END-USER RESEARCH LANDSCAPE MAPPING & FINDINGS

January 2017

The HIV Prevention Market Manager undertook an effort to map the landscape of ongoing and planned work on HIV prevention and adolescent girls and young women (AGYW) and other populations in sub-Saharan Africa (SSA). This document provides a summary and analysis of the end-user projects and studies underway in order to inform collaborations and identify gaps and next steps in research.

HIV Prevention Market Manager

Accelerating Product Introduction
Informing Product Development
Reducing Time to Impact

AVAC Global Advocacy for HIV Prevention

CLINTON HEALTH ACCESS INITIATIVE

Supported by the Bill & Melinda Gates Foundation

PURPOSE

To map the landscape of ongoing and planned[1] work on HIV prevention and adolescent girls and young women (AGYW) and other populations in sub-Saharan Africa (SSA) to *1.*) inform collaborations and 2.) identify gaps and next steps for market research. This document is the first iteration and will be updated on a bi-annual basis. Please contact avac@avac.org with updates or additions to the information included in this mapping.

OVERVIEW

Landscape mapping includes ongoing and planned[1] work on AGYW in SSA. Other populations are also included when projects include AGYW and other populations. Data sources include: structured interviews with key stakeholders, group meetings with organizations (including pharmaceutical product developers, academic researchers, marketing agencies and program implementers), and surveys of ongoing and planned projects. Key stakeholders and organizations interviewed and projects in mapping include those looking at HIV prevention broadly, with a focus on PrEP, but also specific projects with overlapping design, questions, population and geography where findings could be of relevance. Projects will be added to mapping as they are identified[2]. The HIV Prevention Market Manager (PMM) Project undertook this mapping and will update the mapping on a bi-annual basis.

Through the PMM Project, AVAC and CHAI seek to facilitate an efficient and effective rollout of HIV prevention products. The PMM works with partners across the prevention research to rollout spectrum to expand the portfolio of options and ensure appropriate products are available, accessible and used by those who need them most. There is often a delay in moving products from the research and development stage to rollout, uptake and impact. The PMM project addresses this lag by identifying critical gaps and overlaps, facilitating coordination, compiling and disseminating information and providing strategic technical support. Working with the full range of actors and initiatives, the PMM project makes clearer where strategic investments in prevention products are needed and supports accelerated introduction, consistent, correct uptake by end users and informs future product development.

PARAMETERS

Population: Adolescent girls & young women[3] 13-29 [4]

Geography: sub-Saharan Africa

Timeframe: Ongoing (not yet fully complete), and planned work [5]

Focus: Projects, studies and initiatives that include HIV prevention as a parameter or outcome [6]

[1] Timeframe for review includes all projects that are ongoing and planned as of January 2017. Search parameters include previous five years, not exlcluding ongoing studies that began prior to 2012. Several studies that are in the nascent planning stages are not included in full detail and will be included as the review is updated on a bi-annual basis.

[2] This area of work is highly dynamic, with a number of new projects being discussed, funded, designed and/or implemented. This initial landscape map intends to be a living document that can be updated with new initiatives and can, hopefully, be a guide to funders and implementers when considering what is already happening, what gaps might exist and what new work is needed.

[3] The work included in this review includes other populations when they are enrolled in projects covering AGYW.

[4] The work included in this review expands the age range where relevant or where projects include a wider range.

[5] The work included in this review also includes select completed work.

[6] Several projects included in this review are of relevance, but do not have an explicit focus on biomedical HIV prevention.

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I. END-USER RESEARCH LANDSCAPE MAPPING FINDINGS[7]

AIM OF MAPPING PROCESS

The main aim of the mapping process was to respond to an ask by those interviewed for the HIV Prevention Market Manager (PMM) *to document and disseminate the landscape of end-user work already underway as well as identified gaps*. The intent is to share and iterate this report to include additional detail and projects as they begin and as information is available. The report will be disseminated to organizations involved in end-user research to start a process of information sharing and coordination between organizations, as well as to guide the development of the PMM-led research and implementation agenda. The first iteration of the mapping is not exhaustive, but rather an initial survey of projects with an emphasis on Kenya, Malawi, South Africa, Zimbabwe, and oral PrEP. Please notify the PMM of any other projects in other countries, as well as other products including condoms etc. by emailing avac@avav.org, subject line "HIV Prevention Market Manager End-User Mapping." Likewise, we were not attempting to assess the study quality.

The Market Manager identified 34 Stakeholder organizations working on 53 ongoing and planned[8] end-user projects in 14 countries, across the SSA region and globally. A variety of qualitative methods as well quantitative approached have been, or are being used, to capture information from the 38 ongoing and 15 planned projects.[9]

TYPES OF PROJECTS/STUDIES

- Service delivery model
- Acceptability and preference
- User experiences and effect
- Adherence measures
- Community based assessment
- Develop/test IPV intervention
- Discrete-choice experiment
- In-depth interviews
- Feasibility/acceptability
- Focus groups
- Exploratory study and program evaluation
- Consumer insights research
- Human-centered design
- Impact evaluation
- Qualitative and quantitative surveys
- Implementation initiative
- Key informant discussions
- Mental model
- Observational cohort study
- Open label study
- Demonstration project
- Risk of resistance research
- Impact evaluation with nested qualitative and process evaluation studies

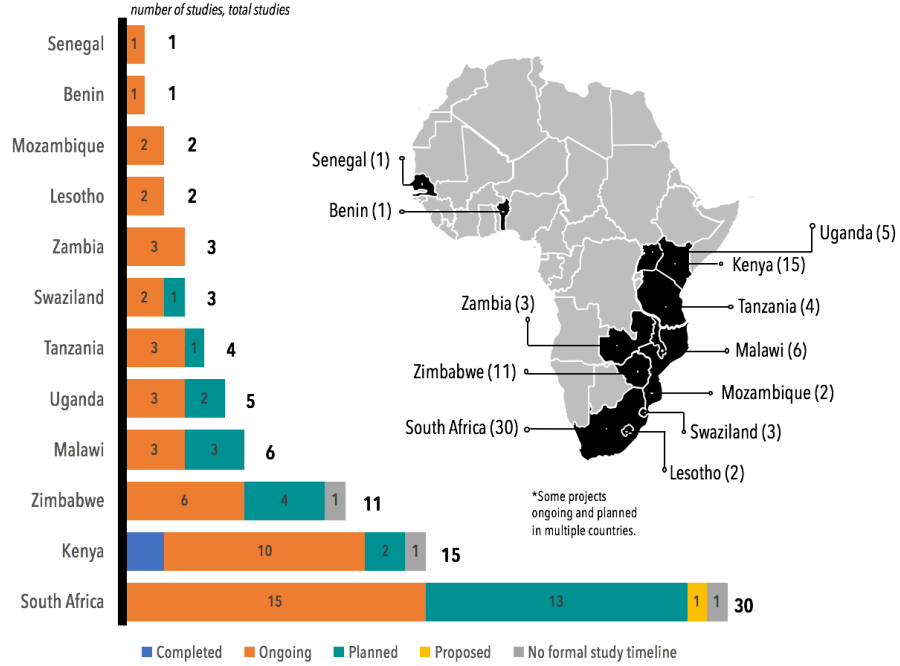
[7] Data collection for mapping is an iterative process to be updated on a bi-annual basis. The mapping will continue to iterate as new projects are identified and as planned projects are able to share further details. The current version of the mapping is a working document. Please contact avac@avac.org with any projects to be included or updates to those included,, subject line "HIV Prevention Market Manager End-User Mapping."

[8] Several project identified are completed and included for relevance to mapping and possible implementation of project outcomes. Completed projects in this iteration of the mapping only include reports and other materials that are being used to inform ongoing or planned efforts. Completed projects or studies that have enrolled participants are not included in this mapping. With such a fast moving and changing field, completed projects may no longer have direct relevance to inform programmatic outcomes.

[9] Status of projects ongoing and planned varies. For example, some planned projects seeking ethics review and some planned projects still early stage development of protocol.

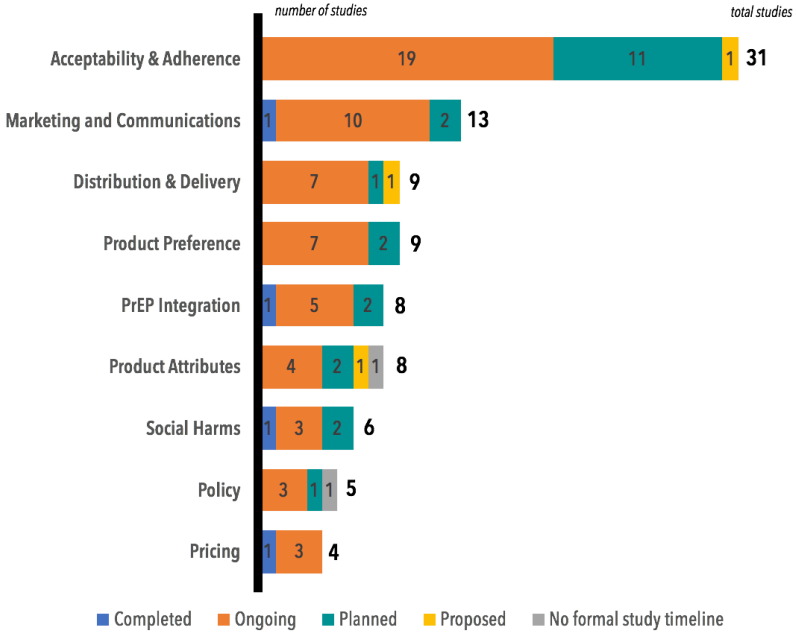
STUDY LOCATION

TOPLINE FINDING
South Africa, Kenya and Zimbabwe are the main study locations.



STUDY AREA

TOPLINE FINDING
Acceptability & adherence, marketing & communications, product preference, distribution & delivery are the main focus areas of the studies.

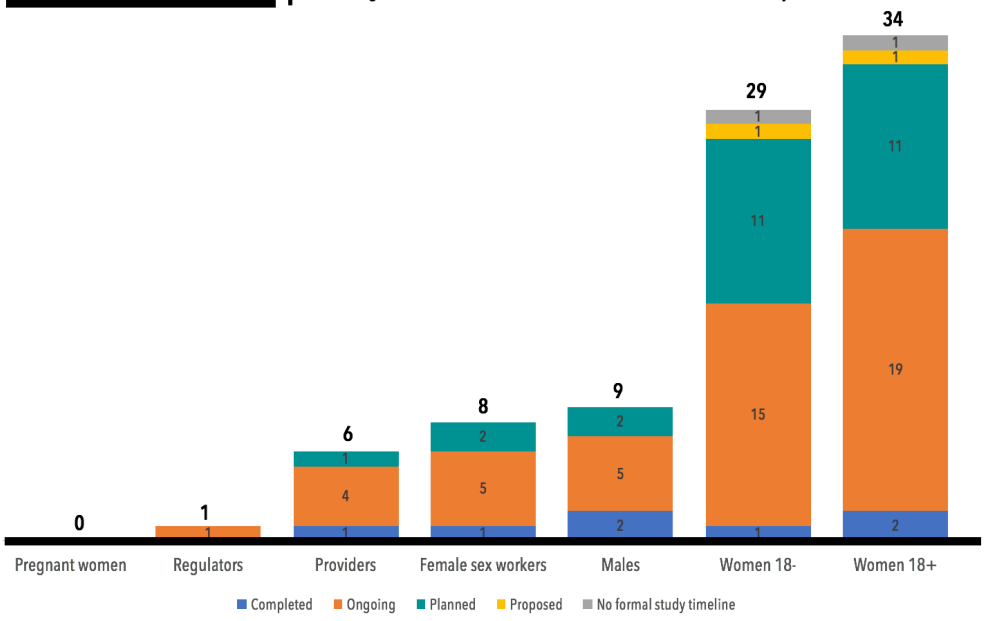


10, *

[10] Search was limited to English language, which may omit studies that did not have information available on English-language databases. Additionally, the PMM is focused on Kenya, Malawi, South Africa and Zimbabwe, and studies underway and planned in these countries are well catalogued. Hence, there may be bias in the study location finding.

