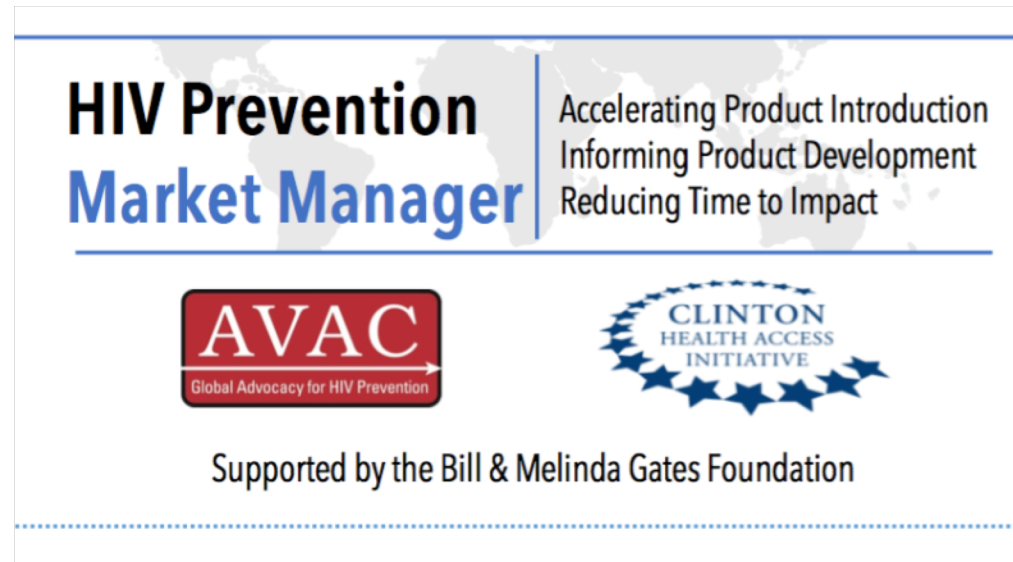


Prevention Market Manager

Analysis of BMGF-Funded PrEP Demonstration Projects

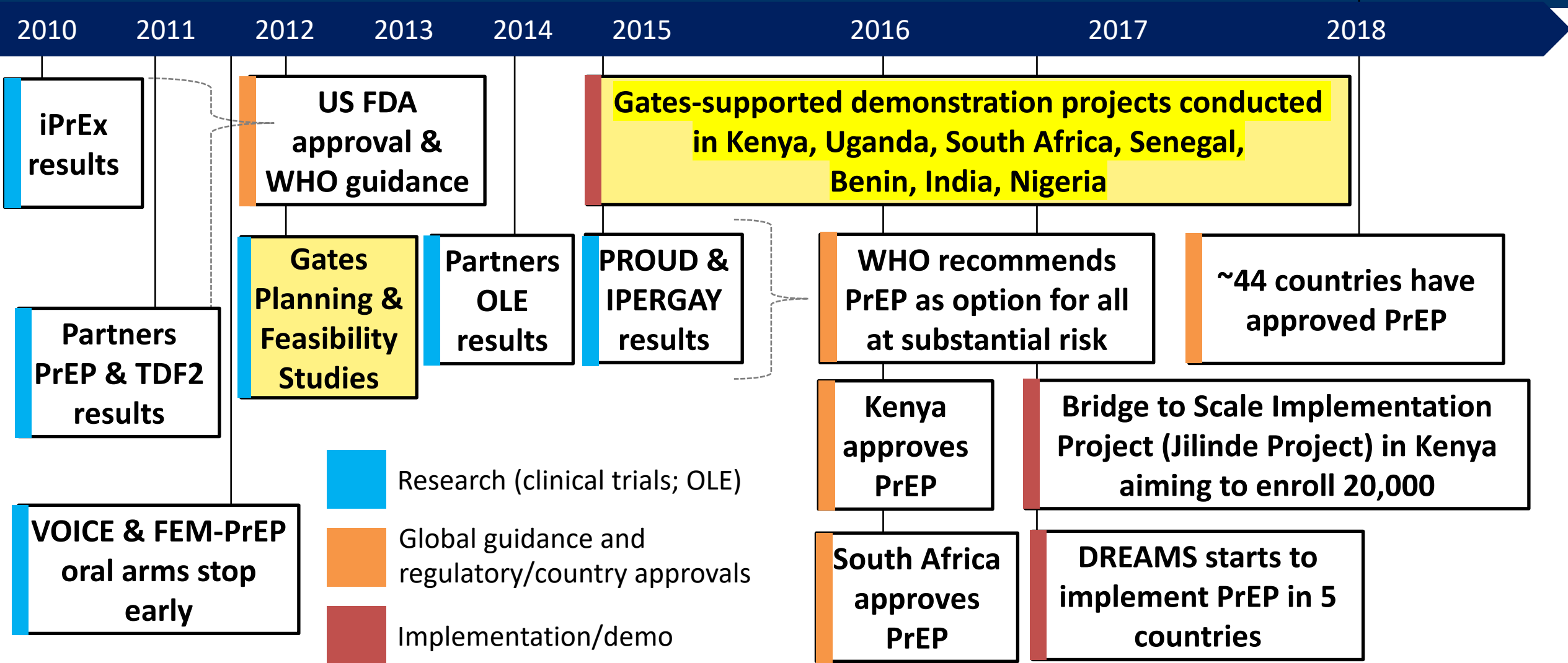


Outline

- Background, Rationale and Objectives for Assessment
- Key lessons and recommendations
 - Project Outcomes: Benefits and Challenges
 - Lessons and Recommendations for PrEP Roll Out
 - Lessons and Recommendations for Next Generation Demonstration Projects
 - Influence of BMGF Demonstration Projects
- Results
 - Data and outcomes
 - Recruitment: contacts made, people reached, screening, initiation
 - Continuation & Retention
- Annex

Background, Rationale and Objectives

Oral PrEP Timeline (as of mid-2018)

