned demo projects on PrEP for AGYW

Ongoing or planned PrEP demo projects included in this analysis

 Detailed information included in this analysis

3 P's for Prevention	Marketing and demand creation to build interest in PrEP
CAPRISA 082	Prospective Study of HIV Risk Factors and Prevention Choices in Young Women in KwaZulu-Natal, South Africa to identify risk factors for HIV acquisition in healthy young women.
CHARISMA	To increase women's agency to consistently and safely use microbicides while mitigating social harms, in particular IPV
Church of Scotland Hospital	Planned project to recruit pregnant teenagers at their first ANC visit and enroll into a comprehensive support program with aim of improving outcomes for mothers and babies. Central focus is assisting mothers return to school, prevent acquisition of HIV, and postpone further pregnancies.
EMPOWER	Project on integrated GBV and stigma reduction through combination HIV prevention methods, including service delivery platforms, barriers to use.
HPTN 084	Assessing the efficacy of Injectable Cabotegravir for PrEP in HIV-uninfected Women
HPTN 083	Study of injectable Cabotegravir compared to Daily Oral TDF/FTC, for PrEP
HPTN 077	Phase 2a Safety, Tolerability and Pharmacology study of Cabotegravir, in HIV-uninfected Men and Women
HPTN 082	Study to assess proportion and characteristics of young HIV-uninfected women who accept versus decline PrEP, and to assess PrEP adherence using drug level feedback.
IMPAACT 2009	Pharmacokinetics, feasibility, acceptability and safety of Oral PrEP for Primary HIV Px during Pregnancy and Breast Feeding in AGYW
MSF SRH Club	Provision of PrEP through public facility SRH club, looking at acceptability, uptake, adherence, retention, adverse events, reasons for taking or discontinuing, feasibility of service delivery model. Real world settings.
MTN034	Phase 2A Crossover Trial Evaluating the Safety of and Adherence to a Vaginal Matrix Ring Containing Dapivirine and Oral PrEP in an Adolescent Female Population.
Plus Pills	Assessing uptake to oral PrEP and effect of conditional incentives based on drug levels on adherence to oral PrEP. PrEP component to examine feasibility/acceptability in adolescent girls and boys
POWER	Project to develop cost-effective and scalable models for implementation of ARV-based prevention products for women, includes scalable microbicide and PrEP adherence support and delivery strategies.
Right to Care	Planned PrEP demo project for AGYW in Johannesburg and Mpumalanga under DREAMS.
Sister Love Innovation Project	New DREAMS adolescent innovation project (in progress)
UNICEF PrEP Demo Program	Project on combination HIV prevention interventions including oral PrEP.
Witkoppen Innovation Project	New DREAMS adolescent innovation project (in progress)

These studies are concentrated around major urban centers in Cape Town, Durban and Joburg



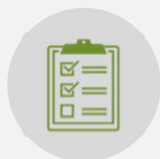
These studies will yield insights over the next several years on effective PrEP strategies for AGYW

Project Name	Country/ Countries	Target Population (years)	2015				2016				2017				2018				2019				2020			
			Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
3Ps Demonstration Project	South Africa	Women 16 - 25	Planned																							
HPTN 084	Sub-Saharan Africa TBD	HIV negative women	Expected start second half of 2017																							
HPTN 083	42 Sites in 8 countries including SA	TGW and Cis-MSM 18 years or older	Launched Dec 2016																							
HPTN 077	South Africa, USA, Malawi and Brazil	Men and women ages 18-65	Feb 2015 - July 2017																							
CAPRISA 082	South Africa	Women 18-30	** Expected Completion April 2021																							
CHARISMA	South Africa	Women 18-30	2015 - 2020																							
Church of Scotland Hospital	South Africa	Adolescent girls	Proposed																							
EMPOWER	South Africa, Tanzania	Adolescent girls 16 -24	Recruitment planned Jun/Jul 2016																							
HTPN 082	South Africa, Zimbabwe	Adolescent girls 16 - 25	**																							
IMPAACT 2009	South Africa, Zimbabwe , Malawi, Uganda		In development																							
MSF SRH Club PrEP Program	South Africa	Adolescent girls 15-24	Expected start April 2017																							
MTN034 (REACH)	South Africa, Zimbabwe , Kenya	Adolescent girls 16-21	Expected start early 2017																							
Plus Pills	South Africa	Adolescent girls and boys 15-19	*																							
POWER	South Africa, Kenya	Adolescent girls and women 16-29	Enrollment to begin July 2016																							
Right to Care	South Africa	Adolescent girls	Proposed																							
SisterLove Innovation Project	South Africa	Adolescent girls	Planned																							
UNICEF (under DREAMS)	South Africa	Adolescent girls	Planned start late 2016																							
Witkoppen Innovation Project	South Africa	Adolescent girls	Planned																							

