

Oral PrEP Introduction Planning Toolkit

STEP 1: SITUATION ANALYSIS



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 and other PrEP products

WHO SHOULD USE THIS TOOLKIT?

This toolkit will be most relevant for:



National governments and ministries of health/HIV agencies to inform national oral PrEP rollout and provide high-level guidance to counties/districts on what factors should be considered to ensure they are prepared to rollout oral PrEP. This toolkit can also be adapted for other products.



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 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.

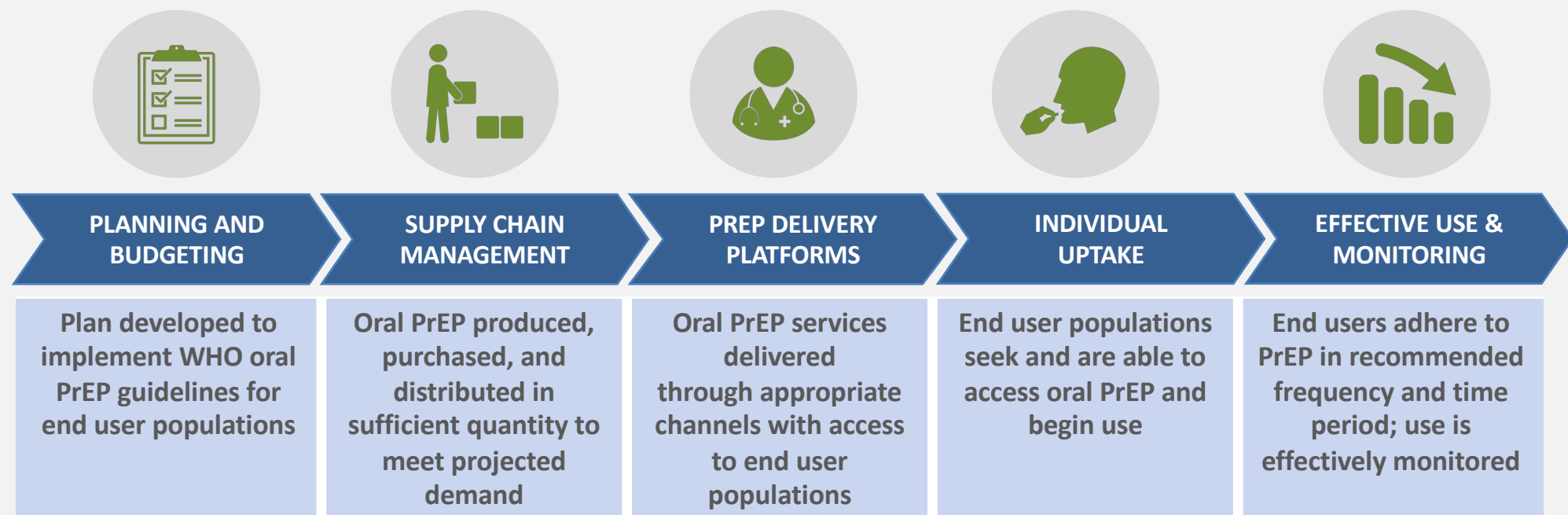
Please acknowledge USAID/OPTIONS with use of this toolkit.

Value Chain for oral PrEP 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 first 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

SITUATION ANALYSIS

Overview of contents

This tool facilitates a structured process to support initial planning for oral PrEP introduction



