

# PRIVATE SECTOR-PREP DELIVERY POLICY AND REGULATORY LANDSCAPE ANALYSIS IN SUB-SAHARAN AFRICA

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Department of Global Health | University of Washington



# OVERVIEW

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  - 4: Contacted subject matter experts



# PROJECT TEAM



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# START OVERVIEW



Leverages leading content expertise from across the University of Washington



Provides high quality research and analytic support to the Bill & Melinda Gates Foundation and global and public health decision-makers



Provides structured mentorship and training to University of Washington graduate research assistants

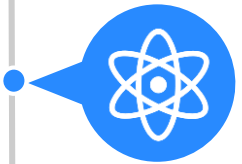
# PROJECT OVERVIEW

# BACKGROUND



## HIV EPIDEMIOLOGY

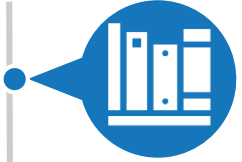
- **37.7 million adults and children** are living with HIV/AIDS
  - The highest burden comes from **sub-Saharan Africa**
  - In 2020, about **1.5 million new infections occurred**
- In 2021:
  - 85% of people living with HIV knew their HIV status
  - 75% were on antiretroviral therapy
  - 68% were virally suppressed



## PrEP OVERVIEW

- PrEP is highly effective for HIV prevention
- PrEP currently exists as either a **pill, vaginal ring, or an injection**
- The **high cost** has been a substantial barrier to its widespread utilization
- 940,000 people in **83 countries** received oral PrEP at least once in 2020
  - African (52%) and Americas region (30%)
- **130 countries** in 2020 reported that they had adopted the WHO recommendations

# PROJECT REQUEST



## RESEARCH GAPS

- Currently, there is a **lack of accessible and cost-effective delivery methods for PrEP**
- Pharmacies may be able to **fill this gap** given their increased privacy, user preference, shorter wait times, and diverse clientele
- In some countries, pharmacists are not allowed to prescribe PrEP

Characteristics of AGYW seeking contraception		
	AGYW seeking contraception at retail pharmacies <sup>1</sup> (n=235)	AGYW seeking contraception at FP clinic at health facilities <sup>2</sup> (n=470)
Accepted PrEP	87%	4%
Accepted HIV self-test kits <sup>4</sup>	71%	19%



## PROJECT OBJECTIVE

- To conduct a landscape assessment of regulatory and policy barriers to PrEP (oral and long-acting) delivery through private sector pharmacies and clinics across Sub-Saharan Africa



# PROJECT OVERVIEW

## MOTIVATION

This work will help the client develop a more **holistic view of the opportunity in using private pharmacies and clinics as an innovative delivery channel for PrEP** and inform the possible development of a broader scale-up strategy aligned with NPP&I existing grants.

## ADDITIONAL CONSIDERATIONS

There was a particular focus on:

- Adolescent girls and young women (AGYW)
- Understanding existing delivery channels for PrEP services
- Political will to engage with injectable PrEP

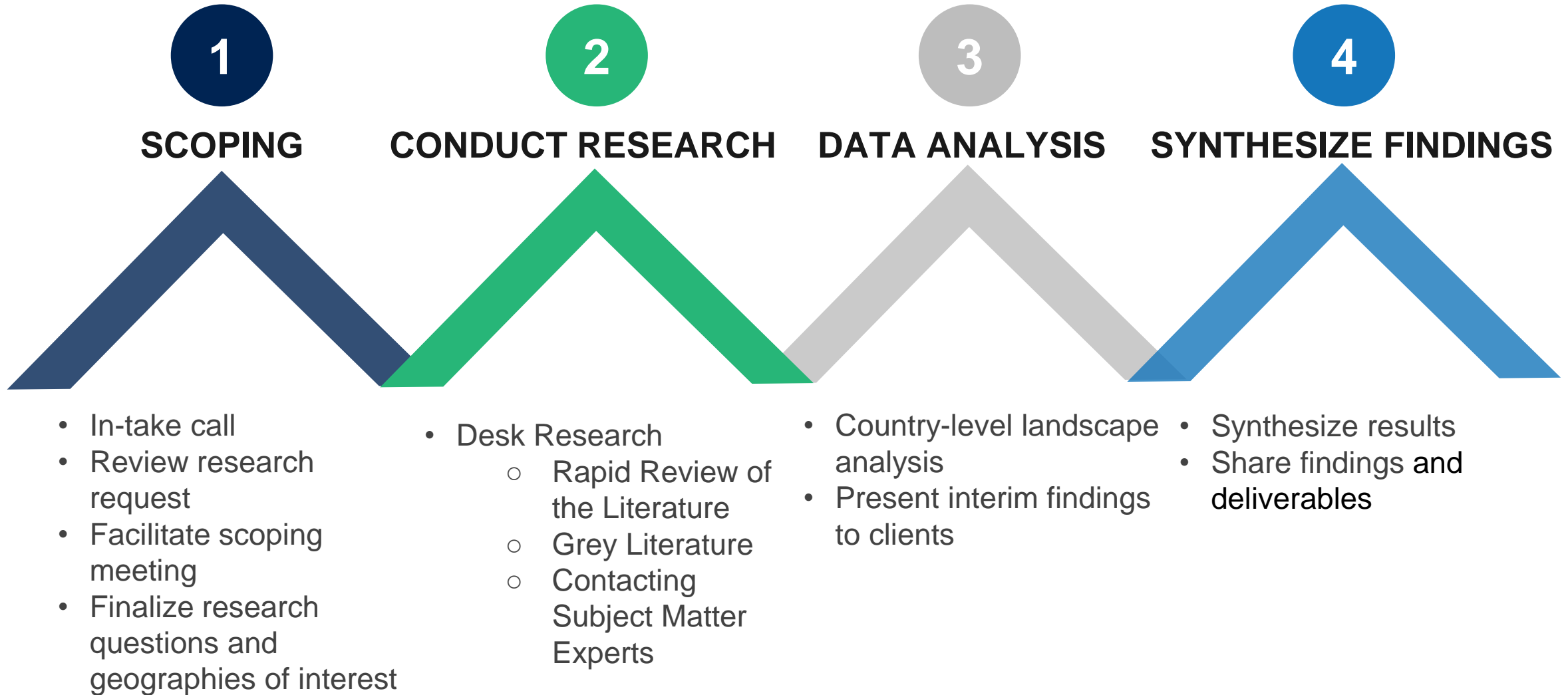
## FOCUS GEOGRAPHIES

- **First Look:** (1) Nigeria, (2) Tanzania
- **Second Look:** (3) Mozambique, (4) Zambia, (5) Ghana, (6) Uganda
- **Third Look:** (7) Eswatini, (8) Zimbabwe, (9) Cameroon, (10) Côte d'Ivoire



# APPROACH

# WORK STREAM



# 1 SCOPING

## Country Selection\*

### Key Considerations:

- Number of people with HIV/AIDS
- Number of adolescents (10-19) with HIV/AIDS
- Number of women (15+) with HIV/AIDS
- Adult prevalence of HIV/AIDS
- Annual deaths from HIV/AIDS
- Catalyst Global results



\*Malawi, South Africa, and Kenya were excluded from consideration due to the existing high-levels of research in these countries

# 1 SCOPING

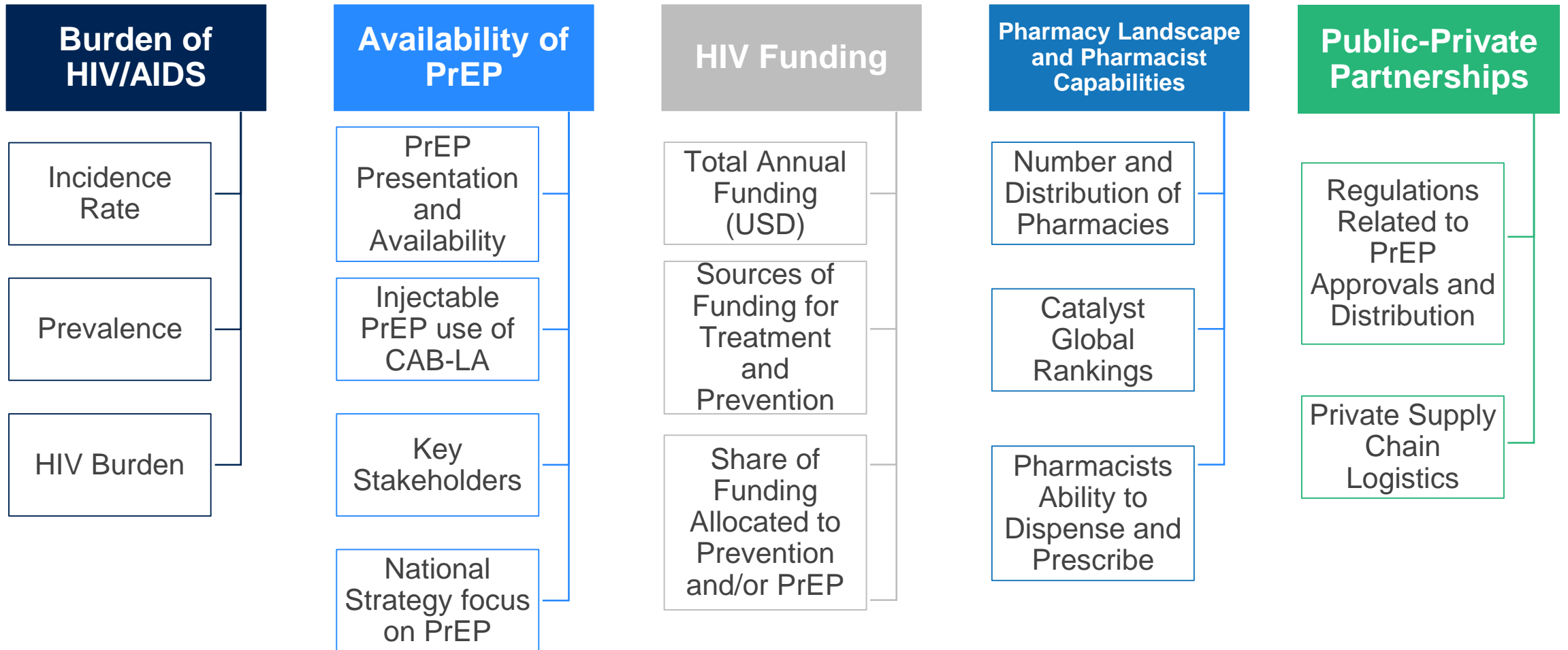
## Research Questions Used to Assess Scaling Potential