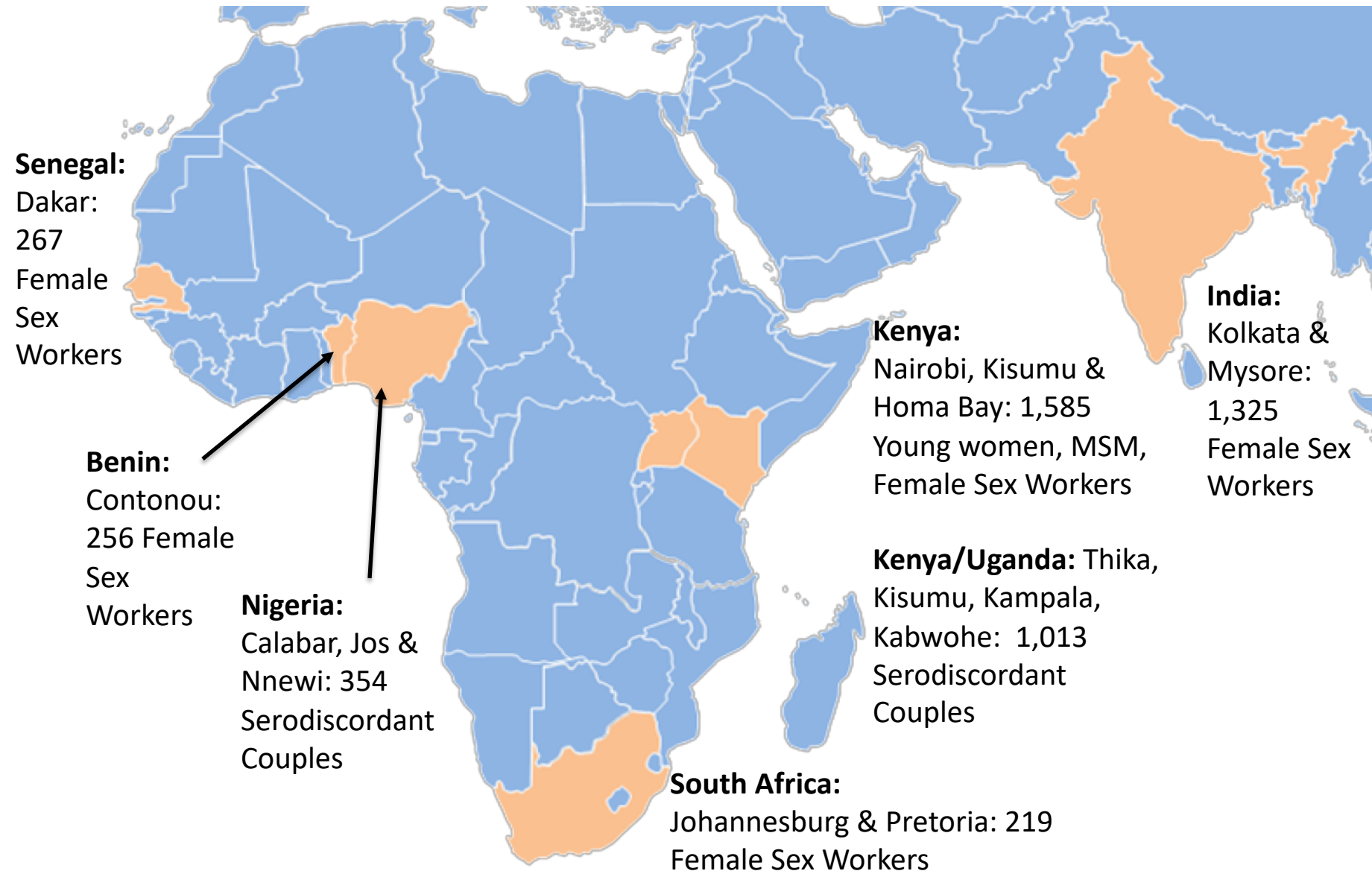


Select implementation and demonstration projects.

For full list see <http://www.avac.org/resource/ongoing-and-planned-prep-evaluation-studies>

For list of countries that have approved oral PrEP see <https://www.avac.org/infographic/regulatory-status-tdfftc-prep>

BMGF PrEP Demonstration Projects



The settings and populations for these early PrEP Demo Projects were designed to:

- Ensure a range of settings, populations, epidemic contexts
- Build on existing relationships and capacity
- Include concentrated, mixed and more generalized epidemics

However, the projects also

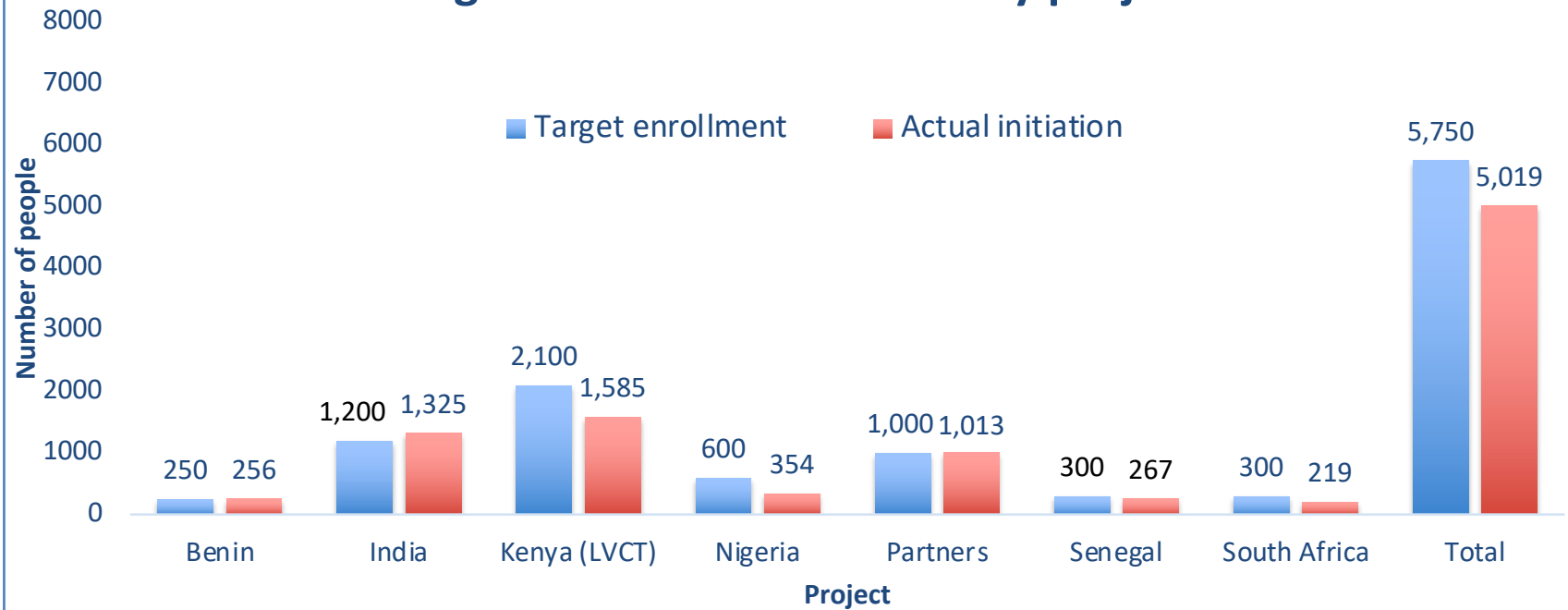
- Primarily focused in Africa, with limited engagement in Asia, and none in Latin America/Caribbean

BMGF PrEP Demonstration Projects: Overview

Country	Location	Organization	Study population(s)	Median age	Number initiated	PrEP service delivery point(s)
Benin	Cotonou	CHU Québec University D'Abomey-Calavi	FSW	31 years	256 FSW	Primary Health Center clinic
India	Kolkata Mysore	University of Manitoba DMSC Ashodaya Samithi	FSW	29 years	1,325 FSW	Community based within national program Tailored per individual, e.g. Peer educator weekly home delivery Weekly or fortnightly clinic pick up
Kenya	Nairobi Kisumu Homa Bay	LVCT	FSW YW MSM	25 years (FSW) 26 years (MSM) 23 years (YW)	Total: 1,585 ▪ FSW: 528 (33%) ▪ MSM: 438 (28%) ▪ YW: 619 (39%)	Private NGO facilities (MSM and FSW) Gov't health center and hospital (YW)
Kenya/ Uganda	Thika Kisumu Kampala Kabwohe	Partners/University of Washington	SDC	30 years	1,013 SDC ▪ HIV- ▪ 67% male ▪ 33% female	HIV care centers; experience with HIV prevention research
Nigeria	Calabar Jos Nnewi	National Agency for the Control of AIDS	SDC	Data forthcoming	354 SDC ▪ HIV- ▪ 57% female ▪ 43% male	HIV clinic (Nnewi) Family Health Output Clinic (Calabar) Decentralized Community PC sites w/ Hub (Jos)
Senegal	Dakar	African AIDS Research Council	FSW	38 years	267 FSW	Ministry of Health clinics
South Africa	Johannesburg Pretoria	Wits RHI	FSW	29.8 years	219 FSW	SW clinics and mobile sites run by Wits RHI

High Level Results: Initiation relative to targets varied across projects and populations

Target and actual initiation by project



Against a target of 5,750

- 5,019 clients initiated on oral PrEP across 7 projects, an average of 717 per project

Target enrollment across projects

2,850 FSW 850 YW
1,600 SDC 450 MSM

Planned project enrollment sizes ranged from 250 to 2,100

- Largest project enrolled 1,585 clients, smallest 219

Screening and recruitment was slow across all the projects

- New intervention
- Myths and misconceptions among potential clients
- Social challenges such as community concerns and civil unrest

Project	Benin	India	Kenya (LVCT)	Nigeria	Partners	Senegal	South Africa	Total
Percentage achievement	102%	110%	75%	59%	101%	89%	73%	87%

Population	FSW	SDC	YW	MSM
Target	2,850	1,600	850	450
Actual	2,595	1,367	619	438
Percentage	91%	85%	73%	97%

PrEP Demo Project Assessment: Methods

- BMGF commissioned PMM to aggregate and analyze learnings from the 7 BMGF-funded oral PrEP Demonstration Projects to draw out key lessons across the projects to inform PrEP introduction as well as future HIV prevention demonstration projects
- Consultants worked with PMM and BMGF staff to review project reports and publications, interviewed key actors working in PrEP internationally and in countries, and spoke with staff while visiting project sites
- Quantitative analysis is based on data in project dashboards which is project level, not individual, data
- Observations are also drawn from project presentations, discussions, interviews and review of available publications and project documents
- Limitations
 - Project level data limited some analyses
 - Data analysis for several of the demonstration projects is ongoing

Definitions

Term	Definition
Adherence/ Effective Use	Taking the medication in the correct dose, at the right frequency and duration as prescribed by the service provider based on the project protocols. Different methods were used to assess adherence including pill count, verbal feedback, MEMS caps, and drug blood levels.
Lost to follow up	People who were actively participating in the project but became lost or unreachable at the time of follow up.
Missed appointments	Participants who were actively participating in the project but missed one or more of the obligatory visits for > 1 month after the scheduled appointment.
Retention/ Continuation	Participants who were retained/continued on PrEP through the study visits. Demo project participants were expected to continue on PrEP for the duration of the project. In contrast, people taking PrEP in health services would likely cycle on and off of PrEP depending on their perceived risk and other factors.
Stopped	Participants who were actively participating in the study but chose to stop PrEP use due to personal reasons.
Withdrawn	Participants who dropped out of the projects. Their reasons mainly related to the exclusion criteria set out at the beginning of the study.

