

Oral PrEP Introduction Planning Toolkit

STEP 2: Oral PrEP Project Landscape



About this toolkit

WHAT IS THE PURPOSE AND CONTENTS OF THIS TOOLKIT?

- This toolkit was developed and used by the OPTIONS Consortium to support planning for the introduction of oral PrEP for HIV prevention in Kenya, Zimbabwe and South Africa.
- This toolkit is designed to help users in other countries plan for the introduction and rollout of oral PrEP

WHO SHOULD USE THIS TOOLKIT?

This toolkit will be most relevant for:



National governments and ministries of health/HIV agencies to inform national and regional oral PrEP roll out and provide high-level guidance to counties/districts on what factors should be considered to ensure they are prepared to rollout oral PrEP



Implementing organizations (e.g., NGOs) to understand national and regional needs related to PrEP delivery and to support effective resource allocation



Donors (e.g., USAID) to initially scope country-specific needs and resource requirements

HOW COULD THE TOOLKIT BE MORE USEFUL?

If you have thoughts, feedback, questions, requests for additional information or other resources that you would like to add to this toolkit, please contact Neeraja Bhavaraju at [FSG](https://www.fsg.org) (an OPTIONS consortium member) at neeraja.bhavaraju@fsg.org.

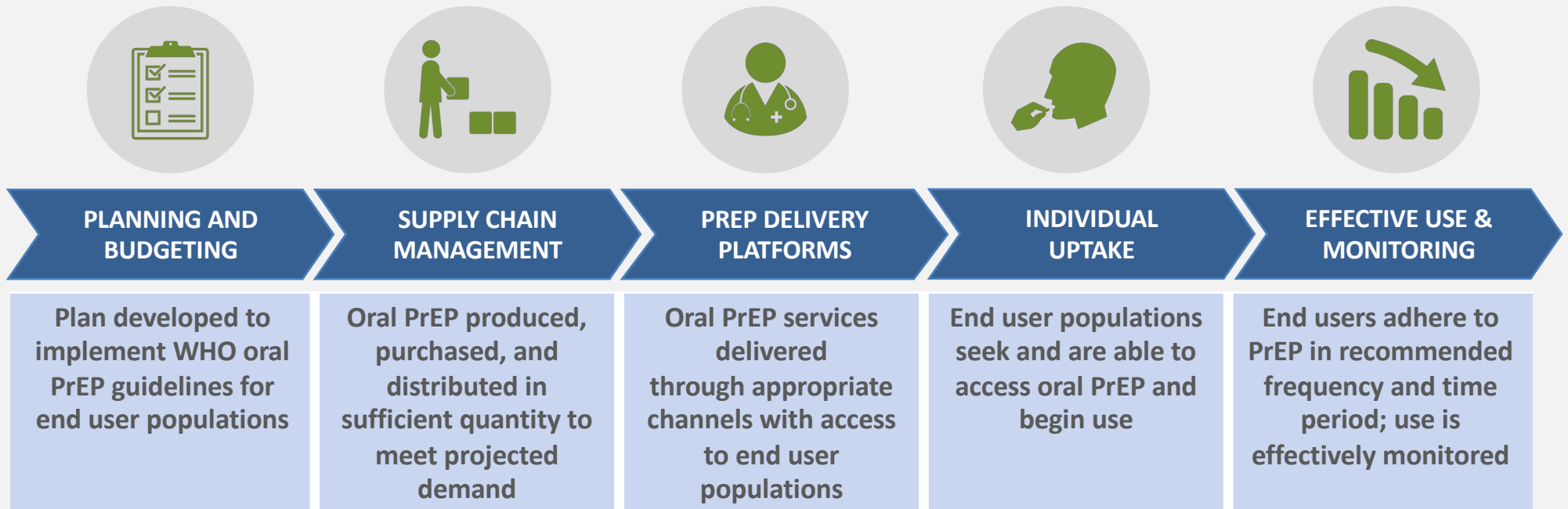
Please acknowledge USAID/OPTIONS with use of this toolkit.

Value Chain for oral PrEP Introduction

The templates, frameworks and tools included in this toolkit are organized along a simplified oral PrEP “value chain” that charts what is needed for national and subnational introduction of oral PrEP through five major stages, from initial planning through to uptake and ongoing monitoring.