1. What is the **burden** of HIV/AIDS?
2. How much **focus** do the COPs and NSFs place on **PrEP**?
3. What is the **current availability** of PrEP?
4. What is the **funding distribution** for HIV/AIDS?
5. What are the current **pharmacy services** and **pharmacist capabilities**?
6. What are the **delivery channels** for health services and community-focused work?
7. What are the existing **public-private** partnerships?





## Indicators by Topic



## Desk Research and Data Sources



### Rapid Review of the Literature

- We searched PubMed/MEDLINE with 6 unique search strings (Appendix 3)
- We identified 187 articles, of which 15 were of relevance after title & abstract screening



### Grey Literature

- We search grey literature including but not limited to: NSF and COP; Reports from WHO & MSF; PEPFAR & Global Fund documents; Global PrEP tracker; Country-specific drug guidelines



### Contacting Subject Matter Experts

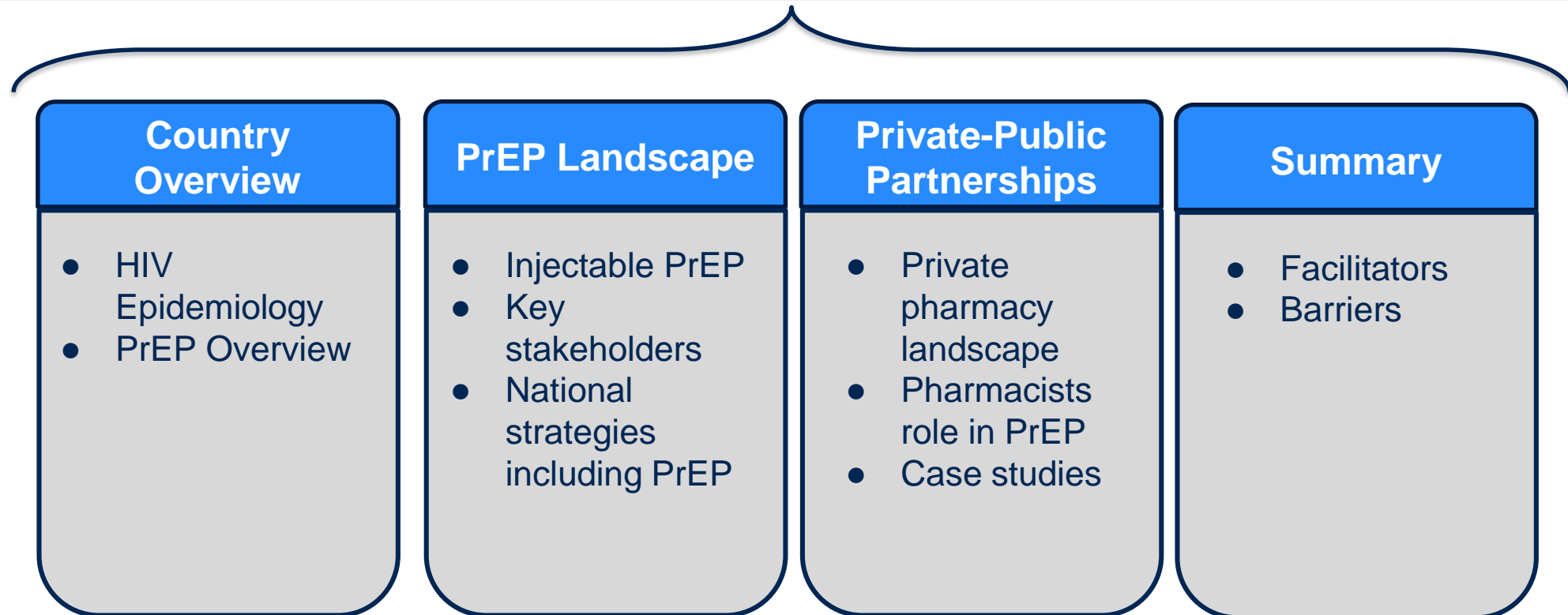
- Content experts & In-country experts (Appendix 4)
- Majority via email, some over Zoom



# 3 DATA ANALYSIS

## Organization of Findings

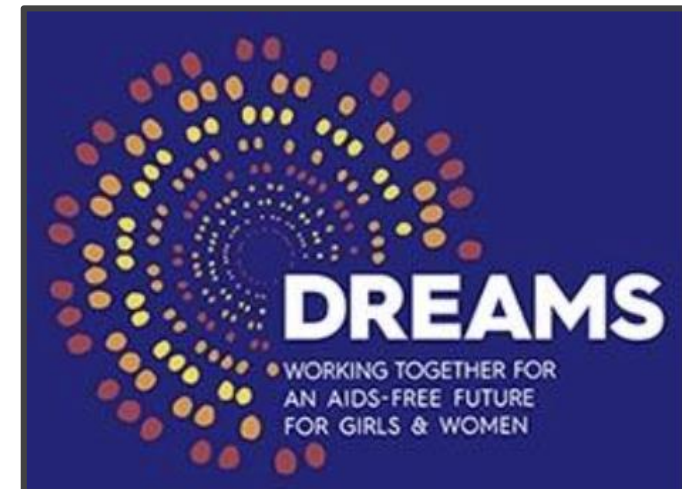
Adapted from the USAID Ready, Set, Launch Barrier Assessment Tool



# APPROACH

## Key Definitions

- **NSP and COP**
  - National strategic plans and country operational plans
- **MOSAIC**
  - Maximizing Options to Advance Informed Choice for HIV Prevention
- **DREAMS**
  - Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe
- **MMD/Decentralized Distribution**
  - Multi-month drug dispensing & decentralized drug distribution
  - Differentiated Service Delivery
- **CATALYST**
  - Catalyzing Access to New Prevention Products to Stop HIV





