

OPTIONS CONSORTIUM: Optimizing Prevention Technology Introduction On Schedule

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FSG
LSHTM
LVCT Health
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Submitted by FHI 360



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ABBREVIATIONS AND ACRONYMS

AGYW	Adolescent Girls and Young Women
ARV	Antiretroviral
ART	Antiretroviral Therapy
BMGF	Bill and Melinda Gates Foundation
CDC	Centers for Disease Control and Prevention
CeSHHAR	Centre for Sexual Health and HIV AIDS Research
CHAI	Clinton Health Access Initiative
CHARISMA	Community Health Clinic Model for Agency in Relationships and Safer Microbicide Adherence
CII	Center for Accelerating Innovation and Impact
CROI	Conference on Retroviruses and Opportunistic Infections
DREAMS	Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe women
EMOTION	Enhancing Microbicide Uptake in High-Risk End Users
FSW	Female Sex Worker
GEMS	Global Evaluation of Microbicide Sensitivity
HSS	Health System Strengthening
ICASA	International Conference on AIDS and STIs in Africa
IPM	International Partnership for Microbicides
IS	Implementation Science
KII	Key Informant Interview
LSHTM	London School of Hygiene and Tropical Medicine
M&E	Monitoring and Evaluation
MOH	Ministry of Health
MOHCC	Ministry of Health and Child Care
MPii	Microbicide Product Introduction Initiative

ABBREVIATIONS AND ACRONYMS (cont.)

MSM	Men Who Have Sex With Men
NACC	National AIDS Control Council
NASCOP	National AIDS and STI Control Programme
NDOH	National Department of Health
NGOs	Nongovernmental Organizations
NIH	National Institutes for Health
OGAC	Office of the US Global AIDS Coordinator
OHA	Office of HIV/AIDS
OPTIONS	Optimizing Prevention Technology Introduction ON Schedule
PAC	Project Advisory Committee
PHSC	Protection of Human Subjects Committee
POWER	Prevention Options for Women Evaluation Research
PI	Principal Investigator
PMEP	Performance Monitoring and Evaluation Plan
PrEP	Pre Exposure Prophylaxis
PSI	Population Services International
QI	Quality Improvement
SANAC	South African National AIDS Council
SAPPH-IRe	Sisters Antiretroviral Therapy Programme for Prevention of HIV- an Integrated Response
SLG	Strategic Leadership Group
SW	Sex Worker
TA	Technical Assistance
TB	Tuberculosis
T&T	Test and Treat

ABBREVIATIONS AND ACRONYMS (cont.)

TOR	Terms of Reference
TWG	Technical Working Group
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
WHO	World Health Organization

EXECUTIVE SUMMARY

This semi-annual report documents the activities and accomplishments of the Optimizing Prevention Technology Introduction ON Schedule (OPTIONS) Consortium, USAID Cooperative Agreement AID-OAA-A-15-00035 during the reporting period, October 1, 2015 - March 31, 2016.

The four objectives of OPTIONS are to 1) develop evidence-based business cases and a coordinated investment strategy for ARV-based prevention product introduction; 2) support country level regulatory approval, policy development, program planning, marketing and implementation strategies for ARV-based prevention product introduction; 3) facilitate and conduct implementation science (IS) to advance the introduction of and access to microbicides and ARV-based prevention technologies; and 4) provide technical assistance and support for health systems strengthening (HSS) with rapid use of data to identify and address implementation bottlenecks throughout the value chain. The OPTIONS Consortium outlines five primary activities in year one- corresponding to each objective listed above and a fifth activity that focuses on extended network collaboration and coordination.

During the six months of the reporting period, the OPTIONS Consortium finalized the administrative start up, established management and communication systems, and hit the ground running in activities one and two. Value chain situation analyses were completed for all three countries (South Africa, Zimbabwe and Kenya), a communications landscape analysis for South Africa was carried out, a modeling gap analysis was conducted and a modeling workplan was developed to address the gaps identified.

OPTIONS in-country partners quickly built relationships with the National Ministries of Health and other key stakeholders. Country specific workplans for year one were developed alongside the ministry and with input from the local USAID mission, and the OPTIONS in-country partners began providing technical assistance to technical working groups and sub-groups as needed. Progress in activities three (IS) and four (HSS) continue to move forward and OPTIONS is working with our counterparts to determine how best to support national working groups in these areas.

Under Activity 5, OPTIONS has taken the lead on providing a forum for an exchange of ideas and information related to PrEP roll out activities. We have established monthly calls with the other four projects that were awarded under the Microbicide Round 3 APS: CHARISMA, POWER, EMOTION, and GEMS, collectively known as the Microbicides Product Introduction Initiative (MPii) projects. An MPii coordination framework was developed in collaboration with USAID and the World Health Organization (WHO) to outline a structure for cross-project coordination and information exchange. The framework includes varying levels of coordination and subcommittees, of which the cross-project end user and modeling subcommittee workstreams are actively engaged. OPTIONS is leading knowledge sharing, communication and coordination outreach activities to projects, funders, product developers, and other stakeholders in the HIV prevention and microbicide field.

PROGRESS TOWARD OBJECTIVES

Activity 1: Development of evidence-based business cases and a coordinated investment strategy for ARV-based prevention product introduction

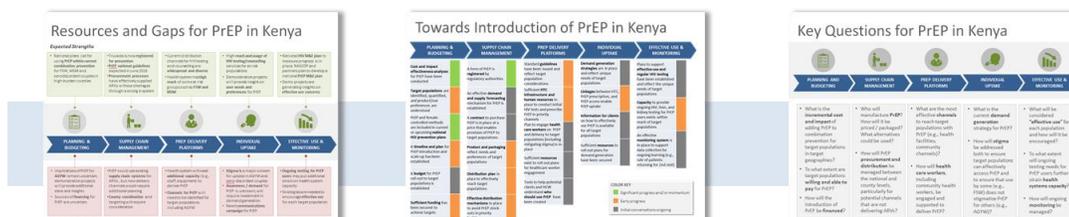
Value chain situation analyses for oral PrEP

Goals of the Value Chain Situation Analyses

- Identify strengths and gaps along the value chain needed to introduce PrEP in each country
- Identify key remaining unknowns for further exploration and decision-making
- Inform stakeholder consultations and planning efforts at country level
- Inform how OPTIONS can best support countries to introduce PrEP

The value chain situation analysis for each country (led by FSG) began in the end of November 2015, when key questions and the template form were developed by the FSG team and sent to country partners. Zimbabwe carried out a desk review to gather this information until USAID mission and ministry buy-in was secured. In addition to the desk review, South Africa and Kenya were able to hold stakeholder consultations to receive direct input and complete the template. Initial drafts of these presentations were prepared by FSG by the end of January 2016. USAID and country partners reviewed the drafts and FSG continued to fine tune the format and structure of the presentations in advance of visits to the Zimbabwe and Kenya USAID missions in February (visits further discussed under Activity 2). Since February 2016, drafts of the situation analyses have been shared with USAID missions and OHA, the other MPii projects, the ministries in Kenya, Zimbabwe and South Africa, Bill and Melinda Gates Foundation (BMGF), and Gilead. In addition to the situation analysis presentation, a collaborative framework (or implementation planning framework) was developed for each country to help guide the planning moving forward (identifying the resources and gaps of each area along the value chain). Country partners will use this tool for planning purposes and keep this tool up to date as policy and guideline planning moves forward. FSG is working on the final updated versions for each country (value chain situation analyses and collaborative frameworks), as well as templates for each. Final deliverables are to be submitted in April 2016 and also made available to the public through www.prepwatch.org following USAID approval and relevant in-country government agreement. See below for examples of the value chain analysis for Kenya.

Sample value chain situation analysis slides for Kenya



Investment scenarios for oral PrEP

While not a part of the OPTIONS year one workplan, early thinking on investment scenarios for oral PrEP began in January 2016 and in March FSG held calls with country partners, Avenir and LSHTM to discuss the utility and direction of these scenarios. At the end of this reporting period FSG was fine tuning the plan for these scenarios for each country, including data sources and availability and applicable timelines.