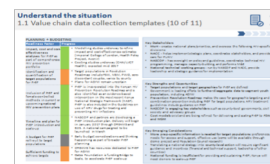
DATA COLLECTION



Guide secondary and primary data collection on oral PrEP landscape

SLIDES 8 - 14

Value chain data collection templates



ANALYSIS & SYNTHESIS



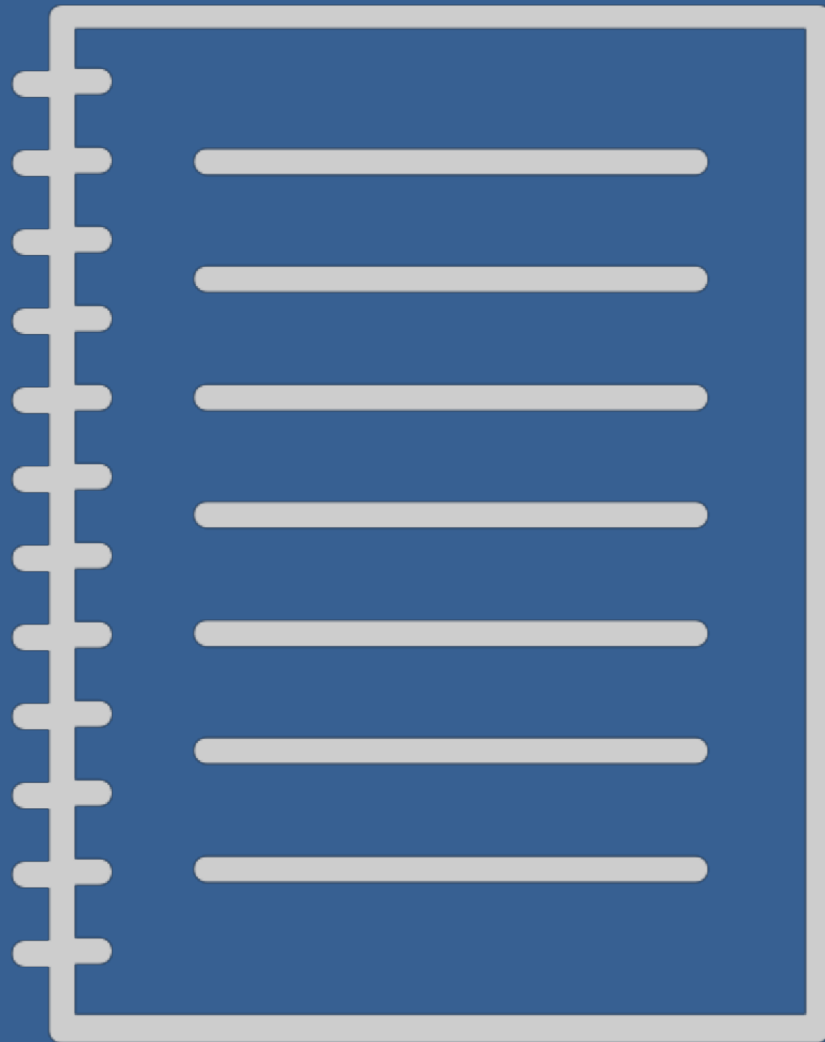
Build a common understanding among stakeholders of what is needed to effectively introduce oral PrEP

SLIDES 17 - 20

Templates to synthesize and present collected data



Completed Situation Analyses to Reference
[South Africa](#) | [Kenya](#) | [Zimbabwe](#)



SITUATION ANALYSIS DATA COLLECTION TEMPLATES

Situation Analysis – Data Collection

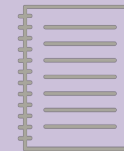


The oral PrEP planning tool is an excel document that catalogues ongoing progress, resources and gaps along the value chain (see related Excel workbook).

OPTIONS_Implementation Planning Framework_29Mar2016 [Read-Only] - Microsoft Excel

