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 us at info@PrEPNetwork.org.

Please acknowledge USAID/OPTIONS with use of this toolkit.
Value Chain for oral PrEP

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

<table>
<thead>
<tr>
<th>PLANNING AND BUDGETING</th>
<th>SUPPLY CHAIN MANAGEMENT</th>
<th>PREP DELIVERY PLATFORMS</th>
<th>INDIVIDUAL UPTAKE</th>
<th>EFFECTIVE USE &amp; MONITORING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan developed to implement WHO oral PrEP guidelines for end user populations</td>
<td>Oral PrEP produced, purchased, and distributed in sufficient quantity to meet projected demand</td>
<td>Oral PrEP services delivered through appropriate channels with access to end user populations</td>
<td>End user populations seek and are able to access oral PrEP and begin use</td>
<td>End users adhere to PrEP in recommended frequency and time period; use is effectively monitored</td>
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</table>
This is the second tool in a series of six

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
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<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SITUATION ANALYSIS</strong></td>
<td><strong>PROJECT LANDSCAPE</strong></td>
<td><strong>ROLLOUT SCENARIOS</strong></td>
<td><strong>DISTRICT READINESS ASSESSMENT</strong></td>
<td><strong>FACILITY READINESS ASSESSMENT</strong></td>
<td><strong>PRIVATE SECTOR ASSESSMENT</strong></td>
</tr>
</tbody>
</table>
| 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 | Assess findings & gaps in projects  
- Survey current and planned studies and implementation projects  
- Identify key questions to inform implementation and assess gaps | 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 | 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 | Assess facility readiness for oral PrEP  
- Assess the readiness of healthcare facilities to deliver oral PrEP  
- Identify areas that require additional investment | 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 |
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
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**

**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?
Data Collection
Sample Survey Questions

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

<table>
<thead>
<tr>
<th>Project Details</th>
<th>Participants</th>
<th>Recruitment</th>
<th>Delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Name</td>
<td>Target Population</td>
<td>Requirements for inclusion</td>
<td>Locations of recruitment</td>
</tr>
<tr>
<td>Include brief description if applicable</td>
<td>See tab 2 for options</td>
<td>See tab 2 for options</td>
<td></td>
</tr>
<tr>
<td>Programme Type</td>
<td>Target Age categories</td>
<td>Requirements for inclusion</td>
<td>Delivery channels (used)</td>
</tr>
<tr>
<td>See tab 2 for options</td>
<td>Please specify exact age ranges</td>
<td>See tab 2 for options</td>
<td></td>
</tr>
<tr>
<td>Sponsor/Funder</td>
<td>Implementing Partner(s)</td>
<td>Requirements for inclusion</td>
<td>Facilities implementing and specific facilities, if possible</td>
</tr>
<tr>
<td>List all relevant partner organisations</td>
<td></td>
<td>See tab 2 for options</td>
<td></td>
</tr>
<tr>
<td>Lead Implementation Org.</td>
<td>Target # of PEP enrollees</td>
<td></td>
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<tr>
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<td></td>
</tr>
</tbody>
</table>

- Project A
- Project B
- Project C
ORAL PrEP PROJECT LANDSCAPE BASIC INFORMATION
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 projects

<table>
<thead>
<tr>
<th>Study/project name</th>
<th>1-2 sentence project description</th>
</tr>
</thead>
</table>

**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

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: 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

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

**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
Basic Information
Geographic Coverage

**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

In Incidence by County
- **High** (rates above nat. average of 0.27)
- **Medium** (incidence rates of 0.1 – 0.27)
- **Low** (incidence rates below 0.1)
### Expected Tool Development

<table>
<thead>
<tr>
<th>Project name</th>
<th>Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>e.g., risk assessment tools, healthcare worker decision guides, facility assessment tools, communications</td>
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</tbody>
</table>

**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
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)

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

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)
**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.

<table>
<thead>
<tr>
<th>PLANNING FOR ORAL PREP ROLLOUT</th>
<th>ORAL PREP DELIVERY PLATFORMS</th>
<th>INDIVIDUAL UPTAKE</th>
<th>EFFECTIVE USE &amp; MONITORING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1 To complete with questions</td>
<td>Q5</td>
<td>Q8</td>
<td>Q11</td>
</tr>
<tr>
<td>Q2</td>
<td>Q6</td>
<td>Q9</td>
<td>Q12</td>
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<tr>
<td>Q3</td>
<td>Q7</td>
<td>Q10</td>
<td>Q13</td>
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<tr>
<td>Q4</td>
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</tbody>
</table>
# 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.

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### CHARACTERISTICS

<table>
<thead>
<tr>
<th>Study</th>
<th>Timeline</th>
<th>Characteristics</th>
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</table>

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

**Characteristics:**
- 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

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**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

<table>
<thead>
<tr>
<th>Question</th>
<th>Status</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td></td>
<td></td>
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<tr>
<td>Q2</td>
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<td>Q9</td>
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<tr>
<td>Q10</td>
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</table>

**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**

*Use the questions identified along the value chain on slide 10*