# FINDINGS

# COUNTRY PRIORITIZATION

## Tier 1

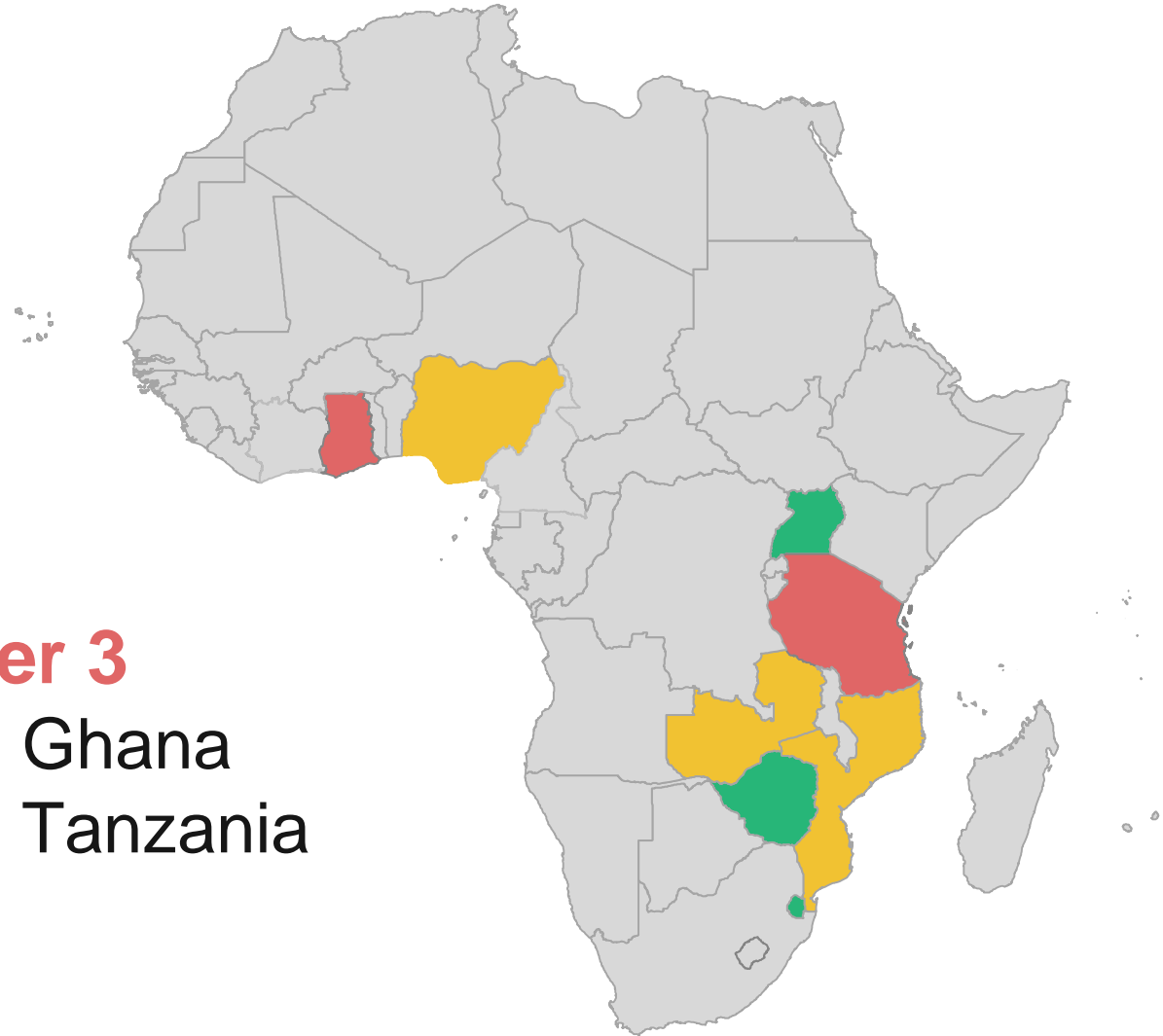
- Zimbabwe\*
- Uganda\*
- Eswatini

## Tier 2

- Mozambique\*
- Nigeria
- Zambia\*

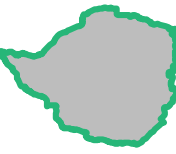
## Tier 3

- Ghana
- Tanzania



# COUNTRY OVERVIEW

Tier	Country	Government contribution towards HIV prevention funding	Proportion of total HIV funding that goes towards prevention	Availability of multiple forms of PrEP	Presence of DREAMS	Presence of MOSAIC	Delivery channels for health services and community-focused work	Political will
1	Zimbabwe	Green	Green	Green	Green	Green	Green	Green
	Uganda	Red	Green	Green	Green	Green	Green	Green
	Eswatini	Green	Green	Green	Green	Green	Yellow	Green
2	Mozambique	Red	Green	Yellow	Green	Red	Green	Green
	Zambia	Yellow	Yellow	Green	Green	Green	Green	Yellow
	Nigeria	Yellow	Yellow	Red	Red	Green	Green	Yellow
3	Tanzania	Yellow	Green	Yellow	Green	Red	Green	Red
	Ghana	Red	Red	Red	Red	Red	Yellow	Red



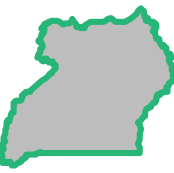
#### Facilitators

- Strong **political will** (national strategies and efforts)
- **Fast approval process** for dapivirine ring and injection
- **History of private/public partnerships** for TB and HIV treatment/prevention
- Oral PrEP is also **available via private sector** providers and pharmacies
  - Although it is expensive and unaffordable for most users through that channel
- Scaling up HIV self-testing via pharmacies
  - Training is also ongoing for pharmacists to train patients on self-injected birth control (DMPA-SC)

#### Barriers

- Pharmacies are highly accessible but also **geographically concentrated** in areas that do not have the highest HIV incidence
- Pharmacists themselves **cannot administer injections**
- High attrition of clinical staff and as HIV programs have continued to grow and increase in complexity, **volume of staff has not increased**





### Country Overview

### PrEP Landscape

### Private-Public Partnerships

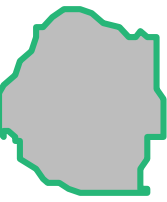
### Summary

#### Facilitators

- Strong international presence of demo projects, pilot studies and funding
- Has a **Community Pharmacy Model** and **DDD for ART (but not for oral PrEP)**
  - The aim to enroll 66% of stable clients in 200 community retail pharmacies across 90 districts
- Strong **Private/Public partnerships** already existing
  - Pharmacy models and testing in Kampala
- **Dapivirine Ring and CAB-LA both approved**, multiple studies for ring and injections underway

#### Barriers

- Pharmacists **can't administer injections** or **dispense oral PrEP**
- PrEP **not fully embraced** by target populations, and is only available at 250 sites
- Although approved, Dapivirine ring has **not been rolled out**
  - There are studies being conducted
- **Insufficient human resources** (for dispensing, education, etc.)
- **Insufficient human resources** for health (HRH) to cover all the key and competing tasks/activities for an efficient provision of impactful care and treatment services
  - E.g., Lack of counselors in clinics



### Country Overview

### PrEP Landscape

### Private-Public Partnerships

### Summary

#### Facilitators

- Ongoing CAB-LA studies and Dapivirine Ring projects/studies
- Sufficient progress toward **95-95-95 targets** (currently at 93%, 98%, 98%) using PrEP-it
- **Private/public partnership**
  - E.g., Veru Inc. for female condoms (lower price)

#### Barriers

- Pharmacy regulation is **not standardized**
- **Chronic medicine shortages** in public health facilities, supply chain problems
- Disjointed decentralized models between clinics and community implementing partners

# MOZAMBIQUE



## Tier 2

### Country Overview

### PrEP Landscape

### Private-Public Partnerships

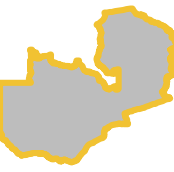
### Summary

#### Facilitators

- **DSD introduced**
  - Community ART groups, family group model, etc. 83 out of 176 private pharmacies ready to start DDD/DSD
- **High domestic health budget** and domestic contributions
- Strong **political will**
- Strong governmental leadership and **community partnership**
- National Strategic Plan is developed with many stakeholders including the government, private sector, civil society, etc.

#### Barriers

- **No MOSAIC presence**
- **No information on pharmacist capabilities**, however private sector is well-regulated
- Public engagement and communication with local partners is **decreasing**



### Country Overview

### PrEP Landscape

### Private-Public Partnerships

### Summary

#### Facilitators

- **DREAMS and MOSAIC programs** exist
- Pharmacists **currently distribute ART** (Corridors of Hope)
- Dapivirine ring is **approved**
- National attention on PrEP
  - **Proposed distribution** of oral PrEP through private pharmacies in 2024, and injectable PrEP in pipeline (in COP 2022)

#### Barriers

- **Retention** issues on PrEP in addition to implementation challenges with programming
- **Low community acceptance of PrEP** in AGYW due to drug packaging and drug fatigue



### Country Overview

### PrEP Landscape

### Private-Public Partnerships

### Summary

#### Facilitators

- Pharmacists currently **administer contraceptive injections and oral PrEP** (regardless of compliance with regulation)
- Strong SHIPS **Private/Public Partnerships** and coordination between community pharmacies and public sector
  - Partnerships in Abuja and Lagos (focused on testing and prevention), and nationwide for ART
- **DSD** are widespread across the country

#### Barriers

- **No ongoing** Dapivirine Ring studies
- **No DREAMS** presence
- Lack of efficiency in legislation of pharmaceuticals
  - This makes it difficult for PEPFAR to engage pharmacies
- Overachieved treatment goals, now struggling to find additional resources to fund national prevention and treatment



## Tier 3

Country  
Overview

PrEP Landscape

Private-Public  
Partnerships

Summary

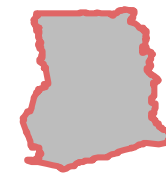
### Facilitators

- **High volume** of public AND private pharmacies
  - ADDO/DLDB program improves access to pharmaceutical services in rural and peri-urban areas
- Planning to **introduce Dapivirine Ring** and already have introduction plans and considerations
- PrEP services **expansion is a goal** in COP 22

### Barriers

- **No MOSAIC presence**
- Low levels of **domestic funding**, contributing to human resource gaps
- **Challenges** with the supply chain infrastructure
- Large **unmet need for PrEP currently** (tracking priority groups and communication)





### Country Overview

### PrEP Landscape

### Private-Public Partnerships

### Summary

#### Facilitators

- Currently have approval for **self-injectable contraceptive** (DMPA-SC)
- Community pharmacies **distribute self-testing kits**

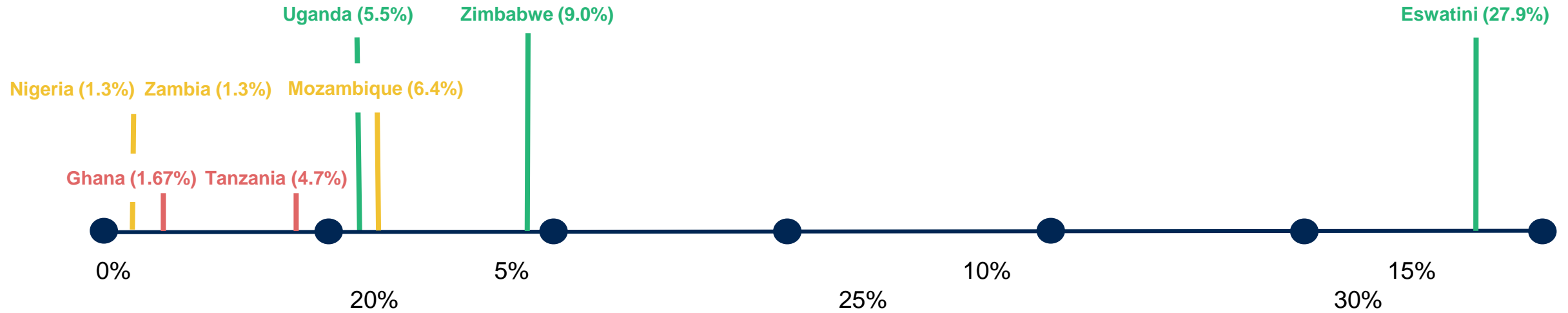
#### Barriers

- DSD model is **only in 3 regions** and in limited facilities
- PrEP is underutilized, however have low burden of HIV
  - Focus from the national policy indicates more attention on **behavior change** and **condom use**
- **No DREAMS or MOSAIC**
- Sustainability challenges threatening slow gains in the HIV response