Project Outcomes

Project Outcomes: Benefits

- These were among the first PrEP demonstration projects and they provided a basic proof of concept by:
 - Demonstrating the **feasibility of services initiating clients on PrEP** across a range of settings and populations at risk
 - Showing that **people at risk are interested in PrEP** and willing to try it
- The demonstration projects helped lay the groundwork for oral PrEP rollout by:
 - **Building capacity** in PrEP delivery within and across countries
 - Helping to **catalyze and inform national roll out** and additional demonstration research
- This work also enhanced key capacities for delivering HIV prevention interventions by:
 - **Expanding experience with demonstration project** design, implementation and data utilization among diverse researchers, implementers and policymakers
 - Strengthening **key population networks and support**

Project Outcomes: Challenges

- Study designs and timing did not sufficiently line up with policy decision-making needs
 - **Study questions and findings did not always align** with the topics and issues prioritized by implementers, policy makers and WHO
 - Varied protocols and indicators **limited the ability to make comparisons and derive lessons across projects**
 - Including **young women and MSM** in only one of the studies meant that **study findings were limited in how they could inform policies and roll out for these critical groups**, including investments such as DREAMS
 - Long implementation and rapidly growing interest in PrEP meant the **timing of findings did not correspond with the policy decision making timeline**
- Projects were not as efficient as planned
 - Extensive planning, slow review processes, and challenges in implementation and analysis meant that **some projects took much longer than anticipated to complete**
- Lessons from PrEP delivery highlighted the difficulty of prevention product introduction
 - **Retention of clients on PrEP was a major challenge** across most of the programs with few strategies shown to be successful in the short timeframe of the projects to have impact
 - **Lack of planning for post-trial PrEP access** for all study participants who wish to continue on PrEP raises ethical and practical concerns

Recommendations for PrEP Roll Out: Program Management & Innovation

- Develop programs where individual clients can access **comprehensive HIV prevention services**, including PrEP, in different locations
- **Explore fast track** PrEP services where clients access PrEP at ARV comprehensive care centers to address concerns about stigma, confidentiality and wait times
- **Identify and invest in providers** who are interested and willing to provide PrEP and attendant services rather than prioritizing by service or location
- Continue to **innovate and evaluate approaches to support clients** to use PrEP, especially continuation
- Determine **which aspects of PrEP information provision and program design are most effective and cost-effective**, including tailoring them to meet individual client needs and preferences
- **Compile and analyze key biological indicators** (e.g. creatinine and plasma blood levels), across all demo projects and roll out efforts and use data to adapt WHO and national guidelines for monitoring and testing

Recommendations for Next Generation Demonstration Projects

Planning

- Coordinate donors and other key actors to ensure investments are synergistic, and avoid overlap, duplication and gaps
- Reorient incentives and deliverables to emphasize timely access to information that can be used for decision making by policymakers and providers throughout the life of the project
- Develop clear description of demonstration projects for diverse stakeholders
- Look ahead to anticipate issues that may arise in the future so that answers are available
- Begin community outreach and sensitization well in advance of the start of the demonstration project

Recommendations for Next Generation Demonstration Projects (2)

Design

- Consult with national and international policymakers and decision makers, including WHO, to prioritize their questions and ensure the demo project answers these questions to inform product introduction
- Balance geographic coverage between and within countries to ensure scientific and political relevance of results, and prioritize settings where the new intervention is likely to be introduced
- Develop realistic recruitment targets large enough to provide meaningful results, and contingency plans to ensure they can be met in a timely manner
- Include sufficient numbers of all relevant populations within the projects or suite of research
- Engage experts in implementation research, service delivery, new product introduction and behavior in project design
- Plan projects with realistic timeframes and interim analyses to ensure that emerging findings can inform policies and new product introduction in real time
- Align study results (interim and final) with implementation plans prior to project initiation and ensure that findings are presented in the context of next steps to introduction and scale up

Recommendations for Next Generation Demonstration Projects (3)

Process

- Locate projects in public facilities/services and in “typical” settings where people access care
- Create synergy across project protocols, data collection and indicators to facilitate analysis, comparison and learning
- Ensure studies can be nimble in responding to changing external circumstances so the studies can be completed, and their findings are relevant
- Reduce clinical and support services over time to levels that are replicable in roll out and assess for cost, acceptability, access, impact
- Adjust follow up schedule to be flexible and responsive to clients’ schedules and needs
- Include provider perspectives as explicit outcome to inform best practices in initial roll out
- Work with IRBs and donors to require that all research products with proven results are made accessible to participants for a period to be determined through consultation

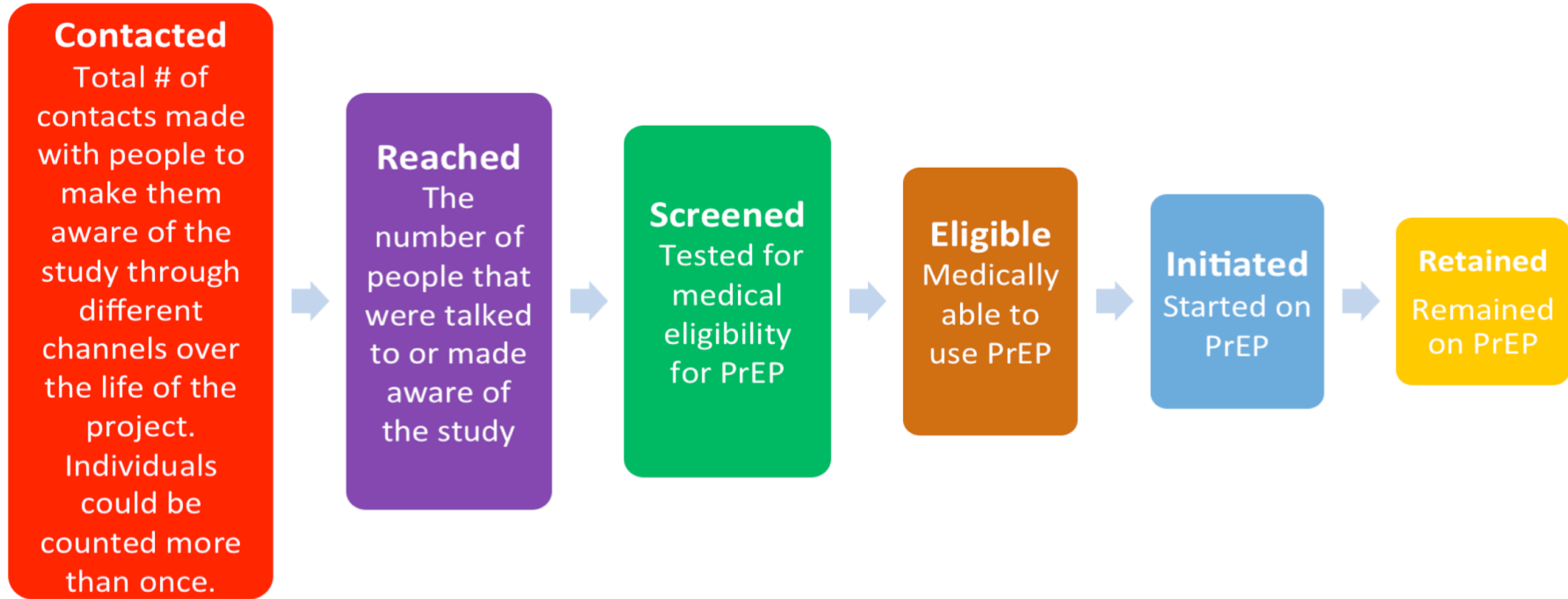
Influence of BMGF-Supported Demonstration Projects