OPTIONS_Implementation Planning Framework_29Mar2016 [Read-Only] - Microsoft Excel									
<div>FileHomeInsertPage LayoutFormulasDataReviewView</div> <div>PasteCutCopyFormat PainterClipboardFontAlignmentNumberConditional FormattingFormat as Table</div> <div>Calibri11NormalBadGoodNeutralExplanatory...InputLinked Cell</div> <div>Styles</div>									
G7									
COUNTRY COLLABORATIVE FRAMEWORK - KENYA									
29-Mar-16									
TO BE POPULATED / COMPLETED BY OPTIONS COUNTRY PARTNERS									
PrEP SITUATION AND KEY STAKEHOLDERS									
Value Chain Component	Readiness Factor	Progress	Current Situation	Existing and Anticipated Non-financial Resources	Funding Resources	Resource Gaps	Notes for the Investment Scenarios (e.g. content times, key audiences)		
PLANNING AND BUDGETING	Impact, cost and cost-effectiveness analyses for PrEP as part of comprehensive HIV prevention portfolio	Significant Ongoing Activity	* Modelling studies underway to refine impact and cost-effectiveness estimates (Health Policy Project, Avenir) * Costing studies underway (CHAIL/VCT Health); expected Q4 2016	Avenir: Conducted costing study for FSW and MSM CHAI / LVCT: Conducting costing study across populations (FSW, MSM, and AGYV) and across delivery channels (NGO and public sector) - results expected Q4 2016 Imperial College of London: Developed model for PrEP impact in Nyanza province Gates Foundation: Funder of studies associated with PrEP demonstration projects					
	Identification and quantification of target populations for PrEP	Early Progress	* Target populations in Revolution Roadmap include FSW, MSM, PWID, zero-discordant couples, varied by county * Plans for AGYV remain uncertain * CHAI: Developing target population size estimates across several countries, including Kenya	Demonstration projects: Can inform target population product and use preferences, expected adherence, etc.					
	Inclusion of PrEP and female-controlled methods in current or upcoming national HIV prevention plans	Significant Ongoing Activity	* PrEP is mentioned in the KASF and included in Revolution Roadmap as part of recommended prevention interventions						
	Timeline and plan for PrEP introduction and scale-up	Early Progress	* Early considerations articulated * NASCOP has asked LVCT Health to support development of an implementation plan					- Given the potential speed of decision-making in Kenya, what is the appropriate time / use for the investment cases?	
SUPPLY CHAIN MANAGEMENT	A budget for PrEP roll-out to target populations	Conversations Initiated	* Early budget considerations and thinking happening as part of broader PrEP planning						
	Regulatory approval of form(s) of oral PrEP by authorities	Significant Ongoing Activity	* Truvada approved for prevention by the Pharmacy and Poisons Board Other forms of oral PrEP in pipeline						
	Effective demand and supply forecasting mechanisms for PrEP	Conversations Initiated	* Strong supply chain management in place for ARVs, which will likely translate to PrEP readiness						
	Manufacturer identification and contract negotiation to purchase PrEP	Conversations Initiated	* Not outside of demonstration projects					- To what extent are pharmaceutical manufacturers a key audience for the investment scenarios?	
	Product and packaging design to meet target population	Early Progress	* Currently a plastic pill bottle, to be refilled monthly; unknown if format will be consistent for other forms of oral PrEP						

Situation Analysis – Data Collection Instructions



This section includes 1 – 2 data collection template slides for each section of the oral PrEP introduction value chain



These readiness factors correspond to each section of the value chain

This space provides room for a brief description of the current state of each component.

Illustrative questions are included in the following slides to guide data collection

The components can be assessed according to the color key to the right. Ratings are meant to indicate relative progress, and are more art than science

PLANNING + BUDGETING	
Readiness Factor	Progress
Cost and impact effectiveness analyses for PrEP have been conducted	
Target populations are identified, quantified, and productive	
Female-controlled methods are included in current or upcoming national HIV prevention plans	
A timeline and plan for PrEP introduction and scale-up has been established	
A budget for PrEP roll-out to target populations is established	
Sufficient funding has been secured to achieve targets	

Key Stakeholders

Key Strengths and Opportunities

Key Emerging Considerations

Funding and other resources

Specify name and describe current or expected role of stakeholders for the components on the left

List key assets and/or strengths in relation to the activities on the left

List key obstacles and/or considerations in relation to activities on the left

List key funding and other resources available/upcoming to enable the activities on the left or others related to this stage of the value chain

COLOR KEY

- Significant progress and/or momentum
- Early progress
- Limited progress

Situation Analysis – Data Collection Templates

Value Chain Section 1: Planning & Budgeting



PLANNING AND BUDGETING

Readiness Factor	Progress
Impact, cost and cost-effectiveness analyses for oral PrEP	<ul style="list-style-type: none"> What is the current thinking on the cost-effectiveness and impact of oral PrEP? What analyses have already been conducted or will be conducted?
Identification and quantification of end user populations for oral PrEP	<ul style="list-style-type: none"> To what extent have decisions about end user populations been made? What data already exists on end user populations?
Inclusion of oral PrEP and female-controlled methods in current or upcoming national HIV prevention plans	<ul style="list-style-type: none"> To what extent is oral PrEP already included in national HIV plans? Is planning for oral PrEP expected to fall within HIV prevention or HIV treatment?
Integration with SRH , family planning, and other programming	<ul style="list-style-type: none"> How can oral PrEP be integrated with broader SRH and other programming, especially for women and AGYW?
Timeline, plan for oral PrEP introduction and scale-up	<ul style="list-style-type: none"> To what extent has a timeline and plan for oral PrEP introduction already been developed?
A budget for oral PrEP rollout to end user populations	<ul style="list-style-type: none"> Is oral PrEP already included in government budgets? At the national/subnational level? Is budgeting for oral PrEP expected to fall within HIV prevention or HIV treatment?
Sufficient funding to achieve end users	<ul style="list-style-type: none"> What global funders have / are expected to commit(ted) funding for oral PrEP scale-up? What is the expected timeline for decisions? What are relevant key milestones?