* Provisional results presented at IAS in July 2016

**Provisional/ baseline results expected

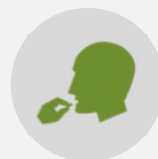
Key questions for AGYW demo projects



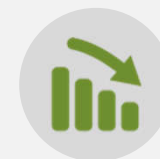
PLANNING FOR PREP ROLLOUT TO AGYW



PREP DELIVERY CHANNELS AND HEALTHCARE WORKERS



INDIVIDUAL UPTAKE AMONGST AGYW



EFFECTIVE USE & MONITORING

Q1

How can PrEP be effectively **targeted** to higher-risk AGYW?

- What practical tools / mechanisms are being used to assess risk and / or suitability for PrEP among AGYW? (both for HCW and self-assessment)
- To what extent are those AGYW that self-select those that are at highest need of PrEP?

Q2

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

Q3

What legal or **ethical considerations** are relevant for PrEP provision to AGYW?

- If provided to persons under 18, what parental consent is required?

Q4

What are the **best channels** to deliver HIV prevention to AGYW, including those who regularly access health services (e.g. SRH) and those who don't currently access health or other public services (e.g., education)?

- How effective is delivery through channels such as youth, school, and mobile clinics, facilities linked to youth clubs, and NGOs working with AGYW?
- What do **AGYW need** in delivery channels (e.g., hours that fit their schedules, friendly staff)?

Q5

What types of **investments** (e.g., expanded lab capacity) are required in various types of facilities to effectively deliver PrEP? What would it cost?

- How will facilities link AGYW to services that are not available on-site, such as lab services?

Q6

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

- What training, communication, messaging or other strategies (e.g., public health campaigns) could be used to generate HCW support for PrEP rollout?

Q7

What are the most effective IEC **messages and strategies** to build awareness, understanding, and / or generate demand for PrEP amongst AGYW and their communities?

- How can these messages and strategies proactively address myths and misconceptions about PrEP?

Q8

How are AGYW **communicating** about PrEP to partners or family members and/or involving them in decisions?

- What, if any, unintended social harms (e.g., intimate partner violence) result from PrEP use?

Q9

How are **"periods of risk"** defined? What strategies / tools (e.g., additional counselling and adherence support) are effective to support AGYW decision-making around on / off decisions for PrEP?

Q10

To what extent are AGYW adhering to PrEP? What strategies effectively support AGYW **daily adherence** to PrEP?

- What characteristics could best predict likelihood of effective use among AGYW?

Q11

To what extent are AGYW getting regular **HIV and STI testing**? What strategies effectively support retention in regular testing?

- What roles can schools, NGOs, or others working with AGYW play in facilitating adherence and regular HIV + creatinine testing (e.g. counseling, creating peer support groups, expanding / initiating HIV + STI testing services)?

Q12

What **information** do health care facilities need to **collect and report** to NDoH? What data are demonstration projects collecting?

Q1 | How can PrEP be effectively targeted to higher-risk AGYW?