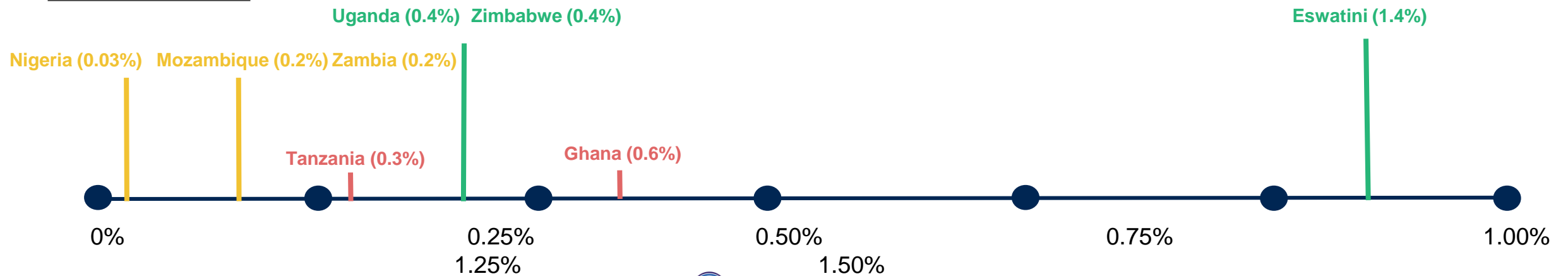
# SYNTHESIS

# COUNTRY PRIORITIZATION

## HIV Epidemiology Prevalence

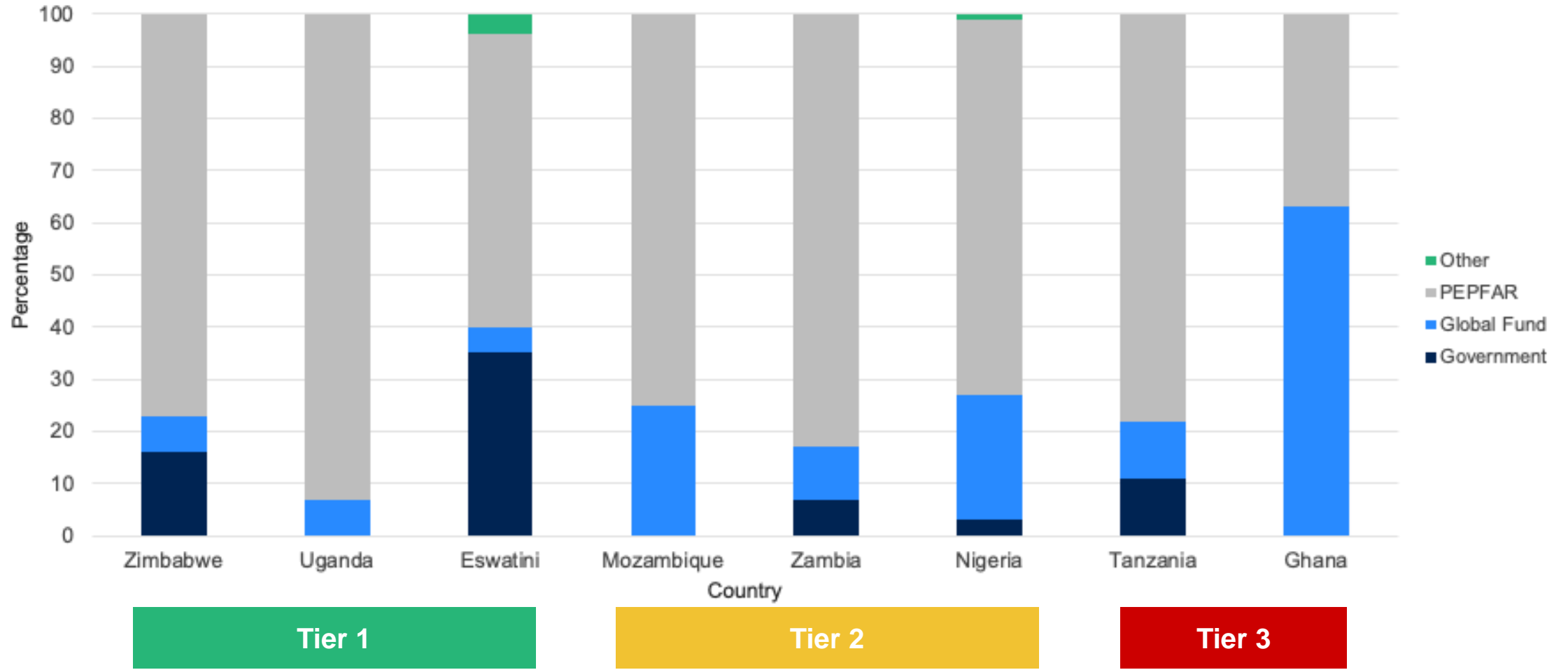


## Incidence Rate



# COUNTRY PRIORITIZATION

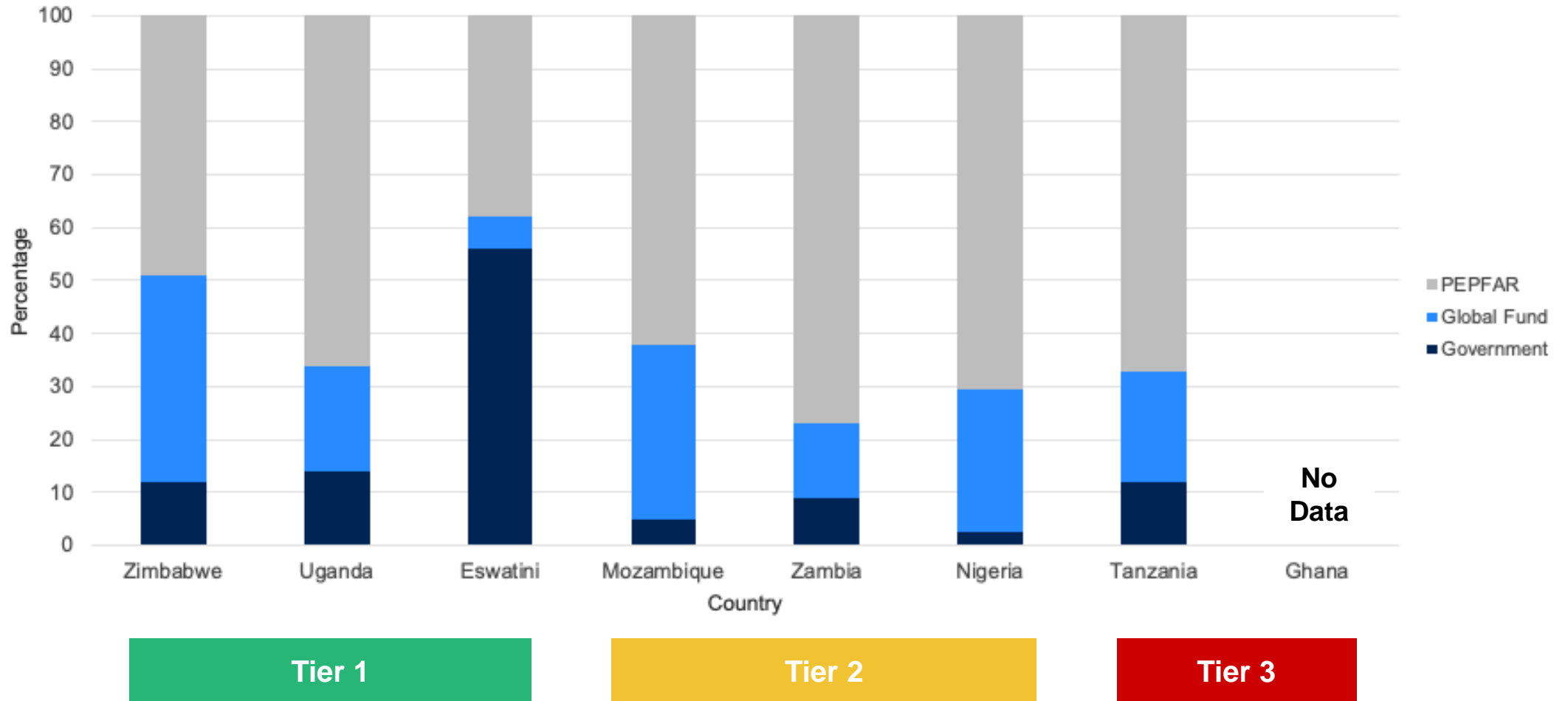
## HIV Overall Funding



\*Data obtained from 2022 COPs

# COUNTRY PRIORITIZATION

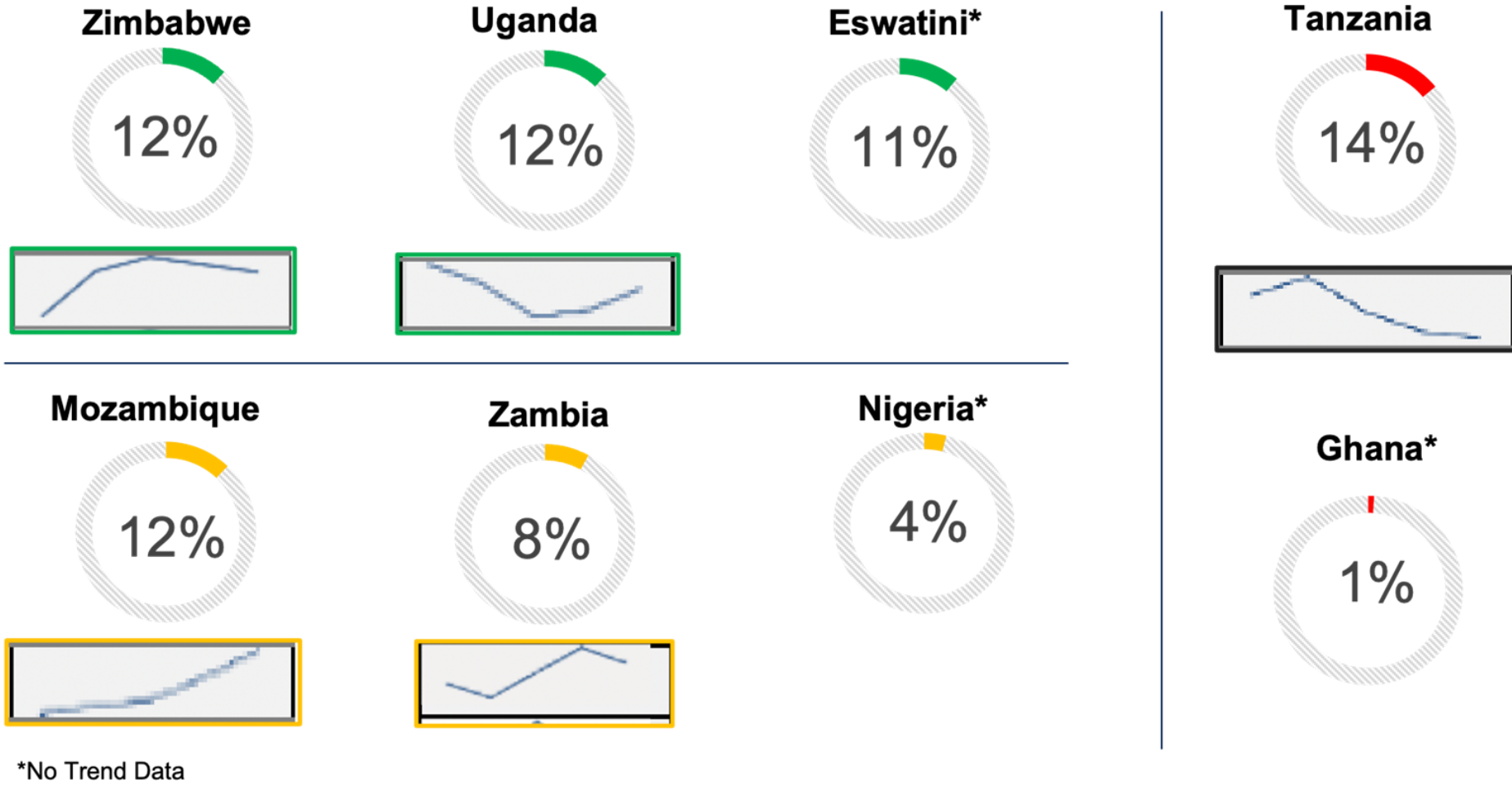
## HIV Prevention Funding



\*Data obtained from 2022 COPs

# COUNTRY PRIORITIZATION

## Prevention Funding Levels and Trends



- Tier 1
- Tier 2
- Tier 3

\*Percentages represent the 2022 proportion of total HIV/AIDS funding allocated towards prevention

\*Trend lines are from 2022 COPs showing 2018-2022 prevention funding



# COUNTRY PRIORITIZATION

COUNTRY NAME	EXISTENCE OF DREAMS* PROGRAM	EXISTENCE OF MOSAIC** PROGRAM	EXISTENCE OF MMD & DECENTRALIZED DISTRIBUTION	EXISTENCE OF PUBLIC-PRIVATE PARTNERSHIPS
<b>Tier 1</b>				
Zimbabwe	Yes	Yes + CATALYST***	MMD + DSD	Yes
Uganda	Yes	Yes + CATALYST***	MMD + DSD	Yes
Eswatini	Yes	Yes	MMD	Yes
<b>Tier 2</b>				
Mozambique	Yes	No	MMD	Yes

\*Partnership To Reduce HIV/AIDS In Adolescent Girls And Young Women

\*\*Maximizing Options to Advance Informed Choice for HIV Prevention

\*\*\*Catalyzing Access to New Prevention Products to Stop HIV

# COUNTRY PRIORITIZATION

COUNTRY NAME	EXISTENCE OF DREAMS* PROGRAM	EXISTENCE OF MOSAIC** PROGRAM	EXISTENCE OF MMD/DECENTRALIZED DISTRIBUTION	EXISTENCE OF PUBLIC-PRIVATE PARTNERSHIPS
<b>Tier 2</b>				
Nigeria	No	Yes	MMD	Yes
Zambia	Yes	Yes	MMD + DSD	Yes
<b>Tier 3</b>				
Tanzania	Yes	No	MMD	Yes
Ghana	No	No	MMD	Yes

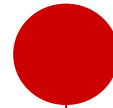
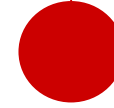
\*Partnership To Reduce HIV/AIDS In Adolescent Girls And Young Women

\*\*Maximizing Options to Advance Informed Choice for HIV Prevention

\*\*\*Catalyzing Access to New Prevention Products to Stop HIV

# CONCLUSIONS & NEXT STEPS

# RECOMMENDATIONS



# KEY GAPS

## NATIONAL STRATEGIC FRAMEWORKS

- Some countries NSF's are Outdated (e.g., Zimbabwe)
- Non-English language reports limit our ability to glean findings
- NSFs may not reflect the countries real time efforts, KII is needed to fill this gap

## PHARMACIST CAPABILITIES

- **Ghana:** Can pharmacists prescribe medications?
- **Tanzania:** Can pharmacists administer injections? Can pharmacists administer birth control injections?
- **Mozambique:** Can pharmacists dispense oral PrEP?
- **Eswatini:** Can pharmacists administer injections? Can pharmacists dispense oral PrEP? Can pharmacists prescribe?

# NEXT STEPS

## KEY INFORMANT INTERVIEWS

- Fill country-specific **gaps**
- Get **up-to-date** information regarding COPs and National Strategic Plans
- Understand who the **key players** are in **implementation** of these strategies
- Investigate what **pharmacists do in practice**
- Gauge **social and political interest** in accessing PrEP at private pharmacies

## COUNTRY EXPANSION

- We were able to complete research for **8 countries**
- There are an additional 12 of interest to the BMGF
- Additional phases of this project should **expand** upon our findings **into these geographies**



# QUESTIONS?

[start@uw.edu](mailto:start@uw.edu)