Key Stakeholders

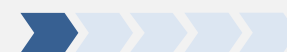
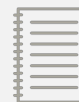
Key Strengths and Opportunities

Key Emerging Considerations

Funding and Resources

Situation Analysis – Data Collection Templates

Value Chain Section 1: End User Populations for PrEP

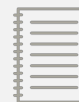


Assessment of End User Populations for PrEP

	Adolescent girls	Young women	Serodiscordant couples	Female Sex Workers (FSW)	People Who Inject Drugs (PWID)	Men who have sex with men (MSM)
Key Indicators	<p>For each population group, include:</p> <ul style="list-style-type: none"> • Size • Contribution to new infections • Prevalence • Current access to HTC or other relevant health services 				<p>Population types are illustrative. Please complete for population types that align with your HIV strategy.</p> <p>Other populations to include could include key commercial / bridging populations, such as miners, truck drivers, fishing/agricultural workers</p>	
Prioritization	<p>For each population group, include:</p> <ul style="list-style-type: none"> • Inclusion/exclusion as priority population in country's national HIV plan • If PrEP guidelines exist or are under development, inclusion/exclusion of this population as priority for oral PrEP delivery • Demonstration projects working with this population 					
Questions	<p>For each population group, include:</p> <ul style="list-style-type: none"> • Key questions that will need to be answered in order to guide implementation for each population 					

Situation Analysis – Data Collection Templates

Value Chain Section 2: Supply Chain Management



SUPPLY CHAIN MANAGEMENT

Readiness Factor	Progress
Regulatory approval of form(s) of oral PrEP by authorities	<ul style="list-style-type: none"> • What is the current situation and timeline? • To what extent will registration be a barrier to effective scale-up of PrEP provision? • What opportunities do you see that could overcome these barriers, or facilitate progress?
Effective demand and supply forecasting mechanisms for oral PrEP	<ul style="list-style-type: none"> • To what extent will supply/demand forecasting for oral PrEP differ from the existing process for ARVs? How? • To what extent will this activity be a barrier to effective scale-up of oral PrEP provision? • What opportunities do you see that could overcome these barriers, or facilitate progress?
Manufacturer identification and contract negotiation to purchase oral PrEP	<ul style="list-style-type: none"> • To what extent will the procurement process for oral PrEP differ from the existing process for ARVs? How? • To what extent will this activity be a barrier to effective scale-up of oral PrEP provision?
Product and packaging design to meet end user population needs and preferences	<ul style="list-style-type: none"> • How will oral PrEP be packaged to meet needs of end user populations? • Who is / will be involved in developing product and packaging design?
Development of distribution plan for oral PrEP to reach end user populations	<ul style="list-style-type: none"> • What is the expected planning process for distribution? • Who is / will be involved in distribution planning?
Effective distribution mechanisms to avoid oral PrEP stock-outs in priority facilities	<ul style="list-style-type: none"> • To what extent will oral PrEP be distributed through existing mechanisms used to distribute ARVs? What might be different? • To what extent will safe distribution be a barrier to effective scale-up of oral PrEP? • What opportunities do you see that could overcome these barriers, or facilitate progress?