While this toolkit is intended to support users primarily with the first stage of the value chain: planning, it is important to analyze assets and gaps at each stage to inform a comprehensive and robust planning process. This framework can also be adapted for other HIV prevention products

Value Chain for oral PrEP



This is the second tool in a series of six

1

SITUATION ANALYSIS

Understand current context for oral PrEP

- Identify existing assets, gaps, challenges, and key questions for PrEP rollout
- Develop a landscape of key stakeholders and ongoing efforts

2

PROJECT LANDSCAPE

Assess findings & gaps in projects

- Survey current and planned studies and implementation projects
- Identify key questions to inform implementation and assess gaps

3

ROLLOUT SCENARIOS

Inform where and how to rollout PrEP

- Define rollout scenarios that differ by counties/districts or population groups
- Highlight considerations and trade-offs between different scenarios

4

DISTRICT READINESS ASSESSMENT

Assess district readiness for oral PrEP

- Assess district/county readiness to introduce and scale oral PrEP
- Support sub-national planning for oral PrEP rollout and scale-up

5

FACILITY READINESS ASSESSMENT

Assess facility readiness for oral PrEP

- Assess the readiness of healthcare facilities to deliver oral PrEP
- Identify areas that require additional investment

6

PRIVATE SECTOR ASSESSMENT

Identify opportunities for oral PrEP in the private sector

- Understand if private sector channels could expand PrEP access
- Compare across channels for ability to effectively deliver PrEP

PROJECT LANDSCAPE

Overview of contents

This tool facilitates a structured process to identify insights and assess gaps in current and planned studies and implementation projects to inform oral PrEP introduction



DATA COLLECTION



Conduct phone or written **survey** of ongoing/planned oral PrEP implementation projects/studies to gather information

SLIDES 7 - 11

Data collection templates and sample survey questions



BASIC INFORMATION



Gather basic information on research studies and implementation projects to enable **improved coordination**