TARGETING		
Study	Timeline	Characteristics
CAPRISA 082	Ongoing March 2016 - April 2021 <i>Currently enrolling, Provisional results mid-2017</i>	Primary objective is to identify risk factors for HIV acquisition in sexually active women (3x in past 3 months) aged 18 – 30; Recording HIV risk perception and behavioural assessment through study
EMPOWER	Ongoing July 2015 - December 2017	AGYW at risk for violence; investigating integrated Gender-based violence and stigma reduction through combination HIV prevention methods
HPTN 082	Ongoing June 2016 - August 2018 <i>Provisional results mid-2017</i>	Includes risk perception scoring, recoding of sexual and substance abuse behaviour; targeting AGYW sexually active in past month
MSF	Under Ethics Review <i>Expected start April 2017</i>	Up to 200 sexually active, HIV-uninfected females ages of 18 - 25
MTN034	Planned <i>Expected start early-2017</i>	<ul style="list-style-type: none"> • Behavioural questionnaire • No planned req. for sexual activity for participation in study • Developing a risk assessment tool
Plus Pills	Completed end 2016	15-19 years old Sexually active in past 12 months Using effective contraception method > 148 ppts enrolled
POWER	Ongoing <i>Formative research completed. Recruitment ongoing. Completion expected 2020</i>	Sexually active AGYW

Insights expected from demo projects

- ✓ CAPRISA, HPTN, and MTN studies will all record behavioral characteristics of study participants to inform identification of risk factors for AGYW
- ✓ CAPRISA and HPTN will yield insights on risk perception scoring for AGYW
- ✓ CAPRISA, HPTN, and MTN studies use different sexual activity thresholds (3x in 3 months vs. any activity in past month vs. no requirement) – a comparison across them could yield insights on the use of sexual activity as a risk factor

Remaining questions about demo projects

- ? How will DREAMS and related studies define criteria for AGYW participation?
- ? How comprehensive are the behavioural assessments and risk perception scoring? What can be learned from the tools used in the CAPRISA, HPTN, and MTN projects?
- ? What insights can Pills Plus yield on risk characteristics differences between girls and boys?

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



BARRIERS TO AGYW UPTAKE

Study	Timeline	Risk characteristics
3Ps	Planned	Assess uptake to oral PrEP and effect of conditional incentives based on adherence
CAPRISA 082	Ongoing March 2016 - April 2021 <i>Currently enrolling, Provisional results mid-2017</i>	Testing acceptability of prevention choices, including PrEP
EMPOWER	July 2015 - December 2017	Will collect data on barriers to PrEP use, with a focus on gender-based violence (GBV) and stigma
HPTN 082	Ongoing June 2016 - August 2018 <i>Provisional results mid-2017</i>	Through IDIs, will collect data on reasons for acceptance/decline and barriers and facilitators to taking PrEP
MSF	Under Ethics Review <i>Expected start April 2017</i>	Looking at reasons for continuing / discontinuing among PrEP users
MTN034	Planned <i>Expected start early-2017</i>	Looking at preferences between PrEP and Ring
Pills Plus	Completed end 2016	Can choose to opt out every 3 months. Adherence support via motivational interviewing, text messaging, and monthly adherence clubs. > Retention 81% at week 36
POWER	Ongoing <i>Formative research completed. Recruitment ongoing. Completion expected 2020</i>	Will conduct research among women and health care providers, focusing on motivators and obstacles for initiation of and adherence to microbicides and PrEP

Insights expected from demo projects

- ✓ 3Ps, EMPOWER, HPTN, MSF, Pills Plus, and POWER studies will collect data and yield insights on reasons for PrEP decline and barriers to uptake, including on challenges such as gender-based violence and stigma
- ✓ CAPRISA and MTN034 will yield insights on product acceptability and its potential to act as a “barrier” to uptake

Remaining questions about demo projects

- ? How comprehensive is data collection in the 3Ps, EMPOWER, HPTN, MSF, Pills Plus, and POWER studies? Is all data self-reported? What types of factors will they include and how will they gather the information?
- ? To what extent will POWER yield insights on the role of healthcare workers and their potential to act as a barrier to PrEP uptake?