Key Stakeholders

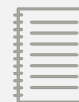
Key Strengths and Opportunities

Key Emerging Considerations

Funding and Resources

Situation Analysis – Data Collection Templates

Value Chain Section 3: Oral PrEP Delivery Platforms



PREP DELIVERY PLATFORMS

Readiness Factor	Progress
Issuance of standard clinical guidelines for prescription and use of oral PrEP	<ul style="list-style-type: none"> • <i>What is the current situation? What is the timeline?</i> • <i>Who will issue treatment guidelines for public and private healthcare workers? Who influences these decisions?</i> • <i>To what extent will this activity be a barrier to effective scale-up of oral PrEP provision? How do you see overcoming these barriers?</i>
Sufficient infrastructure and human resources to conduct initial HIV tests and prescribe PrEP in priority channels	<ul style="list-style-type: none"> • <i>To what extent do the healthcare facilities that reach end user populations have capacity to deliver oral PrEP?</i> • <i>How is this expected to change in the next 1-3 years?</i> • <i>What are potential barriers? Ways to address these barriers?</i>
Plan to engage health care workers on PrEP and delivery to end user populations (including mitigating stigma)	<ul style="list-style-type: none"> • <i>What types of HCWs will be able to prescribe / dispense oral PrEP?</i> • <i>To what extent is there a plan for how HCWs will be trained to deliver oral PrEP?</i> • <i>Is it expected that HCWs who do not currently prescribe ARVs will be prescribing oral PrEP? If so, what additional support is planned for them?</i>
Tools to help potential clients and HCW understand who should use PrEP have been created	<ul style="list-style-type: none"> • <i>To what extent are HCWs aware, able and willing to prescribe oral PrEP when it becomes available?</i> • <i>To what extent have tools to help potential clients and HCW understand who should use oral PrEP been created?</i>
Sufficient resources to rollout plans for healthcare worker engagement	<ul style="list-style-type: none"> • <i>To what extent will there be sufficient funding to build needed healthcare capacity?</i> • <i>Why? What specific challenges do you anticipate?</i> • <i>What opportunities do you see that could overcome these barriers, or facilitate progress?</i>

Key Stakeholders

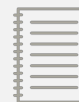
Key Strengths and Opportunities

Key Emerging Considerations

Funding and Resources

Situation Analysis – Data Collection Templates

Value Chain Section 3: Oral PrEP Delivery Platforms

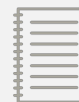


Assessment of Potential Delivery Channels for Oral PrEP

	Channel #1	Channel #2	Channel #3	Channel #4
Context	For each channel, include: information on size, management, geographic distribution			These channels will vary by country, but could include: public hospitals, comprehensive care clinics, maternal health clinics, family planning clinics, private hospitals and clinics, youth health centers, and mobile clinics, among many others. Customize your analysis to capture a representative set of channels for oral PrEP delivery in your country.
Population reach	For each channel, include: data on #of people accessing services and frequency of access and/or on HIV prevalence/incidence characteristics			
Assets	For each channel, include: existing assets channel can leverage to effectively deliver oral PrEP			
Needs	For each channel, include: investments required for channel to deliver oral PrEP (e.g., laboratory equipment)			
Research	For each channel, include: research efforts related to delivery channel (e.g., demo projects, costing studies)			

Situation Analysis – Data Collection Templates

Value Chain Section 4: Individual Uptake



INDIVIDUAL UPTAKE	
Readiness Factor	Progress
Clear and informative communications on oral PrEP for general public audiences	<ul style="list-style-type: none"> • <i>What is the current awareness of oral PrEP in the country?</i> • <i>To what extent has a clear and informative communications plan for oral PrEP education and awareness been developed?</i> • <i>What existing efforts are underway?</i>
Development of demand generation strategies targeted to unique needs of different populations	<ul style="list-style-type: none"> • <i>To what extent have demand generation plans been developed for HCT (or oral PrEP specifically)?</i> • <i>To what extent do end user populations currently understand and demand oral PrEP?</i> • <i>What organizations are expected to implement demand generation activities for oral PrEP?</i>
Linkages between HTC, oral PrEP prescription, and oral PrEP access to enable uptake	<ul style="list-style-type: none"> • <i>To what extent do/will linkages between HTC, oral PrEP prescription, and access enable oral PrEP uptake?</i> • <i>What organizations are expected to establish and ensure effective linkages to enable oral PrEP uptake?</i> • <i>To what extent will lack of effective linkages be a barrier to effective scale-up of oral PrEP?</i> • <i>What opportunities do you see that could overcome these barriers, or facilitate progress?</i>
Information for clients on how to effectively use oral PrEP for all end user populations	<ul style="list-style-type: none"> • <i>What is the funding plan for oral PrEP demand generation / what is it likely to be?</i> • <i>To what extent will there be sufficient funding for oral PrEP demand generation?</i>