SLIDES 13 - 18

Templates to collect and present basic information on projects



RESEARCH GAP ANALYSIS

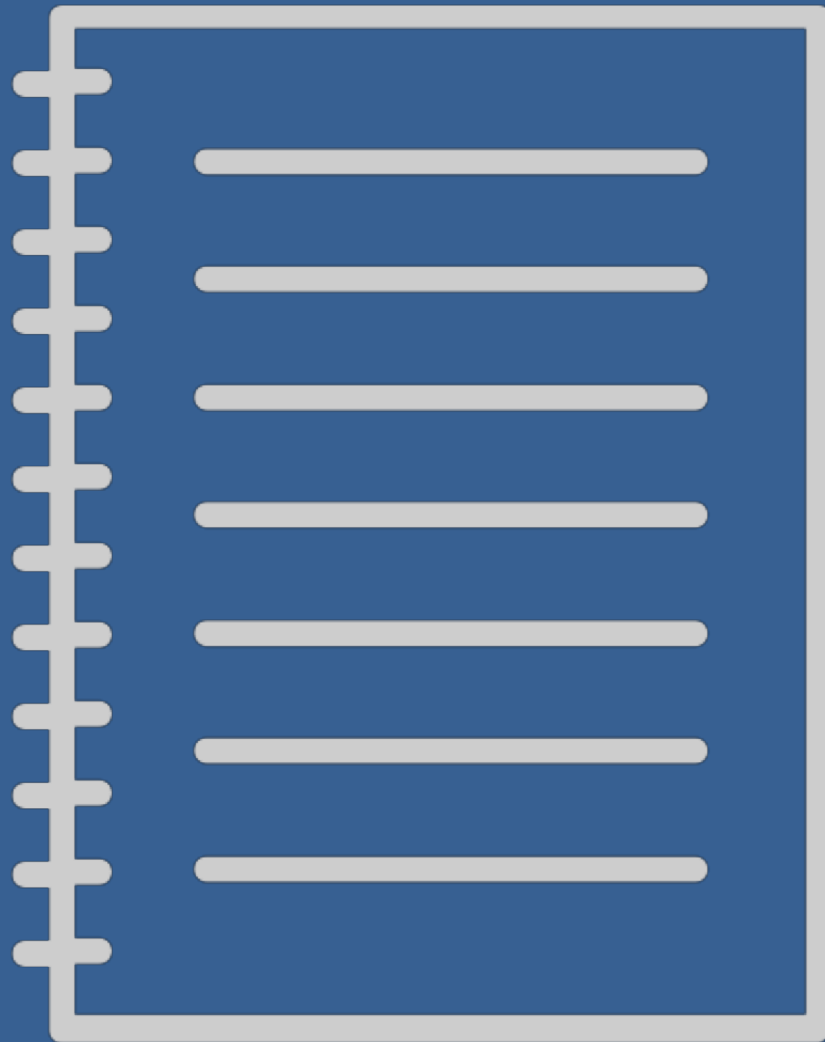


Build a common understanding of expected insights and gaps in the oral PrEP research relative to what is needed to effectively introduce oral PrEP

SLIDES 20 - 23

Templates to synthesize and present collected data

Completed Project Landscapes to Reference
[South Africa](#) | [Kenya](#) | [Zimbabwe](#)



**Oral PrEP PROJECT
LANDSCAPE
DATA COLLECTION**

Data Collection

Survey Guidance



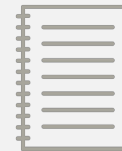
- Studies and implementation projects can be difficult to track, as they are funded and implemented independently by a range of different actors
- A survey of projects can help country governments and working groups develop a comprehensive understanding of ongoing research and implementation, expected insights from ongoing projects, and remaining gaps in the research agenda
- The survey can be developed in a written document or an Excel file and distributed to project Principal Investigators (PIs)
- Experience suggests that holding in-person meetings or phone / Skype calls with each PI is a more productive way to get responses and gather insights from the projects

CASE STUDY: SOUTH AFRICA

- Survey was prompted by the National Department of Health, with a specific focus on better understanding how studies and projects could inform planning for PrEP rollout to AGYW
- OPTIONS / Wits RHI developed and distributed a survey to project PIs, but received few responses. They then switched to scheduling phone calls with each PI to solicit information and received many more responses
- Wits RHI shared collected data with FSG, also part of the OPTIONS Consortium, to develop the analysis. The completed analysis can be downloaded [here](#)

Data Collection

Define Key Questions



PLANNING FOR ORAL
PREP ROLLOUT



ORAL PREP DELIVERY
PLATFORMS



INDIVIDUAL UPTAKE



EFFECTIVE USE &
MONITORING

Q1 To complete with questions

Q2

Q3

Q4

Q5

Q6

Q7

Q8

Q9

Q10

Q11

Q12

Q13

GOAL: Define the key questions that need to be answered to inform oral PrEP rollout

DIRECTIONS: Consult with key government / technical working group stakeholders to define key relevant questions for oral PrEP rollout. Organize these questions along the various components of the oral PrEP value chain.

Data Collection

Sample Questions for Analysis



- What are the **characteristics of high-risk user populations** and how can oral PrEP be effectively **targeted** to higher-risk populations?
- What are the major **barriers to oral PrEP uptake** for end user populations and how can they be addressed?
- What service delivery and civil society **channels** will most effectively reach different end user populations?
- What types of **investments** are required to effectively deliver oral PrEP through these channels? What are the cost implications?
- How can negative **health care worker attitudes** be effectively mitigated?
- What are the most effective **messages and strategies** to build awareness and/or generate demand for oral PrEP amongst end user populations?
- How are users **communicating** about oral PrEP to partners or family members and/or involving them in decisions?
- How are “**seasons of risk**” defined? What strategies/tools are effective to support users’ decision-making around on/off decisions for oral PrEP?
- To what extent are participants adhering to oral PrEP? What messages and strategies effectively support **daily adherence** to oral PrEP?
- To what extent are participants getting regular **HIV and STI testing**? What messages and strategies effectively support retention in regular testing?
- What do **PrEP users need** in delivery channels (e.g., hours that fit their schedules, friendly staff)?
- What strategies effectively reach **rural populations**?
- What are prevalent myths / misunderstandings around oral PrEP use? How can they be effectively addressed?
- What **information** should healthcare facilities **collect and report** to MOH?