Demand creation and communication market shaping strategy

McCann Global Health led the development of a communications landscape analysis summarizing the current landscape for potential oral PrEP users (and HIV prevention methods generally) including sex worker, AGYW, and public health provider populations in South Africa. The objective of this landscaping was to develop a comprehensive understanding of existing knowledge around target audiences from a market-based perspective (i.e. understanding audiences as consumers), as well as to reveal gaps in knowledge for further exploration in forthcoming market intelligence activities. OPTIONS and MPii partners suggested literature to include, and key experts and stakeholders were interviewed for the analysis. The communications landscape analysis was presented to and reviewed in depth by OPTIONS leadership and external experts in the field (behavioral scientists working in oral PrEP from FHI 360 and RTI International) during the development phase and finalized in the end of January 2016. The landscape analysis has also been shared with USAID, CAMI Health, the MPii end-user subcommittee, WHO, and product developers (ViiV, Janssen, the International Partnership for Microbicides (IPM), and Gilead). Once gaps in knowledge were identified through the landscape analysis, a market intelligence plan for further communications data collection (qualitative and quantitative) in South Africa was developed and a South African vendor to carry out this work was selected at the end of March 2016.

Modeling activities

The modeling activities began with a review of PrEP modeling literature that was conducted by AVAC with input from Avenir Health. The literature review was completed, summarized and submitted to USAID in December 2015. This work, along with responses to email and phone outreach to other HIV modeling groups, was compiled into a gap analysis identifying what has already been accomplished in PrEP modeling and what PrEP modeling priorities remain. The gap analysis found that, while much modeling has been conducted and is ongoing regarding PrEP, there are gaps in modeling necessary to support/expedite country roll-out in Kenya and Zimbabwe (but not currently for South Africa). The primary immediate needs are to identify appropriate target populations for PrEP and assist the countries in developing targets for PrEP roll-out to these populations, including impact and cost-effectiveness estimates for different roll-out scenarios.

Based on the recommendations from the gap analysis, and in consultation among the OPTIONS modelers and other OPTIONS partners, the modeling group created a workplan for PrEP modeling to be

conducted in Year 1 and started outlining PrEP modeling activities for Year 2. The in-depth dive into the gap analysis to ensure OPTIONS work in this area did not duplicate existing efforts extended the timeline for the development of the modeling workplan (per the OPTIONS Performance Monitoring and Evaluation Plan (PMEP)) from February to March 2016. The workplan was completed on schedule with this revised deadline. The modeling groups agreed that LSHTM would focus on Zimbabwe and Avenir would focus on Kenya. For the remainder of the current project year, both groups will modify existing models (based on findings from the gap analysis) to create preliminary estimates of cost-effectiveness and impact of rolling out PrEP to specific subpopulations within each country and then work with country teams to provide the modeling input necessary for PrEP implementation plans. During Project Year 2 the modeling groups would adapt the models to conduct more detailed analyses on subpopulations based on country-specific data, possibly leading to revised recommendations for program focus.

Go/No-Go decisions

The dapivirine ring trial results were released at the Conference on Retroviruses and Opportunistic Infections (CROI) in February this year. Leading up to this, OPTIONS had met with IPM on several occasions in 2015 and hosted a call with product developers in February 2016 that included IPM, Janssen and ViiV. Given the positive ring results and with input from USAID, various discussions amongst OPTIONS leadership, the Strategic Leadership Group (SLG), OPTIONS country partners, and the other MPii projects are taking place in early April 2016 to discuss the ways in which our work can be adapted to best contribute toward ring next steps.

Activity 2: Support country level regulatory approval, policy development, program planning, marketing and implementation strategies for ARV-based prevention product introduction

The USAID missions had not participated in the development of the Microbicides Round 3 APS or in the awarding of the MPii cooperative agreements, so one of the highest priorities for OPTIONS this reporting period was to work closely with USAID/OHA to engage the USAID missions and ensure that OPTIONS' work would be jointly planned and aligned with mission in-country work and priorities. This engagement process included sharing information about the MPii projects, email and telephonic discussions, and in-person meetings with USAID mission leadership over the course of many months.

Early in the reporting period all country teams developed stakeholder directories that included local country contacts who will be critical to engage with during product introduction activities (government, academics, regulatory bodies, product manufacturers/distributors, NGOs, advocates, etc). Shortly after the completion of the directories, each country partner initiated discussions with stakeholders in local government and with implementing partners to establish buy-in and support for OPTIONS as well as start to think through the specific role that OPTIONS could play within a national technical working group for oral PrEP. While challenging to get these appointments in place, with support of USAID

Washington, OPTIONS' in-country partners were very successful in securing buy-in from national governments and identifying a contributory role for OPTIONS as policy and guideline development moved forward.

Throughout this reporting period, the in-country partners gathered necessary information to support the development of the value chain situation analyses. Information was collected through interviews with local stakeholders including government officials, USAID missions, and those familiar with demonstration projects, as well as desk reviews of published and grey literature, country-level policies and guidelines. Information was provided to FSG for synthesis through phone calls, emails, and written resources.

Most recently, all three OPTIONS countries developed country-specific workplans in collaboration with the national ministries. FSG aided in the development of these workplans through the development of the collaborative framework (or implementation framework, as described in Activity 1 above) which outlined the gaps and next steps as determined by the value chain situation analyses. As of the end of this reporting period, country partners are meeting with national governments and/or the USAID missions to review workplans and receive feedback to ensure they align with and are informed by national and USAID mission priorities.

Truvada was approved by the Medicines Control Council for use as PrEP in South Africa in November 2015, and by the Pharmacy and Poisons Board in Kenya in December 2015. Gilead expects to submit its filing in Zimbabwe during the next reporting period, with support from the OPTIONS in-country partner (Pangaea).

Wits RHI serves as the regional coordinating partner for country-level OPTIONS work. Regional coordination efforts during this reporting period included Wits RHI participating in the Kenya mission visit with LVCT Health, FSG and USAID/OHA in February 2016, and the development of an activity tracking tool across countries. Throughout the reporting period, FHI 360 led bi-monthly calls with country partners and OPTIONS leadership to share information and coordinate activities; these will shift to monthly calls going forward and Wits RHI will convene smaller monthly calls amongst the country team project managers. Country specific progress with oral PrEP rollout during this reporting period is provided below.

[Kenya](#)

Conversations between USAID/OHA, OPTIONS leadership, LVCT Health, and the USAID Kenya mission began in September 2015 and an in-person meeting was held in Nairobi in October 2015 with the OPTIONS Project Director, LVCT Health, USAID/OHA team and USAID Kenya mission team. LVCT Health continued to engage with the USAID mission and met with National AIDS Control Council (NACC) and National AIDS and STI Control Programme (NAS COP) in November 2015. Soon after the national

approval of Truvada for oral PrEP, LVCT Health met again with NASCOP to explore the possible role OPTIONS could play in the development of oral PrEP guidelines and implementation plans.

In February 2016, FSG, the OPTIONS Deputy Director from Wits RHI, and USAID/OHA traveled to Kenya to support LVCT Health when presenting the preliminary results of the value chain situation analysis to the USAID mission and solicit the mission's input on next steps in country. During this visit FSG also gathered input from key decision-makers to further develop the value chain situation analyses. Meetings were held with the FHI 360 Kenya Country Director (Peter Mwarogo), Sex Workers Outreach Programme and the female sex worker (FSW) demonstration project team, Global Communities (regarding DREAMS implementation), and the Principle Investigator (PI) for the Partners Demo Project (Dr. Nelly Mugo). Following the meeting with the USAID mission, the value chain situation analysis was also shared with NASCOP who then prioritized certain activities for immediate action, leading to the development of the OPTIONS in-country workplan for Kenya.

The technical working group for the national ARV guidelines in Kenya is led by NASCOP/CDC. It has established three committees that will respond to the WHO guidance on test and treat (T&T) and oral PrEP, including HIV testing and counseling (OPTIONS/LVCT Health is co-chairing) and the PrEP and treatment committees (OPTIONS/LVCT Health is participating on both). The current timeline for the development of national PrEP guidelines is June 2016, with the development of a PrEP implementation plan to follow shortly thereafter. OPTIONS/LVCT Health will provide technical assistance for the development of the implementation plan for PrEP rollout.

South Africa

Information about the MPii projects and OPTIONS was shared with the USAID South Africa mission in September 2015 and the OPTIONS Project Director met informally about OPTIONS with mission staff (Olarotimi Oladoyinbo) in Johannesburg in October 2015. OPTIONS/Wits RHI engaged early in the project with the South African National Department of Health (NDOH), including OPTIONS SLG Chair Helen Rees meeting with Yogan Pillay, Deputy Director-General at the NDOH, to discuss next steps forward for oral PrEP rollout following the release of WHO Normative Guidance for PrEP in September 2015. The OPTIONS/Wits RHI team has worked closely with the NDOH throughout this reporting period to provide leadership, technical and administrative support for the PrEP technical working group (TWG), and facilitated the engagement of other MPii projects in the TWG.