# THANK YOU



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# APPENDIX 1

# COUNTRY-SPECIFIC FINDINGS

# TIER 1 COUNTRIES



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### HIV Epidemiology

- Zimbabwe is home to 1.34 million people living with HIV (PLHIV)
- Among adults 15+ years living with HIV, 61% were females. Annual all-cause deaths among PLHIV have declined over the past decade from 135,198 in 2003 to 26,305 in 2021
- Total annual new HIV infections declined nationally from a high of 233,861 in 1991 to 22,822 in 2021
- Prevalence and incidence rate of HIV in Zimbabwe stands at 9% and 0.4% respectively

### PrEP Overview

- Funding: Out of \$48,792,537 invested towards HIV prevention in 2022, \$5,362,243 was spent solely on PrEP driven totally by PEPFAR
- Oral PrEP launched Q3 2017 with 130 PrEP sites and 15k people currently on oral PrEP. MSM and FSW are the highest PrEP users and there is no current use of private pharmacy for HIV delivery

# ZIMBABWE



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Injectable PrEP

- There is no current use of CAB [LA] in Zimbabwe. Apretude, cabotegravir LA for HIV PrEP produced by Viiv Healthcare was approved in Nov 2022 by Medicines Control Authority of Zimbabwe (MCAZ) for use.
- Ring is approved, and there have been feasibility studies on ring rollout via private channels

### Key Stakeholders

- Ministry of health and child care (MOHCC), PrEP Technical Working group (TWG), Funders (eg; PEPFAR, Clinton access, Population Services International)
- Drug Approval: Medicines Control Authority of Zimbabwe (MCAZ) is a statutory body established by an act of Parliament.
- Sector central supply chain managed by NatPharm, which supports the public and not-for-profit private sector

### National Strategies Including PrEP

- The Country Operation Plan and the Implementation Strategy for PrEP are two documents highlighting Zimbabwe's coordination plan for PrEP.
- Zimbabwe has a robust PrEP strategy that can be leveraged for CAB scale up
- PrEP initiation platforms are through VMMC, DREAMS, KPs and OVC as highlighted in the frameworks





## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Private Pharmacy Landscape

- Supply Chain System: commodities are procured and distributed through the MOH supply chain systems for HIV commodities.
- HIV testing: pharmacy-based distribution was preferable to clinic-based distribution in urban areas

### Pharmacists Capabilities

- Can pharmacists administer injections: No
- Can pharmacists administer birth control injections: No
- Can pharmacists dispense oral PrEP: Yes
- Can pharmacists prescribe: No
- The number of pharmacies across the country has increased from 287 in 2011 to 933 in 2020
- Zimbabwean pharmacists only dispense medications according to the doctor's prescription and have no authority to diagnose and prescribe independently, renew/extend prescriptions, change drug dosage/formulation, make therapeutic substitution, prescribe for minor ailments, initiate prescription drug therapy, order and interpret laboratory tests, and or administer a medicine by injection
- Sexual Gender Based Violence Clinics and Population Services International Clinics distribute oral PrEP