- Stakeholders (researchers, policymakers, project participants) **voiced appreciation to BMGF for taking on implementation questions early through demonstration projects**, before global guidance
- Investment has been **influential in national and international guidelines and policy decisions**
 - Early evidence in a range of settings and populations helped inform development of WHO guidelines on PrEP demonstration projects
 - Project staff served on national technical and guideline committees
- Demo projects **informed additional PrEP demonstration and implementation research**

Results:

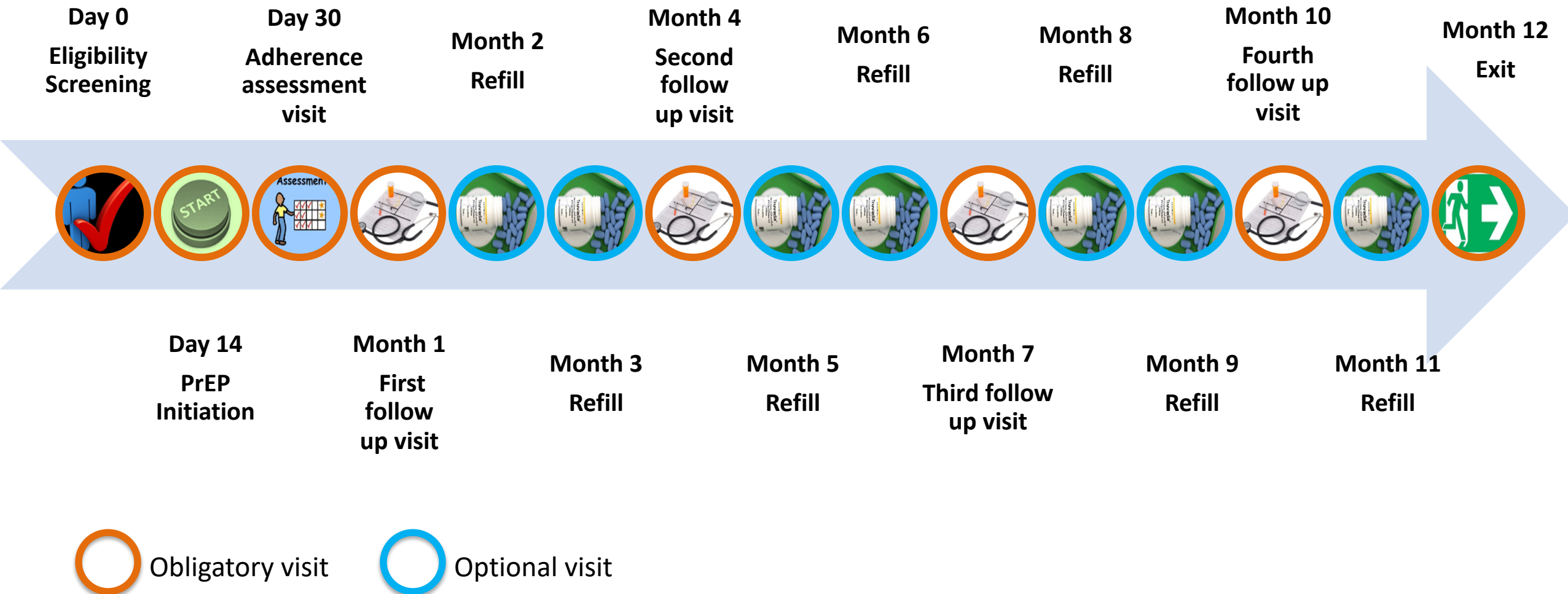
Contacts, Screening, and Initiation

Illustrative cascade



- Contacts with individuals were made through a variety of channels including health workers and peers
- Following contact, appointments were set with potential clients for screening and eligibility assessment
- Projects had a 10-14 day waiting period between screening and initiation

General Pathway to PrEP Across Projects



Outreach and Contacts:

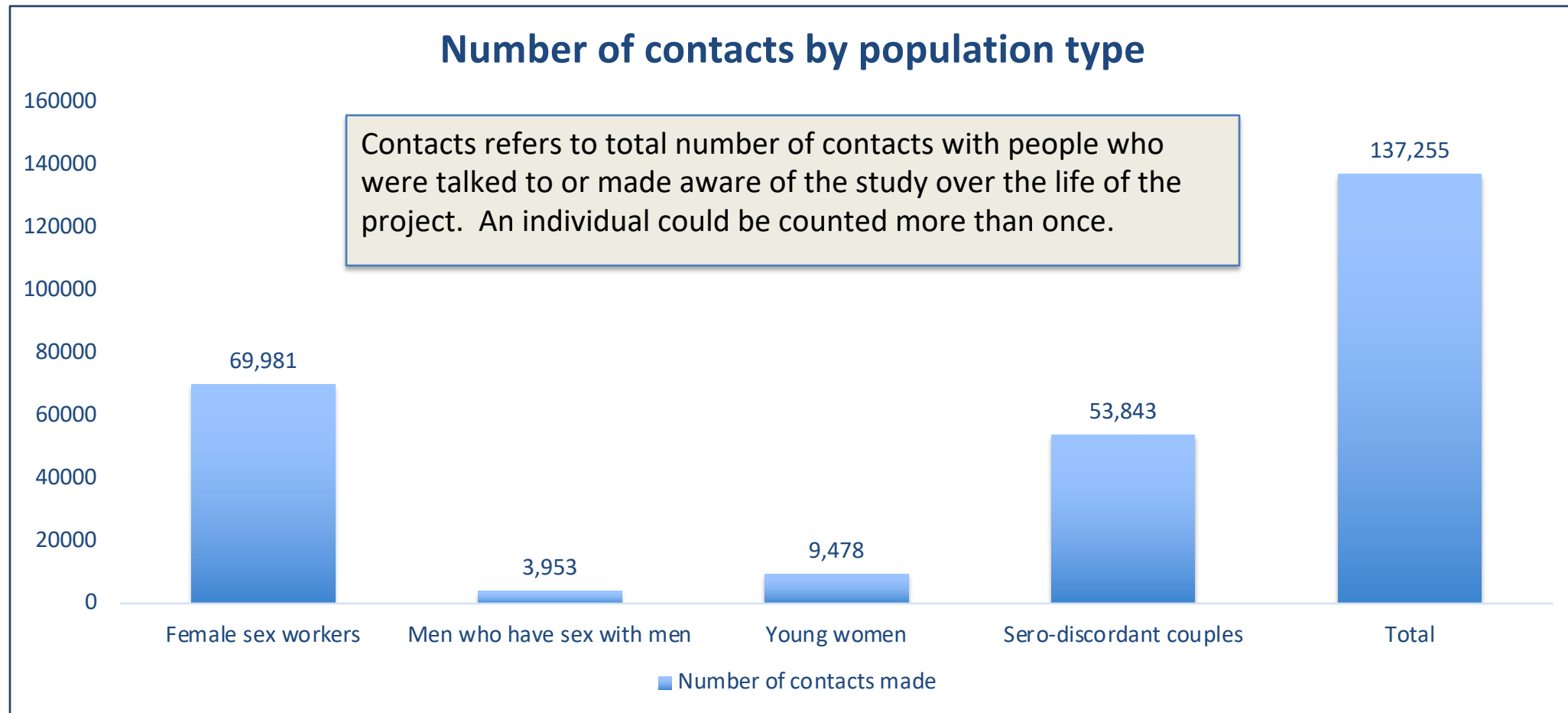
Projects conducted extensive outreach to large numbers of contacts



- The India and Nigeria teams made the most contacts with potential clients with an average of 9.8 and 8.0 contacts per person reached respectively
- The number of contacts per person reached ranged from 1.2 in South Africa to 9.8 in India
- There was some variation in how information on contacts and people reached was captured and interpreted across the projects
- Figures are not available for Partners and Senegal

Outreach and Contacts:

Most contacts made with FSWs, reflecting the targeted study populations



- The highest number of contacts were made with female sex workers, representing 84% of total contacts made. FSWs comprised 59% of the target enrollment across projects and 52% of those actually enrolled
- The average number of contacts made per person reached was 3.7 for FSW, 2.8 for MSM, and 1.7 for YW
- Figures are not available for Senegal and Partners