The first South African TWG meeting was convened in October 2015, and has continued to meet monthly. OPTIONS/Wits RHI has a key coordination role (alongside CHAI) in the South African TWG. Specifically, OPTIONS role within the TWG during this reporting period includes:

- Develop the TWG Terms of Reference

- Write the National Policy and Guidelines Documents, coordinating and incorporating expert feedback and inputs
- Provide technical input into Guidelines development: priority population targeting, PrEP implementation plans
- Contribute to national core curriculum development for service provider (clinicians, counsellors, etc) training materials
- Convene an AGYW Technical Working group to focus on research agenda, evidence gaps, service delivery models for AGYW, communications, and end user needs for this target population
- Compile a PrEP implementation landscape analysis on national and international demonstration projects aimed at PrEP use in AGYW as described below

Key outcomes and decisions made by the TWG in this reporting period are as follows:

- The national strategy will combine both Test & Treat and PrEP guidance.
- Three documents will be developed: national policy, guidelines, and a costed implementation/operationalization plan. The policy and guidelines were initially developed to include all priority populations with a phased implementation, particularly for sex workers, men who have sex with men (MSM) and AGYW. Early in 2016 it was determined that the guidelines would move forward focusing only on sex workers; other populations (first MSM, then AGYW) will be prioritized at a later date (to be determined). The guidelines will be entitled: *Guidelines for Expanding Combination Prevention and Treatment Options for Sex Workers: Oral Pre-Exposure Prophylaxis (PrEP) and Test and Treat (T&T)*.
- The TWG recommended that a sub-committee on AGYW be established to synthesize current research, and identify research gaps as well as lessons learned to make recommendations to the TWG.
- The Deputy President launched the National Sex Worker HIV Plan (2016-2019) in March 2016, with the goal of launching PrEP for sex workers in June 2016. By the end of the reporting period, the initial T&T and PrEP rollout sites were selected and assessed for readiness. OPTIONS is responsible for preparing the communications and provider training materials required for the launch in collaboration with ongoing PrEP and sex worker programs in South Africa.

The AGYW subcommittee convened for the first time in March 2016 and will continue meeting on a monthly basis. The first meeting of this subcommittee aimed to discuss the terms of reference (TOR) for the subcommittee and to start the discussion for determining the data NDOH will need to move forward with PrEP rollout for this population, what information will be learned from the current and upcoming

demonstration and implementation projects, and what gaps will remain. The terms of reference for this working group are under review by the group.

In January 2016, Wits RHI, AVAC and FHI 360 worked to develop a tool to synthesize and analyze information from current and planned oral PrEP demonstration and implementation projects taking place in South Africa. This PrEP implementation landscape analysis was conducted, in response to the AGYW sub-committee request, as a way to assess and summarize PrEP project findings, specific AGYW target populations, locations, and information gaps in a user friendly way. To assist with this summary, AVAC updated and circulated their PrEP landscape analysis questionnaire (a questionnaire that AVAC routinely circulates to PIs for project updates) to the South African demonstration project PIs to collect updated information on these projects and ensure that the scope of questions of interest to the South African TWG was included. Given the lack of response by several projects and to try to gain a more in-depth look at the current demonstration projects ongoing in the country, Wits RHI has been conducting site visits and interviews with demonstration program managers and practitioners. In these interviews, OPTIONS is confirming data already provided, or obtained through a desk analysis, and asking in-depth questions in areas such as project status, recruitment, target population, service delivery, data collection (types, timeline), and tools developed. Through this process additional demonstration projects have been identified and included in the PrEP implementation landscape analysis. These activities will continue into the next reporting period.

Zimbabwe

Conversations between USAID/OHA, OPTIONS leadership, Pangaea, and the USAID Zimbabwe mission began in September 2015, including an in-person meeting in Harare between OPTIONS/Pangaea and the USAID Zimbabwe mission team. Pangaea continued to engage with the USAID mission through the subsequent months, sharing information via email and telephonically. Pangaea also reached out to the CESHAR/SAPPHIRE project and PSI (USAID/DREAMS main implementing partner) at the mission's request to share information about OPTIONS and promote collaboration with other PrEP initiatives in country. In February 2016, a face-to-face meeting was held in Harare with the USAID mission, USAID/OHA, OPTIONS FSG and Pangaea teams. The draft value chain situation analysis was reviewed and the mission encouraged OPTIONS to move forward in supporting national efforts for PrEP rollout.

While awaiting mission guidance and support for OPTIONS to initiate activities in Zimbabwe, the Pangaea team continued to engage with the Ministry of Health and Child Care (MOHCC) through their other organizational work/roles in country, and learned of MOHCC's plans to form/re-constitute a guidelines adaptation committee. This committee will serve as the TWG for the policy guidelines adaptation work related to the 2015 WHO Normative Guidance, including adapting the guidelines on PrEP for Zimbabwe. In this context, the MOHCC asked Pangaea to co-chair the PrEP subcommittee and lead the guideline development process for PrEP. Hence, and now with USAID mission support and encouragement, Pangaea is well placed to identify ways that OPTIONS can contribute substantively to

PrEP rollout in Zimbabwe. The first meeting of the guidelines adaptation committee was held in March 2016. At this meeting, the MOHCC developed terms of reference and set up sub-committee working groups, of which PrEP is one. There have been several meetings held that have started the PrEP guideline development process with OPTIONS/Pangaea co-chairing the process with the MOHCC. Guidelines on PrEP in Zimbabwe are on target to be completed and approved by July 2016.

Activity 3: Facilitate and conduct implementation science (IS) to advance the introduction of and access to microbicides and ARV-based prevention technologies

Implementation Science

During this reporting period, country partners began thinking about implementation science through stakeholder discussions around oral PrEP during the development of the value chain situation analysis and also per TWG requests (as per PrEP implementation landscape analysis conducted in South Africa in Activity 2 above). Consortium level strategic thinking on implementation science will take place in the next reporting period.

Process Documentation

During this reporting period, OPTIONS initiated our ongoing process evaluation of the efforts undertaken by the Consortium to support product introduction and roll-out, and to explore how these efforts vary across the three OPTIONS countries, which are at different levels of preparedness for PrEP introduction. At the beginning of this reporting period, FHI 360 designed a process documentation data collection instrument that was organized around project milestones. At the end of each quarter, Consortium members were asked to use the tool to report on their activities during that quarter. FHI 360 is currently reviewing and synthesizing data from the process documentation, and will develop best practices and share lessons learned across the Consortium as these findings emerge.

Related to process documentation and best practices, the USAID Center for Accelerating Innovation and Impact (CII) asked the OPTIONS team to provide input on ways their Idea to Impact scale-up framework could be customized and applied to oral PrEP and microbicides. Several members of the OPTIONS team met with the USAID CII staff, including FSG who gave an overview of the value chain situation analysis approach implemented by OPTIONS.

Activity 4: Provide technical assistance and support for health systems strengthening (HSS) with rapid use of data to identify and address implementation bottlenecks throughout the value chain

ARV-Based Product Introduction Clearinghouse

AVAC continued to build out its PrEPWatch website (www.prepwatch.org) with existing and new information, tools and resources to create an ARV-based product introduction clearinghouse. The



The [USAID-Supported Initiatives](#) web page on PrEPWatch offers an overview of all five MPii projects.

at the beginning of April 2016. Additionally, new pages were created, including a landing page that offers an overview of the MPii projects. Country close-up pages for Kenya, South Africa and Zimbabwe offer details about oral PrEP introduction, dapivirine ring engagement, and OPTIONS activities as applicable. Site architecture will continue to evolve and new pages will be created as additional materials are developed by the MPii projects, including an anticipated end-user or demand creation web page.

Interactive map: AVAC worked with the web developer to add Kenya, South Africa and Zimbabwe to the interactive map on the PrEPWatch home page. The interactive map was launched in mid-February and will click to the country close-up pages beginning in early April 2016.

Password protected portal: AVAC conducted an assessment with MPii project leads and determined that there was a need for a password-protected portal where materials not yet approved for public dissemination could be shared among MPii projects. It will be a landing page on PrEPWatch that is accessible via password only. From the landing page, users link to a Google Drive, organized with folders. Here, MPii projects may upload documents and materials. The portal will be finalized and invitations sent to MPii projects and USAID contacts at the beginning of April 2016.

[Health Systems Strengthening \(HSS\) Activities](#)

USAID/OHA and OPTIONS leadership began discussions on the HSS workstream in December 2015, building off a summary of HSS activities across MPii workstreams developed by USAID/OHA (Nagesh Borse). The value chain situation analyses led by FSG, while broader than health system issues alone, serve as the OPTIONS HSS gap analysis. USAID/OHA and the OPTIONS team (FHI 360, AVAC, Wits RHI,

OPTIONS/AVAC team worked with the web developer to revise the site architecture, develop new pages, build an interactive map and create a password-protected portal.