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Case Studies

- MOSAIC (Maximizing Options to Advance Informed Choice for HIV Prevention (MOSAIC) is a five-year (2021-2026) global project funded by the US President's Emergency Plan for AIDS Relief (PEPFAR) through the US Agency for International Development (USAID) to help women prevent HIV by accelerating introduction and scale-up of new and emerging biomedical prevention products.)
- CATALYST (Catalyzing Access to New Prevention Products to Stop HIV (CATALYST) is MOSAIC's flagship product introduction study. The study will provide and assess an enhanced service delivery package that includes oral PrEP, PrEP ring, and injectable cabotegravir. )
- DREAMS presence
- Private/Public Partnerships since 2014/2016



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### HIV Epidemiology

- Uganda has a population of 45.3 million (2022) and about 1.4 million people are currently living with HIV
- For adults aged 15 and above, HIV prevalence was estimated at 5.8% with an incidence rate of 0.4%.
- AGYW are mostly affected and has the attention of HIV implementers with a target to initiate 180k of AGYW on PrEP in FY22

### PrEP Overview

- Tenofovir disoproxil fumarate (TDF)-based daily or event-driven (ED) oral PrEP, the monthly dapivirine vaginal ring and injectable cabotegravir are the three PrEP methods currently recommended by WHO and approved for use in Uganda.
- There are 5 completed Oral PrEP projects, 1 ongoing vaginal ring project, 2 ongoing injectable PrEP - shows a lot of activities ongoing in the country
- CAB PrEP is expected to be included in PEPFAR 23 COP
- PrEP is only available at 250 sites nationwide
- The Dapivirine Vaginal Ring and CAB-LA has not been rolled out as a National Program



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Injectable PrEP

- CAB-LA was approved in December 20, 2022

### Key Stakeholders

- They have a fully integrated DREAMS program and plans to reach more AGYW in COP22
- They are plan to strengthen community-based initiation and refills for PrEP to enhance service uptake.
- Drug Approval: All drugs to be manufactured or imported into Uganda have to be registered with the National Drug Authority, Uganda

### National Strategies Including PrEP

- SEARCH (Sustainable East Africa Research in Community Health)
- All strategies includes PrEP and plans for ring and CAB-LA roll out.



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Private Pharmacy Landscape

- 2022: Pharmacies do not conduct HIV testing (besides offering oral self-test kits) or deliver PrEP.
- Some retail drug shops in rural areas operated by pharmacists sell and administer vaccines; however, national regulations do not allow provision of immunization services by pharmacists.

### Pharmacists Capabilities

- Can pharmacists administer injections: Yes
- Can pharmacists administer birth control injections: No
- Can pharmacists dispense oral PrEP: Yes
- Can pharmacists prescribe: No



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### HIV Epidemiology

- Despite a small population of 1,093,028, Eswatini has the highest HIV epidemic in the world with 215,208 people living with HIV and a HIV prevalence of 27%.
- 5,694 new infections occur per year and in 2022, 2,176 people died as a result of HIV/AIDS infection.
- Adolescent girls and young women are the most infected population with a prevalence rate of 14% for females (15-24) as against 4.1% for males in the same age category.
- New HIV infections and deaths among PLHIV in Eswatini have been on the decline, which is a clear indicator of progress towards epidemic control. Eswatini is one of only three countries that has achieved the ambitious 95-95-95 fast track targets.

### PrEP Overview

- Funding: PrEP is driven by PEPFAR 100% with an investment of \$698,821 out of \$14,238,367 invested in HIV prevention. Other major source of fundings are from PEPFAR, USAID, CDC and Peace Corps
- PrEP information or enrollment is included in the primary package of DREAMS interventions for AGYW aged 15-29.



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Injectable PrEP

- CAB LA is currently not approved for use in Eswatini however, there is an ongoing study evaluating the efficacy of CAB LA in HIV prevention.

### Key Stakeholders

- Ministry of Health
- Drug Approval: the Medicines Regulatory Unit in the Ministry of Health is currently responsible for medicines' registration; however, a medicines' regulatory authority and pharmacy council are still to be established in Eswatini

### National Strategies Including PrEP

- PreP strategy is included in The National HIV and AIDS Strategic Framework (NSF) 2018-2023
- Eswatini introduced oral PrEP in 2017 as a demonstration project to learn lessons that will inform its adoption to high risk groups
- MMD Strategy



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Private Pharmacy Landscape

- Patients in Eswatini may be forced to buy medicines from the private sector due to the chronic medicines shortages in Eswatini public health facilities.
- No relevant documentation of standardized registration and regulation process of private health providers and pharmacies

### Pharmacists Capabilities

- Can pharmacists administer injections: Unknown
- Can pharmacists administer birth control injections: Unknown
- Can pharmacists dispense oral PrEP: Unknown
- Can pharmacists prescribe: Unknown
- The number of pharmacists registered with the Eswatini Medical and Dental Council (EMDC) is 279, while trading licenses issued by the Manqoba Khumalo-led Ministry of Commerce, Industry and Trade for pharmacies are 447.
- Clinics are manned by nurses who are responsible for prescribing and dispensing medicines; health centers have nurses and doctors responsible for prescribing while pharmacy technicians dispense medicines; and hospitals have nurses and doctors responsible for prescribing while pharmacists and pharmacy technicians dispense medicines.

### Case Studies

- EBH Eswatini Business Health & Wellness (previously <http://swabcha.org.sz/>)
- Eswatini Ministry of Health and PEPFAR agreed to adopt the 6-month prescriptions and refills (6MMS/D) strategy for Eswatini
- Veru Inc. has partnered with governments, donor agencies (including African countries) “to build successful reproductive and sexual health programs and policies that integrate [the] FC2 female condom” (Veru Inc., 2019).



# TIER 2 COUNTRIES

# MOZAMBIQUE



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### HIV Epidemiology

- About 2.1 million people are estimated to be living with HIV in Mozambique with almost 1.7 million on life-saving ART.
- Mozambique currently has a prevalence rate of 6.4% and an incidence rate of 0.2% for its adult population.
- AGYW are most infected population with a prevalence rate of 5.0% as against 2.4% for males in the same age bracket.

### PrEP Overview

- In Mozambique, PrEP is offered as Oral PrEP TDF/xTC (TDF products and generics)
- Mozambique offers a comprehensive package of differentiated service delivery based on client needs, including three-month drug dispensing (3MDD) as a current standard of care, and 6MDD recently approved and in process of national roll out as of April 2022
- The DSD model involves using private pharmacies as dispensing/collection points for ARV pickups and considerations to include PrEP both in the DSD model and national scale up.
- As of March 2022, 22% of the HFs supported by DREAMS (64/283) were implementing PrEP

# MOZAMBIQUE



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Injectable PrEP

- CAB LA is not currently approved for use in Mozambique and there are no ongoing projects for either ring or CAB LA.

### Key Stakeholders

- PEPFAR Mozambique and GF are the main sources of funds for the HIV response, accounting for approximately 83% of HIV expenditures making them the key stakeholders for HIV program in the country.

### National Strategies Including PrEP

- Decentralized Drug Distribution (DDD) model is currently in use for ARTs in Mozambique.
- Mozambique has an integrated PrEP program offered to KPs and through the DREAMS program with PEPFAR contributing up to 8% of its funds towards DREAM project in assigned regions.
- However, policy framework mentions plans to scale PrEP as a national program by advocating for introduction of new PrEP products and integrating private pharmacy in its PrEP DSD model.

# MOZAMBIQUE



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Private Pharmacy Landscape

- MOH approved DDD model is being implemented in 33 health facilities and 77 private pharmacies across the country's 11 provinces.
- 83 of the 176 private pharmacies were deemed ready to start DDD.
- The private health sector is regulated and both private and public facilities require licenses for operating.
- Pharmacists' society representatives consider that there is not enough available workforce. Pharmacists are not directly involved in the administration of vaccines but, depending on the countries, pharmacists are part of the teams at the ministries of health in charge of logistics, distribution and monitoring following immunisation.

### Pharmacists Capabilities

- Can pharmacists administer injections: No
- Can pharmacists administer birth control injections: No
- Can pharmacists dispense oral PrEP: No
- Can pharmacists prescribe: No

### Case Studies

- On first-line regimen with tenofovir, lamivudine, and dolutegravir (TLD) or tenofovir, lamivudine, and efavirenz (TLE)
- differentiated service delivery (DSD) models have been introduced. These include fast-track, multi-month dispensing (MMD), community ART groups, family group model, and adherence clubs
- Project Last Mile: GPS and medicine storage partnership



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### HIV Epidemiology

- Currently, an estimated 1,869,259 people live with HIV in Nigeria. The national HIV prevalence rate is at 1.4% among adults 15 years old and above and an incidence rate of 0.03% with a higher prevalence among AGYW (1.8%) compared to men (1.0%).
- Nigeria has an estimated demographic population of 219,243,344.
- 1,769,656 PLHIV are currently receiving ART across all SNU, bringing the country's treatment coverage to 91%

### PrEP Overview

- PrEP is being offered as Oral PrEP TDF/XTC since 2020 Q3 with over 400K initiations as at Q3 2022.
- Vaginal Ring was not approved and there are no ongoing demo projects
- Federal Ministry of Health included PrEP in the national guideline for HIV prevention and treatment with focus on serodiscordant couples (SDC) and key populations (KPs).
- Across implementation programmes, oral PrEP is primarily offered in one-stop shops for KPs alongside STI, tuberculosis, and other HIV services



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Injectable PrEP

- CAB-LA not approved, not submitted for approval

### Key Stakeholders

- The HIV response in Nigeria remains heavily dependent on international donors with PEPFAR and the Global Fund accounting for 71% and 27% respectively of the \$799m reported HIV spending in 2021
- National Alignment Program: Platform of the joint agreement between the three principal funders of the HIV program in Nigeria; PEPFAR, the Global Fund and the Government of Nigeria.