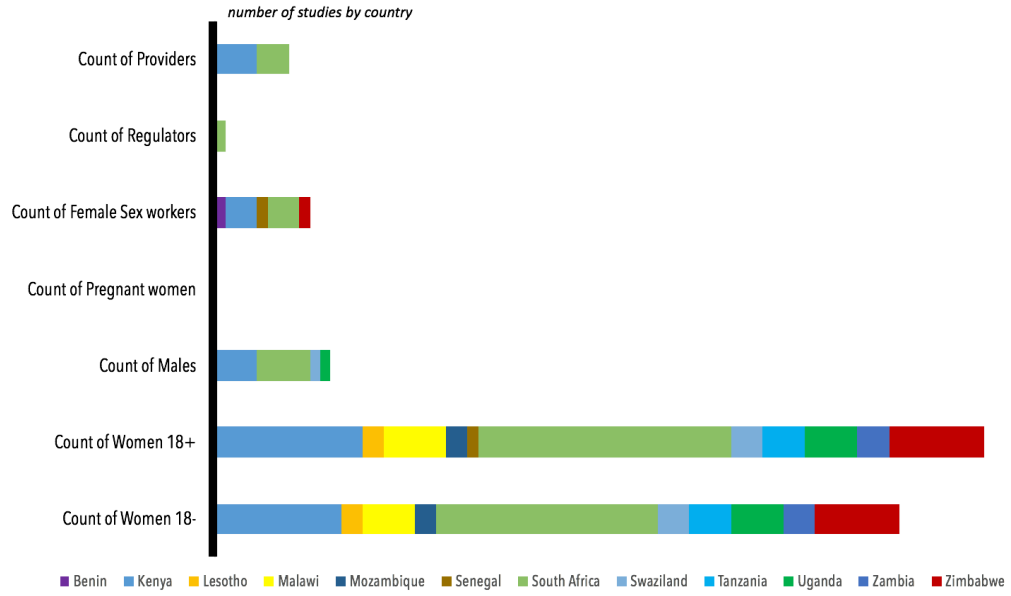
* Studies included in this graphic and those that follow with "no formal study timeline" have not published a timeframe for the study, or will not be starting/completing by a set date.

TARGET AUDIENCE | **TOPLINE FINDING**
Main target audiences are women 18 + and women 18 –, with very little work done on influencers.



[11]

TARGET AUDIENCE

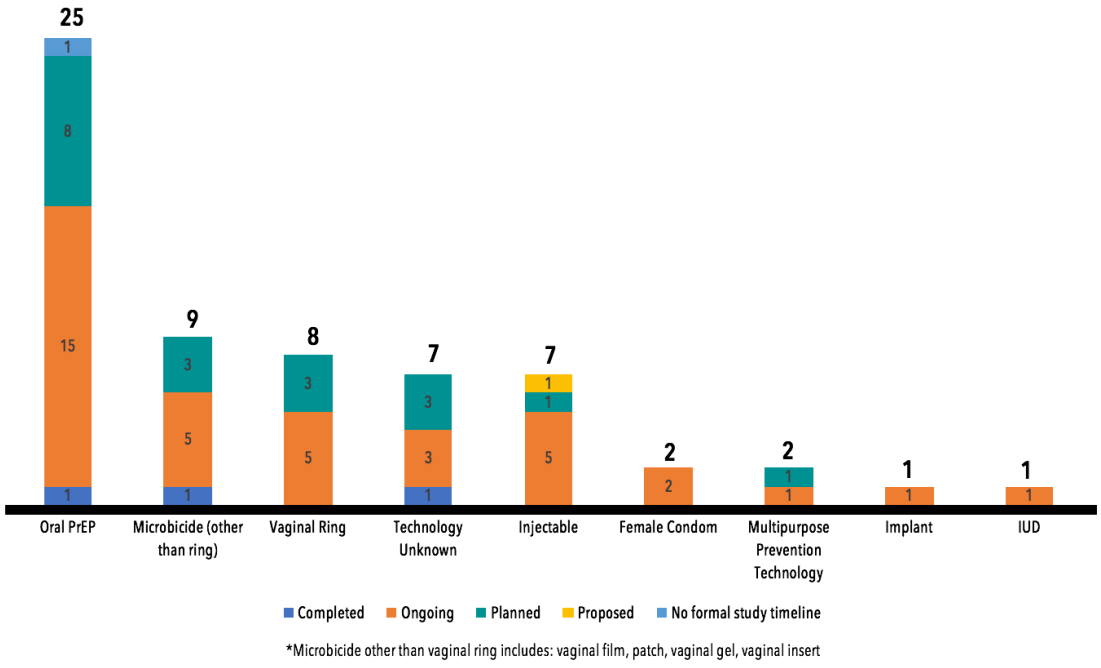


[11] Most studies focused on women in the general population, with 29 studies looking at women under 18 and 34 studies studying women over 18.

TECHNOLOGY

TOPLINE FINDING

Main research emphasis is on oral PrEP. Focus on injectables and implants low.



*Microbicide other than vaginal ring includes: vaginal film, patch, vaginal gel, vaginal insert

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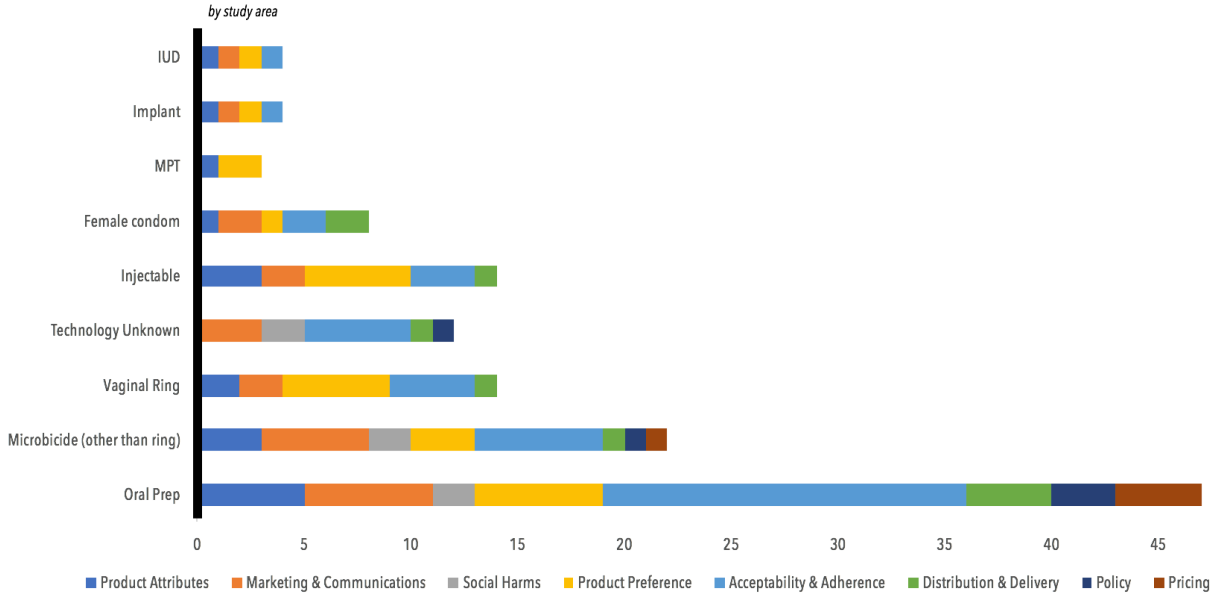
TECHNOLOGY



[12] Male condoms included only as part of prevention package in studies and not disaggregated. Specific studies focused on male condom to be included in subsequent iterations as relevant.

END-USER RESEARCH LANDSCAPE MAPPING TOPLINE FINDINGS

- Acceptability and adherence, marketing and communications, product preference, distribution and delivery are the main focus areas of the studies.
- The majority of studies are ongoing, with many planned or proposed to start in the next one to two years (2017/2018). 75 percent of the studies will last more than 12 months.
- Majority of the studies are qualitative.
- South Africa, Kenya and Zimbabwe are the main study locations.
- Most studies focused on women in the general population, with 29 studies looking at women under 18 and 34 studies studying women over 18. Very little work is ongoing and planned on influencers.
- Main research emphasis is on oral PrEP. Focus on injectables and implants low.
- Not enough information to fully understand study size as many studies do not provide information on total enrollment. When studies do include enrollment figures, often they are not disaggregated by population (i.e., gender, age, other factors).
- Study quality unable to be assessed.

II. METHODOLOGY OF END-USER RESEARCH MAPPING

KEY STAKEHOLDER INTERVIEWS AND MEETINGS

Key stakeholder interviews and meetings were conducted at AIDS 2016 in Durban, South Africa. Interviews were held with "key opinion leaders" (KOLs) within organizations working on PrEP or other HIV prevention methods and AGYW in SSA.

Information and data provided was organized into a framework of key topic areas on end-user engagement. Topics addressed in the interviews and meetings included:

- Type of AGYW end-user work (HCD, focus groups, etc.)?
- Range/parameters of AGYW end-user work (geography, age distribution)?
- Key findings and questions that will be answered by AGYW end-user work?
- Next steps for Market Manager (i.e., further information gathering needs, or ways in which Market Manager can enable collaboration/information sharing with organization interviewed)

SURVEY OF PROJECTS AND STUDIES (DEMONSTRATION PROJECTS, IMPLEMENTATION INITIATIVES ETC.)

Information on studies and projects with end-user related hypotheses was collected via survey, desk research and KOL knowledge. Information collected included details organized along the following parameters:

- Name of Study
- Organization
- Purpose of study (hypothesis or theory)
- Design
- Location
- Population
- Results
- Next research question or implementation intervention they are undertaking as a result of study result
- Timing
- Other relevant information

Information on each project will be collected, collated and updated bi-annually in order to ensure an accurate and up to date mapping and analysis.

III. END-USER RESEARCH LANDSCAPE MAPPING AND ANALYSIS STEPS AND STATUS

Status		
First iteration complete, ongoing information collection	**1 End User Research Landscape**	
	Interviews, meetings, surveys & outreach to determine ongoing & planned efforts around AGYW 13-29 and other populations in SSA.	*Complete*
	Collation of findings into mapping; iterative process.	*First iteration complete; ongoing process*
	Stakeholder outreach ongoing to collect additional information & ensure up to date mapping.	*Ongoing process*

Information Collection Parameters

- Name of Study
- Organization
- Purpose of study (hypothesis or theory)
- Design
- Location
- Population
- Results (preliminary)
- Next research question/ implementation effort as a result of study
- Timing of project
- Other relevant information

2 End User Research Landscape Mapping

First iteration complete; ongoing information collection and collation

Includes mapping ongoing and planned projects and initiatives across end user research parameters

	Study Area	Target Audience	Technology	Study Location
	Acceptability & Adherence Marketing & Communications Distribution & Delivery Product Preference PrEP Integration Product Attributes Social Harms Policy Pricing	Women 18+ Women 18- Males Female sex workers Providers Regulators Pregnant women	Oral PrEP Microbicide (other than ring) Vaginal Ring Technology Unknown Injectable Female Condom Multipurpose Prevention Technology Implant IUD	South Africa Kenya Zimbabwe Malawi Uganda Tanzania Swaziland Zambia Lesotho Mozambique Benin Senegal
Project Name	✓	✓	✓	✓

3 End user product adoption continuum

Analysis of mapping complete*

**See analysis report*

Includes mapping factors identified in projects and interviews across the end user adoption/ adherence continuum to understand further gaps in knowledge and develop a generalized understanding of AGYW

	Awareness	Evaluation	Uptake	Adherence	Championing
Internal Factor	✓	✓	✓	✓	✓
External Factor	✓	✓	✓	✓	✓