Revised site architecture and New web pages: AVAC revised the site architecture so that users may access more information on product introduction in an easier, more user-friendly way, which will be launched

FSG) had a face-to-face meeting in January 2016 to review the draft situation analyses and agreed that OPTIONS contributions to HSS are best described as applying systems thinking to HIV prevention product introduction. The group reviewed resources such as the FHI 360 Rapid Diagnostic Tool for Health Systems and the FHI 360 Microbicides Readiness Tool. Possible HSS activities were discussed, such as supporting the development of standardized monitoring and evaluation (M&E) templates for oral PrEP rollout, and working with the South African NDOH to identify 3-4 interested districts (i.e. change agents) for initial implementation and provide more intensive training and HSS/Quality Improvement (QI) technical assistance (TA) (e.g. breakthrough collaborative) to those district managers to implement the guidelines and inform the broader scale-up. OPTIONS will move forward in supporting the development of standardized M&E templates for oral PrEP in the next reporting period.

Activity 5: OPTIONS Cross-cutting Activities and Extended Partner Engagement

As part of OPTIONS mandate to ensure that information is shared among projects, funders, and other stakeholders in the microbicides field, we have undertaken several activities to facilitate this exchange during this reporting period.

MPii Coordination Activities

OPTIONS has led the MPii coordination for the five projects. We hosted four MPii project lead calls in this reporting period. Although work is still ramping up for each project, this has been a good forum to share ideas and information and ensure that the five projects are coordinating their work, particularly at the country level.

OPTIONS worked closely with USAID/OHA and WHO in November-December 2015 to develop the MPii Coordination Framework, which describes the general approach to coordination and communication among the MPii projects across four levels:

- Level 1: Core oversight of MPii Coordination by USAID, WHO and OPTIONS
- Level 2: Internal MPii project coordination between CHARISMA, GEMS, EMOTION, POWER and OPTIONS, and coordination across project workstreams
- Level 3: Coordination between MPii Projects and the HIV Prevention Extended Network (USAID, WHO, UNAIDS, UNITAID, BMGF, OGAC/DREAMS, NIH, product developers, etc.)
- Level 4: USAID Coordination of MPii project messaging and dissemination (public communications)

During this reporting period, OPTIONS supported a number of cross-MPii workstream activities. We helped coordinate two end user workstream meetings. The first, in November 2015, provided the opportunity for the POWER, EMOTION and OPTIONS projects to share workplans and discuss

opportunities to collaborate and share results. The second, in January 2016, included presentations on past and current work and findings from the three MPii project end-user teams as well as a presentation on CAMI Health's end user activities. The modeling workstream met for the first time in January 2016 and during this call the group decided that its primary focus would be information-sharing. A follow up meeting between OPTIONS' partner LSHTM and GEMS' partner University College London (Andrew Philips) was held in March; conversations will continue between the two projects to explore possible points of collaboration. The OPTIONS modeling team also met with modelers from the USAID-funded LINKAGES project, and more modeling coordination plans are underway.

Following the workstream meetings held in January 2016, a need to revise the MPii communications framework was identified to ensure that communication was happening within and between organizations effectively (USAID, WHO, and MPii projects). FHI 360 worked with USAID/OHA and WHO to revise the framework and make clear the lines of communication and the expectations of the workstream leads. This led to a modeling coordination call that was held in March 2016 with USAID/OHA (Nagesh Borse and Delivette Castor), WHO (Liz McGrory) and OPTIONS (Katharine Kripke, Elizabeth Gardiner, Martha Larson) to determine the best way to coordinate cross MPii modeling activities. The end user workstream leads are planning a similar meeting for May 2016.

Extended Network Engagement

OPTIONS published the inaugural issue of the MPii newsletter. The process was managed by the OPTIONS Communication Officer and the first issue was published in February 2016. OPTIONS created the template and reached out to the MPii project leads to get updates and content for the newsletter. In general the response to the newsletter was positive and it resulted in several inquiries expressing interest in receiving OPTIONS deliverables around the communications landscape analysis and the value chain situation analyses.

After the publication of the MPii newsletter, OPTIONS reached out to several of the recipients to ask them to participate in an MPii Extended Network call, anticipated to be a forum for various groups working on HIV prevention implementation to share project updates and facilitate connections/collaboration. The first call MPii Extended Network call is scheduled for May 2016.

OPTIONS submitted two abstracts and three workshop applications to the AIDS 2016 conference¹ as a way to engage with a wider audience. In addition to AIDS 2016, we submitted two abstracts to the HSR conference being held in Vancouver in November 2016., and we anticipate to hear back our abstract submissions to both conferences in April 2016.² Currently, we are working with MPii projects EMOTION and POWER on a joint end-user submission to HIV R4P 2016 in October 2016.

OPTIONS Communication Activities

OPTIONS communications activities include our internal consortium communication processes, as well as our communications approach with external stakeholders and media.

Within the first few months of the project, the OPTIONS team set up a Microsoft SharePoint site and invited all consortium partners to participate and collaborate. It is on our OPTIONS SharePoint site that we post announcements, share photos and resources, and house all final project documents and materials. This is one example of OPTIONS' effort to foster transparency among its partners.

We regularly have full consortium, OPTIONS leadership, workstream specific, country partner, communications committee, and strategic leadership group calls. These calls have resulted in a rich exchange of information and ensure that all relevant OPTIONS partners and workstreams are engaged in the current work, challenges, and next steps.

External communications norms were finalized in our OPTIONS Communications Framework. This framework outlines an objective of "promoting coordination and empowering stakeholders at the global and country levels to expedite ARV-based HIV prevention product introduction and access."

To accomplish this objective, we created six sub-committees, each led by OPTIONS Communications Committee members:

- Communications Management
- Partner Communications Support

¹ After the reporting period ended, we heard that of the AIDS 2016 submissions, two of our workshop proposals were accepted: "The HIV prevention landscape for women: A look at new and emerging HIV prevention options, including PrEP, vaginal rings and new products in development"- Global Village Youth Workshop and "What do we need to access and deliver PrEP?: tapping into the unheard voices of end-users and providers to support country-level advocacy and ensure equitable access to PrEP"- Scientific Skills Development Workshop

² After the reporting period, we learned that one of the two abstracts we submitted was accepted. The accepted abstract is *Accelerating the Curve: Preparing Health Systems for the Introduction of Oral PrEP in South Africa, Kenya and Zimbabwe*

- HIV Prevention Implementation Communications Working Group (ICWG)
- Media Monitoring & In-country Outreach
- ARV-based Product Introduction Clearinghouse
- Policy and Technical Briefs

Through these subcommittees, we work to respond to the technical communications and branding needs of the project and the consortium partners.

Finalizing Administrative Start-up Activities

During this reporting period, OPTIONS executed the remaining subawards and now all OPTIONS partners are working under fully signed subagreements. We revised and received USAID/OHA approval for the year one workplan and the year one PMEP.

GENDER INTEGRATION

OPTIONS conducted a gender analysis at the beginning of the project to identify how gender norms and inequalities may affect women's ability to access and use ARV-based prevention products. The draft gender analysis was presented to the consortium at the Year 1 work planning meeting in September. As the OPTIONS work plan was re-tooled to shift from focusing on microbicides to oral PrEP at USAID's request, the gender analysis was also updated to include oral PrEP. Based on the findings of the gender analysis, we developed a strategy for integrating gender into OPTIONS project activities, with the goal of developing a delivery platform that minimizes gender-related barriers to effective product use, while promoting individual rights and agency. The strategy includes guiding questions, developed in collaboration with OPTIONS Consortium partners, to help partners consider how to integrate gender into their specific project activities. USAID Gender Advisors gave input on drafts of the OPTIONS Gender Analysis and Strategy between September and December and approved it in December 2015. Since this time the strategy has been shared as a reference/model for the GEMS and CHARISMA MPii project leads.

The following are examples of ways that OPTIONS has integrated gender into project activities from January to March 2016. The OPTIONS gender advisor reviewed draft deliverables, including the McCann landscape analysis presentation and the FSG situation analysis interim findings, and suggested additional ways to integrate gender. OPTIONS has been able to influence the development of PrEP guidelines at the national level to ensure that the processes and guidelines are gender sensitive. In Zimbabwe, Pangaea noted during a PrEP guidelines committee meeting that no MSM groups were represented, leading to the addition of two groups representing sexual minorities and sex workers to the committee. In South Africa, Wits RHI ensured that the definition of sex workers in the PrEP Guidelines for Sex Workers includes women, men, and transgendered people. Additionally, based on the recommendation

from the gender analysis that men be engaged in the rollout of PrEP and microbicides, Wits RHI is also considering how best to engage men and boys in the rollout of PrEP to adolescent girls and young women in South Africa. Finally, FHI 360 published the review article “Optimizing HIV prevention for women: a review of evidence from microbicide studies and considerations for gender-sensitive microbicide introduction” in *JIAS* November 2015, displaying our thought leadership in the technical area of gender and ARV-based HIV prevention products.