These strategic questions can be translated into a survey to capture information from studies and implementation projects. Some common components of previous surveys include:





- *Project name , brief description, and status (i.e., ongoing, planned, completed)*
- *Sponsor / funder, lead organizations, and implementing partners*
- *Purpose of study (e.g., specific research questions, modeling or cost analysis objectives)*
- *Location(s), target population(s), criteria used to enroll participants in study, and age range of participants*
- *Delivery channels used (e.g., hospitals, family planning clinics, testing centers, mobile clinics), type of personnel dispensing oral PrEP (e.g., doctors, nurses)*
- *Data being collected with respect to: sexual behavior and HIV incidence among oral PrEP users, acceptability of and adherence to oral PrEP among different subpopulations, oral PrEP users' communications and relationships, behavioral characteristics of participants, and barriers to oral PrEP use*
- *Support provided to oral PrEP users, including communications / demand generation, adherence support, decision-making guidance*
- *Costs of programs with different implementation characteristics (outreach style, where program is conducted, by whom)*
- *Methods of engaging and supporting healthcare workers to effectively deliver oral PrEP*
- *Type of tools that are being created during the project (i.e., tools that can be shared/used beyond project, such as risk screening/assessment, user/community engagement and enrollment etc.)*

Data Collection

Data Collection Excel Template



Collecting data from the survey in an Excel file enables easy comparison across projects and responses. A sample Excel template can be found here.

   														
ORAL PrEP INTRODUCTION PLANNING TOOLKIT														
STEP 2: RESEARCH SURVEY - DATA COLLECTION TEMPLATE														
Project Details					Participants					Recruitment		Delivery		
Project Name	Programme Type	Sponsor/Funder	Lead Implementation Orgs.	Implementing Partner(s)	Target Population	Target Age categorization	Target # of PrEP enrollees	Requirements for inclusion	Requirements for exclusion	Locations of recruitment	Recruitment strategies	Location: County/District(s)	Delivery Channels Used	Facilities implementing
<i>Include brief description if applicable</i>	<i>See tab 2 for options</i>	<i>List related project donors</i>			<i>See tab 2 for options</i>	<i>Please specify exact age ranges</i>		<i>See tab 2 for options</i>	<i>See tab 2 for options</i>			<i>List counties / districts where project operates</i>	<i>See tab 2 for options</i>	<i>List specific facilities, if possible</i>
Project A														
Project B														
Project C														



ORAL PrEP PROJECT LANDSCAPE

BASIC INFORMATION

Basic Information Overview



Slides 12 - 15 can be used as a first step in organizing data from the survey along key dimensions of:

- Project description (slide 14)
- Timeline (slide 15)
- Target populations (slide 16)
- Geography (slide 17)

Basic Information

Summary of ongoing and planned research

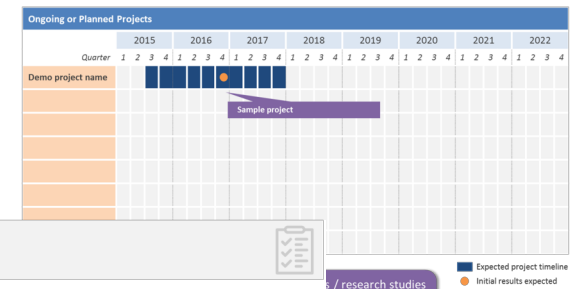
Ongoing or planned PrEP demo projects	Detailed information included
Demo project name	

There may be current or planned demo projects that did not respond to the survey. You may grey these projects out to indicate they are not part of the analysis.

GOAL: Provide an overview of the ongoing and expected demo projects and their objectives.
DIRECTIONS: Specify name and describe current or expected demo project.

Basic Information

Research Timeline



Basic Information

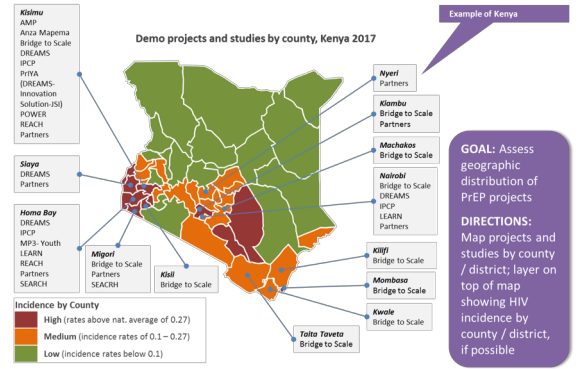
Population Coverage

Demo project name	MSM	FSW	Sero-discordant couples	AGYW	Bridging Populations

Additional populations (e.g., FSWID) can be added as needed.