**Adapted from PSI continuum*

IV. END-USER STAKEHOLDER MAPPING OVERVIEW: AGYW, SSA AND HIV PREVENTION

Stakeholder Organization	Project / Study Name	Project Type	Biomedical HIV prevention product(s) (if applicable)	Other Project Partners (if applicable)	Donor (if applicable)	Countries
Ayazazi	Youth friendly HIV services (counselling and link to treatment)	Service delivery model	Female condom	MatCH	Simon Fraser University	South Africa
Coalition Advancing Multipurpose Innovations (CAMI)	Strategic Evaluation Framework: Field-wide context, limitations, and next steps for market-based strategies in HIV-prevention and multi-purpose prevention technologies (MPTs) product development	Key Informant Discussions	Multi-purpose prevention technologies (MPTs)	Routes2Results	USAID/OHA	Global
CAPRISA	CAPRISA 082	Observational cohort study	Oral PrEP	N/A	USAID	South Africa
Centre for Sexual Health and HIV/AIDS Research Zimbabwe (CeSHHAR)	SAPPH-Ire	PrEP Demonstration Project	Oral PrEP	N/A	DFID, UNFPA	Zimbabwe
Centre hospitalier universitaire de Québec	Benin Demonstration Project	PrEP Demonstration Project	Oral PrEP	N/A	BMGF	Benin
Church of Scotland Hospital	Church of Scotland Hospital Demonstration Project	PrEP Demonstration Project	Oral PrEP	N/A	To come	South Africa
CONRAD	EMOTION	Human-centered design; in-depth qualitative interviews	Oral tablet, vaginal ring, injectable, patch, vaginal insert, vaginal film, intrauterine device, and implant	FHI 360, Lancet Laboratories, UCL, Statistical Center for HIV/AIDS Research and Prevention (SCHARP), Ideo, Instant Grass, Abt Associates/ Matchboxology	USAID (MPii)	South Africa, Kenya, Zimbabwe
	Quatro Study	Acceptability, preferences, user experience and effect	Vaginal gel; vaginal insert; vaginal film; intravaginal ring (IVR)	RTI International; UZ-UCSF Collaborative Research Programme; MatCH Research	USAID, BMGF	South Africa, Zimbabwe
	TRIO Study	Acceptability and preference	Vaginal gel; vaginal insert; vaginal film; intravaginal ring (IVR)	RTI International	BMGF	Kenya, South Africa
Desmond Tutu Foundation	CHAMPS (Pluspills; UChoose)	PrEP Demonstration Project	Oral PrEP	None	NIAID	South Africa

Stakeholder Organization	Project / Study Name	Project Type	Biomedical HIV prevention product(s) (if applicable)	Other Project Partners (if applicable)	Donor (if applicable)	Countries
	UNICEF PrEP Demo Program	PrEP Demonstration Project	Oral PrEP	None	UNITAID	South Africa (Brazil, Thailand)
	3Ps for Prevention Study	PrEP Demonstration Project	Oral PrEP	None	BMGF, NIH	South Africa
FHI 360	Communications and Marketing strategies for microbicide gel	Toolkit, materials, approach	Tenofovir gel	None	USAID	SSA
HIV Prevention Trials Network (HPTN)	HPTN 082	Open label study	Oral PrEP	Wits RHI, University of Washington	DAIDS, NIAID, NIMH	South Africa, Zimbabwe
International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT)	IMPAACT 2009	Observational study	Oral PrEP	Wits RHI	DAIDS	Zimbabwe, South Africa, Malawi, Uganda
International Partnership for Microbicides (IPM)	HCD study on vaginal ring	Human-centered design	Dapivirine ring	Dalberg	USAID	South Africa, Uganda
Jhpiego	Bridge to Scale	Implementation initiative	Oral PrEP	International Center for Reproductive Health Kenya (ICRHK), Populations Services Kenya, NASCOP, Avenir Health	BMGF	Kenya
Johnson & Johnson	DREAMS focus groups	Focus groups, in-depth interviews, consumer insights research, consumer insights, general analytics and real-world evidence	Oral PrEP	FHI 360	N/A	Kenya, Lesotho, Malawi, Mozambique, South Africa, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe
Kenya Medical Research Institute (KEMRI)	Focus groups on MPTs	Focus groups	MPTs	N/A	To come	Kenya
London School of Hygiene and Tropical Medicine (LSHTM)	EMPOWER	PrEP Demonstration Project; implementation science	Oral PrEP	Wits RHI, London School of Hygiene and Tropical Medicine	DfID	South Africa

Stakeholder Organization	Project / Study Name	Project Type	Biomedical HIV prevention product(s) (if applicable)	Other Project Partners (if applicable)	Donor (if applicable)	Countries
	What is the impact of the combined DREAMS package on HIV incidence and other key outcomes among AGYW and male partners?	Impact evaluation	Oral PrEP	KEMRI; African Population & Health Research Center; Africa Centre for Population Health	BMGF	Kenya
	What is the impact of a combination DREAMS package which includes an offer of oral PrEP to the highest risk AGYW?	Impact evaluation with nested qualitative and process evaluation studies	Oral PrEP	CeSSHAR	BMGF	Zimbabwe
	Product preferences and attributes when considering	Discrete-choice experiment	Injectables, microbicides, vaginal ring, diaphragm, male and female condoms	University of Bristol	USAID/PATH & OPTIONS (USAID)	South Africa
LVCT Health	LVCT Health PrEP demonstration project	PrEP Demonstration Project	Oral PrEP	Sex Workers Outreach Programme (SWOP)	BMGF	Kenya
Maternal Adolescent and Child Health (MatCH)	Female condom surveys and interviews	Surveys/interviews	Female condom	N/A	USAID	South Africa
McCann	OPTIONS	Qualitative and quantitative	Oral PrEP	FHI 360, AVAC, Wits RHI, LVCT Health, Pangea	USAID (MPii)	South Africa, Kenya, Zimbabwe
Microbicide Trials Network (MTN)	MTN-034/IPM 045	Open label study	Oral PrEP	MTN, IPM	NIH, NIAID, NIMH, NICHD	South Africa, Zimbabwe
	MTN 032	Qualitative In-Depth Interviews and focus groups	Dapivirine ring	IPM	NIH	Malawi, South Africa, Uganda, Zimbabwe
	MTN 031/IPM 043	Open label study	Dapivirine ring	IPM, Wits RHI	DAIDS, NICHHD, NIMH, NIH	South Africa, Malawi
Mylan	Oral PrEP product characteristics / packaging	Interviews/focus groups	Oral PrEP	Ipsos	N/A	Kenya, South Africa
New York University	MP3-Youth	PrEP Demonstration Project	Oral PrEP	N/A	NIH	Kenya
National Institutes of Health (NIH)	Understanding and Addressing the Multi-level Influences on Uptake and Adherence to HIV Prevention Strategies Among Adolescent Girls and Young Women in Sub-Saharan Africa (RFA-MH-17-550)	Research Project Grant	TBD	TBD	NIMH, NICHD	SSA

Stakeholder Organization	Project / Study Name	Project Type	Biomedical HIV prevention product(s) (if applicable)	Other Project Partners (if applicable)	Donor (if applicable)	Countries
	Understanding and Addressing the Multi-level Influences on Uptake and Adherence to HIV Prevention Strategies Among Adolescent Girls and Young Women in Sub-Saharan Africa (RFA-MH-17-555)	Exploratory/Developmental Grant	TBD	TBD	NIMH; John E. Fogarty International Center; NICHD	SSA
	Understanding and Addressing the Multi-level Influences on Uptake and Adherence to HIV Prevention Strategies Among Adolescent Girls and Young Women in Sub-Saharan Africa (R34) (RFA-MH-17-560)	Planning Grant	TBD	TBD	NIMH	SSA
President's Emergency Plan for AIDS Relief (PEPFAR)	DREAMS Initiative	Large scale implementation initiative with multiple projects	Oral PrEP	PEPFAR, BMGF, Girl Effect, J&J, Gilead and ViiV, country partners/grantees	PEPFAR, BMGF, Girl Effect, J&J, Gilead and ViiV	Kenya, Lesotho, Malawi, Mozambique, South Africa, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe
Population Council	Community-based girl-centered programming	Community based assessment; program impact	N/A	To come	BMGF, PEPFAR	Kenya, Zambia
	PrEP for AGYW	Feasibility/acceptability; program evaluation	Oral PrEP	To come	BMGF, PEPFAR	Tanzania, Kenya and/or Uganda
	Male partner study	Exploratory study and program evaluation	N/A	To come	BMGF, PEPFAR	South Africa, Swaziland, Uganda
	Building Evidence to Guide PrEP Introduction for Adolescent Girls and Young Women	Guidance	Oral PrEP	DREAMS partners	BMGF	Kenya, Lesotho, Malawi, Mozambique, South Africa, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe

Stakeholder Organization	Project / Study Name	Project Type	Biomedical HIV prevention product(s) (if applicable)	Other Project Partners (if applicable)	Donor (if applicable)	Countries
Population Services International (PSI)[13]	Adolescents 360	Human-centered design	N/A	IDEO.org, the Center on the Developing Adolescent from the University of California, Berkeley, Triggerise and Ogilvy & Mather Africa, PSI/Ethiopia, PSI/Tanzania and Society for Family Health Nigeria	BMGF, Children's Investment Fund Foundation	Ethiopia, Nigeria, Tanzania
Reseau Africain De Recherche Sur Le SIDA	Senegal PrEP demonstration project	PrEP Demonstration Project	Oral PrEP	N/A	BMGF	Senegal
Routes2Results	Messaging for MTN 034	Qualitative and quantitative interviews	Oral PrEP, dapivirine ring	MTN	NIMH	Kenya, Zimbabwe, South Africa
RTI International	End-user research to optimize adherence to injectable HIV prevention approaches	Discrete-choice experiment	Injectables	N/A	To come	South Africa
	TRIO Study	Acceptability and preference	Vaginal gel; vaginal insert; vaginal film; intravaginal ring (IVR)	RTI International	BMGF	Kenya, South Africa
	CHARISMA	Develop/test IPV intervention	Dapivirine ring; other microbicides and MPTs	Wits RHI, FHI 360, Sonke Gender Justice, University of Washington	USAID (MPii)	South Africa, potential scale-up in Malawi, Uganda, Zimbabwe
SWOP Kenya	LVCT Health PrEP demonstration project	PrEP Demonstration Project	Oral PrEP	LVCT Health	BMGF	Kenya
United Nations Children's Fund (UNICEF)	UNICEF PrEP Demo Program	PrEP Demonstration Project	Oral PrEP	Desmond Tutu HIV Foundation	UNITAID	South Africa (Brazil, Thailand)
University of Pittsburgh	GEMS	Risk of resistance research	Oral PrEP	IDEO, CAPRISA, RTI International, Abt Associates	USAID (MPii)	Kenya, South Africa, Zimbabwe

[13] Project not included in full project catalogue due to scope outside of landscape mapping scope; however included in mapping overview to ensure full landscape is seen. PSI works in the field the review covers. Further iterations of mapping to assess inclusion of project.