HUMAN SUBJECTS PROTECTION

We are working with FHI 360’s Protection of Human Subjects Committee (PHSC) to determine if McCann’s proposed market intelligence work in South Africa is considered human subjects research, or if it falls under market research. FHI 360 will submit the protocol for their market intelligence work and data collection instruments to PHSC for their review in the next reporting period. McCann’s subcontractor in South Africa (Bataleur), who would implement the protocol, will follow market research industry ethical standards in conducting this work. The other work of the OPTIONS Consortium does not involve human subjects contact, and therefore, does not require PHSC review or approval.

ENVIRONMENTAL COMPLIANCE

During this reporting period we received our revised IEE and the language in our award was modified to reflect the OPTIONS activities. There were no OPTIONS activities in this reporting period that might directly or indirectly affect the environment. Specifically, we did not procure, store, manage or dispose of health commodities; train in methods that might result in the generation of hazardous medical waste; nor generate, store, manage or dispose of hazardous and highly hazardous medical waste. OPTIONS will continually assess our activities and if/when we engage in activities that might have an impact on the environment we will take steps to lessen its impact.

SUCCESS STORIES

ICASA 2015 Satellite Session: “Adapting the WHO Guidelines on oral PrEP: What will it take?”

At the International Conference on AIDS and STIs in Africa (ICASA) 2015 conference in Harare, Zimbabwe in November, the OPTIONS Consortium, with USAID/PEPFAR and WHO, co-hosted a satellite session, “Adapting the WHO guidelines on oral PrEP: What will it take?” Approximately 130 conference



Approximately 130 people attended the ICASA 2015 satellite session about adapting the WHO guidelines on oral PrEP, which was co-hosted by the OPTIONS Consortium, USAID/PEPFAR and WHO.



Dr. Rachel Baggaley (WHO), Owen Mugurungi (AIDS & TB Zimbabwe), and Manju Chatani (AVAC) speak at the ICASA 2015 session hosted by OPTIONS, USAID, PEPFAR, and WHO.

attendees assembled to discuss the implications for country programs of the new WHO guidelines on the use of antiretroviral therapies (ART) for the prevention and early treatment of HIV infection.

Following the session, AVAC’s Mitchell Warren shared the following response from a colleague with the OPTIONS Consortium:

“Just wanted to shoot you a quick email because a couple colleagues and I went to the satellite session this morning on nationalizing the WHO guidelines for PrEP and it was fantastic. It was a 7 am meeting on the 4th day of the conference, so I was expecting no more than 10 people to show up. Instead the room was packed full - they actually brought in extra chairs, and it was standing room only! Honestly it was the best attendance I've ever seen at a 7 am conference session. There was some good discussion and (equally importantly) lots of enthusiasm in the room...”

After opening remarks from Dr. Owen Mugurungi, AIDS & TB Programme in Zimbabwe, Dr. Rachel Baggaley gave an overview of the new WHO guidelines. Then a panel discussion brought together global and country-level policy makers, researchers, implementers, end-users and advocates to discuss key challenges of putting the guidelines into practice and to begin to think through next steps for PrEP rollout.

MEDIA COVERAGE AND PUBLICATIONS

“USAID announces microbicide awards.”

USAID.gov

6 Aug 2015

<http://1.usa.gov/1VbvobB>

“USAID announces microbicide awards.”

AVAC’s News Digest, Volume 16, Issue 32

7 Aug 2015

<http://bit.ly/1VbuPyL>

“FHI 360 to support three new USAID awards to advance microbicide research, development and introduction for HIV prevention.”

FHI360.org

20 Aug 2015

<http://bit.ly/1RslCke>

“Satellite Session: Adapting the WHO guidelines on oral PrEP: What will it take?”

AVAC Advocates’ Network

25 Nov 2015

<http://bit.ly/1pObmYR>

“AVAC @HIVpxresearch for #ICASA2015.”

Twitter

3 Dec 2015

See Annex B

“Want a healthy world? Let the HIV response lead the way.”

Huffington Post

25 Nov 2015

<http://huff.to/1LCrjoe>

“South Africa has excelled in treating HIV – prevention remains a disaster.”

The Conversation

30 Nov 2015

<http://bit.ly/1QLbyU0>

“Planning for HIV preexposure prophylaxis introduction: lessons learned from contraception.”

Current Opinion in HIV & AIDS

Jan 2016

<http://bit.ly/1PeSn53>

“Approval of Truvada a game changer in anti-HIV/AIDS effort.”

The East African

9 Jan 2016

<http://bit.ly/1OmVHal>

“Six advocates for PrEP speak out.”

UNAIDS Community Advocacy Update

Feb 2016

<http://bit.ly/1PI0llp>

“Opinion: A possible game-changer in HIV prevention.”

Eyewitness News and The Conversation

Mar 2016

<http://bit.ly/21FICQ7>

“Why Africa needs PrEP: A two-in-one pill to prevent HIV infection.”

Mail & Guardian’s Bhekisisa Centre for Health Journalism

10 Mar 2016

<http://bit.ly/1pfyz6G>

DOCUMENTATION OF BEST PRACTICES

While the project is still young, there are a number of successes and best practices related to stakeholder and partner engagement to highlight during this reporting period.

Early engagement with USAID global and local missions

As mentioned under Activity 2, one of the highest priorities for OPTIONS in the early months of the project was to work closely with USAID/OHA to engage the USAID missions and ensure that OPTIONS work would be jointly planned and aligned with mission in-country work and priorities. This early engagement was critical for the work to efficiently move forward and materials were developed to communicate effectively about the work proposed across all five MPii projects, as well as OPTIONS' specific scope of work.

Early engagement at the country level to ensure appropriate direction applicability of work

Country partners began engaging with national government and key stakeholders immediately once the OPTIONS cooperative agreement was awarded. Country partners used existing relationships with their national governments as a platform to discuss and introduce the OPTIONS Consortium and, through the value chain situation analysis data collection template, they were able to quickly organize and facilitate directed conversations about next steps for oral PrEP across all aspects of the value chain. Relationship building with and engagement of the national ministries within South Africa, Kenya and Zimbabwe has led to a process by which all OPTIONS work is country directed and, therefore, nationally prioritized and relevant.

Early development of cross-project coordination systems

A very early activity for the OPTIONS Consortium was to develop the MPii coordination framework with USAID and WHO, as described under Activity 5. This activity followed the first Project Advisory Committee (PAC) meeting when meeting participants discussed and prioritized the need for clear coordination and structure across the five MPii projects. This framework was widely shared across the MPii projects and updated as needed to provide further clarification and structure. OPTIONS has led cross-project sharing opportunities through regular MPii calls and, based on partner feedback, developed a password protected page on PrEPWatch to allow for the sharing of resources and draft reports as soon as possible between the projects. This page on PrEPWatch will be in use early in the next quarter.

Preparatory work to ensure added value without duplication

OPTIONS has spent considerable time conducting pre-activity analyses to identify areas where we can provide real added value and ensure that our work is not duplicative. We have tried to remain nimble and flexible and respond to clear needs that are systematically identified rather than moving forward

with activities based on what we think is needed. We applied this thinking in our modeling summary and gap analysis, our value chain situation analyses, investment scenario planning, and our communication market shaping strategy. In the case of the modeling gap analysis, when we realized that there was significant modeling work happening in South Africa, we were able to quickly adjust our planned work and focus on Zimbabwe and Kenya rather than conduct unnecessary modeling activities in South Africa. FSG's work with the country partners on the value chain situation analysis and investment scenario planning has been driven by country needs and takes into account other implementers in country who may be doing similar work. With respect to the communication market shaping strategy, OPTIONS first conducted a communications landscape analysis in South Africa to identify what is known and what the gaps are in this area and has currently tabled work in this area in order to respond to the immediate needs of the South African TWG.

PLANNED ACTIVITIES FOR NEXT PERFORMANCE PERIOD

Activity 1

Value chain situation analyses and investment scenarios

- Situation analyses (finalized April 2016), collaborative frameworks and corresponding templates provided to USAID, made publicly available on PrEPWatch, and shared with broader audience (UNITAID, OGAC etc), as appropriate
- Collaborative frameworks updated regularly by country partners; feeding into development of investment scenarios (FSG)
- Investment scenarios plan to be finalized with FSG beginning work on these in July 2016. Monthly check-ins in May and June 2016 with country partners and modeling teams will take place to ensure this timeline and plan is still appropriate.