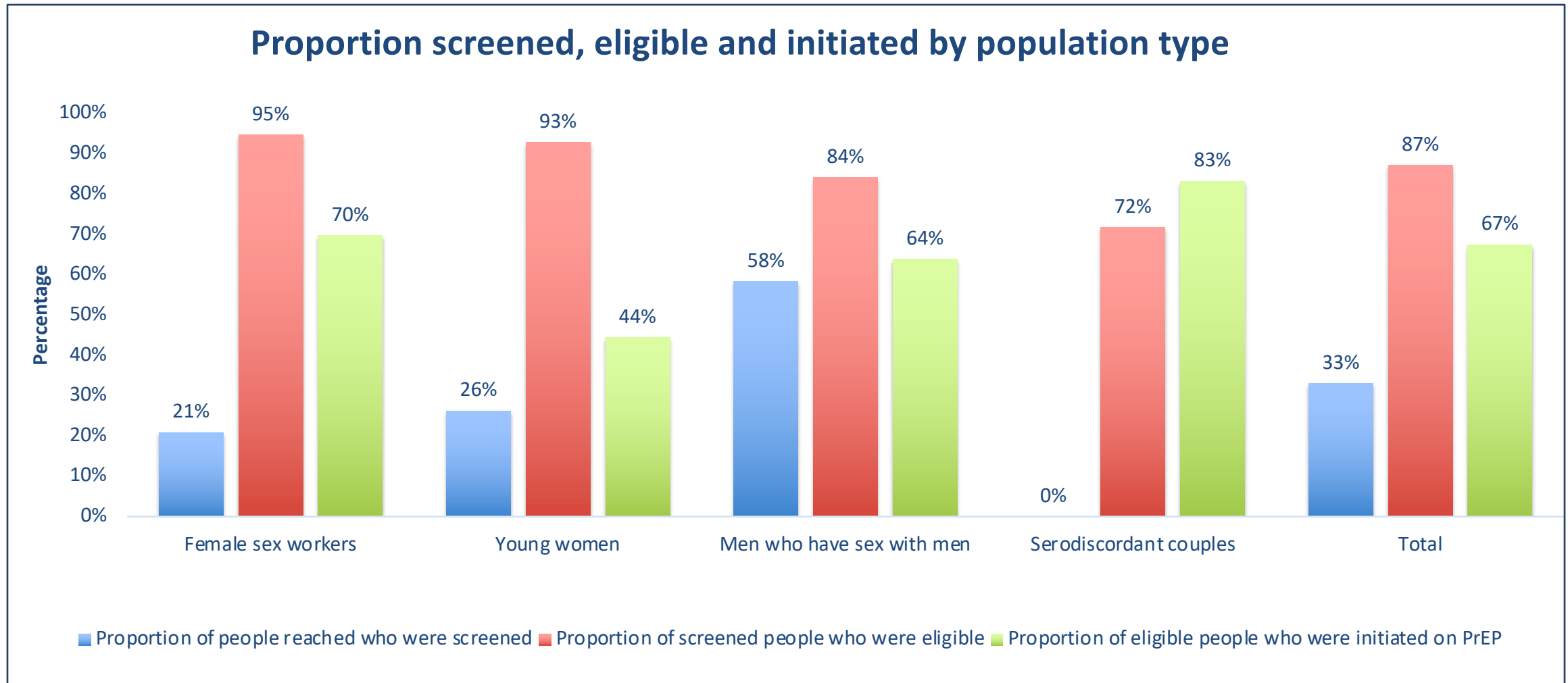
Screening, Eligibility and Initiation on PrEP

Screening, Eligibility and Initiation:

Eligibility criteria for PrEP Demonstration Projects

- While some criteria differed by population, general eligibility requirements were:
 - Informed consent
 - ≥ 18 years and older
 - Good general health, confirmed by medical history and physical examination
 - HIV negative (defined as a negative 4th generation HIV ELISA test prior to enrollment)
 - Serum creatinine \leq upper limit of normal (ULN) & calculated creatinine clearance of at least 70 mL/min
 - Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) < 2.5 times ULN
 - Hemoglobin > 8.5 g/dL
 - No reported intention to relocate out of the study area during the course of the study
 - Self-reported use of effective contraceptive method and intention to continue to use it
 - Without signs or symptoms of acute HIV infection (acute retroviral syndrome)
 - Risk, including
 - Serodiscordant couples: HIV+ partner not virally suppressed and intention to maintain relationship; risk per risk screening tool
 - In Partners, serodiscordant couples were scored according to a risk scoring tool that identified couples at higher risk based on: younger age, fewer children, uncircumcised (HIV- men), cohabiting, unprotected sex in previous month, and high plasma HIV RNA samples in HIV+ partner
 - MSM and YW: at risk per risk scoring tools
 - FSW: Active sex work (paid sex within the past six months)

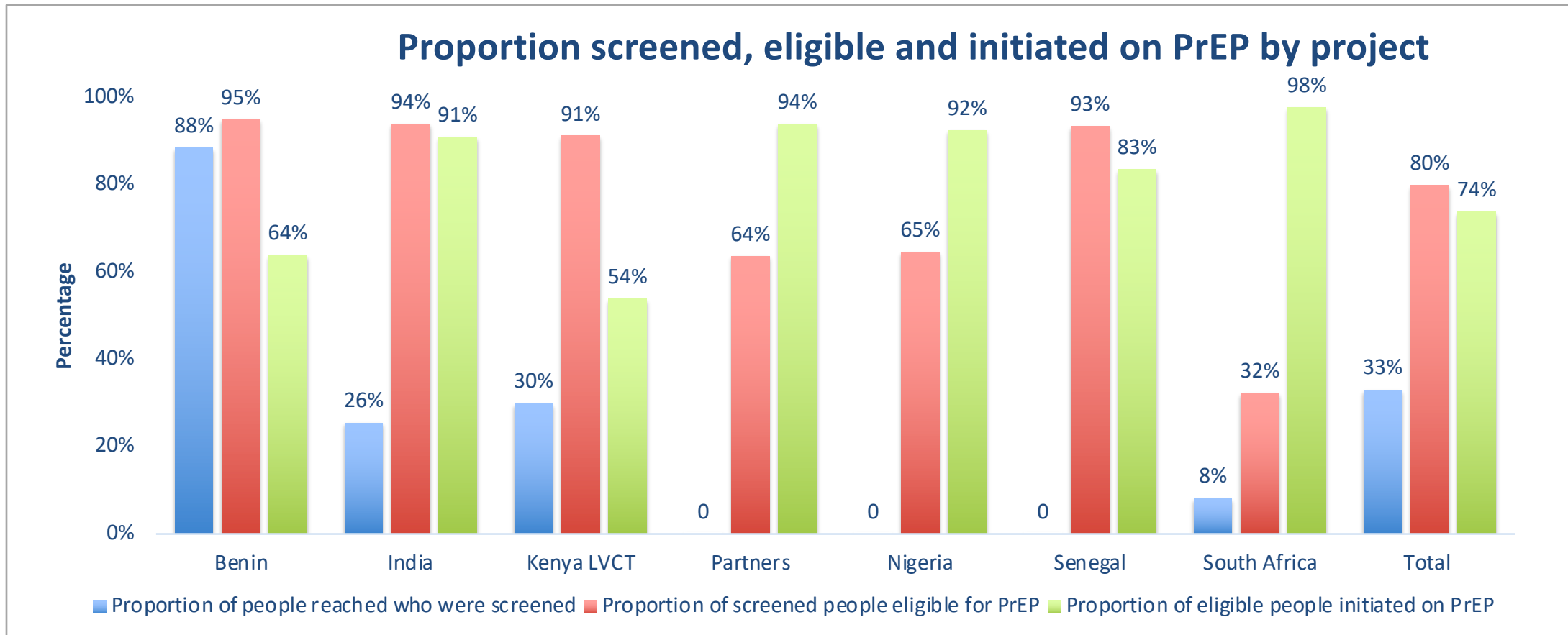
Screening, Eligibility and Initiation: A majority of people screened across populations were eligible for PrEP



- Initiation on PrEP among those eligible was highest among serodiscordant couples
- A high proportion of the young women screened were eligible for PrEP, but less than half were initiated

Screening, Eligibility and Initiation:

Most of those eligible were initiated on PrEP

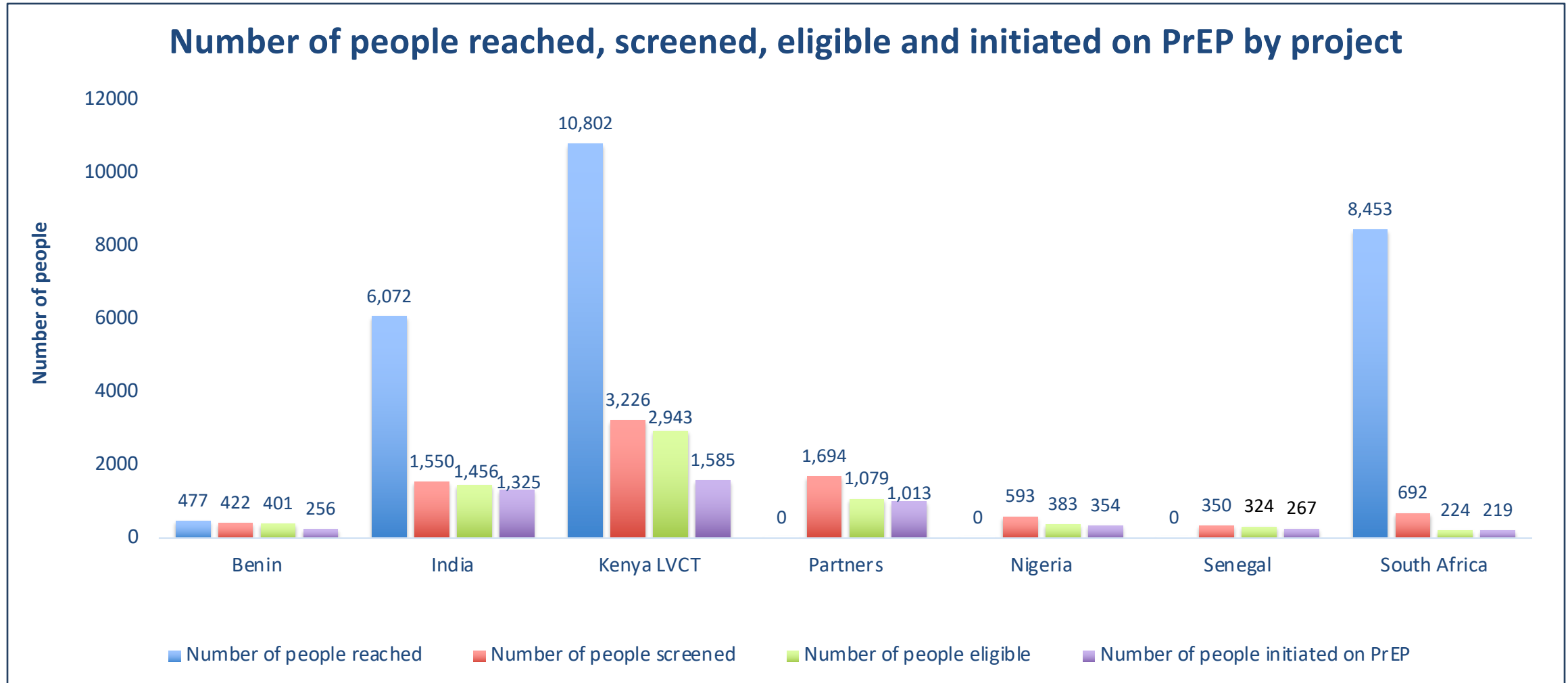


- Some clients were lost at each stage: screening, eligibility, initiation. Only 33% of those reached were screened
- The majority of people screened in all projects were eligible for PrEP, except in South Africa (range: 32%-95%)
- The majority of eligible people in all of the projects were initiated on PrEP (range: 54%-94%)

Figures presented for serodiscordant couples here include partners later determined to be ineligible for PrEP

Screening, Enrollment and Initiation:

Kenya LVCT had the highest target, number reached and initiated on PrEP



- People dropped out at different stages of the process, from reached to PrEP initiation and follow up
- The biggest drop off was between reached and screening

**Number of people/couples reached not available for Partners, Nigeria and Senegal*

Number and proportion of eligible clients initiated on PrEP by project and population type

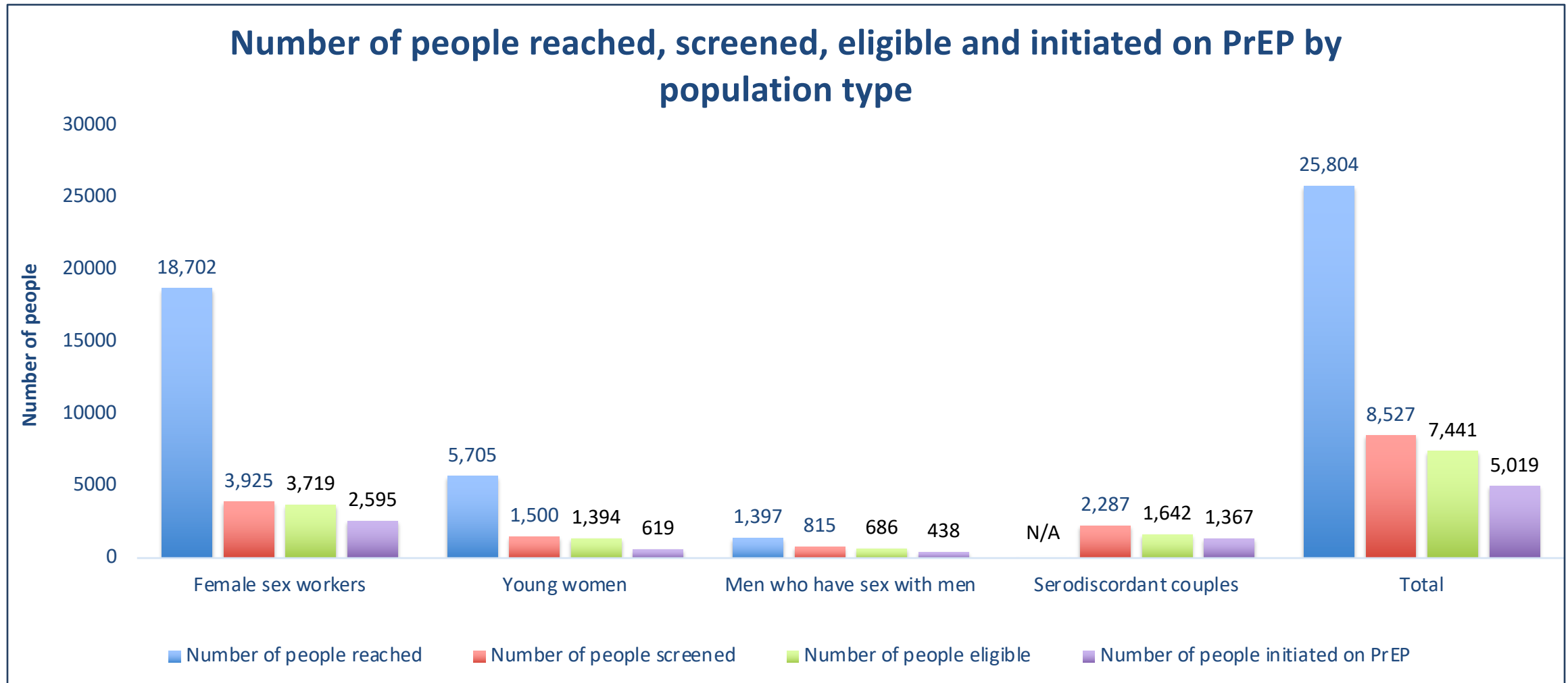
By project:

	Benin	India	Kenya (LVCT)	Kenya/Uganda (Partners)	Nigeria	Senegal	South Africa	Total
Eligible	290	1,433	2,758	1,079	383	324	334	7,631
Initiated	256	1,325	1,585	1,013	354	267	219	4,972
Proportion (initiated/eligible)	88%	92%	57%	94%	92%	86%	66%	65%

By population type:

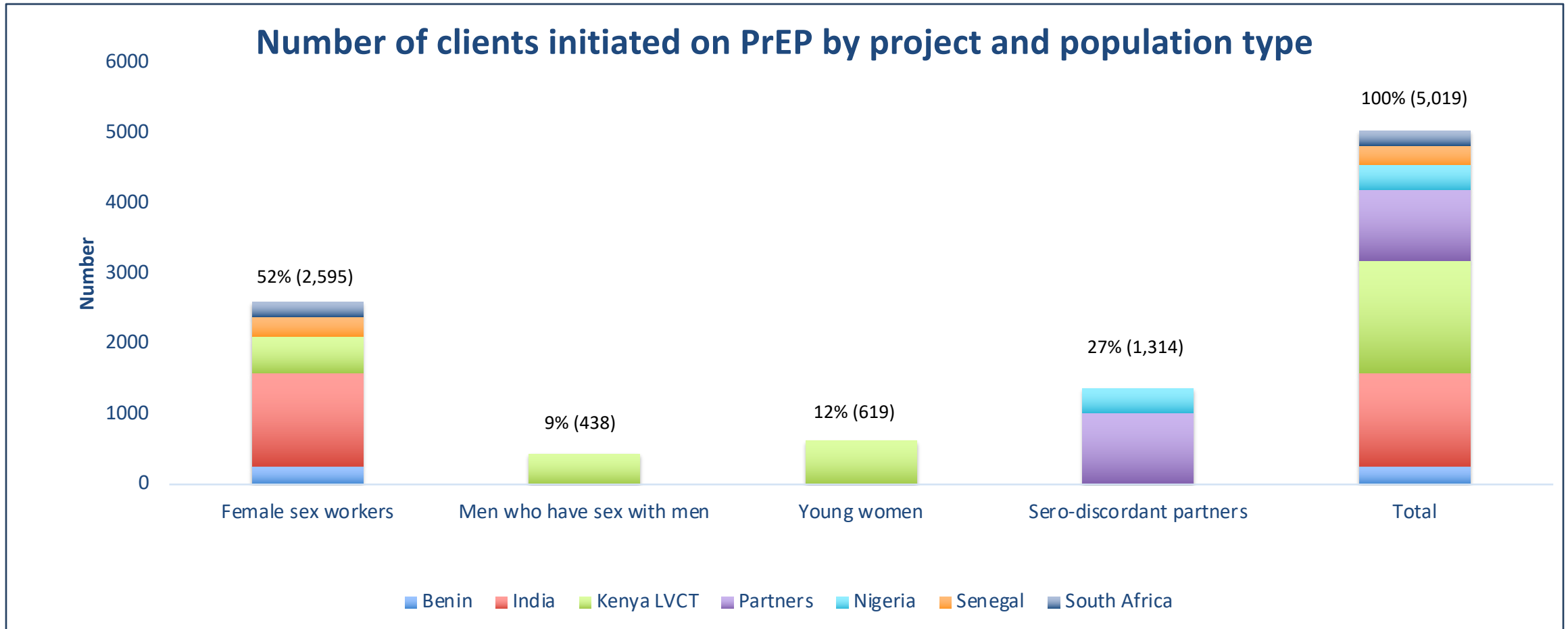
	MSM	YW	FSW	SDC
Eligible	686	1,394	3,719	1,462
Initiated	438	619	2,595	1,367
Proportion (enrolled/eligible)	64%	44%	70%	94%

Across populations, 5 people were reached for each client initiated on PrEP



- In aggregate, the projects were designed to include more FSW than any other population group, and FSW were reached and initiated on PrEP more than any other group
- SDCs had the greatest proportion of eligible clients initiated on PrEP

The majority of people initiated on PrEP were FSW, also the largest target group (59%) and largest initiated group (52%)



Total number of clients initiated on PrEP = 5,019, by project:

- Kenya LVCT (1,585)
- Partners (1,013)
- Senegal (267)
- South Africa (219)
- India (1,325)
- Nigeria (354)
- Benin (256)

Reasons for Ineligibility

- Reasons for ineligibility for PrEP included:
 - HIV positive test results (most common)
 - Hepatitis B infection
 - High creatinine levels
 - Other health conditions
 - Pregnancy/ breastfeeding*
 - Inadequate sexual intercourse in the 3 months prior to screening (low risk)
- *Among sero-discordant couples*
 - Viral load suppression among the HIV positive partners at presentation
 - No intention to maintain their relationship

*During the time the demonstration projects were underway, WHO issued a technical brief *Preventing HIV During Pregnancy and Breastfeeding in the Context of PrEP* (2017). Following a systematic review (2016) that found little evidence for safety concerns related to PrEP use in early pregnancy, and minimal evidence of FTC/TDF in breastmilk, the technical brief states that “Based on the available safety data, WHO considers that PrEP should not be discontinued during pregnancy and breastfeeding for women who continue to be at substantial risk of HIV infection. PrEP can also be considered as an additional prevention choice for HIV negative pregnant women who are at substantial risk of HIV as part of a comprehensive PMTCT program.” It notes that women should make this choice following a review of risks and benefits with a health-care provider. <http://apps.who.int/iris/bitstream/handle/10665/255866/WHO-HIV-2017.09-eng.pdf>

Common Reasons Cited for Not Initiating PrEP Among Eligible Clients

- Reasons cited for not initiating PrEP across populations and projects:*
- Lost to follow up
- Late for appointment (> 1 month)
- Refused PrEP (without specifying reason)
- Fear of side effects
- Needed more time to think about PrEP
- Stigma: clients not wanting to be seen with pills or at the clinic
- Not wanting to take a pill daily
- Need to consult partner/ spouse (most common among YW)

* These are the project-level categories as reported across the demonstration projects.

HIV Prevalence Among Clients at Screening by Project & Population Type

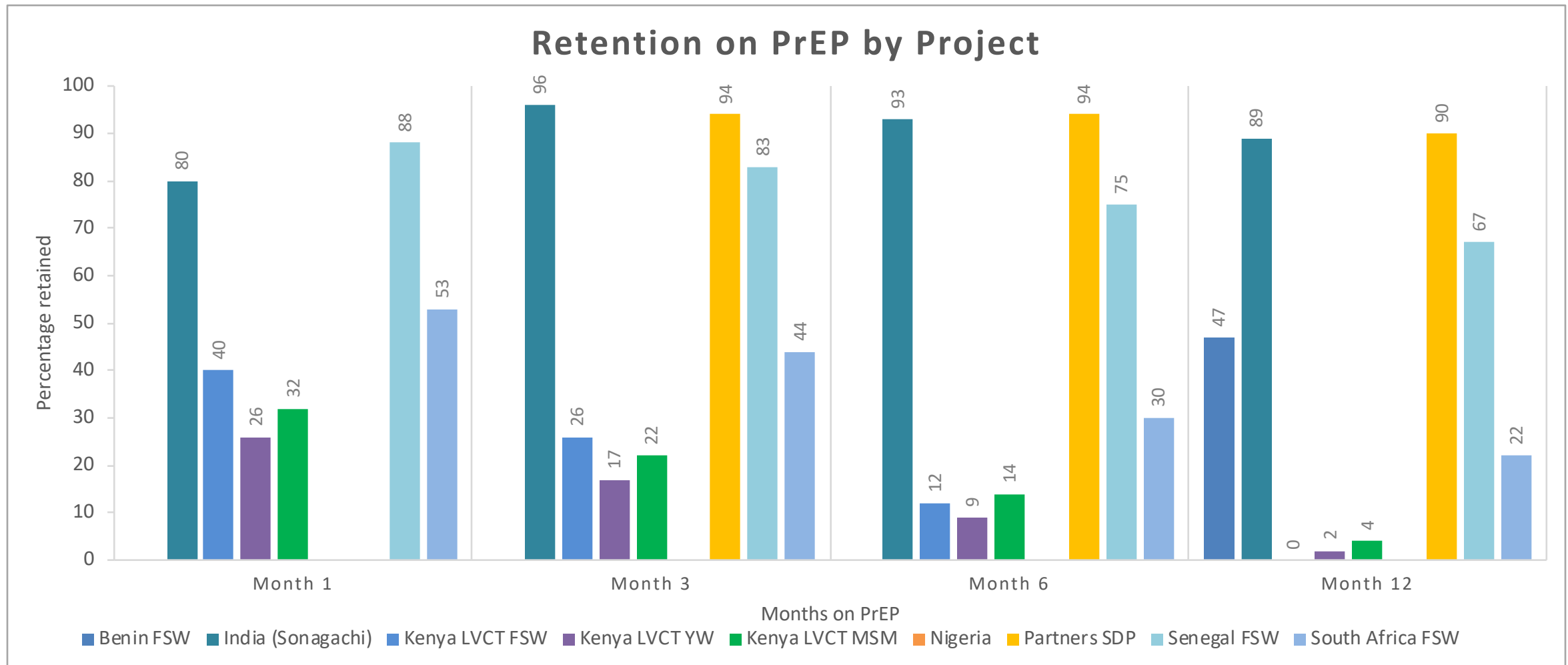
HIV prevalence at screening by project								
	Benin	India	Kenya (LVCT)	Kenya/Uganda (Partners)	Nigeria	Senegal	South Africa	Total
Number of clients screened	422	1,550	3,226	3,388	1,186	350	692	10,810
Number HIV positive	111	23	185	1,692	593	8	341	2,953
HIV prevalence	26.3%	1.4%	5.7%	*50%	*50%	2.3%	49.3%	27%