Stakeholder Organization	Project / Study Name	Project Type	Biomedical HIV prevention product(s) (if applicable)	Other Project Partners (if applicable)	Donor (if applicable)	Countries
University of Washington	HPTN 082	Open label study	Oral PrEP	HPTN, Wits RHI	DAIDS, NIAID, NIMH	South Africa, Zimbabwe
	POWER	Mental model, in-depth interviews	Oral PrEP; dapivirine ring	Desmond Tutu HIV Foundation, Kenya Medical Research Institute (KEMRI), Wits Reproductive Health and HIV Institute (WRHI), Carnegie Mellon University , Massachusetts General Hospital (MGH), RTI International	USAID	Kenya, South Africa, Zimbabwe
Wits WRHI	EMPOWER	PrEP Demonstration Project	Oral PrEP	Wits RHI, London School of Hygiene and Tropical Medicine	DfID	South Africa, Tanzania
	TAPS Demonstration Project	PrEP Demonstration Project	Oral PrEP	N/A	BMGF	South Africa
	HPTN 082	Open label study	Oral PrEP	HPTN, Wits RHI, University of Washington	DAIDS, NIAID, NIMH	South Africa
	DOMA	Adherence measures	Dapivirine ring	N/A	To come	South Africa
	DCE	Discrete-choice experiment	Oral PrEP	N/A	To come	South Africa
	Focus groups	Focus groups	Oral PrEP	STRIVE	To come	South Africa
	WRHI Youth CAB	CAB	Oral PrEP	Across projects	Multiple funding sources	South Africa

V. CATALOGUE OF ONGOING AND PLANNED END-USER WORK [14]

Projects, studies and initiatives ordered by type:

- Discrete-choice experiments
- Focus groups, in-depth interviews, surveys
- Implementation initiatives
- PrEP demonstration projects
- Other research (open label extension studies, implementation science, etc.)
- Modeling, Policy Research
- Completed projects

DISCRETE-CHOICE EXPERIMENTS

Name of Study	DCE: Preferences for ARV-based prevention
Organization	Wits RHI
Purpose of study (hypothesis or theory)	To determine the demand and uptake for HIV prevention technologies and predict changes in uptake according to product characteristics in three distinct cohorts: adult females, adult males and adolescent girls.
Design	Discrete choice experiment
Location	Gauteng, South Africa
Population	Adult females, adult males and adolescent girls
Results	Planned
Next research question or implementation they are undertaking as a result of study result	Planned
Timing	Planned

Name of Study	End-user research to optimize adherence to injectable HIV prevention approaches
Organization	RTI International
Purpose of study (hypothesis or theory)	Three year study to identify key product attributes, end-user preferences, and health service delivery determinants relevant to youth's adherence to sustained-release injectable PrEP , and to use these findings to inform product optimization and future research and programmatic activities.
Design	Formative data will be gathered using a socio-ecological framework. This data will explore end- user factors at the individual, intrapersonal, and structural levels that influence uptake of and adherence to new health technologies. The formative data will then inform the design of a computerized, questionnaire-based,

[14] Includes interviews, surveys and other outreach. Organized by project type to the extent possible, with overlap in projects that include more than one study type. Further organization of studies to come. Information on each study included is not meant to be full and comprehensive information such as that included in full study protocols, but is meant to provide an understanding of each study in the context of this mapping. For additional information on any study included, please contact avac@avac.org.

	discrete-choice experiment (or choice-format conjoint analysis) that will be administered to 600 PrEP-naive youth residing in a high-density township in Cape Town.
Location	South Africa
Population	Information to come
Results	Information to come
Next research question or implementation they are undertaking as a result of study result	Project will determine the key product design and health delivery system attributes that are most preferable and salient to adherence for an injectable PrEP method for young people.
Timing	Proposed

FOCUS GROUPS, IN-DEPTH INTERVIEWS, SURVEYS

Name of Study	TRIO Study (Tablets, Rings, and Injectables as Options for women)
Organization	CONRAD
Purpose of study (hypothesis or theory)	Seeks to evaluate the acceptability of three multipurpose, prevention technologies (MPTs) as delivery forms for HIV prevention and unintended pregnancy among young women in Kenya. The three MPTs include, tablet, Ring and Injection.
Design	Focus groups
Location	Kenya, South Africa
Population	Women (age range to come)
Results	Health Care Worker (HCW) perspectives: - Injection: time consuming to administer, but familiar because of depo. - Pill: less discrete than an injection and like an ARV hence associated with HIV. It is not removable ("once you take it, it's in your stomach") - Ring: partner may feel during sex; it can be removed, it's a simple product and there's limited burden on the provider - Implant: time intensive to administer, but highly discrete and reduced adherence concern.
Timing	Began late-2015; results are preliminary as study is not final

Name of Study	AGYW Focus Groups; Youth CAB
Organization	Wits Reproductive Health and HIV Institute
Interviewees	*Deborah Baron,* FACTS Consortium Manager
Purpose of study (hypothesis or theory)	How to reach AGYW with HIV prevention options. *Interview focused broadly on Wits work with AGYW, and specifically on findings from focus groups.
Design	AGYW focus groups ongoing (led by Sinéad Delany-Moretlwe & Jonathan Stadler, STRIVE). Additionally, WRHI Youth CAB work across projects.
Location	South Africa
Population	AGYW 16-24 years old
Results (preliminary)	Initial qualitative/observed findings from focus groups: - buy-in from local "celebrity" ambassadors (e.g., local musicians) who are not traditional celebrities, . but relevant to the district/city/community helps buy in. - the Truvada bottle is seen as only for someone who is HIV-positive. - some AGYW reporting desire for co-packaging with contraception to minimizestigma and maximize ease of access to desired/needed health products. - Social media/mobile reminders and informational groups are important. - The need for anonymous platforms is key–adolescents are often sharing phones and want information to disappear as quickly as possible. South Africa NDOH working on an anonymous platform.

	- paper is archaic to AGYW and there are reports of AGYW disposing of the IEC materials in the PrEP demo project at the site exits. Ensuring information is provided in a youth-friendly way is key. - Local context in program planning is key. For example, different districts/cities use different slang (i.e., in Cape Town the use of "I'm going to Jo'burg tonight" is meant to imply having sex), and have different influencers. - AGYW influences and language is fast moving and always evolving, ensuring relevance of materials and services to population is key.
Next research question/ implementation effort as a result of study	To inform PrEP delivery to AGYW in Wits demonstration project and implementation efforts.
Timing of project	Publication process underway for AGYW focus groups.

Name of Study	**Oral PrEP product characteristics and packaging**
Organization	Mylan
Interviewees	*Kellen Thomas (External Partnerships and Policy, Infectious Disease); Ya'ir Aizenman (ARV Coordination and Planning)*
Purpose of study (hypothesis or theory)	Examine product characteristics of oral PrEP in order to understand what modifications to the product may lead to uptake and adherence.
Design	Oral PrEP user-oriented market research study with Ipsos. 60-90 minute in-depth interviews will be conducted.
Location	Kenya and South Africa
Population	Women currently on PrEP (18-30); women at risk (18-30); sex workers; Primary care providers (Doctors/Nurses), KOLs and other at-risk people.
Results (preliminary)	All research undertaken from this study will be made public.
Next research question/ implementation effort as a result of study	Study will inform changes made to the TDF/FTC pill and packaging.
Timing of project	Planned
Other relevant information	Key product issues discussed include: - Size of the pill and possibly scoring the pill so that it is breakable. - Blister packs instead of bottles, which may come with challenges due to Tenofovir's stability. - Color and distinguishing the pill from that taken for treatment. - Smoother coating so it is easier to swallow. - Co-packaging with contraception.

Name of Study	**Female Condom Survey**
Organization	MatCH
Interviewees	*Mags Beksinska, Technical Advisor at MatCH, University of Witwatersrand*
Purpose of study (hypothesis or theory)	Evaluate South Africa's national female condom (FC) program. Surveyed 4,000 women (18+) on end-user preferences.
Design	Survey and interviews
Location	South Africa
Population	Women 18 years and older
Results (preliminary)	Initial data from survey show: - Reasons for non-use of female condoms include: trusting their partner, using another method of protection, and fear of product. - Reason for use is it is a dual protection product that is woman control, ease of use once they understand insertion and buuy-in of male partners which is key. - Product: the FC that mimics tampon insertion has had good reception in a population that has about 30-40% use of tampons.

	- Branding and packaging importance with female condom (i.e., pink packaging, but more importantly, the type of female condom). - Use of female condom differs by province and depends on the provider. In some rural settings use and knowledge are very high, while in urban settings use is low. Often the provider can be linked to high/low use.
Next research question/ implementation effort as a result of study	To inform national program.
Timing of project	Data not yet available, to be published next year.

Name of Study	**Ayazazi Youth HIV Prevention Cohort**
Organization	Ayazazi
Interviewees	*Angela Kaida, Canada Research Chair Tier II in Global Perspectives in HIV and Sexual Reproductive Health*
Purpose of study (hypothesis or theory)	Interdisciplinary study looking to better understand HIV risk among youth aged 16-24
Design	Youth (200 males and females aged 16-24) will be divided into 8 focus groups in order to rank HIV prevention options (held in July 2016), in Durban and Soweto. Paper will be published.
Location	South Africa (Soweto and central Durban)
Population	Youth (200 girls and boys) 16-24
Results (preliminary)	- Barriers to reaching most at-risk youth include lack of parental consent. If youth don't have parental consent they can't be part of the study (i.e., don't have a guardian or don't want to talk to their parents). High levels of retention in the study have been linked to the parental consent - Risk perception of participants is low. Nearly all participants say they are not at risk, however 30-40% will go on to acquire HIV in the next 10 years, and many have lost parents to HIV. When asked if their peers are at risk they say yes. - Importance of youth-friendly language in service delivery (ensuring language that doesn't problematize and gets at openness). Stigmatized behaviors are an example, such as saying, "lots of sexual partners," and then having an AGYW think, "I'm not a slut so I'm not at risk." It should be more nuanced, such as: "having sex with partners within your age group with condoms means you are not at risk." - Youth are a highly mobile population spending time at school, work or with a boyfriend (visiting one in another area etc.) Often they have limited money and phones that are shut off. Retention is a huge challenge in this study, as well as with programs engaging youth in general. - Physical service delivery space important. Ayazazi in central Durban is downtown in a commercial office building and very different outreach efforts are reported between that site and the Soweto clinic site. A safe and trusting space needs to be created. Ayazazi is housed in a downtown, commercial office building in Central Durban, which requires very different outreach mechanisms than the clinic site in Soweto. They need to create a safe space to develop trust with the community. - Youth as part of service delivery. It is important for youth to see themselves reflected in their care: sex, gender, race and levels of privilege. - Missed opportunity with STIs. We have a picture of what HIV looks like before there is an infection with STIs, and STI testing should be a trigger for HIV risk. Seeing very high rates of BVI (60%). - Lack of understanding by providers and program implementers of fundamental sexual health and sexuality of AGYW. The complexities of expectations vs. reality (virginity before marriage etc.), and the understanding that AGYW may enjoy sex and may want to have sex with more than one partner *without judgement* in service delivery and program planning. A need to assess what stigmas the entire service delivery team has. "We can all be challenged on what it means to provide youth-friendly care in a non-stigmatized, rights-based framework." Youth-centered clinics does not mean youth-centered care (Note: LVCT reiterated this explaining LVCT clinics are not truly youth friendly).

	- Use of mobile devices is key in reaching AGYW, but first understanding what percentage have a mobile phone, what percentage share phones and who does not have access to a mobile phone. Mxit is the most popular platform used by study participants (a combination of WhatsApp and Facebook). - Prevalence of sexual violence in AGYW is extremely high. - AGYW care about their own health, but the number of external forces and structural drivers they have to overcome that are out of her control are significant. The basic assumption should not be that a girl does not care about her health or not want to use PrEP. HIV is transmitted at an individual level but the risk is created at a community level. - Blessers (generally wealthy, older men, who provide generally younger women with financial incentive to enter into a relationship) come up, but only in the context of access to money, and economic opportunity is the real issue of importance. - Ayazazi not currently linking to PrEP for prevention. - Lessons from contraception option uptake in clinics could be applicable. Low uptake of oral contraception; fear of needles when asked if want to use depo; more girls using implant, but reports of girls removing the implant due to early side effects, as well as myths about the implant circulating.
Next research question/ implementation effort as a result of study	To provide an example of youth friendly services for broader implementation in South Africa.
Timing of project	Youth engaged approaches to research paper to be published late-2016. Publishing full data 2017, including risk data.
Other relevant information	"What if we get to the end of HIV and the same structures that produced and reproduced HIV still exist?"