Communications market shaping strategy

- Respond to immediate need from South Africa TWG to develop communication materials and training curriculum for oral PrEP launch for sex workers at 14 facilities on June 1st. McCann working closely with Wits RHI on the communications aspect of this request.
- Market intelligence work in South Africa to be further discussed with TWG and in-country stakeholders to ensure buy-in of approach and direction. With TWG engagement and support, protocol and data collection instruments to be finalized, market intelligence research conducted and report and findings produced.

Modeling activities

- Compile information gathered from HIV researchers on current/planned activities into one document and share with other modelers
- Develop existing models for Kenya and Zimbabwe to quickly answer if there are subpopulations for which providing PrEP may provide a large additional epidemiological impact and to rank subpopulations by relative cost-effectiveness
- Analyze existing data from South Africa about user preferences for ARV-based prevention
- Conduct detailed and comprehensive survey of PrEP demonstration studies
- Begin detailed literature review to collect data and estimates on total size of subpopulations of interest in each country, sexual behavioral data for subpopulations, HIV prevalence/incidence, existing intervention coverages, and health system capacity

Dapivirine ring next steps

- Further scoping with IPM, global level activities with respect to the dapivirine ring
- Conduct a gap analysis on dapivirine ring to identify immediate and long term modeling needs
- Conduct some preliminary cost-effectiveness modeling of the ring to inform the development of an advocacy brief.

Activity 2

General

- Oral PrEP guidelines developed in each country and countries will have, or be working on, implementation plans
- Maintain the implementation planning framework document provided by FSG to reflect current country status and progress
- Collect information on service delivery models, by key population. A template provided by FSG will be used to capture this information

Kenya

- Convene a think tank to determine Kenya's modeling needs for PrEP
- In partnership with NACC and NASCOP, adapt the PrEP implementation landscape analysis tool developed by Wits RHI and complete this information

- Continue to contribute to the development of the PrEP guidelines and provide technical assistance to develop a national PrEP advocacy plan and a national PrEP implementation plan
- Provide technical assistance in the development/review of terms of reference for the ARV guidelines working group
- Conduct a desk review of IS research to identify needs and gaps and review current PrEP messages based on feedback from demonstration study participants
- Support NASCOP in the development of national reporting tools in preparation for roll out
- Develop minimum requirements for sites' readiness to implement PrEP

South Africa

- Collaborate with McCann on the development of communications materials for the June 1 launch for sex workers in SA; develop the provider training curriculum for this launch
- Develop implementation tools and resources for PrEP rollout in coordination with NDOH, SANAC, and current PrEP and sex worker (SW) programs in South Africa.
- Conduct overall analysis of the data collected from the roll out of PrEP in the sex worker programs throughout the first year. This will include analyzing trends – uptake, bottlenecks, number tested onto treatment/on PrEP, age breakdown of uptake, etc., and providing feedback to the partners
- Provide support and technical assistance for the MSM rollout, followed by AGYW
- Determine need for technical and policy briefs with WHO and NDOH and develop these briefs as needed
- Support the development of M&E and facility or site readiness tools for National PrEP and T&T rollout for sex workers
- Engage with the National TB/HIV Implementation Science Advisory Committee – the national priority IS areas for AGYW will be shared with the AGYW sub-committee for further discussion in line with the findings from the PrEP implementation landscape analysis.
- Provide regional oversight and support to Pangaea and LVCT Health activities, as needed

Zimbabwe

- Work with MOHCC to support any adaptations to the overarching TORs and lead/support the process for developing TORs for the PrEP sub-committee if needed.

- PrEP subcommittee of guideline adaptation committee in Zimbabwe will begin convening (co-chaired by Pangaea)
- Convene consultations with civil society, and end-users to solicit input into guidelines development at the start of the guideline development process, and to review draft guidelines prior to finalization
- Support the regulatory process for getting Truvada approved for use as PrEP in Zimbabwe
- Provide support to MOHCC on price negotiations with Gilead and with potential generic manufacturers
- Convene PrEP demonstration project/research task force including CeSSHAR, UZ-UCSF, MOH, USAID, and any other groups involved in PrEP roll-out to share information on actual roll-out of PrEP at country-level including what works and what isn't working
- Conduct key informant interviews (KII) as needed to provide additional information for the task force and/or protocol development, e.g. with NatPharm, civil society groups, Ministry of Health (MOH), service providers- discuss gaps identified with OPTIONS implementation science team (also related to Activity 3)
- Once PrEP guidelines are finalized and adopted, ensure the transition of the adaptation committee to a PrEP guideline implementation committee

Activity 3

- Finalize the OPTIONS implementation plan for IS in Project Quarter 3. This will include a focus on the FSG work in South Africa, which will provide a summary and gap analysis of the IS work related to AGYW.
- Hold conversations with FSG and modelers to explore potential IS contributions for the Zimbabwe/Kenya investment scenarios, as well as conversations with country partners regarding current TWG conversations around IS needs and questions
- Use knowledge gaps to develop an implementation science agenda in each country. Preliminary discussions indicate that local governments will likely be looking for information on demand creation strategies for the different target populations, early analysis of PrEP roll out data (trends, bottlenecks, demographic breakdowns, etc.), as well as how to support implementation after the end of demonstration projects.
- Adapt/apply PrEP implementation landscape analysis tool in Kenya; perhaps in Zimbabwe
- Continue process documentation through quarterly reports

Activity 4

- Liaise with WHO, OGAC, USAID, TWGs to develop guidelines and/or tools for standardized M&E
- Update Interactive map on PrEPWatch.org home page to include links to country close-ups for Kenya, South Africa and Zimbabwe
- Revise PrEPWatch site architecture, new web pages and password-protected portal will be launched
- Create process for submitting documents for posting to PrEPWatch
- Continue development of PrEPWatch site architecture and create new pages as content becomes available

Activity 5

- Plan and hold the year two OPTIONS workplanning meeting in Johannesburg, South Africa
- Participate in AIDS 2016 activities, plan and host two workshops for AIDS 2016: *"The HIV prevention landscape for women: A look at new and emerging HIV prevention options, including PrEP, vaginal rings and new products in development"*- Global Village Youth Workshop and *"What do we need to access and deliver PrEP?: tapping into the unheard voices of end-users and providers to support country-level advocacy and ensure equitable access to PrEP"*- Scientific Skills Development Workshop
- Continue regular calls with the OPTIONS consortium team, including weekly leadership calls, monthly full consortium calls, monthly communication committee calls, monthly Activity 2 calls and monthly small group country coordination calls
- Continue to hold MPii workstream meetings, as well as workstream coordination calls (as needed)
- Continue MPii coordination calls with MPii coordination team (USAID, WHO, and OPTIONS)
- Continue regular calls with the MPii Project leads
- MPii Extended Network calls will happen regularly in the next reporting period
- Produce and disseminate the MPii quarterly newsletter
- Streamline the abstract submission process and finalize documentation related to this
- Finalize OPTIONS publications policy and share the template with other MPii projects

- Continue to provide support to partners related to the integration of gender into project activities
- Continue to update the OPTIONS Gender Analysis and Strategy, as needed, to incorporate new information as PrEP introduction progresses and as OPTIONS project activities evolve to be responsive to in-country needs

ANNEX 1—Updated M&E Indicators Table

Performance indicators	Type of indicators	Data Source	Means of collection	Deliverable	Estimated Completion Date	Complete? (y/n)
Activity #1: Development of business cases and investment strategy						
1.1) Define key issues for a situation analysis (across oral PrEP and dapivirine ring prevention methods)	Output	<ul style="list-style-type: none"> • Consortium partner knowledge • Interviews/ meetings • Existing literature 	<ul style="list-style-type: none"> • Desk review and interviews 	Country-specific situation analysis (in PowerPoint and Word) for each of the three priority countries.	March 2016	No (Estimated April 2016)
1.2) Conduct a value chain analysis focused on PrEP introduction and develop interim country engagement materials	Output	<ul style="list-style-type: none"> • Existing literature • Input from OPTIONS partners, product developers and other global stakeholders • Situation analysis 	<ul style="list-style-type: none"> • Desk review and interviews • FSG workshop • Situation analysis data collection tool 	Country-specific materials for OPTIONS partners to engage with key stakeholders and test early findings (5-10 page document and 5-10 page presentation included in situation analysis presentation).	March 2016	No (Estimated April 2016)