Basic Information

Geographic Coverage




Basic Information

Summary of ongoing and planned projects



Ongoing or planned PrEP studies and implementation projects

 Detailed information included

Study/project name	1-2 sentence project description
[Grey]	
[Orange]	
[Grey]	
[Orange]	
[Orange]	
[Orange]	
[Orange]	
[Orange]	
[Orange]	
[Orange]	

There may be current or planned studies or projects that did not respond to the survey. You may grey these projects out to indicate they are not part of the analysis.

GOAL: Provide an overview of the ongoing and expected studies and implementation projects and their objectives

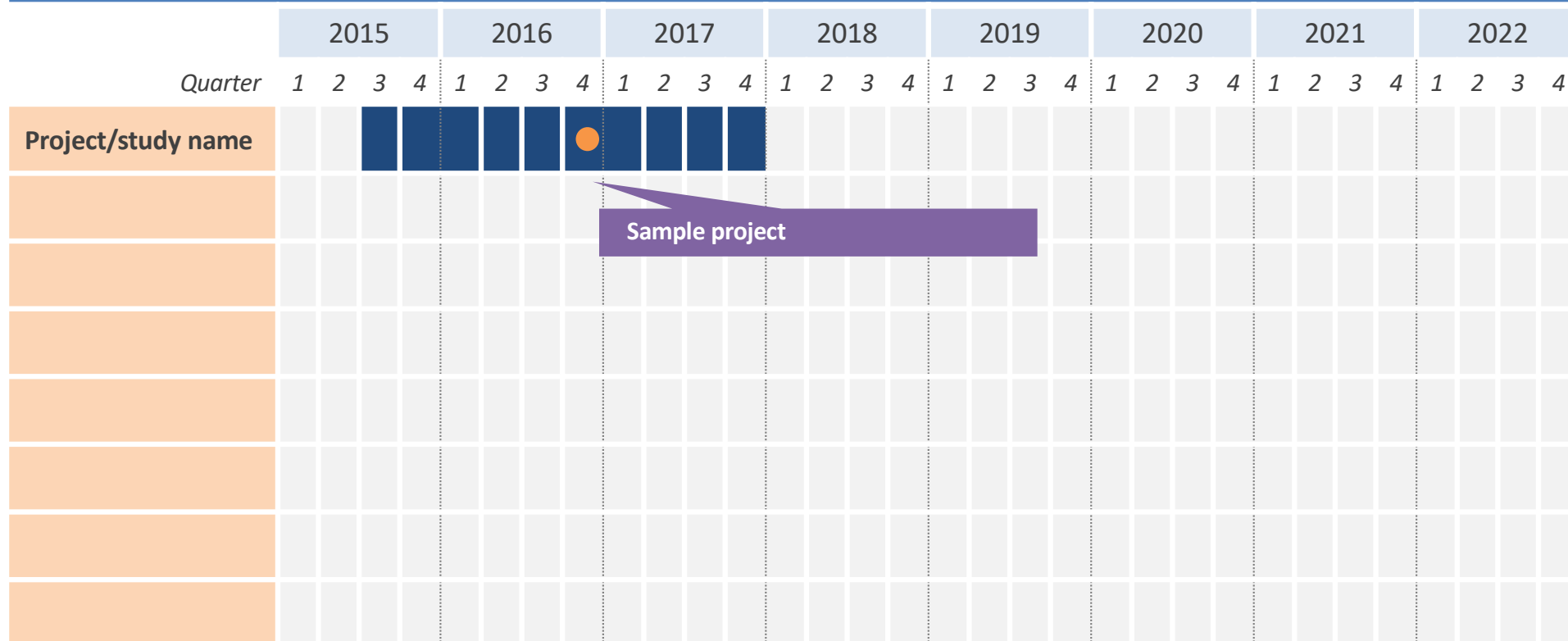
DIRECTIONS: Specify name and describe current or expected objective of each study/project