Name of Study	**Optimizing Prevention Technology Introduction On Schedule (OPTIONS) / McCann**
Organization	OPTIONS, Sponsored by USAID and conducted by FHI 360/Wits RHI/AVAC
Interviewees	*Briana Ferrigno, Vice President, Group Director at McCann Global Health*
Purpose of study (hypothesis or theory)	Studies will support project aims to: develop evidence-based business cases and coordinated investment strategies for the introduction of prevention products; support country level regulatory approval, policy development, program planning, and *marketing and implementation strategies*; facilitate and conduct implementation science; and provide technical assistance and support for health systems strengthening with rapid use of data to identify and address implementation bottlenecks throughout the value chain. **Additional information to come on specifics of national campaign work. Planning for national campaign guidance development work.*
Design	Market intelligence work, possibly including focus groups, aiming to fill gaps in existing research on acceptance of HIV prevention products and PrEP, and to gain greater understanding of the end user and their influencers.
Location	South Africa, Kenya, Zimbabwe
Population	AGYW
Results (preliminary)	AGYW landscape analysis completed, findings not yet available. Currently in planning stages.
Next research question/ implementation effort as a result of study	Information to come.
Timing of project	Study is ongoing: 2015-2020; end-user/demand creation work planned.

Name of Study	**KEMRI MPT Preferences Focus Groups**
Organization	KEMRI
Interviewees	*Everlyne Ombati*
Purpose of study (hypothesis or theory)	To assess multipurpose prevention technology (MPT), HIV prevention and contraceptive product preferences in AGYW.
Design	Focus groups

Location	Kenya
Population	AGYW (age range to come)
Results (preliminary)	Initial round of focus groups completed, second round planned
Next research question/ implementation effort as a result of study	Information to come.
Timing of project	Initial focus group outcomes available (so see my above comment)

Name of Study	**The Quatro Study**
Organization	CONRAD
Purpose of study (hypothesis or theory)	Assess the acceptability, preferences, user experience and effect on sexual behavior of four different vaginal microbicide or multi-purpose technology (MPT) delivery forms, using placebo products in 18-30-year-old African women. The study also examines adherence to the dosage forms through objective markers, developed for each dosage form prior to the commencement of the study.
Design	Key informant interviews to determine provider attitudes towards the different products, including rapidly disintegrating vaginal insert, intravaginal ring (IVR), film, gel. Key informant interviews to explore appropriate educational and marketing materials and messages for each delivery form.
Location	South Africa, Zimbabwe
Population	Women 18-30 years old
Results	April 2017
Timing	Ongoing
Other relevant information	Measures: - Change from baseline in ratings and relative preference rankings of four vaginal delivery forms - Attributes least and most favored for the vaginal delivery forms as measured by discreet choice experiment - Adherence assessed by self-report via questionnaire - Adherence assessed by objective biomarkers, utilizing antibodies, tagged recombinant proteins, biochemical assays and/or spectroscopy

HUMAN-CENTERED DESIGN (HCD) PROJECTS

Name of Study	**Johnson & Johnson and DREAMS**
Organization	*Johnson & Johnson*
Interviewees	*Benjamin Tiede, Strategy & Project Management Lead, Global Public Health at Johnson & Johnson; Bob Bowden Public Health Impact & Outcomes Research at Johnson & Johnson; Abela Agnarson, Director Public Health Impact & Outcomes Research at Johnson & Johnson; Anna Caravaggio Senior Director, HIV/DREAMS Program and Consumer Capability Leader at Johnson & Johnson; Bianca Botha, Portfolio Manager South and Sub-Sahara Africa at Johnson & Johnson; Lynn Leonard Global Commercial Access Leaderfor Janssen Global Public Health at Johnson & Johnson*
Purpose of study (hypothesis or theory)	To understand broad behaviors and attitudes of AGYW by asking the following two key questions: - What does your life look like today? - What are your dreams/hopes?
Design	Using human-centered design (HCD) techniques in workshops run by FHI 360. FHI 360 selects the girls and collates the data of each workshop. They are using DREAMS ambassadors to assist with the HCD work
Location	Kenya, Lesotho, Malawi, Mozambique, South Africa, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe (All DREAMS countries)
Population	AGYW 15-24 years old

Results (preliminary)	Output will be a consumer segmentation study that will be published.
Next research question/ implementation effort as a result of study	The end result of the workshops will be actionable data that segments girls and provides profiles of how to reach each type of girl with product and programming in order to package a toolkit for each girl with products, services and messages.
Timing of project	Zambia and South Africa have been completed and participant reaction has been positive. Aim is to get to all 10 countries by the end of September.
Other relevant information	- Rural and urban girls are included in the same workshop, finding that the deep behaviors are the same across socio-economic divides, but there is a guardianship split between those girls who have parents/guardians and those who don't. - Data thus far showing that the differences between girls geographically is minute, and looking for a deeper understanding of segmentation (age groups etc.)

Name of Study	**HCD Ring Study**
Organization	*IPM, Dalberg, USAID*
Interviewees	*Melanie Kahl, Design Impact Group, Dalberg - Global Development Advisors*
Purpose of study (hypothesis or theory)	To conduct an human centered design study around acceptance of the dapivirine ring to address the question: How might we increase and sustain use of DPV(/MPT) rings by better understanding and engaging young Sub-Saharan African women and their influencers in the service journey?
Design	Human centered design study
Location	South Africa, Uganda
Population	AGYW (18-21 and 22-28) and influencers (young men representative of partners; health practitioners; community leaders
Results (preliminary)	In planning stages, expected start early-2017.
Next research question/ implementation effort as a result of study	Deliverables expected include: DPV(/MPT) Ring Guide (customer personas and journey maps tailored to each country context; awareness building, service delivery and user engagement and experience concepts; preliminary recommendations and branding approaches based on research and prototyping); Strategic Launch Roadmap (document that describes the recommended strategy for reaching users with DPV products in new markets based on research conducted.)
Timing of project	In initial planning stages and seeking ethics review, hoping to start October/November.

Name of Study	**Enhancing Microbicide Uptake in High-Risk End Users (EMOTION) / CONRAD**
Organization	Sponsored by USAID and conducted by CONRAD
Interviewees	*Gustavo Doncel, Scientific and Executive Director at CONRAD*
Purpose of study (hypothesis or theory)	To develop new product attributes, packaging, dispensing systems, messaging, dosing preferences, and branding for two lead HIV prevention products, as well as at least two new alternative drug delivery systems.
Design	- Building on the piloted human-centered design study in South Africa (Project KAROO) with HCD firm IDEO to test product dosage, packaging, branding, outreach and marketing campaigns. Interview women, their partners and community members to better understand drivers for and barriers to product use. Participants invited to share opinion on: oral tablet, vaginal ring, injectable, patch, vaginal insert, vaginal film, intrauterine device, implant. - Project Kalahari: Round 1) Product and pack design preferences: Eight PrEP products – oral tablet, vaginal ring, injectable, patch, vaginal insert, vaginal film, intrauterine device, and implant. - Project Kalahari Round 2) live prototyping experiments, including brand and touchpoints for a holistic experience based on the design principles generated in Round 1 - Marketing study using controlled market behavior simulation methodology
Location	South Africa, Kenya, Zimbabwe
Population	Women who are at the highest risk of HIV infection, especially young unmarried women, including those who: live with their parents, have a current or past history of intimate partner violence and exchange sex for money.

Results (preliminary)	Information to come.
Next research question/ implementation effort as a result of study	Increase uptake and correct and consistent use of ARV-based HIV prevention products by women at high risk of HIV infection using an end-user centered strategy. This research informs design, packaging, access and messaging in order to increase demand, use and adherence.
Timing of project	Study is ongoing: 2015-2020, (phase I completed, results of Phase II presented at R4P conference, October 2016.)

IMPLEMENTATION INITIATIVES

Name of Study	**Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe (DREAMS)**
Organization	Sponsored by PEPFAR/BMGF/Nike Foundation
Purpose of study (hypothesis or theory)	Learn how to scale-up a core package of evidence-based interventions to address the many interlocking challenges that face AGYW in Eastern and Southern Africa.
Design	Multidisciplined study to support large scale implementation initiative.
Location	Kenya, Lesotho, Malawi, Mozambique, South Africa, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe
Population	Adolescent girls and young women, <24
Results	TBD
Next research question or implementation they are undertaking as a result of study result	Implementation of package of interventions to reduce HIV infections in AGYW.
Timing	Ongoing;
Other relevant information	Lessons learned to emerge from oral PrEP provision settings. Additional information on Innovation Challenge recipient projects to be added as relevant.

Name of Study	**Bridge to Scale / Jilinde**
Organization	Sponsored by the BMGF and conducted by JHPIEGO
Purpose of study (hypothesis or theory)	- Learn and develop new ways of delivering oral PrEP to most at risk populations - Assess barriers to service
Design	At scale implementation project
Location	Kenya
Population	Adolescent girls and young women, MSM, FSW
Results	In start-up phase
Next research question or implementation they are undertaking as a result of study result	Develop creative strategies for implementation of a simple evidence-based intervention for protection from HIV infection in a complex, real-world environment.
Timing	Study is ongoing: 3 years

PREP DEMONSTRATION PROJECTS

Name of Study	**IPCP-Kenya** **2 interviews, 1 project description*
Organization	Sponsored by BMGF and conducted by LVCT Health, SWOP
Purpose of study (hypothesis or theory)	To demonstrate effective delivery and impact of oral HIV PrEP as part of a combined prevention package for target populations, in a real world setting.

Design	Demonstration project and health systems strengthening
Location	NGOs and public hospitals in Nairobi, Kisumu and Homabay Counties, Kenya
Population	Female sex workers (>18), MSM (>18), young women at high HIV risk (15 -29 years old); Target number of enrollees: 2,100
Results	Available mid-2017 Costing data scheduled to be available September 2016
Next research question or implementation they are undertaking as a result of study result	- Validate tools for risk identification and indications for PrEP initiation among young women (YW) at high HIV risk. - Document PrEP side effects and adverse events among MSM, FSW and YW at high HIV risk. 1. Monitor safe uptake of PrEP among pregnant women. 2. Determine acceptability of HIV re-testing among MSM, FSW and YW at high HIV risk. - Develop tools and strategies to promote uptake and sustained adherence to PrEP as part of a combination prevention package. - Demonstrate effective delivery of oral HIV PrEP as part of a combined prevention package among MSM, FSWs and YW at high risk of HIV. - Model the impact and cost effectiveness of PrEP in a combination prevention package. - Collect provider requirements and perspectives to support future capacity building of PrEP providers.
Timing	Study is ongoing: 09/2015-12/2016
Other relevant information	- Collecting behavioral data: condom use, number of sexual partners, partner HIV status. - Collecting qualitative data on PrEP acceptability. - Collecting adherence data: self-reports, pharmacy refills, 5% drug testing level.

Name of Study	**IPCP-Kenya** *2 interviews, 1 project description
Organization	*LVCT Health*
Interviewees	*Wanjiru Mukoma, Executive Director, LVCT Health; Michael Kiragu, PI IPCP Project, LVCT Health*
Purpose of study (hypothesis or theory)	To provide evidence on the deliverability of PrEP as part of HIV combination prevention package in Kenya
Design	Demonstration project
Location	Nairobi, Kisumu and Homabay Counties, Kenya
Population	At risk AGYW **Note: Project also enrolls self-identifying sex workers and MSM.*
Results (preliminary)	- Local champions and/or local "celebrities" are needed to ensure buy-in. For example in one PrEP demo project community local boys said that PrEP is a pill for "promiscuous girls." The project worked to get the buy-in of several male champions and paired them with girls. Having male and female champions can be important. In another community the local "celebrity" is the older women. - Community-wide approach is needed instead of focusing only on the girl. By month three of recruitment, the project did not have any girls on PrEP and realized they needed to switch focus from a girl-centered approach to a community-wide mobilization approach. This community approach differed by setting and focused on key influencers in each setting (i.e., family, peers etc.) Enrollment numbers increased following community interventions. - IEC materials development was conducted in collaboration with each community. For AGYW enrolled in the project, the posters and pamphlets have less of an impact than for MSM and sex workers. LVCT Health has a mobile health platform for youth, One-2-One, that is very successful at reaching youth with health messages. Youth need an anonymous platform to ask questions. The most at-risk youth in the LVCT project are not involved with social media.