Performance indicators	Type of indicators	Data Source	Means of collection	Deliverable	Estimated Completion Date	Complete? (y/n)
1.3) Develop a demand creation and communication market shaping strategy and plan to support the introduction and scale up of HIV-prevention products	Output	<ul style="list-style-type: none"> End-users In-country experts EMOTION, POWER and CHARISMA teams McCann expertise 	<ul style="list-style-type: none"> Desk review Survey/analysis 5c's workshop 	Summary report or PowerPoint of existing end-user data	December 2015	Yes
				Market Intelligence report and presentation of findings	May 2016 <i>(will be delayed due to shifting in-country priorities)</i>	No
				Transformational Brief and presentation	July 2016 <i>(will be delayed due to shifting in-country priorities)</i>	No
				Communications Strategy and presentation	August 2016 <i>(will be delayed due to shifting in-country priorities)</i>	No
				Marketing Plan and presentation	September 2016 <i>(will be delayed due to shifting in-country priorities)</i>	No
1.4.) Gather information on cost of PrEP delivery	Process	<ul style="list-style-type: none"> Existing literature, in-country stakeholder discussions 	<ul style="list-style-type: none"> Desk review Discussions 	N/A	March 2016	Yes, ongoing

Performance indicators	Type of indicators	Data Source	Means of collection	Deliverable	Estimated Completion Date	Complete? (y/n)
1.5) Conduct modeling of cost and impact of PrEP	Output	<ul style="list-style-type: none"> Existing literature Other modelers OPTIONS modeling team (Avenir, LSHTM, Wits RHI) 	<ul style="list-style-type: none"> Literature review Collaboration with other modelers 	PrEP modeling summary (a PowerPoint or Word/Excel document)	December 2015	Yes
				Detailed workplan for OPTIONS based on identified needs and gaps	February March 2016	Yes (Submitted April 3, 2016)
1.6) Conduct joint scoping of dapivirine ring launch plan with IPM	Process	FHI 360, AVAC, FSG, McCann, IPM	<ul style="list-style-type: none"> Discussions, face to face meetings Existing plans/ documents 	N/A	March 2016 (ongoing)	Ongoing
Activity #2: Support country level regulatory approval, policy development, program planning, marketing and implementation strategies for ARV-based prevention product introduction						
2.1) Establish OPTIONS project team to coordinate in-country activities and determine cross-country working model	Output	<ul style="list-style-type: none"> Consortium partners USAID mission 	In person collaboration and meetings	High level country specific workplans/one-pager outlining proposed OPTIONS work within each country	December 2015 March 2016	Yes (Submitted April 7, 2016)

Performance indicators	Type of indicators	Data Source	Means of collection	Deliverable	Estimated Completion Date	Complete? (y/n)
2.3) Establish/engage with National Working Groups (NWG) in South Africa, Kenya, and Zimbabwe	Output	<ul style="list-style-type: none"> Key stakeholders (in-country) 	<ul style="list-style-type: none"> In-country collaboration and consultation 	Draft ToR for NWGs in each country (and a template ToR developed for other countries to use).	June 2016	No
2.4) Gather information for situation analysis in collaboration with OPTIONS leadership	Process	<ul style="list-style-type: none"> FSG, In-country partners, Wits RHI, FHI 360 External partners Existing literature, grey papers, websites, etc. 	<ul style="list-style-type: none"> Discussions with stakeholders, implementing partners, demonstration partners. Desk review 	N/A (deliverables associated with Activity 1.1)	March 2016	Yes
2.5) Adapt collaborative framework and value chain analysis at country level	Output	<ul style="list-style-type: none"> Activities 1.2 and 2.4 	<ul style="list-style-type: none"> Analyze and refine data Meetings with NWGs 	County-specific collaborative frameworks (presentation or document)	April September 2016	No
2.6) Policy/Technical briefs developed	Output	<ul style="list-style-type: none"> WHO recommendations , information on new products and emerging issues, published and grey literature 	<ul style="list-style-type: none"> Desk review 	Completed Policy/Technical briefs	September 2016	No
2.7) Additional country support provided (if requested)	Process	TBD	TBD	TBD	TBD per USAID guidance	No

Performance indicators	Type of indicators	Data Source	Means of collection	Deliverable	Estimated Completion Date	Complete? (y/n)
Activity #3: Facilitate and conduct implementation science (IS)						
3.1) Existing IS evidence compiled and synthesized to support the value chain analysis, modeling, and investment cases.	Output	<ul style="list-style-type: none"> Published and grey literature Key stakeholders 	<ul style="list-style-type: none"> Desk review 	Country-specific IS research agendas	September 2016	No
3.2) Systematically document the product introduction process to assess alignment with plans and identify drivers/obstacles to success	Output	<ul style="list-style-type: none"> All OPTIONS partners 	<ul style="list-style-type: none"> Quarterly completion of data collection instrument 	Data collection instrument and instructions	November 2015	Yes
				Process documentation report	End of project	No
Activity # 4: Provide technical assistance and support for health systems strengthening (HSS)						
4.1) Existing and emergent data/evidence/tools from ongoing and future demonstration projects and implementation studies gathered and revisited periodically	Process	<ul style="list-style-type: none"> Clinical trials, OLEs, early demonstration projects, IS research, other product introduction activities 	<ul style="list-style-type: none"> Collection and collation of data 	N/A	Ongoing	Ongoing
4.2) Web-based clearinghouse for existing OPTIONS-developed tools and materials developed	Process	<ul style="list-style-type: none"> Activity 4.1 Software designers 	<ul style="list-style-type: none"> Assessment of functionality of the clearinghouse 	N/A	March 2016, with development ongoing	Yes, Ongoing (released April 11)
4.3) Liaise with WHO, OGAC, USAID, and NWGs to develop guidelines and/or tools for standardized M&E	Output	<ul style="list-style-type: none"> WHO, OGAC, USAID input and existing tools 	<ul style="list-style-type: none"> Desk review Analysis 	Suggested M&E guidelines, indicators and tools	September 2016	No

Performance indicators	Type of indicators	Data Source	Means of collection	Deliverable	Estimated Completion Date	Complete? (y/n)
Activity #5: OPTIONS Cross-cutting Activities and Extended Network Engagement						
5.1) Year 1 workplanning meeting held with all OPTIONS partners	Output	<ul style="list-style-type: none"> All OPTIONS Partners 	<ul style="list-style-type: none"> In person collaboration 	First face-to-face Activity 1 workplanning meeting held and meeting summary generated	September 2015	Yes
5.2) Complete administrative project start up activities, including putting all sub agreements in place.	Output	<ul style="list-style-type: none"> Subagreement and administrative documentation 	<ul style="list-style-type: none"> Review of project files 	8 subagreements finalized	October 2015	Yes
5.3) Communication plan finalized and communications team for consortium set up	Process/Output	<ul style="list-style-type: none"> Communications strategy document developed by FHI 360, AVAC, and Wits RHI 	<ul style="list-style-type: none"> Review of project files, FHI 360 internal expertise and consortium meetings/discussions 	N/A	December 2015	Yes
5.4) Quarterly coordination calls among OPTIONS members (full consortium) and quarterly meetings of OPTIONS Strategic Leadership Group (SLG) held	Process	<ul style="list-style-type: none"> Consortium partners 	<ul style="list-style-type: none"> Schedule and hold regular calls, collaboration 	N/A	Ongoing	Ongoing
5.5) Performance Monitoring and Evaluation Plan finalized and M&E and Strategic Information mechanisms to use data in real-time to drive project planning and implementation established	Process/Output	<ul style="list-style-type: none"> PMEP, FHI 360, Consortium partners 	<ul style="list-style-type: none"> Review of project files, FHI 360 internal expertise and consortium meetings/discussions 	PMEP with indicator matrix	December 2015 and ongoing	Yes, ongoing
5.6) Web-based document and data repository for OPTIONS developed	Process	<ul style="list-style-type: none"> OPTIONS partners 	<ul style="list-style-type: none"> FHI 360 internal expertise and consortium collaboration 	N/A	Established by Sept 2015, ongoing maintenance and input	Yes, ongoing