Key Stakeholders

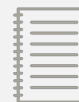
Key Strengths and Opportunities

Key Emerging Considerations

Funding and Resources

Situation Analysis – Data Collection Templates

Value Chain Section 5: Effective Use & Monitoring



EFFECTIVE USE + MONITORING

Readiness Factor	Progress
Established plans to support effective use of oral PrEP and regular HIV, creatinine testing that reflect the unique needs of end user populations	<ul style="list-style-type: none"> <i>To what extent do you expect effective use to be a barrier for scale-up of oral PrEP?</i> <i>How will effective use vary by population?</i> <i>What stakeholders will be responsible for developing a plan and/or executing programming around effective use?</i> <i>What data already exists?</i>
Capacity to provide ongoing HIV and creatinine level testing for oral PrEP users accessible to end user populations	<ul style="list-style-type: none"> <i>What will protocols be for ongoing testing?</i> <i>To what extent will insufficient HIV and other (e.g., creatinine) testing capacity be a barrier to scale-up of oral PrEP?</i>
Monitoring system to support data collection for ongoing learning (e.g., rate of patients returning for 2nd visit, non-HIV STI rates)	<ul style="list-style-type: none"> <i>How has / will oral PrEP be integrated into existing health monitoring systems? What indicators will be tracked?</i> <i>What will need to change? Who will need to be involved?</i>

Key Stakeholders

Key Strengths and Opportunities

Key Emerging Considerations

Funding and Resources



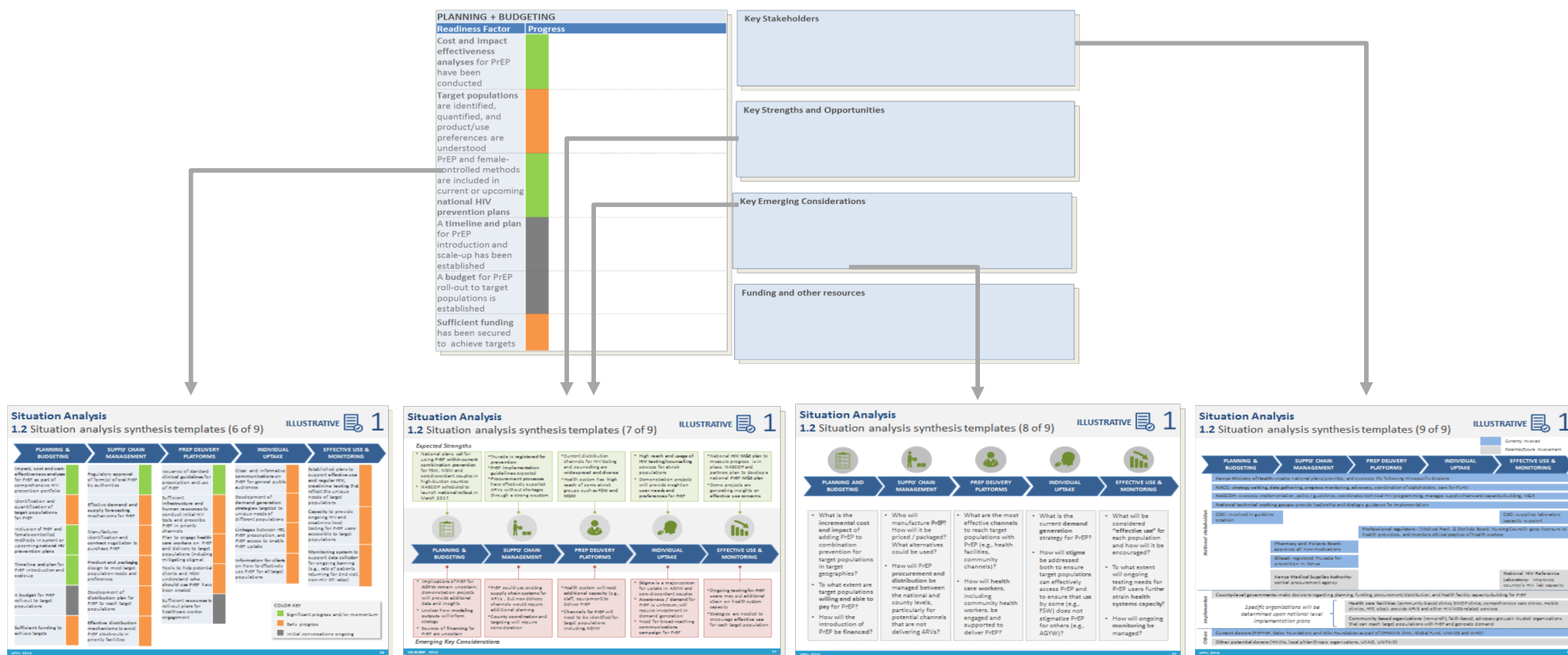
SITUATION ANALYSIS

SYNTHESIS & ANALYSIS TEMPLATES

Situation Analysis – Synthesis & Analysis Instructions



The next set of slides will summarize information from the data collection templates so that it can be easily shared with key stakeholders.