	- Stigma with Truvada seen as a pill for HIV-positive people was addressed in each setting with small groups of girls (i.e., "I don't want to be seen with HIV pills; how do I disclose to my partner when they can hear the pills rattling; I have to show my friends I have ARVs in my pocket"). - Low level of HIV knowledge. In most settings in the project, except for Homabay, the community and population was research naïve, and there was a low level of knowledge around HIV, PrEP and research. - Level of intimate partner violence is very high in AGYW. One project participant said, 'for the first time I feel like I'm in control of my health.' Her partner said she was promiscuous when he found her pills and beat her up. She understood her risk of HIV and was able to leave him. - Risk perception among PrEP users, there are three types of AGYW they are seeing, 1.) Those who very clearly understand their risk and are early PrEP adopters, 2.) Those who know their risk and need some counselling and information on PrEP, 3.) Those who absolutely do not perceive their risk and don't think they need PrEP. - For AGYW accessing PrEP and family planning in one place (i.e., at government SRH facilities) is key. - Importance of healthcare workers in providing stigma and judgement free services and the personal journey of the healthcare worker to understand PrEP as HIV prevention.
Next research question/ implementation effort as a result of study	Lessons learned to be shared with OPTIONS to develop into a blog/webinar series to inform other projects and implementation efforts.
Timing of project	Preliminary findings on community engagement to be published at R4P conference in October 2016.
Other relevant information	"The decision to take PrEP is not entirely autonomous, there are powerful outside influences on girls–who you relate to, who endorses it–that affect if they'll take it."

Name of Study	**IPCP-Kenya** **2 interviews, 1 project description*
Organization	*LVCT Health*
Interviewees	*Martin Muthare, Care and Treatment Coordinator/Trainer at LVCT Health; Dorothy Muthoni Njeru*
Purpose of study (hypothesis or theory)	LVCT Health PrEP demo project, see LVCT Health PrEP demonstration project for additional information.
Design	Demonstration project
Location	Kenya (Nairobi)
Population	AGYW **Note: Project also enrolls sex workers and MSM.*
Results (preliminary)	- Public health clinic in Korogocho slum serving AGYW who engage in "survival sex." Due to the nature of the sexual encounters described by the AGYW attending clinic they are all categorized by clinic staff as sex workers whether self-identified or not - High level of violence in community - Some AGYW going to SWOP clinic farther away due to public health clinic next to (in same compound as) HIV treatment clinic - Losing of pills is normal occurrence (muggings, house fires, etc.) - Truvada has no value in the community - Don't like the bottle that says "Truvada" prominently - Identify Truvada as for HIV+ people - Older age group seem more willing to adhere
Next research question/ implementation effort as a result of study	Lessons learned to be shared with OPTIONS to develop into a blog/webinar series to inform other projects and implementation efforts.
Timing of project	Preliminary findings on community engagement to be published at R4P conference in October 2016.
Other relevant information	*Every* AGYW who came in to clinic met criteria included in risk profiling tool to identify most at risk women.

Name of Study	Benin Demonstration Project
Organization	Sponsored by BMGF and conducted by CHU de Québec (Canada)
Purpose of study (hypothesis or theory)	To assess feasibility and usefulness of integrating Treatment as Prevention (TasP) PrEP in the combination prevention package offered to FSWs in Benin; identify best way to successfully implement TasP and PrEP in this setting and to ensure their adoption by national policymakers as part of the HIV prevention package for FSWs.
Design	Demonstration project
Location	Primary healthcare clinics in Cotonou, Benin
Population	FSW, 18-59 years old; Target number of enrollees: 250
Results	Expected Feb 2017
Next research question or implementation they are undertaking as a result of study result	- How to promote regular HIV testing among a well-defined population of FSWs in Cotonou. - Evaluate if PrEP for HIV prevention can be implemented with success among the defined population of HIV-negative FSWs and if, in such case, it can be adopted by national policymakers as a preventive intervention - Assess the impact of PrEP on the HIV epidemic among FSWs, their clients and the general population in Benin. - Assess the costs generated by the intervention and evaluate the cost-effectiveness of PrEP and how costs vary by patient characteristics and adherence level.
Timing	Study is ongoing: 10/2014-01/2017
Other relevant information	- Data is also being collected on sexual behavior and condom use with clients as well as longer-term partners (boyfriend/husband/ concubine). - As of February 2016, the acceptability of PrEP was 87% and the detectable blood level of Tenofovir disoproxil fumarate (TVD) for overall scheduled visits (14th Day, 6-Month and 12-Month follow-up visits) was 65.7%.

Name of Study	Choices For Adolescent Methods Of Prevention In South Africa (CHAMPS)
Organization	Sponsored by NIAID and conducted by the Desmond Tutu HIV Foundation
Purpose of study (hypothesis or theory)	Address the gap in effective HIV prevention interventions for young people in South Africa through a novel approach to combining different HIV prevention strategies into an optimized prevention 'menu' for adolescents, from which young women and men at risk of HIV infection may choose a particular combination of strategies to meet their specific needs and circumstances.
Design	Demonstration project
Location	Masiphumelele and Soweto, South Africa
Population	Adolescent men and women, 15-19 years old; target number of enrollees: 150
Results	TBD
Next research question or implementation they are undertaking as a result of study result	- Results will have direct applications in enhancing specific HIV prevention interventions and in the design of a robust trial to evaluate a novel approach to combining biological and behavioral prevention modalities. - The findings from the three pilot studies will feed into a fourth study that will examine adolescents' decision making around HIV prevention, the efficacy of a 'menu' approach for HIV prevention options, and the impact of messaging about each option on the adolescents' selection.
Timing	Study is ongoing: 7/2011-10/2016
Other relevant information	Consists of 4 pilot studies: 1. "MACHO": male circumcision 2. "Pluspills": oral Pre-exposure prophylaxis (PrEP) 3. "UChoose": modes of PrEP delivery (injectable, oral and vaginal ring) 4. "iChoose": adolescent decision-making about prevention - Contains modelling and costing component to determine the impact of interventions on the South African adolescent epidemic.

	– An examination of the ethical-legal challenges surrounding research on and implementation of biomedical prevention strategies in adolescents also forms a part of this project.

Name of Study	Church of Scotland Hospital Demonstration Project
Organization	Conducted by Church of Scotland Hospital
Purpose of study (hypothesis or theory)	To improve health outcomes for the mothers and babies. Central focus will be assisting young mothers to return to school, prevent acquisition of HIV and postponing further pregnancies. Other adherence strategies will be investigated as well.
Design	This demonstration project will recruit teenagers at first ANC visit and enroll them into a comprehensive support program involving an interactive curriculum of health education, parenting, HIV prevention, family planning, improving developmental milestones for babies, addressing their challenges etc.
Location	Church of Scotland Hospital, Kwazulu-Nata, South Africa
Population	Pregnant teenagers
Results	TBD
Timing	Planned project

Name of Study	EMPOWER (Enhancing Methods of Prevention and Options for Women Exposed to Risk) Consortium
Organization	Sponsored by Wits RHI/LSHTM/DFID and conducted by Wits RHI, London School of Hygiene and Tropical Medicine
Purpose of study (hypothesis or theory)	- Investigate the social norms and inequalities that drive HIV, integrating violence prevention and combination prevention, including PrEP. - Aims to assess whether it is feasible, acceptable, and safe to offer oral PrEP as part of a combination prevention package that addresses gender based violence (GBV) and HIV.
Design	Demonstration project, Implementation science research
Location	Hillbrow (WRHI), South Africa and Wanza, Tanzania
Population	AGYW, 16-24 years old, Target number of enrollees: 500
Results	TBD
Timing	Study is planned: Mid-2016-12/2017

Name of Study	HPTN 082: Evaluation of daily oral PrEP as a primary prevention strategy for young African women: A Vanguard Study
Organization	Sponsored by DAIDS/NIAID/NIMH and conducted by HPTN/Wits RHI/University of Washington
Purpose of study (hypothesis or theory)	To evaluate whether HIV-uninfected sub-Saharan African women ages 16-25 who are at high risk for HIV infection will initiate PrEP and achieve sufficient adherence, using scalable adherence support interventions, to achieve HIV prevention benefits from this promising biomedical prevention intervention.
Design	Open label study
Location	Clinical HPTN research sites in Hillbrow (WRHI) and Cape Town (DTHF), South Africa and suburban Harare (UZ-UCSF), Zimbabwe
Population	Adolescent girls and young women, 16-25 years old; Target number of enrollees: 400
Results	Expected July 2018
Next research question or implementation they are undertaking as a result of study result	Secondary objectives: - Assess the reasons for eventual PrEP acceptance among women who initially decline PrEP at enrollment but elect to accept PrEP during follow up.

	- Assess correlates of early and delayed acceptance of PrEP, including socio-demographic factors, individual-level and partner-level characteristics, and risk practices. - To assess correlates of PrEP adherence at Weeks 13, 26, and 52, after adjusting for study arm - Assess the proportion of young women who discontinue PrEP, timing of discontinuation, and factors associated with PrEP discontinuation. - Assess the specificity and predictive value of a PrEP readiness tool [based on the HIV Prevention Readiness Measure (HPRM) and PrEP Beliefs Measure (PBM)] to predict uptake and adherence to oral PrEP. - Explore qualitative factors that influence women's decisions to use PrEP, to adhere to PrEP, and acceptability of PrEP in the first 3 months after PrEP acceptance. - Compare adverse events between young women taking PrEP and young women who are not taking PrEP. - Assess HIV incidence in those who accept PrEP compared to those who do not, and to assess the association with detectable TFV in PrEP users who acquire HIV infection during the study.
Timing	Study is planned: 06/2016-08/2018
Other relevant information	- Study includes exploratory objective being modeled: To estimate the potential impact of PrEP use on HIV acquisition in young African women. - Collecting data on behavioral covariates: partnership characteristics and partner HIV status, sexual behaviors, HIV risk perception, HIV stigma - Collecting data on HIV seroconversion - Collecting data on individual-level characteristics: social support, depression, alcohol and drug use, history of intimate partner violence. Social impacts (benefits and harms) to be collected and reported and every effort will be made to provide appropriate counseling as necessary and/or referral to appropriate resources.

Name of Study	**Right to Care (Demonstration Project under DREAMS)**
Organization	Sponsored by PEPFAR/BMGF/Nike Foundation
Purpose of study (hypothesis or theory)	Proposed demonstration project under the DREAMS partnership, to reduce HIV infections among AGYW- which includes efforts to address poverty, gender inequality, sexual violence, lack of education and PrEP.
Design	Demonstration project
Location	Johannesburg and Mpumalanga, South Africa
Population	Adolescent girls and young women, <24 years old
Results	TBD
Timing	Study is planned

Name of Study	**Senegal Demonstration Project**
Organization	Sponsored by BMGF and conducted by Reseau Africain De Recherche Sur Le SIDA
Purpose of study (hypothesis or theory)	Hypothesis: - A sustainable HIV PrEP program for FSW in Dakar, Senegal is feasible - It is feasible to provide daily oral PrEP with FTC/TDF for 12 months to FSW at MoH run clinics (Pikine, Mbao, Rufisque and Diamniadio Health Centers) in Dakar.
Design	Demonstration project do we have enrolment numbers
Location	Public general health clinics in Dakar, Senegal
Population	FSW, >18 years old; Target number of enrollees: 350
Results	Expected by March 2017
Next research question or implementation they are undertaking as a result of study result	Develop policy recommendations and guidelines for best practice for service delivery to support the wider introduction of PrEP for FSW in Senegal.

Timing	Study is ongoing: 04/2014-12/2016
Other relevant information	- Depending on availability of funds, may undertake costing analysis to explore feasibility of integrating PrEP within STI clinics where FSW are followed. - Collecting data on sexual behavior: sexual activity, risk perception, contraceptive use, alcohol and drug use. - Collecting data on PrEP adherence and acceptability: MEMS cap data, pill count, self-reports, blood measures.