Q3 | What legal or ethical considerations are relevant for PrEP provision to AGYW?



ETHICAL AND LEGAL CONSIDERATIONS		
Study	Timeline	Risk characteristics
CAPRISA 082	Ongoing March 2016 - April 2021 <i>Currently enrolling, Provisional results mid-2017</i>	AGYW aged 18+
Church of Scotland Hospital	<i>TBD</i>	Parental consent <i>not required</i> (pregnant AGYW considered emancipated minors)
EMPOWER	July 2015 - December 2017	AGYW ages 16 - 24 Parental consent <i>only</i> for participation in study
HPTN 082	Ongoing June 2016 - August 2018 <i>Provisional results mid-2017</i>	AGYW ages 16 - 25 Parental consent required for participation in study and use of PrEP
MSF	Under Ethics Review <i>Expected start April 2017</i>	AGYW ages 18-25
MTN034	Planned <i>Expected start early-2017</i>	AGYW ages 16 - 24 Parental consent required for participation in study and use of PrEP or other products
Pills Plus	Completed end 2016	AGYW and Boys ages 15-19 Parental consent required
POWER	Ongoing <i>Formative research completed. Recruitment ongoing. Completion expected 2020</i>	Need for parental consent for 16/17 year olds will be determined by IRB

Insights expected from demo projects

- ✓ Comparisons between studies that require parental consent for product use (e.g., 3Ps, HPTN, MTN, Pills Plus) and those that do not require it (e.g., Church of Scotland Hospital, EMPOWER) could yield insights on impact of parental consent on AGYW PrEP uptake

Remaining questions about demo projects

- ? What other legal / ethical considerations are relevant outside of parental consent – for example, are studies recording incidences of harm arising from uptake of PrEP?

Q4 | What are the **best channels** to deliver HIV prevention to AGYW? Including those who regularly access health services and those who don't currently access health or other public services



DELIVERY CHANNELS

Study	Timeline	Risk characteristics
CAPRISA 082	Ongoing March 2016 - April 2021 <i>Currently enrolling, Provisional results mid-2017</i>	Fixed facilities: eThekweni - attached to STI and chest clinic / PMB – linked to PHC offering FP services Pharmacist and medical doctor on staff to dispense
EMPOWER	July 2015 - December 2017	Research Site/Youth Friendly clinic (Ward 21, second floor) PrEP dispensed by a clinician in Ward 21 pharmacy
HPTN 082	Ongoing June 2016 - August 2018 <i>Provisional results mid-2017</i>	Research Site/Youth Friendly clinic (Ward 21, second floor) PrEP dispensed by a clinician in Ward 21 pharmacy
MSF	Under Ethics Review <i>Expected start April 2017</i>	Site C Youth Clinic; SRH Clubs PrEP dispensed by a nurse
MTN034	Planned <i>Expected start early-2017</i>	Clinical Crossover Trial
Pills Plus	Completed end 2016	Research centers: Masiphumelele and Soweto.
POWER	Ongoing <i>Formative research completed. Recruitment ongoing. Completion expected 2020</i>	Cape Town - mobile clinics; Joburg - fixed primary care facilities and leveraging AIP 's 16 priority youth friendly clinics

Insights expected from demo projects

- ✓ Comparisons across the different types of sites used in the demonstration projects will yield insights – for example, on the differences in ability to reach high-risk AGYW through public facilities vs. youth clinics vs. mobile sites
- ✓ Comparisons across projects could also yield insights on the relative benefits and challenges of dispensing PrEP through clinicians, nurses, or pharmacists – for example, are nurses or pharmacists able to spend more time counselling AGYW on use of PrEP? Is one other the other more closely linked to uptake / adherence?