### National Strategies Including PrEP

- All strategic documents include PrEP and the roadmap for scale-up. The documents are up to date and clearly indicates an alignment effort of PEPFAR, Global Funds and GON.



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Private Pharmacy Landscape

- Between 2016 and 2019, USAID’s Sustainable Financing Initiative provided funding to establish ARV refill services at 117 private clinics and 320 private pharmacies across four states in Nigeria, enabling nearly 18,000 patients to pick up medication closer to home; 95 percent of patients picked up their refills on time, and 93 percent of patients were retained in the model after one year.
- In 2020, enrolled clients experienced little disruptions to pickup, despite a transportation lockdown and public health worker strike caused by COVID-19.

### Pharmacists Capabilities

- Can pharmacists administer injections: No, not legally
- Can pharmacists administer birth control injections: Yes
- Can pharmacists dispense oral PrEP: Yes
- Can pharmacists prescribe: Yes, they do prescribe but unsure if it is regulated
- Pharmacy Engagement: Lack of efficiency in the legislation of pharmaceuticals was also flagged in the COP22. It was noted that application of these legislations is limited due to insufficient awareness and poor utilization of legal information



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Case Studies

- RISE project has developed a suite of tools including an adherence calendar, script for virtual adherence support and case management diary to help health care workers provide enhanced case management and virtual support to clients on MMD.
- SHIPS Private/Public Partnerships in Abuja and Lagos (focused on testing and prevention)
- Dispensing fee of ₦1,000 (US\$2.74) per visit irrespective of the quantity of ARVs dispensed, and the PEPFAR/implementing partner provides no funds to the CP. This amount was negotiated with the professional association for CPs and may vary based on the socioeconomic variables in each community.
- A baseline assessment in Nigeria found that 92 percent of CPs were willing to provide the services, more than 30 percent of clients were willing to access services at a CP, and up to 20 percent of clients were willing to pay the dispensing fee for ART refills. In addition, public sector health workers were, for the most part, comfortable with devolving clients to community pharmacies for their drug refills.





## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### HIV Epidemiology

- 1,336,056 Zambians are estimated to be living with HIV.
- Number of new HIV infections in Zambia still exceeds the number of deaths amongst PLHIV. New infections among young women are consistently more than double those among young men
- In 2021, over 40% (14,611) of new HIV infections in Zambia occurred among AYP (15-24) with AGYW bearing the greatest burden: AGYW comprise 78% of new infections for this growing population.

### PrEP Overview

- PrEP was casually mentioned in the National HIV/AIDS strategic framework and was not in the objective of the NASF goal for the 2017-2021 period.
- 1,069 sites across 104 districts offering PrEP; this accounts for 90% of districts in the country as of COP21 Q1
- PrEP continuation is a challenge. Retention rate decreases to 20% after 12 months of initiation.
- Funding Landscape: HIV programs fund majorly comes from the Zambian Government, Global Funds and PEPFAR. Global Funds contributes 1% of the PrEP funds while PEPFAR contributes 99%. Govt largest contributions (60%) in HIV programing is in Laboratory services and treatment monitoring.



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Injectable PrEP

- No current injectable PrEP and no submissions for approval ongoing at the moment.

### Key Stakeholders

- Technical Assistance support: GFATM, UNAIDS, MOH
- Network of Zambian People Living with HIV (NZP+)
- Technical Working Groups (TWGs) and the NASF Technical and Steering Committee
- Drug Approval: Zambia Medicines Regulatory Authority (ZAMRA)

### National Strategies Including PrEP

- The National strategy framework mentioned PrEP casually and does not highlight adequate plans for integration into programs. It is worth noting that the NASF was developed in 2016 and runs till 2021. This could mean that PrEP was still in the early pipeline phase
- Country Operational Plan 2022 (driven mostly by PEPFAR) which is the most recent plan fully highlights plans to increase PrEP retention among AGYW.
- PEPFAR Zambia has plans to work with the MoH to advocate for the introduction and eventual inclusion of injectable PrEP into national guidelines



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Private Pharmacy Landscape

- The government has given instructions to all public health facilities that going forward, no private laboratory or pharmacy will be allowed to operate within these premises in order to bring sanity to hospitals while restoring efficient operations of the hospital laboratories
- Private Pharmacies and other drug outlets have been documented to be major and trusted source of health information and services in the community particularly in the rural and peri-urban areas. This is attributed to close proximity to the community, perceived better quality of services compared to the public health facilities, and friendlier and faster services
- Central Dispensing Units: dispensing activities are centralized and generally automated, but delivery/pick-up of medication by clients occurs at alternative pick-up points, which may include lockers, informal retail outlets, churches, supermarkets, health facilities, or CPs. Once the patient is enrolled, they choose a convenient pick-up point where the medicine will be sent. The public health facility provides a one-month supply of medicines and subsequently sends a script of the next five-month supply to the CDU. The CDU unit dispenses a prescribed supply of medicines, dispatches the patient's medicine package to the selected pick-up point, and notifies the patient through an SMS.

### Pharmacists Capabilities

- Can pharmacists administer injections: No
- Can pharmacists administer birth control injections: No, only if specially trained
- Can pharmacists dispense oral PrEP: No
- Can pharmacists prescribe injections: No
- Self injectable contraceptive: Yes DMPA-SC



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Case Studies

- Corridors of Hope 2014: Private pharmacists present an opportunity to improve quality of HIV interventions in poor human resource capacity settings. Oral ART.
- JSI has been doing some Private public partnerships but not sure to what extent and if private pharmacies are involved (Anjali Sharma <Anjali.Sharma@cidrz.org>).
- For CIDRZ, 2024 we have proposing distribution of PrEP through private pharmacies as a differentiated service delivery. It will be a pilot implementation science project to inform policy. The CP is engaged on the principle of corporate social responsibility; however, the pharmacist receives a stipend of approximately US\$75 per month, which is equivalent to the amount paid to a lay volunteer at the facility level. Sustainability of the monthly payments to the CP is an issue.
- MOSAIC project through FHI 360
- INTERVAL trial: Facility-based, multi-month dispensing of antiretroviral therapy

# TIER 3 COUNTRIES

# TANZANIA



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### HIV Epidemiology

- Tanzania has an estimated population of 61,280,743. (NBS 2022).
- HIV Prevalence among adults (15+) in Tanzania was estimated to be 4.7% with an incidence rate of 0.3%
- An estimated 1.7 million people live with HIV/AIDS in Tanzania
- HIV prevalence among AGYW (15 -24yrs) is higher (2.28%) when compared to men in the same age bracket (1.24%).

### PrEP Overview

- PrEP is being offered as oral PrEP in Tanzania
- No PrEP demonstration activities or projects ongoing
- IPM's Dapivirine Vaginal Ring registration is currently under review as indicated by PrEP Watch.
- Most PrEP funding comes from Global Funds and PEPFAR.



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Injectable PrEP

- CAB LA is currently not approved for use in Tanzania but a study indicates FSWs willingness to use CAB LA over oral PrEP.

### Key Stakeholders

- Policy frameworks indicates highest HIV program funders to be the highest key stakeholders in HIV delivery and PEPFAR, WHO, UNAIDS, and GFATM are the First Level Actors
- Implementers on the national level are the second level actors: Tanzania Commission for AIDS (TACAIDS) National AIDS Control Program (NACP)
- Grassroot implementers identifiers as third level actors: CSO groups namely, Non State Actors (NSA), KVP Forum, National Council of People Living with HIV (NACOPHA), and the Adolescent and Young Adults (AYA)

### National Strategies Including PrEP

- Frameworks indicates large unmet need for PrEP in Tanzania and intentions to address this need through advocating for introductions of alternative PrEP options such as the dapivirine vaginal ring (DPVr) and long acting cabotegravir (LA-CAB).
- In 2021, the GOT adapted and advanced key policies to move Tanzania closer to epidemic control. This included implementing 6MMD, and PrEP Scale-up



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Private Pharmacy Landscape

- More than 6,000 public and private pharmaceutical outlets
- 2014 Study: Majority (70.4%) of drug dispensers were not trained pharmaceutical personnel. The level of dispensing skills ranged from low (25.7%) to medium (70.4%). Majority of drug dispensers had low (11.4%) to medium (83.2%) levels of knowledge about dispensing of 'prescription only' medicines.
- A part I pharmacy is a fully fledged pharmacy unit operating under the direct supervision of a pharmacist. In these premises, a pharmacist is assisted by a pharmaceutical technician, pharmaceutical assistant and other drug dispensers. A part II pharmacy is a drug store that sells drugs that appear in the schedule of part two poisons list of the Tanzania Food and Drug Authority Act of 2003.

### Pharmacists Capabilities

- Can pharmacists administer injections: Unknown
- Can pharmacists administer birth control injections: Unknown
- Can pharmacists dispense oral PrEP: Yes, and the ring
- Can pharmacists prescribe: No
- 2014 study: Many drug dispensers said that many pharmacies do not have rooms for counseling patients and clients, which affects confidentiality.