Name of Study	**Sisters Antiretroviral therapy Programme for Prevention of HIV –an Integrated Response (SAPPH-Ire)**
Organization	Sponsored by DFID/UNFPA and conducted by (CesHHAR)
Purpose of study (hypothesis or theory)	- To enhance HIV treatment and prevention among highway-based sex workers at seven sites by increasing uptake and frequency of testing, demonstrate acceptability and feasibility of delivering PrEP, maximize retention in care, promote timely initiation of ART for those eligible, and maximize adherence to both ART and PrEP. - Hypothesize that this targeted and dedicated approach to the delivery and support of HIV testing, PrEP and ART will reduce the proportion of sex workers who are infectious with HIV in comparison with the current WHO-guideline standard services offered to sex workers with referral to government ART clinics. This effect will come about through decreasing incident HIV infection, time before HIV-infected SWs are diagnosed, and time to initiation of ART, and by increasing adherence and retention in care.
Design	Demonstration project
Location	Zimbabwe
Population	FSW, 15-24 years old; Target number of enrollees: 1,000 – 1,500
Results	TBD
Timing	Study is ongoing

Name of Study	**The TAPS Demonstration Project**
Organization	Sponsored by the BMGF and conducted by Wits reproductive Health Institute
Purpose of study (hypothesis or theory)	To evaluate whether oral PrEP and immediate treatment can be rolled out within a combination prevention and care approach tailored to needs of 400 HIV-negative and 300 HIV-positive female sex workers.
Design	Advocacy, demonstration project (trial), implementation science research, modelling, observational cohort study, policy guideline support study
Location	Study sites include: FSW Programme within existing Public Sector and NGO clinics in the RHI Research Centre, Hillbrow, Johannesburg and Sediba Hope Clinic, Pretoria, South Africa
Population	FSW, >18 years old
Results	First publication of year 1 data is imminent
Next research question or implementation they are undertaking as a result of study result	Assessment of cost and other resource implications to model cost effectiveness of integrating PrEP and immediate treatment into existing HIV prevention and care services. Also combine data with existing data sets from previous local studies to model the impact of PrEP and immediate treatment on the HIV epidemic.
Timing	Study is ongoing: 03/2015-04/2017
Other relevant information	- Collecting data on sexual behavior: partner type, frequency of sex, use of contraception and STI prevention methods, disclosure. - Collecting data on adherence: questionnaires, in-depth interviews, drug levels, clinic attendance. - Collecting social determinants data: migration, experiences of violence and stigma, social support, engagement with other supportive services.

Name of Study	UNICEF PrEP Demo Program
Organization	Sponsored by UNITAID and conducted by the Desmond Tutu HIV Foundation
Purpose of study (hypothesis or theory they are testing)	Increase accessibility of PrEP for eligible adolescent population in the project implementation areas, demonstrate effective use of PrEP among adolescents enrolled on the project; and, generate knowledge on the use of PrEP by eligible adolescents shared.
Design	Demonstration project
Location	Western Cape, Gauteng, KwaZulu-Natal, South Africa (Belo Horizonte, Salvador and Sao Paulo, Brazil; Bangkok, Chiang Mai, Maha Sarakham and Sogkhla, Thailand)
Population	Sexually active adolescents, 15-19 years old, Target number of enrollees: 2,500 in Brazil, 10,000 in South Africa, 2,500 in Thailand
Results	TBD
Timing	Planned: End 2016-2021
Other relevant information	- The project will address regulatory, structural and capacity challenges in offering PrEP to adolescents, thus expanding availability and use of PrEP - Test different models for improving adherence including adherence improvement self-management strategies, SMS reminders, PrEP peer brothers and sisters, support groups, resilience support, m-Health and the use of social media. - Map available technical capacities to implement PrEP among adolescents as well as the HIV expenditure on PrEP within national HIV programs.

Name of Study	3Ps for Prevention Study (Perception, Partners, Pills)
Organization	Sponsored by the BMGF/NIH and conducted by the Desmond Tutu HIV Foundation
Purpose of study (hypothesis or theory)	- Phase 1: Enumerate the demand for PrEP and describe the characteristics of PrEP uptake and initiation among young South African women in the context of a PrEP social marketing campaign in Masiphumelele township. - Phase 2: To assess the effect of an incentive provided at months 2 and 3 and conditioned on young women's PrEP adherence, measured by Tenofovir drug levels at 1 and 2 months after initiating PrEP.
Design	Demonstration project; observational cohort study, open label
Location	Research centers in Cape Town, South Africa
Population	AGYW, 16-25 years old; Target number of enrollees: 200
Results	TBD
Next research question or what implementation they are undertaking as a result of study result	- Secondary objectives: Explore factors, including knowledge of current partner HIV status, that influence young women's PrEP initiation and adherence over 12 months. 2. To assess social benefits and harms associated with PrEP use. - Exploratory objective: Assess HIV incidence among PrEP users, and PrEP adherence and viral resistance among women who seroconvert.
Timing	Study is planned: expected start 11/2016
Other relevant information	- Behavioral data will be recorded.

OTHER RESEARCH (OPEN LABEL EXTENSION STUDIES, IMPLEMENTATION SCIENCE, ETC.)

Name of Study	POWER (Prevention Options for Women Evaluation Research)
Organization	Sponsored by USAID and conducted by University of Washington
Purpose of study (hypothesis or theory)	Develop cost-effective and scalable models for implementation of ARV-based prevention products for women
Design	Implementation science research, observational cohort study, open-label
Location	Public and private family planning clinics, testing centers, general health clinics and NGOs in Kisumu, Kenya; Johannesburg and Cape Town, South Africa
Population	AGYW, 16-25 years old. Target number of enrollees: 1,500 Kenya, 1,500 South Africa
Results	Expected in 2019 with preliminary data sooner
Next research question or implementation they are undertaking as a result of study result	- Conduct formative research, focusing on motivators and obstacles for initiation of and adherence to microbicides and PrEP, in order to develop effective communication and decision tools and delivery strategies that meet women's needs. - Establish open prevention cohorts of HIV-uninfected women and pilot scalable microbicide and PrEP adherence support and delivery strategies. From the formative work, design coordinated pilot activities to evaluate optimized adherence support and effective delivery models for PrEP and microbicides. - Conduct costing and cost-effectiveness analyses and modeling of successful piloted delivery approaches. Identify optimized packages for multiple contexts. - Disseminate findings and provide technical assistance. Translate successful approaches to deliver microbicides and PrEP for African women at risk to programmatic settings.
Timing	Study is ongoing: 07/2015-06/2020
Other relevant information	Focus is on real-world implementation therefore collection of behavioral data is minimal.

Name of Study	DOMA (Development and Validation of Self-Reported Measures for Vaginal Ring Adherence)
Organization	Wits RHI
Purpose of study (hypothesis or theory)	To develop and validate self-reported measures for vaginal ring adherence.
Design	Two-stage formative research study including: 1) consultations and cognitive interviews, and 2) a cross-sectional survey
Location	South Africa
Population	Clinical trial staff and community opinion leaders 2) Women, aged 18 and older, who have exited from a clinical trial testing the safety and/or effectiveness of a contraceptive or HIV prevention product, including a vaginal ring, a vaginal gel or oral pre-exposure prophylaxis (PrEP) 3) Women, aged 18-45, drawn from communities in which clinical trial(s) took place, but who have not participated in a clinical trial.
Results	Planned
Timing	Planned

Name of Study	Community-based girl-centered programming
Organization	Population Council, sponsored by BMGF and PEPFAR
Purpose of study (hypothesis or theory)	How effective is community-based girl-centered programming at 1) identifying and reaching the most vulnerable AGYW; 2) linking AGYW to and retaining them in services plus reducing their HIV risk (costing component included)

Design	Community based assessment; program impact
Location	Kenya, Zambia
Population	AGYW and their influencers
Results	Information to come
Timing	Study is ongoing

Name of Study	**Male partner study**
Organization	Population Council, sponsored by BMGF and PEPFAR
Purpose of study (hypothesis or theory)	1.) From the perspective of male partners, what are the sexual dynamics with AGYW, and their HIV risk understanding? What are the profiles of male partners of AGYW in different 'hot spots'? 2.) What programs successfully link male partners of AGYW with clinical HIV services? Were the 'right' men reached?
Design	Exploratory study and program evaluation
Location	South Africa, Swaziland, Uganda
Population	AGYW and their influencers
Results	Information to come
Timing	Planned

Name of Study	**PrEP for AGYW**
Organization	Population Council, sponsored by BMGF and PEPFAR
Purpose of study (hypothesis or theory)	To assess 1.) what are key considerations for introducing PrEP for AGYW? and 2.) What are lessons from projects rolling out PrEP in 'real world' settings?
Design	Feasibility/acceptability; program evaluation
Location	Tanzania, Kenya and/or Uganda
Population	AGYW
Results	Information to come
Timing	Planned

Name of Study	**CAPRISA 082**
Organization	Sponsored by USAID/CAPRISA and conducted by CAPRISA
Purpose of study (hypothesis or theory)	- Identify risk factors for HIV acquisition in healthy young women. - Measure the acceptability of, uptake and adherence to the range of behavioral and biomedical prevention options, including PrEP (when available). - Measure HIV and other STI incidence rates. - Assess trends in sexual behavior. - Measure pregnancy rates.
Design	Observational cohort study
Location	CAPRISA research sites in Umgungdlovu and eThekwini Districts, South Africa
Population	AGYW18-30 years old; Target number enrollees: 2,500
Results	Publish date not known, interim data may be available Q3/4 2017
Timing	Study is ongoing: 3/2016-4/2021
Other relevant information	- Collecting data on sexual behavior, HIV risk perception, risk reduction methods, alcohol/drug consumption - Collecting data on acceptability of expanded HIV prevention options including perceptions of ease of use. - Collecting blood and genital specimens to assess risk exposure, PrEP adherence and Tenofovir resistance in sero-converters.

Name of Study	IMPAACT 2009 (DAIDS ID 30020): Pharmacokinetics, Feasibility, Acceptability and Safety of Oral Pre-Exposure Prophylaxis for Primary HIV Prevention during Pregnancy and Breast Feeding in Adolescents and Young Women
Organization	Sponsored and conducted by IMPAACT Network
Purpose of study (hypothesis or theory)	- Designed to characterize adherence over time among women who initiate once daily oral PrEP during pregnancy and continue in the first 6 months following delivery, and to compare pregnancy outcomes among women who take PrEP and women who decline PrEP during the antenatal period. - To determine TVF-DP thresholds associated with optimal adherence to FTC/TDF.
Design	Observational study
Location	Clinical research sites in Zimbabwe, South Africa, Malawi, Uganda
Population	AGYW, 16-24 years old; Target number of enrollees: 200
Results	TBD
Next research question or implementation they are undertaking as a result of study result	Secondary objectives: - Identify individual, social, and structural barriers and facilitators to PrEP uptake during pregnancy, and to adherence and continued use at different time points during pregnancy and breastfeeding. - Compare reported sexual risk behavior and incidence of sexually transmitted infections among women who initiate PrEP during pregnancy and those who decline PrEP over the observation period. - Compare HIV incidence in women who initiate PrEP during pregnancy and those who decline PrEP over the observation period. - Compare antiretroviral drug resistance among mothers and infants who acquire HIV with and without exposure to FTC/TDF for PrEP.
Timing	Study is planned, expected start Q1 2017
Other relevant information	- Collecting data on sexual behavior and practices - Collecting data on acceptability - Collecting data on adherence through DBS testing with near real-time feedback to inform adherence counseling

Name of Study	MTN-034/IPM 045
Organization	Sponsored by MTN/IPM/NIH/NIAID/NIMH/NICHD
Purpose of study (hypothesis or theory)	- Assess preference at beginning of study (after counseling and being shown Truvada and the dapivirine vaginal ring). - Assess change in preferences over 6 months after each phase of oral PrEP or dapivirine vaginal ring. - Assess choice of product after using both oral PrEP and dapivirine ring. - Collect safety and adherence data.
Design	Open label
Location	Clinical research sites in Johannesburg (WRHI), Emavundleni, Chatsworth, South Africa; Kisumu, Kenya; Spilhaus, Zimbabwe
Population	AGYW, 16-21 years old; Target number of enrollees: 300
Results	TBD
Timing	Study is planned, expected start: Q1 2017
Other relevant information	- Includes adherence support program - Behavioral questionnaires in development - Adherence may be assessed through PK levels, drug residue in rings and possible hair samples.