Remaining questions about demo projects

- ? Additional data needed on different sites (e.g., use of SRH and family planning clinics, mobile sites, youth clinics) and what types of information are being collected?
- ? What are the cost / investment implications across different types of sites?

Q5 | What types of investments are required to effectively deliver PrEP through these channels? What are the cost implications?



INVESTMENTS REQUIRED		
Study	Timeline	Risk characteristics
CAPRISA 082	Ongoing March 2016 - April 2021 <i>Currently enrolling, Provisional results mid-2017</i>	Not planned
EMPOWER	July 2015 - December 2017	Not planned
HPTN 082	Ongoing June 2016 - August 2018 <i>Provisional results mid-2017</i>	Not planned
MSF	Under Ethics Review <i>Expected start April 2017</i>	Not planned
MTN034	Planned <i>Expected start early-2017</i>	Not planned
Pills Plus	Completed end 2016	Not planned
POWER	Ongoing <i>Formative research completed. Recruitment ongoing. Completion expected 2020</i>	Micro-costing analyses and mathematically modeled impact assessments will consider costs incurred (e.g., service delivery and support activities tested in Aim 3) and costs averted (e.g., HIV prevented, social and health)

Insights expected from demo projects

- ✓ POWER appears to be the only demonstration project collecting costing information (the TAPS project also collects costing information for sex worker programs)
- ✓ Given that POWER is also exploring a range of delivery channels, this project could yield insights on costing across different delivery models (e.g., mobile sites, clinics)
- ✓ The POWER costing studies could also include insights on costs of communications and ongoing testing in addition to initial PrEP delivery

Remaining questions about demo projects

- ? What will be included in the POWER costing studies (e.g., demand generation / communications, healthcare worker training, delivery, ongoing testing and requisite lab equipment)?
- ? Who is conducting the POWER costing studies?
- ? To what extent can costing components be added to or conducted simultaneously with other demonstration projects?

Q6 | How can negative health care worker attitudes be effectively mitigated?



HEALTHCARE WORKER ATTITUDES

Study	Timeline	Risk characteristics
CAPRISA 082	Ongoing March 2016 - April 2021 <i>Currently enrolling, Provisional results mid-2017</i>	Not planned
EMPOWER	July 2015 - December 2017	Not planned
HPTN 082	Ongoing June 2016 - August 2018 <i>Provisional results mid-2017</i>	Not planned
MSF	Under Ethics Review <i>Expected start April 2017</i>	Not planned
MTN034	Planned <i>Expected start early-2017</i>	Not planned
Pills Plus	Completed end 2016	Not planned
POWER	Ongoing <i>Formative research completed. Recruitment ongoing. Completion expected 2020</i>	Looking at health care worker attitudes and perceptions through formative research (mental model methodology)

Insights expected from demo projects

- ✓ POWER interviewed providers in the formative research
- ✓ OPTIONS is planning to do a provider KAP survey to look at KAP, acceptability, perceptions, among PrEP naïve providers in regards to PrEP provision for AGYW (planned for second half of 2017)

Remaining questions about demo projects

- ? Are any other ongoing or planned demonstration projects studying healthcare workers and their interactions with AGYW?
- ? How will ongoing or planned demonstration projects monitor the physicians, nurses, pharmacists and others who come into contact with AGYW? Can this monitoring yield insights on effective vs. ineffective interactions between AGYW and healthcare workers?

Q7 | What are the most effective messages and strategies to build awareness and generate demand for PrEP amongst AGYW?