Basic Information

Research Timeline



Ongoing or Planned Projects



- Expected project timeline
- Initial results expected

GOAL: Track ongoing and planned studies and implementation projects

DIRECTIONS: Specify name and complete with expected timeline and key milestones for all projects and studies included in analysis

Basic Information

Population Coverage



	MSM	FSW	Serodiscordant couples	AGYW	Bridging Populations
Project/study name					
					<p>Additional populations (e.g., PWID) can be added as needed</p>
				Sample project	

GOAL: Assess populations included in studies and implementation projects
DIRECTIONS: Specify name and complete with target populations reached for all projects and studies included in analysis

Population included in study / project

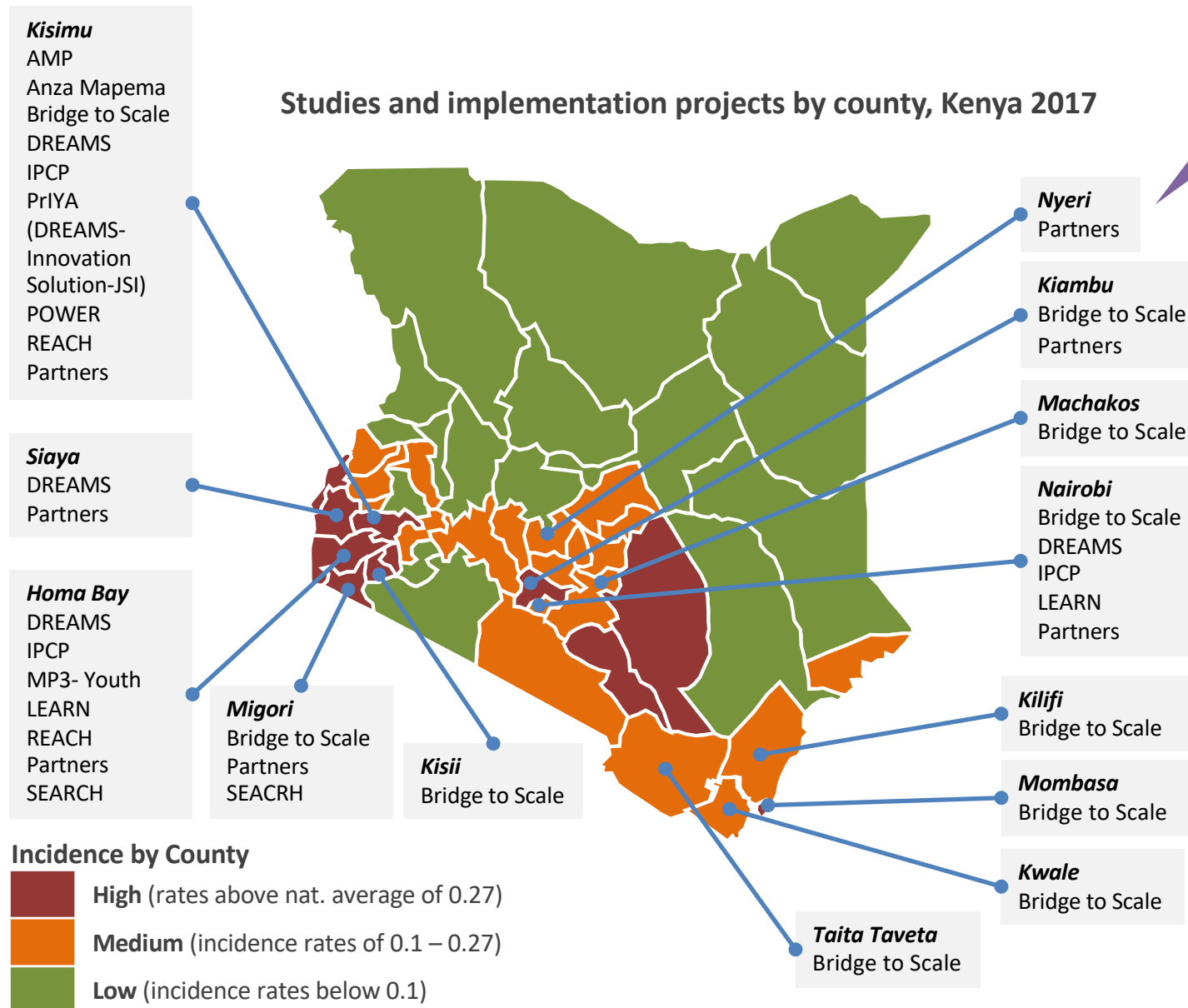
Basic Information

Geographic Coverage



Example of Kenya

Studies and implementation projects by county, Kenya 2017



GOAL: Assess geographic distribution of oral PrEP projects

DIRECTIONS: Map projects and studies by county / district; layer on top of map showing HIV incidence by county / district, if possible

Basic Information



Expected Tools Developed by Studies and Projects

Expected Tool Development

Project	Tools
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Project name	<i>e.g., risk assessment tools, healthcare worker decision guides, facility assessment tools, communications</i>

GOAL: Aggregate the various tools and resources that will be created as part of the studies and implementation projects, highlighting potential areas for collaboration, comparison, and gaps
DIRECTIONS: List the tools each study/project plans to create along with a brief description when the tools will be available



**ORAL PrEP PROJECT
LANDSCAPE**

GAP ANALYSIS

Project Gap Analysis Overview



The project gap analysis can be conducted in three steps:

1

Define key questions that government or other stakeholders feel are most relevant to inform oral PrEP implementation (~10 – 15 questions)

Slide 20

2

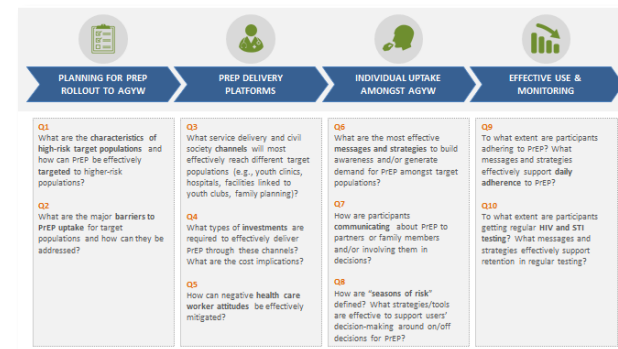
Based on data collected in the survey, complete one slide per question, identifying key insights and gaps across projects

Slide 21