Name of Study	MTN 032
Organization	MTN
Purpose of study (hypothesis or theory)	MTN-032 is an exploratory sub-study of the ASPIRE and HOPE trials that will explore socio-contextual and trial specific issues which affected participants' adherence to the dapivirine vaginal ring.
Design	Utilizes qualitative in-depth interviews (IDIs) and focus-group discussions (FGDs)
Location	Malawi, South Africa, Uganda, Zimbabwe
Population	Women
Results	January 2018
Timing	Ongoing
Other relevant information	Study measures: - Factors affecting product use adherence - Socio-contextual and trial specific issues which affected participants' adherence to the dapivirine vaginal ring (VR) will be captured by IDI and/or FGD. - Perceptions of HIV risk - HIV risk and perceptions of HIV risk in general and specific to their motivation to participate in the ASPIRE and/or HOPE trial(s) and to use study product (or not) during their participation in ASPIRE and/or HOPE will be captured by IDI and/or FGD. - Product use patterns - Factors influencing product initiation and patterns of use during ASPIRE and/or HOPE will be captured by IDI and/or FGD. - Perceptions of various adherence support interventions - Participants' perceptions of various adherence support interventions and engagement activities implemented (or not implemented) during ASPIRE and/or HOPE will be captured by IDI and/or FGD. - Understanding of ASPIRE results and ring efficacy - Participants' understanding of the ASPIRE results and ring efficacy, and the impact of this understanding on their intention and/or ability to join HOPE and continue in follow-up, and on their adherence to the dapivirine VR as part of an open label extension trial as compared to adherence in a Phase 3 safety and effectiveness trial will be captured by IDI and/or FGD.

Name of Study	UChoose (part of CHAMPS)
Organization	Desmond Tutu HIV Centre
Purpose of study (hypothesis or theory)	This study will enroll sexually active, healthy HIV-negative girls aged 16-17 to assess and compare the acceptability and preference for a monthly vaginal ring, bi-monthly injectable contraception or daily dose oral contraception, as proxy for female-controlled ARV-based HIV prevention methods.
Design	Examining female preferences for method of PrEP delivery through the use of different contraceptive options (oral, injectable and vaginal ring)
Location	South Africa
Population	150 adolescent girls aged 16 and 17 years
Results	Not yet published
Timing	Ongoing

Name of Study	Community Health clinic model for Agency in Relationships and Safer Microbicide Adherence (CHARISMA)
Organization	Sponsored by USAID and conducted by RTI International
Purpose of study (hypothesis or theory they are testing)	To support women's agency to safely use ARV-based prevention products and reduce vulnerability to intimate partner violence, by identifying improved approaches to measure and address the beneficial impacts and harmful social effects–particularly IPV–of microbicide use; developing and pilot testing the CHARISMA intervention designed to increase women's agency to consistently and safely use microbicides and mitigate

	IPV; and disseminating knowledge generated and promote uptake of promising practices for future microbicide and multipurpose prevention technology (MPT) implementation projects.
Design	Implementation science
Location	South Africa, potential scale-up in Malawi, Uganda, Zimbabwe
Population	Women, 25 years and older
Results	TBD
Next research question or what implementation they are undertaking as a result of study result	Inform development of a novel social benefits-harms tool that will facilitate assessment of and response to the range of positive and negative effects of microbicide use experienced by these women.
Timing– or next steps for market manager	Study is ongoing: 2015-2020

Name of Study	MTN 031/IPM 043
Organization	DAIDS/NICHHD/NIMH, NIH
Purpose of study (hypothesis or theory)	To determine if a financial incentive conditional on the prior month's product use promotes adherence to a silicone elastomer vaginal matrix ring containing 25 mg of dapivirine, when inserted once every 4 weeks. Another primary purpose of this study is to assess what effect, if any, the provision of adherence results has on participant adherence.
Design	Open label trial Participants will be randomized (1:1:1) to one of three groups: - Group 1: Participants receive adherence feedback and a financial incentive if adherent to study product - Group 2: Participants receive adherence feedback, but no financial incentive - Group 3: Participants do not receive adherence feedback, nor a financial incentive - Participants will attend monthly study visits for a total of 12 months. It is anticipated that this study will take approximately 9-12 months to enroll the target sample size.
Location	South Africa, Malawi
Population	Women 18-45; Target number of enrollees: 450
Results	Planned
Timing	Planned

MODELING, POLICY RESEARCH

Name of Study	Global Evaluation of Microbicide Sensitivity (GEMS)
Organization	Sponsored by USAID and conducted by University of Pittsburgh
Purpose of study (hypothesis or theory)	To better characterize risk of resistance with topical ARV-based microbicides and PrEP agents and the possible effects on future HIV treatment options; model and analyze potential public health harms, benefits, and costs of different intervals and requirements for HIV testing for users of microbicides in resource-constrained settings; develop and evaluating evidence-based policy recommendations for the frequency of HIV testing and resistance monitoring; and monitor sero-converters in ARV-based prevention programs for resistance.
Design	Mathematical modelling, policy development
Location	Kenya, South Africa, Zimbabwe
Population	AGYW
Results	TBD
Next research question or implementation they are undertaking as a result of study result	Inform policies and define programmatic considerations related to use of ARV-based HIV prevention products and risk of resistance.
Timing	Study is ongoing: 2015-2020

Other relevant information	- Laboratory studies: Comprehensively characterize resistance risk as learned from clinical trials and demonstration studies to understand the duration of time an infected person can be on product before resistance is selected as well the impact of resistance on response to future ART regimens. - Mathematical Modeling: Use mathematical modeling to identify the most effective and efficient HIV testing and resistance monitoring strategies during PrEP roll-out. - Policy Development: Generate policy recommendations for HIV diagnostic testing frequency and ARV resistance monitoring based on laboratory and modeling data. - Resistance Monitoring During Roll-Out: Monitor seroconverters from PrEP roll-out program for ARV resistance in selected clinics in South Africa, Zimbabwe and Kenya.

COMPLETED PROJECTS (OTHER)

Name of Study	Gender-Specific Combination HIV Prevention for Youth in High Burden Settings (MP3-Youth)
Organization	Sponsored by the NIH and conducted by New York University
Purpose of study (hypothesis or theory)	To evaluate the feasibility and acceptability of a gender-specific combination HIV prevention package for youth in high burden settings.
Design	This demonstration project will pilot a combination package of gender-specific interventions in western Kenya in a mobile health delivery format using integrated services delivery. Interventions include: Male-Specific Intervention Package (HIV counseling and testing; facilitated linkage to care for HIV-positive; condoms; VMMC); Female-Specific Intervention Package (HIV counseling and testing; facilitated linkage to care for HIV-positive; contraception/family planning; PrEP; conditional cash transfer).
Location	Public family planning clinics, public general health clinics and mobile clinics in Kenya
Population	AGYW, adolescent men, 15-24 years old (only enrolling adolescent female arms on PrEP), Target number of enrollees: 50
Results	Available November, 2016
Next research question or implementation they are undertaking as a result of study result	Phase 2 of the study is modelling and primarily focused on determining the most cost effective and efficacious combinations of HIV prevention interventions for male and female youth.
Timing	Study is completed: 11/2015-04/2016
Other relevant information	Data was collected on sexual behaviors, attitudes, sexual histories, characteristics of sex partners, risk behaviors, SES, attitudes about HIV interventions.

Name of Study	Building Evidence to Guide PrEP Introduction for Adolescent Girls and Young Women
Organization	Population Council, funded by BMGF
Purpose of study (hypothesis or theory)	To provide DREAMS country teams with practical guidance on building evidence to guide PrEP introduction for AGYW.
Design	Guidance for DREAMS
Population	Women
Results	Advocacy and communication tools that can eventually be adapted locally to meet the needs of specific audiences, including potential microbicide providers, end users, and their partners.
Timing	Completed

Name of Study	Communicating about Microbicides with Women in Mind
Organization	FHI 360, funded by USAID

Purpose of study (hypothesis or theory)	Key communication and audience-specific processes, messages and materials that assist country-level policy makers and program implementers in planning for the potential, future introduction of vaginal microbicide gels so they are accessible to women.
Design	- A framework and set of procedures that could assist local country planners to plan and implement communication activities related to potential introduction of topical/vaginal microbicide gels (or other ARV-based prevention products) so that women may use them - Messages and materials, tailored to the needs of women in different sexual and/or HIV risk contexts, that could be used to generate interest in microbicides if/when new microbicide options become available - Materials and processes that assist health care providers in a range of health settings to identify and counsel women at high risk of HIV about the potential use of new, female initiated technologies
Population	Women
Results	Advocacy and communication tools that can eventually be adapted locally to meet the needs of specific audiences, including potential microbicide providers, end users, and their partners.
Timing	Completed

VI. END-USER STAKEHOLDER INTERVIEW NOTES - WHAT WE'RE HEARING

Below is a topline summary of key points/topics stakeholders discussed during interviews focused on the end user (AGYW) and HIV prevention. The list below is not exhaustive and is not representative of the depth of knowledge and discussion during the interviews, but portrays the topics and areas of understanding by key stakeholders.

COMMUNICATIONS

National Campaign

- VMMC campaigns and female condom campaigns (nationwide ads, posters, TV/radio spots) are effective when national and local contexts are taken into consideration (i.e., language used, images and messages have different meaning in different geographic settings). Effectiveness of national campaigns varies.

Social media (& print media)

- Print materials do not resonate with AGYW (i.e., archaic).
- Anonymous platforms for information sharing are widely used (i.e., mobile phones are often shared, thus the need for anonymity when accessing HIV prevention information and services).
- Different access to phones/social media use in different high-risk groups (i.e., some high-risk groups lack access to mobile phones, while others share phones among a group).
- Messages should be decoupled from HIV, social media about sex, relationships or other issues broadly resonates with AGYW.
- Social media can be used to cultivate the "feel" of the service/product and as a non-judgmental space.

COMMUNITY INTERVENTIONS & ENGAGEMENT (INFLUENCERS IN COMMUNITY)

- Layers of community influencing health decision making (i.e., male partners, health practitioners, family all have different levels and types of influence).

Community Campaigns

- Need to move away from "girl-centric" approaches to "community oriented" to ensure broad community buy-in.

Family

- Family is not always important in the decision to use PrEP, but is important in decision to *not* use PrEP (i.e., privacy).

Local celebrities / peers

- Local "celebrity" endorsement of PrEP (i.e., celebrity means those that the AGYW in the community look up to and respond to, possibly older women, local actresses/musicians, or boys) can have a large influence on AGYW PrEP use.

HCWs (providers and all clinic/site staff)

- Influence comes from every staff member who interacts with AGYW, not just doctor/nurse. For example, the receptionist, intake worker, etc.
- Youth-friendly staff/services are important to ensure uptake and especially, retention.
- Providers heavily influence awareness, knowledge and use of a product.

END USER (AGYW)

- AGYW have a low perception of HIV risk, but an interest in overall wellbeing and health
- High levels of violence are experienced nearly daily by many AGYW. Muggings and assault are not atypical to an AGYW's daily life.
- Most, if not all, high-risk AGYW engage in "survival sex," and may be classified by clinics as sex workers.

PRODUCT CHARACTERISTICS (INCL. BRANDING/PACKAGING)

- Product Characteristics for oral PrEP could be addressed that resonate with AGYW: disassociate with HIV; co-packaging in a wellness kit with contraceptive; size of pill; texture of pill; the need for anonymity and minimizing of rattling noise; color of pill same as treatment; pill bottle size and same as HIV treatment bottle.
- Other products: many AGYW have a fear of needles when presented with the choice to use depo; implant side effects and myths have affected uptake and adherence in South Africa (i.e., some AGYW are pulling out the implant due to the side effects in the first few weeks).

DELIVERY CHANNEL

- Distance to the delivery setting is a key challenge many AGYW face.
- Co-location with other services (i.e., family planning) is desirable.
- AGYW are more likely to go receive services when HIV prevention is not associated with HIV treatment services or near an HIV clinic.