DEMAND GENERATION		
Study	Timeline	Targeting methods
3Ps	Planned	<ul style="list-style-type: none"> Local social marketing campaign
CAPRISA 082	Ongoing March 2016-April 2021 <i>Prov. results mid-2017</i>	<ul style="list-style-type: none"> Recruiting from STI, FP, and primary health clinics or nearby
EMPOWER	July 2015 - December 2017	<ul style="list-style-type: none"> Recruiting through local CBOs and events, in coordination with other demo projects Using social media communications
HPTN 082	Ongoing June 2016 – August 2018 <i>Provisional results mid-2017</i>	<ul style="list-style-type: none"> Recruiting through adolescent clinic, word of mouth, community events Communications include flyers and an informational movie about PrEP
MSF	Under Ethics Review <i>Expected start April 2017</i>	<ul style="list-style-type: none"> Recruiting at Khayelitsha Site C Youth Clinic Strategies include counsellor health talks during waiting periods, advertising existence of clubs and PrEP, linking PrEP to contraception.
MTN034	Planned <i>Expected start early-2017</i>	<ul style="list-style-type: none"> Mix of urban and rural sites In urban sites – looking at youth clubs, FP clinics, potentially secondary schools, and coordinating with existing HIV prevention programs At rural site (120 km from Durban), working through adolescent FP clinic and using 2-day workshop to discuss HIV prevention, pregnancy, and STIs
Pills Plus	Completed end 2016	<ul style="list-style-type: none"> Cape Town - recruiting from youth center and high school Soweto - recruit from school youth club
POWER	Ongoing <i>Formative research completed. Recruitment ongoing. Completion expected 2020</i>	<ul style="list-style-type: none"> Recruiting through CBOs, social media, and HTS clinics, primary care, and RH services; Will produce educational video, decision tool

Insights expected from demo projects

- ✓ Significant coverage of different methods of recruitment and communications around PrEP between the different demo projects should yield insights on effective practices
- ✓ Recruitment channels that are covered by demo projects could include: existing HIV / STI prevention programs, FP clinics / SRH services, HTS clinics, primary health clinics, local CBOs, and secondary schools
- ✓ Communications tools covered by demo projects include: social media, flyers, videos, word-of-mouth, discussions / workshops with health counsellors

Remaining questions

- ? How can we best understand the efficacy of these methods?
- ? What is the content of the messaging and how does that differ across projects (e.g., messages of safety vs. empowerment)?

Q8 | How are AGYW communicating about PrEP to partners or family members and/or involving them in decisions?



PARTNER / FAMILY MEMBER INVOLVEMENT		
Study	Timeline	Risk characteristics
CAPRISA 082	Ongoing March 2016-April 2021 <i>Currently enrolling, Provisional results mid-2017</i>	<p><i>No current awareness of research being conducted on how AGYW engage with their partners or families around PrEP use (beyond requirements for parental consent – see slide 9)</i></p>
CHARISMA	Ongoing 2015 -2020	
EMPOWER	July 2015 - December 2017	
HPTN 082	Ongoing June 2016 - August 2018 <i>Provisional results mid-2017</i>	
MSF	Under Ethics Review <i>Expected start April 2017</i>	
MTN034	Planned <i>Expected start early-2017</i>	
Pills Plus	Completed end 2016	
POWER	Ongoing <i>Formative research completed. Recruitment ongoing. Completion expected 2020</i>	

Insights expected from demo projects

- ✓ To be determined – possibly POWER or CHARISMA?

Remaining questions about demo projects

- ? Is any ongoing or planned demonstration project studying this issue?

Q9 | How are “periods of risk” being defined? What strategies / tools are support AGYW decision-making around on/off decisions for PrEP?