3

Summarize expected progress across key questions, noting where many projects will inform a question (in green), where few projects will inform a question (orange), and where no projects are addressing the question (gray)

Slide 22



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

CHARACTERISTICS	Timeline	Characteristics	Insights expected from demo projects
Anza Mapema	Ongoing Jan 2017 – Jun 2018	MSM and; known partner HIV- or unknown status; received money in exchange for sex; had an STD; injected drugs; had sex with 3 or more partners.	✓ Anza Mapema, Bridge to Scale, DREAMS, and SEARCH studies will record behavioral data of study participants, which could yield insights into relevant risk factors for target populations.
AMP Study	Ongoing Aug 2015– Nov 2020	AGYW, FSW, PWID, sero-discordant couples, female fisherfolk, college students, partners of boda boda riders and truck drivers	✓ Demo projects will yield insights into a diverse set of target populations: AGYW, MSM, FSW, and sero-discordant couples
Bridgeto Scale (JHPIEGO)	Ongoing Jul 2018 – Jun 2020	AGYW ages 18-24	
Consumer Demand Driven PrEP for AGYW	Ongoing Oct 2016–Sep 2018	AGYW ages 18-24	
DREAMS	Ongoing 2016-2017	AGYW ages 18-24, ongoing HIV risk meets national criteria Sexual history will be collected	
IPCP	Ongoing 2014-2017	Women ages 15 – 29; MSM/FSW – 18+ yrs	
LEARN	Ongoing Oct 2016 – Sept 2018	Will be working through existing CBOs, support groups/clubs and networks to understand risk perception, and risk factors for AGYW	
Partners	Planned Jan 2017 – Dec 2022	Sero-discordant couples	
PHYA	Planned Sep 2016 – Sep 2018	HIV-uninfected women attending MCH/FP clinics classified as at substantial risk of HIV. 15-45 year old women, with 50% in 15-24 year age group	

Remaining questions about demo projects

- ? How will DREAMS and related studies define criteria for AGYW participation? What sexual history and behavioral data will be collected?
- ? How comprehensive are the behavioral assessments and self-risk perception tools? What can be learned from the SEARCH and Bridge to Scale tools?
- ? What insights will studies yield about the relationship between self-perceived risk and actual risk? Adherence?