Synthesize the performance assessment for each stage along the value chain to highlight areas that may need investment

Synthesize strengths and emerging considerations along the value chain to inform planning

Leverage considerations and other unknowns or information gaps to identify remaining key questions along the value chain

Map key stakeholders to understand who is involved or could be involved in oral PrEP planning along the value chain

Situation Analysis – Synthesis & Analysis Templates

State of Progress on PrEP Introduction



PLANNING & BUDGETING	SUPPLY CHAIN MANAGEMENT	PREP DELIVERY PLATFORMS	INDIVIDUAL UPTAKE	EFFECTIVE USE & MONITORING
Impact, cost and cost-effectiveness analyses for oral PrEP as part of comprehensive HIV prevention portfolio	Regulatory approval of form(s) of oral PrEP by authorities	Issuance of standard clinical guidelines for prescription and use of PrEP	Clear and informative communications on oral PrEP for general public audiences	Established plans to support effective use and regular HIV, creatinine testing that reflect the unique needs of user populations
Identification and quantification of end user populations for oral PrEP	Effective demand, supply forecasting mechanisms for oral PrEP	Sufficient infrastructure and human resources to conduct initial HIV	Development of demand generation strategies targeted to unique needs of	Capacity to provide ongoing HIV and
Inclusion of PrEP, female-controlled methods in current or upcoming national HIV prevention plans				
Integration with SRH, family planning, and other programming				
Timeline and plan for PrEP introduction and scale-up	Development of distribution plan for oral PrEP to reach end users	Tools to help potential clients and HCW understand who should use oral PrEP	effectively use oral PrEP for all end user populations	(e.g., rate of users returning for 2nd visit, non-HIV STI rates)
A budget for oral PrEP rollout to end user populations	Effective distribution mechanisms to avoid oral PrEP stock-outs in priority facilities	Sufficient resources to rollout plans for healthcare worker engagement		
Sufficient funding to achieve targets				

GOAL: To understand the current state of progress of each of these components along the value chain.

DIRECTIONS: Update the progress bars based on the assessment made for your country per the color key in the data collection templates.

COLOR KEY

- Significant progress and/or momentum
- Early progress
- Limited progress

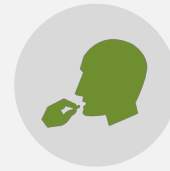
Situation Analysis – Synthesis & Analysis Templates

Strengths and Considerations for PrEP Introduction



Expected Strengths

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PLANNING &
BUDGETING

SUPPLY CHAIN

PREP DELIVERY

INDIVIDUAL

EFFECTIVE USE &
MONITORING

GOAL: To outline the expected strengths and challenges or considerations that are emerging along the various components of the value chain.

DIRECTIONS: For each stage of the value chain, include 1-3 expected strengths and/or assets that could be leveraged for PrEP delivery in the green boxes, and 1-3 expected barriers and/or obstacles that need to be addressed for successful PrEP delivery in the red boxes.

Emerging Key Considerations

Situation Analysis – Synthesis & Analysis Templates

Key Questions to Inform Rollout of PrEP



PLANNING AND
BUDGETING



SUPPLY CHAIN
MANAGEMENT



PREP DELIVERY
PLATFORMS



INDIVIDUAL
UPTAKE



EFFECTIVE USE &
MONITORING

- Question 1
- Question 2
- Question 3

GOAL: To identify the remaining key questions about PrEP and its introduction along the value chain.

DIRECTIONS: List the key outstanding concerns, information gaps, and unknowns for each stage of the value chain.

Situation Analysis – Synthesis & Analysis Templates

Stakeholder Map for PrEP Introduction



You can categorize stakeholders by **type**, **value chain stage** and **involvement status**



Currently involved

Potential/future involvement