PERIODS OF RISK		
Study	Timeline	Risk characteristics
CAPRISA 082	Ongoing March 2016-April 2021 <i>Currently enrolling, Provisional results mid-2017</i>	Will collect data on “PrEP cycling” and PrEP interruptions
EMPOWER	July 2015 - December 2017	Not planned
HPTN 082	Ongoing June 2016 - August 2018 <i>Provisional results mid-2017</i>	Will collect information on “cycling reasons”
MSF	Under Ethics Review <i>Expected start April 2017</i>	Not planned
MTN034	Planned <i>Expected start early-2017</i>	Not planned
Pills Plus	Completed end 2016	Can opt in/out of PrEP at the 3-monthly visits
POWER	Ongoing <i>Formative research completed. Recruitment ongoing. Completion expected 2020</i>	Not planned

Insights expected from demo projects

- ✓ To current knowledge, only CAPRISA and HPTN have an explicit focus on data collection around PrEP cycling

Remaining questions about demo projects

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

Q10 | To what extent are AGYW adhering to PrEP? What messages and strategies effectively support **daily adherence** to PrEP amongst AGYW?



ADHERENCE		
Study	Timeline	Risk characteristics
3Ps	Ongoing	Assess uptake to oral PrEP and effect of conditional incentives based on adherence. Assess effectiveness of social marketing campaign
CAPRISA 082	Ongoing March 2016-April 2021 <i>Currently enrolling, Provisional results mid-2017</i>	Will collect adherence data, comparing across prevention options, collecting info on acceptability of taking PrEP daily
EMPOWER	July 2015 - December 2017	Will measure adherence across different channels (youth clubs vs. standard counselling vs. SMS)
HPTN 082	Ongoing June 2016 - August 2018 <i>Provisional results mid-2017</i>	Will assess the difference in PrEP adherence using drug level feedback in young women taking PrEP randomized to two arms – one receiving DL feedback, one not
MSF	Under Ethics Review <i>Expected start April 2017</i>	Currently deciding how to measure adherence
MTN034	Planned <i>Expected start early-2017</i>	Will include adherence support (exact plan TBD)
Pills Plus	Completed end 2016	TDF drug levels taken 3 monthly. Drug level feedback offered to participants. Adherence support via motivational interviewing, text messaging and monthly adherence clubs. > Adherence 36% at week 36
POWER	Ongoing <i>Formative research completed. Recruitment ongoing. Completion expected 2020</i>	Will pilot and adapt scalable adherence support interventions (two-way SMS, peer support groups including rewards) and delivery strategies (peer groups for resupply, self-testing)

Insights expected from demo projects

- ✓ Many of the studies will collect adherence data
- ✓ A few have also outlined specific strategies for supporting AGYW adherence, which will yield results on effective strategies – these studies include EMPOWER, HPTN, MTN, Pills Plus, and POWER
- ✓ These projects also use a variety of adherence support, including youth clubs, peer-support groups, SMS, and counselling
- ✓ POWER will also be looking at the option of self-testing and its implications

Remaining questions about demo projects

- ? What other studies include specific strategies to support PrEP adherence?
- ? To what extent are these strategies realistic in a non-study setting?
- ? What investments or costs are involved in implementing these adherence strategies? To what extent will these be included in costing analyses?

Q11 | To what extent are AGYW getting regular HIV and STI testing? What messages and strategies effectively support retention in regular testing?



HIV AND STI TESTING

Study	Timeline	Risk characteristics
CAPRISA 082	Ongoing March 2016-April 2021 <i>Currently enrolling, Provisional results mid-2017</i>	Initiation, monthly visits for 3 months, then quarterly visits
EMPOWER	July 2015 - December 2017	Month 1 screening, then quarterly visits
HPTN 082	Ongoing June 2016 - August 2018 <i>Provisional results mid-2017</i>	Visits at week 4, 8, 13, 26, 39 and exit
MSF	Under Ethics Review <i>Expected start April 2017</i>	Anticipate monthly visits for 6+ months then once every 2-3 months. Ideally would like to time PrEP provision with contraception cycles
MTN034	Planned <i>Expected start early-2017</i>	Unknown
Pills Plus	Completed end 2016	Screened, Enrolled, month 1 – have to take PrEP, month 2– have to take PrEP, month 3– have to take PrEP, 3 monthly visits from here onwards and can opt in/out of PrEP
POWER	Ongoing <i>Formative research completed. Recruitment ongoing. Completion expected 2020</i>	N/A