Question	Status	Notes
Q1 What are the characteristics of high-risk target populations and how can PrEP be effectively targeted to them?	Green	Studies use differing "risk factors" to identify study participants; a comparison across them will be informative
Q2 What are the major barriers to PrEP uptake for target populations and how can they be addressed?	Orange	Some will test product acceptability, but little is known about plans to capture barriers to uptake
Q3 What service delivery and civil society channels will most effectively reach different target populations?	Green	Coverage across different types of delivery channels (e.g., primary care clinics, FP clinics, NGO sites)
Q4 What types of investments are required to effectively deliver PrEP through these channels?	Green	Bridge to Scale, IPCP, and Partners are collecting costing data
Q5 How can negative health care worker attitudes be effectively mitigated?	Gray	No awareness of current plans to study this aspect
Q6 What are the most effective strategies to build awareness and generate demand for PrEP amongst target populations?	Green	Significant focus on demand through various recruitment and communications strategies across demo projects
Q7 How are participants communicating about PrEP to partners or family members and/or involving them in decisions?	Gray	No awareness of current plans to study this aspect
Q8 How are "periods of risk" defined? What strategies / tools support users' decision-making around on/off decisions?	Orange	Consumer Demand Driven PrEP for AGYW will capture retention through risk periods, but unclear how those are defined. There is little / no focus on this in other studies
Q9 To what extent are participants adhering to PrEP? What messages and strategies effectively support adherence?	Green	Significant focus on adherence and strategies
Q10 Are participants getting regular HIV/STI testing? What strategies effectively support retention in regular testing?	Orange	Study seem to have a different testing protocol; comparisons across them may be useful

Data Collection

Define Key Questions



PLANNING FOR ORAL
PREP ROLLOUT



ORAL PREP DELIVERY
PLATFORMS



INDIVIDUAL UPTAKE



EFFECTIVE USE &
MONITORING

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GOAL: Define the key questions that need to be answered to inform oral PrEP rollout

DIRECTIONS: Consult with key government / technical working group stakeholders to define key relevant questions for oral PrEP rollout. Organize these questions along the various components of the oral PrEP value chain.

Project Gap Analysis

Expected Insights and Gaps Along the Value Chain



Q1 | Question (*ex: What are the **characteristics of high-risk target populations** and how can PrEP be effectively **targeted** to those populations?*)



Use the questions identified in the previous template and create one slide per question

CHARACTERISTICS

Study	Timeline	Characteristics

Expected timeline:
- Status (e.g., completed, ongoing, planned)
- Start and end dates (e.g. Nov 2016- Dec 2018)

Provide a brief description of how each study or project is contributing to the research on this question, if applicable.
This space can also be used to describe relevant characteristics of the project

Insights expected from projects

- ✓ e.g., three projects are collecting data on risk characteristics to inform targeting
- ✓ Describe what insights are expected from studies and implementation projects regarding the question

Remaining questions about projects

- ? e.g., To what extent are self-selecting PrEP users those at highest risk?
- ? Include outstanding questions about project plans and research agenda, and also specific gaps not being addressed

GOAL: Identify the relevant characteristics of and insights emerging from studies and projects related to each of the questions along the value chain

Project Gap Analysis

Key Questions Overview



Question	Status	Notes
Q1		
Q2		
Q3		
Q4		
Q5		
Q6		
Q7		
Q8		
Q9		
Q10		

Use the questions identified along the value chain on slide 10

GOAL: Provide an overview of the extent to which current and planned studies and implementation projects are tackling key questions and identify gaps in the research

DIRECTIONS: Update the status of each question per the legend below. Include a brief rationale for the status selected, including an overview of what is and is not being answered by current and planned projects

- Significant coverage
- Some projects address topic
- No projects address topic