Country  
Overview

PrEP Landscape

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Summary

## Case Studies

- Accredited Drug Dispensing Outlets (ADDO) established in 2003 to improve access to essential medicines and pharmaceutical services to population in rural and per-urban areas with no pharmacies (part II pharmacies, duka la dawa baridi (DLDB)).
- There are no policies that limit the ability of licensed private providers from offering HIV services, or that limit the ability of local manufacturing of HIV commodities if they are prequalified by WHO. Tanzania is expanding PrEP services to private pharmacies (From COP 2022)
- PEPFAR/T will intensify distribution of HIVST in male-dominated workplaces, both public and private (as well as formal and informal) workplaces.



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### HIV Epidemiology

- Ghana is estimated to have a total population of 31,188,329, and an estimated 347,370 PLHIV
- Ghana has an estimated HIV prevalence of 1.67% and incidence rate of 0.6%.
- 73.91% of adolescents and youths living with HIV are females, highlighting the heightened vulnerability of adolescent girls and young women in this age group to HIV infection.

### PrEP Overview

- DSD is implemented only in select facilities within priority regions: Greater Accra, Brong-Ahafo, Eastern, Western and Ashanti
- Program priority for HIV prevention in the NSP 2016-2020 for the general population was targeted at behaviour change intervention and condom use although PrEP scale up was mentioned.
- Shifting focus to AGYW and administering PrEP to KP's at risk was mentioned as a new initiative under the 2021-2025 framework



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Injectable PrEP

- CAB-LA and IPM Vaginal ring are not approved in the country and there are no ongoing projects

### Key Stakeholders

- Drug Approval: Ghana Food and Drugs Authority
- The National AIDS Control Program (NACP) and Policy, Planning, Monitoring & Evaluation (PPME)

### National Strategies Including PrEP

- Ghana has a West African Regional Operational plan (ROP) and an updated national strategic plan (2021-2025) produced in 2020.
- Framework indicates increased health spending but a larger dependent on external donors
- The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) capped its commitment to fund the cost of commodities to a maximum of 125,000 PLHIV on treatment. As the number of PLHIV on treatment continues to increase, the cost of commodities supply will increase, which means the GoG will need to increase financial resources to pay for the additional supply needs.



## Country Overview

## PrEP Landscape

## Private-Public Partnerships

## Summary

### Private Pharmacy Landscape

- 2021 Study: Overall, regulatory compliance was low, particularly across rural locations, where most of the facilities failed to meet laid down provisions regarding practice, staff, and premises requirements.
- 2019 Study: majority of the respondents believe that community pharmacists are responsive, friendlier and have the capacity to handle minor ailments, they are indeed using community pharmacies for the treatment of minor ailments.
- Private sector distributes self-testing kits

### Pharmacists Capabilities

- Can pharmacists administer injections: training to administer COVID vaccination (2021)
- Can pharmacists administer birth control injections: No, and not legal to dispense although 97% do (2014)
- Can pharmacists dispense oral PrEP: No
- Can pharmacists prescribe: Unknown
- Self Injectable Contraceptive: Yes, DMPA-SC

### Case Studies

- WAAF, a private sector partner, was the first of the two EpiC partners to begin offering PrEP.
- In August 2020, WAAF initiated the first individuals on daily PrEP at its on-site clinic in Accra, called the International Health Care Center (IHCC), as well as through its mobile clinics.

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# APPENDIX 3

# SEARCH STRINGS

Search String	Results
<p><a href="#">Broadest Search</a></p> <p>((("pre exposure prophylaxis"[Title/Abstract] OR "prep"[Title/Abstract] OR "hiv prophylaxis"[Title/Abstract]) AND ("pharmacy"[Title/Abstract] OR "pharmacies"[Title/Abstract] OR "pharmacist"[Title/Abstract] OR "pharmacy-delivered"[Title/Abstract]))</p>	139
<p><a href="#">Specifying Injectable PrEP/CAB-LA</a></p> <p>("CAB-LA"[Title/Abstract] OR "injectable pre exposure prophylaxis"[Title/Abstract] OR "injectable prep"[Title/Abstract] OR "injectable hiv prophylaxis"[Title/Abstract] OR "cabotegravir"[Title/Abstract]) AND ("pharmacy"[Title/Abstract] OR "pharmacies"[Title/Abstract] OR "pharmacist"[Title/Abstract] OR "pharmacy-delivered"[Title/Abstract])</p>	7
<p><a href="#">Including Country Names</a></p> <p>("pre exposure prophylaxis"[Title/Abstract] OR "prep"[Title/Abstract] OR "hiv prophylaxis"[Title/Abstract]) AND ("pharmacy"[Title/Abstract] OR "pharmacies"[Title/Abstract] OR "pharmacist"[Title/Abstract] OR "pharmacy-delivered"[Title/Abstract]) AND ("Tanzania"[Title/Abstract] OR "Nigeria"[Title/Abstract] OR "Ghana"[Title/Abstract] OR "Uganda"[Title/Abstract] OR "Mozambique"[Title/Abstract] OR "Zambia"[Title/Abstract] OR "Eswatini"[Title/Abstract] OR "Swaziland"[Title/Abstract] OR "Zimbabwe"[Title/Abstract] OR "Ivory Coast"[Title/Abstract] OR "Côte d'Ivoire"[Title/Abstract] OR "Cameroon"[Title/Abstract])</p>	0

## Search String

## Results

### Broadest Search

("pharmacists"[Title/Abstract] OR "pharmacy"[Title/Abstract]) AND ("Tanzania"[Title/Abstract] OR "Nigeria"[Title/Abstract] OR "Ghana"[Title/Abstract] OR "Uganda"[Title/Abstract] OR "Mozambique"[Title/Abstract] OR "Zambia"[Title/Abstract] OR "Eswatini"[Title/Abstract] OR "Swaziland"[Title/Abstract] OR "Zimbabwe"[Title/Abstract] OR "Ivory Coast"[Title/Abstract] OR "Cote d'Ivoire"[Title/Abstract] OR "Cameroon"[Title/Abstract])) AND (2006:2023[pdat]) 34

### Including Delivery

("pharmacists"[Title/Abstract] OR "pharmacy"[Title/Abstract]) AND ("deliver"[Title/Abstract] OR "delivery"[Title/Abstract]) AND ("united states"[Title/Abstract] OR "US"[Title/Abstract]) AND ("Tanzania"[Title/Abstract] OR "Nigeria"[Title/Abstract] OR "Ghana"[Title/Abstract] OR "Uganda"[Title/Abstract] OR "Mozambique"[Title/Abstract] OR "Zambia"[Title/Abstract] OR "Eswatini"[Title/Abstract] OR "Swaziland"[Title/Abstract] OR "Zimbabwe"[Title/Abstract] OR "Ivory Coast"[Title/Abstract] OR "Cote d'Ivoire"[Title/Abstract] OR "Cameroon"[Title/Abstract]) 5

### Including Prescription

("pharmacists"[Title/Abstract] OR "pharmacy"[Title/Abstract]) AND ("prescription"[Title/Abstract] OR "prescribe"[Title/Abstract]) AND ("united states"[Title/Abstract] OR "US"[Title/Abstract]) AND ("Tanzania"[Title/Abstract] OR "Nigeria"[Title/Abstract] OR "Ghana"[Title/Abstract] OR "Uganda"[Title/Abstract] OR "Mozambique"[Title/Abstract] OR "Zambia"[Title/Abstract] OR "Eswatini"[Title/Abstract] OR "Swaziland"[Title/Abstract] OR "Zimbabwe"[Title/Abstract] OR "Ivory Coast"[Title/Abstract] OR "Cote d'Ivoire"[Title/Abstract] OR "Cameroon"[Title/Abstract]) 4



# APPENDIX 4

# CONTACTED SUBJECT MATTER EXPERTS

## Subject Matter Experts

- **Monisha Sharma** (UW: Global Health & Epidemiology)
- **Jared Baeten** (UW: Allergy and Infectious Disease & Global Health; Gilead Science, Vice President)
- **Renee Heffron** (UW: Global Health; UAB: CFAR Director)
- **Katrina Ortblad** (UW: Global Health)
- **Andy Stergachis** (UW: Global Health, Pharmacy, Epidemiology, Health Metrics, Health Systems)
- **Anjali Sharma** (UW: Global Health; Center for Infectious Disease Research in Zambia)
- **Gabrielle O'Malley** (UW: Global Health)
- **Sarah Gimbel** (UW: Global Health, Center for Global Health Nursing)
- **Kenneth Ngure** (UW: Global Health)
- **Kenneth Mugwanya** (UW: Global Health & Epidemiology)
- **Connie Celum** (UW: Global Health, Epidemiology, Allergy and Infectious Diseases)

## In-Country Content Experts

### Tanzania

- **Katherine Wilson** (UW: Global Health)

### Uganda

- **Timothy Muwonge** (Makerere University)
- **Andrew Mujugira** (UW: Global Health & Makerere University)

### Mozambique

- **Baltazar Chilundo** (UW: Global Health)
- **Maria de Fátima Cuembelo** (UW: Global Health & Epidemiology)

### Zambia

- **Margaret Kasaro** (UNC: Global Health & Zambia Institute for Global Health)

### Eswatini

- **Harriette Nuwagaba-Biribonwoha** (Columbia University: Research Director of ICAP in Eswatini)

### Zimbabwe

- **Nyaradzo Mgodzi** (Zimbabwe; University of Zimbabwe)