Performance indicators	Type of indicators	Data Source	Means of collection	Deliverable	Estimated Completion Date	Complete? (y/n)
5.7) Project teams established and cross-consortium work planning ongoing	Process	N/A	N/A	N/A	Ongoing	Ongoing
5.8) Field support explored through engagement with USAID Global and USAID missions	Process	<ul style="list-style-type: none"> USAID Global Microbicide technical team, Wits RHI, Pangaea, LVCT Health, FHI 360 	<ul style="list-style-type: none"> In-country meetings and collaboration 	Working document of possible areas for field support investment	Ongoing	Ongoing
5.9) Gender analysis approved	Output	<ul style="list-style-type: none"> FHI 360 USAID gender advisor, OPTIONS partners, in-country stakeholders 	<ul style="list-style-type: none"> Review of project files, analysis, and collaboration 	Gender analysis plan	December 2015, ongoing	Yes, ongoing
				Gender analysis report and integration plan	September 2016	No
5.10) Communication/collaboration strategy among USAID Microbicide Round 3 (MR3) APS grantees determined	Process	<ul style="list-style-type: none"> All MR3 grantees USAID input WHO input 	<ul style="list-style-type: none"> Input from other MR3 grantees through conversations, meetings and document review. 	Communication/collaboration strategy developed with USAID MR3 grantees and provided to USAID	December 2015, ongoing	Yes, ongoing
5.11) Communications/collaboration strategy with product developers, normative bodies, and other donors established with regular ongoing engagement	Process	<ul style="list-style-type: none"> IPM, Gilead, ViiV, UNAIDS, WHO, Gates, other donors USAID input WHO input 	<ul style="list-style-type: none"> Collation of information gathered through conversations and meetings 	Communication/collaboration strategy developed with product developers, normative bodies, other donors, and provided to USAID (same as 5.10 document)	December 2015, ongoing	Yes, ongoing

ANNEX 2—AVAC Twitter Feed for OPTIONS-hosted ICASA 2015 satellite session on PrEP

On December 3, 2015, OPTIONS hosted a satellite session at the ICASA conference in Harare, Zimbabwe. The session, called “*Adapting the WHO guidelines on oral PrEP: What will it take?*” aimed to explore the issues countries must grapple with in adapting WHO guidelines on oral PrEP in their settings to identify issues and critical next steps required to guide the adaptation of the normative guidance at country-level. Panelists included, among others, OPTIONS partner Wanjiru Mukoma of LVCT Health, Rachel Baggaley of the WHO, and Michelle Moorhouse of OPTIONS consortium partner Wits RHI.

The session was well received with thoughtful and enthusiastic discussion during the event.

Below you will find some of AVAC’s tweets from the session:



[AVAC @HIVpxresearch](#)

Come to Adapting WHO guidelines on oral PrEP: What will it take? Happening now 7-8:30 room 6, breakfast & convo on next steps for [#PrEP!](#)

[11:52 PM - 2 Dec 2015](#)



[AVAC @HIVpxresearch](#)

The science is there 4 [#PrEP](#). Now have 2 make sure we implement guidelines Dr Mugurungi head HIV/TB Zim MOH

[12:30 AM - 3 Dec 2015 · Harare, Zimbabwe, Zimbabwe](#)



[AVAC @HIVpxresearch](#)

Baggaley [@WHO](#) on guidelines 4 PrEP. Reflect that we know [#PrEP](#) works & Adherence & impact increasing. ICASA2015

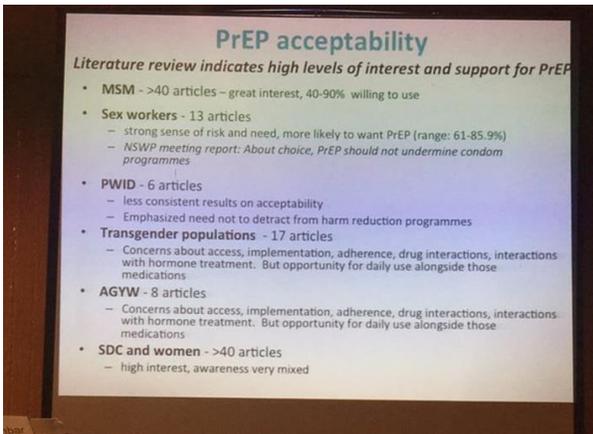
[12:33 AM - 3 Dec 2015 · Harare, Zimbabwe, Zimbabwe](#)



[AVAC @HIVpxresearch](#)

Baggaley on [#PrEP](#) acceptability. High level of interest and support but varies across populations. [#icasa2015](#)

12:35 AM - 3 Dec 2015 · [Harare, Zimbabwe, Zimbabwe](#)



[AVAC @HIVpxresearch](#)

Baggaley- Stand alone [#PrEP](#) projects not practical. Have 2 link in STI, family planning clinics, community settings 4 key pops [#ICASA2015](#)

12:40 AM - 3 Dec 2015 · [Harare, Zimbabwe, Zimbabwe](#)



[AVAC @HIVpxresearch](#)

Baggaley - info is key. Cant expect people to come forward for [#PrEP](#) if the aren't informed.

12:42 AM - 3 Dec 2015 · [Harare, Zimbabwe, Zimbabwe](#)



[AVAC @HIVpxresearch](#)

Amanda: we want [#PrEP](#) 2 additional px option 4 all. Not just sex workers but for other young women.
[#ICASA2015](#)

[12:54 AM - 3 Dec 2015](#) · [Harare, Zimbabwe, Zimbabwe](#)



[AVAC @HIVpxresearch](#)

Dr Mukoma [@LVCTKe](#) Kenya prevention revolution recognizes need to have high impact px options like
[#PrEP](#) [#icasa2015](#)

[12:57 AM - 3 Dec 2015](#) · [Harare, Zimbabwe, Zimbabwe](#)



[Cheryl Case Johnson @ccasejohn](#)

Policy makers should make [#PrEP](#) 1. Accessible & 2. A prevention method for all [#OfferPrEP](#) [#icasa2015](#)
[12:54 AM - 3 Dec 2015](#)



[AVAC @HIVpxresearch](#)

Mukoma: [#PrEP](#) champion policy makers, advocacy, community invlmt key in Kenya's decisions around [#PrEP](#) implementation [#ICASA2015](#) [@LVCTKe](#)
1:01 AM - 3 Dec 2015 · [Harare, Zimbabwe, Zimbabwe](#)



[AVAC @HIVpxresearch](#)

Mukoma: [#PrEP](#) champion policy makers, advocacy, community invlmt key in Kenya's decisions around [#PrEP](#) implementation [#ICASA2015](#) [@LVCTKe](#)
1:01 AM - 3 Dec 2015 · [Harare, Zimbabwe, Zimbabwe](#)



[AVAC @HIVpxresearch](#)

Mugurungi- some people say [#PrEP](#) is not an African thing. We have to show evidence it is. [#ICASA2015](#)
1:07 AM - 3 Dec 2015 · [Harare, Zimbabwe, Zimbabwe](#)



[AVAC @HIVpxresearch](#)

Dr. Moorehouse [@WitsRHI](#)- bottom line [#PrEP](#) works when you take it [#ICASA2015](#)
1:10 AM - 3 Dec 2015 · [Harare, Zimbabwe, Zimbabwe](#)



[AVAC @HIVpxresearch](#)

Moorehouse [#PrEP](#) not daily treatment 4 life. It's Something u need 2 manage 4 your seasons of risk.
[#ICASA2015](#)
1:13 AM - 3 Dec 2015 · [Harare, Zimbabwe, Zimbabwe](#)



[AVAC @HIVpxresearch](#)

Caroline sex worker from Kenya. Meaningful engagement with community key to moving [#prep](#) forward, making it work.

[1:20 AM - 3 Dec 2015](#) · [Harare, Zimbabwe, Zimbabwe](#)



[AVAC @HIVpxresearch](#)

Question for Dr Mugurungi of Zim MOH. How will you implement [#PrEP](#) given gov's position on msm, sex workers. [#ICASA2015](#)

[1:23 AM - 3 Dec 2015](#) · [Harare, Zimbabwe, Zimbabwe](#)



[AVAC @HIVpxresearch](#)

Mugurungi -- media a key stakeholder as we prepare for roll out of [#PrEP](#) in Zim. [##ICASA2015](#)

[1:26 AM - 3 Dec 2015](#) · [Harare, Zimbabwe, Zimbabwe](#)



[AVAC @HIVpxresearch](#)

Mugurungi will use [#VMMC](#) as model for how we plan [#prep](#) implementation. [#ICASA2015](#)

[1:27 AM - 3 Dec 2015](#) · [Harare, Zimbabwe, Zimbabwe](#)



[AVAC @HIVpxresearch](#)

Mugurungi: will use public health approach for ensuring access to [#PrEP](#) other px options 4 msm, sex workers, key pops in Zim. [#ICASA2015](#)

[1:45 AM - 3 Dec 2015](#)



[AVAC @HIVpxresearch](#)

Mugurungi: [#PrEP](#) can be a game changer. We need to find out how we can implement it for the right people & respect human rights. [#ICASA2015](#)

[1:46 AM - 3 Dec 2015](#)