Insights expected from demo projects

- ✓ The protocol for frequency of visits and testing is different across different studies – while many studies begin with monthly visits, then transition to quarterly visits at different rates
- ✓ Comparison across studies could yield insights about the frequency of visits, its implication on outcomes, adherence, and continued AGYW participation / drop-out in the studies

Remaining questions about demo projects

- ? How are visits configured in other demo projects?
- ? 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 developed by demo projects

Study	Timeline	Anticipated Tools
CAPRISA 082	Ongoing March 2016-April 2021 <i>Currently enrolling, Provisional results mid-2017</i>	<ul style="list-style-type: none"> • Risk assessment tool • Acceptability and PrEP interruptions • Tools for counseling based on FHI360 oral PrEP counseling document for use by nurses, counsellors, and clinicians
EMPOWER	July 2015 - December 2017	<ul style="list-style-type: none"> • Curriculum for clubs and job aids • Working with ASPEN and the Clinicians Society to adapt/pilot their training materials • Process Evaluation will provide qualitative data from health workers and participants
HPTN 082	Ongoing June 2016 - August 2018 <i>Provisional results mid-2017</i>	<ul style="list-style-type: none"> • PrEP promotion video used in recruitment - mainly for SA sites • PrEP readiness tool being developed by the Network • Qualitative Component: in-depth interviews around barriers to PrEP use
MSF	Planned <i>Expected start late-2016</i>	<ul style="list-style-type: none"> • Training and education materials • Screening and enrollment, stationary to use, youth friendly materials
MTN034	Planned <i>Expected start early-2017</i>	<ul style="list-style-type: none"> • Risk assessment tool to be developed
Pills Plus	Completed end 2016	<ul style="list-style-type: none"> • Videos • Pamphlets • Risk rating tool
POWER	Ongoing <i>Formative research completed. Recruitment ongoing. Completion expected 2020</i>	Unknown

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

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

Question	Status	Notes
Q1 How can PrEP be effectively targeted to higher-risk AGYW?		Studies use differing “risk factors” to identify study participants; a comparison across them will be informative
Q2 What are the major barriers to PrEP uptake for AGYW and how can they be addressed?		Several studies (HPTN 082, POWER) collect data on barriers and AGYW who decline PrEP; others will study product acceptability
Q3 What legal or ethical considerations are relevant for PrEP provision to AGYW?		Collection of data on parental consent, but no other specific legal/ethical considerations noted
Q4 What service delivery and civil society channels will most effectively reach AGYW?		Coverage across different types of delivery channels (e.g., mobile, primary care clinics, FP clinics)
Q5 What types of investments are required to effectively deliver PrEP through these channels?		Only one study (POWER) explicitly includes costing component
Q6 How can negative health care worker attitudes be effectively mitigated?		POWER formative research and OPTIONS Provider KAP Survey
Q7 What are the most effective strategies to build awareness and generate demand for PrEP amongst AGYW?		Significant focus on demand through various recruitment and communications strategies across demo projects
Q8 How are AGYW communicating about PrEP to partners or family members and/or involving them in decisions?		No awareness of current plans to study this aspect
Q9 How are “ periods of risk ” defined? What strategies / tools support AGYW decision-making around on/off decisions?		CAPRISA and HPTN 082 studies explicitly discuss and track “PrEP cycling,” but little focus on this (and strategies for communications) in other studies
Q10 To what extent are AGYW adhering to PrEP? What messages and strategies effectively support adherence ?		Significant focus on adherence and strategies for encouraging adherence across studies
Q11 Are AGYW getting regular HIV/STI testing ? What strategies effectively support retention in regular testing?		Each study has a different testing protocol; comparisons across them may be useful
Q12 What information do health care facilities need to collect and report to NDoH? What data are demonstration projects collecting?		Subcommittee of AGYW TWG meeting to determine how and what data to report to NDOH