HIV prevalence at screening by population type				
	Female sex workers	Men who have sex with men	Young women (18-29)	Sero-discordant couples
Number screened	3,925	815	1,500	4,574
Number testing HIV positive	505	94	69	2,285
HIV prevalence	12.9%	11.5%	4.6%	50%*

*prevalence of 50% represents the positive partners among the sero-discordant couples in the Partners and Nigeria projects

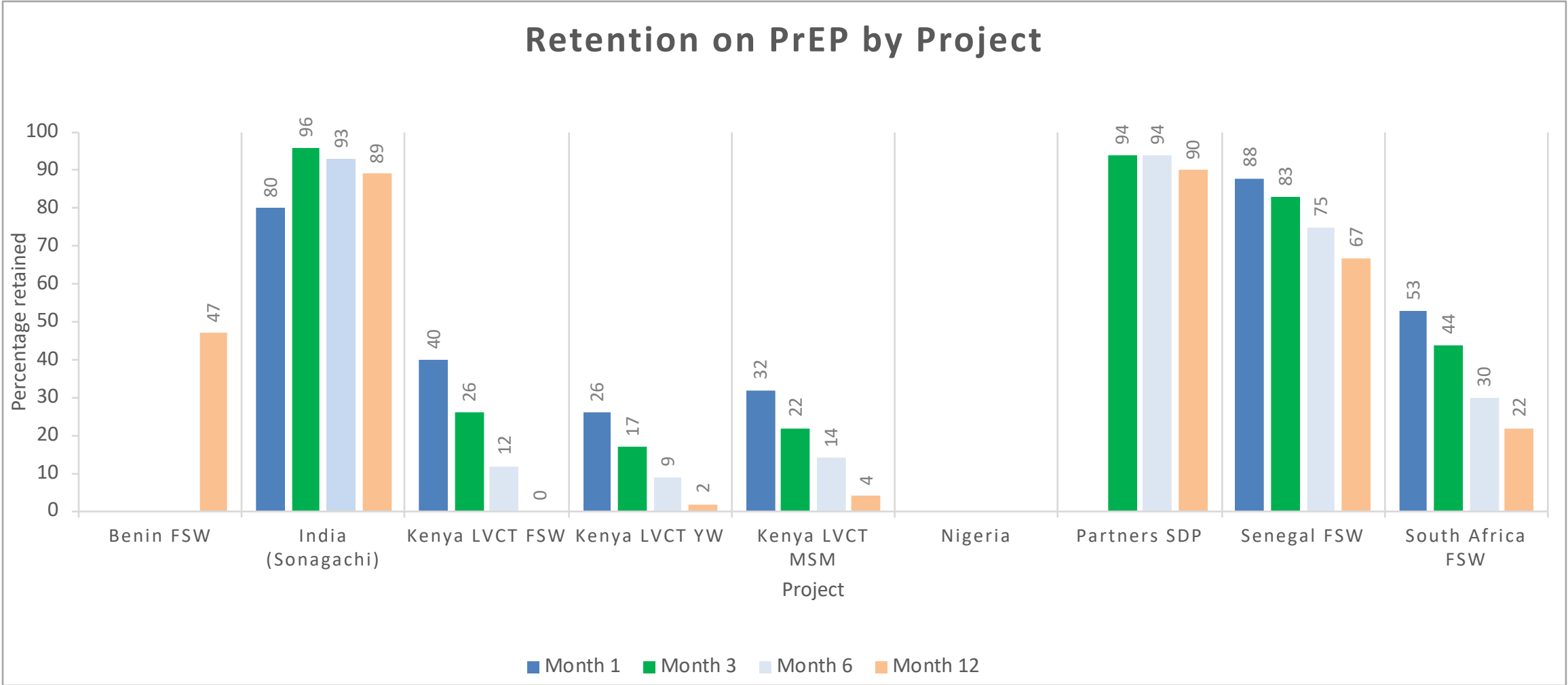
PrEP Continuation & Retention

Retention on PrEP was highest among SDC and FSW in India and Senegal. It was challenging for many of the other projects and populations



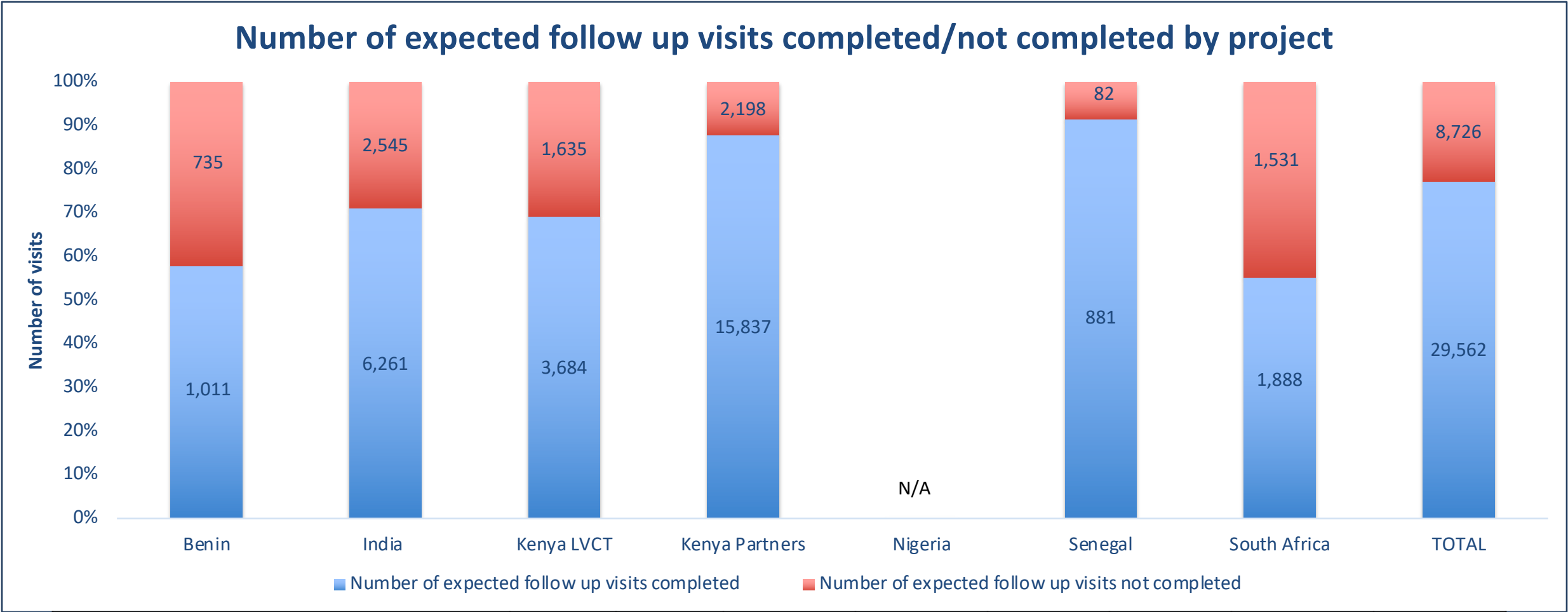
- Retention refers to participants who remained on PrEP
- Retention at 6 months ranged from 9% to 94% and at 12 months from 0 to 90%
- Missing values are due to differences in follow up intervals measured in projects

Retention on PrEP was highest among SDC and FSW in India and Senegal



- Retention refers to participants who remained on PrEP
- Retention at 6 months ranged from 9% to 94% and at month 12 from 0 to 90%
- Missing values are due to differences in follow up intervals measured in projects

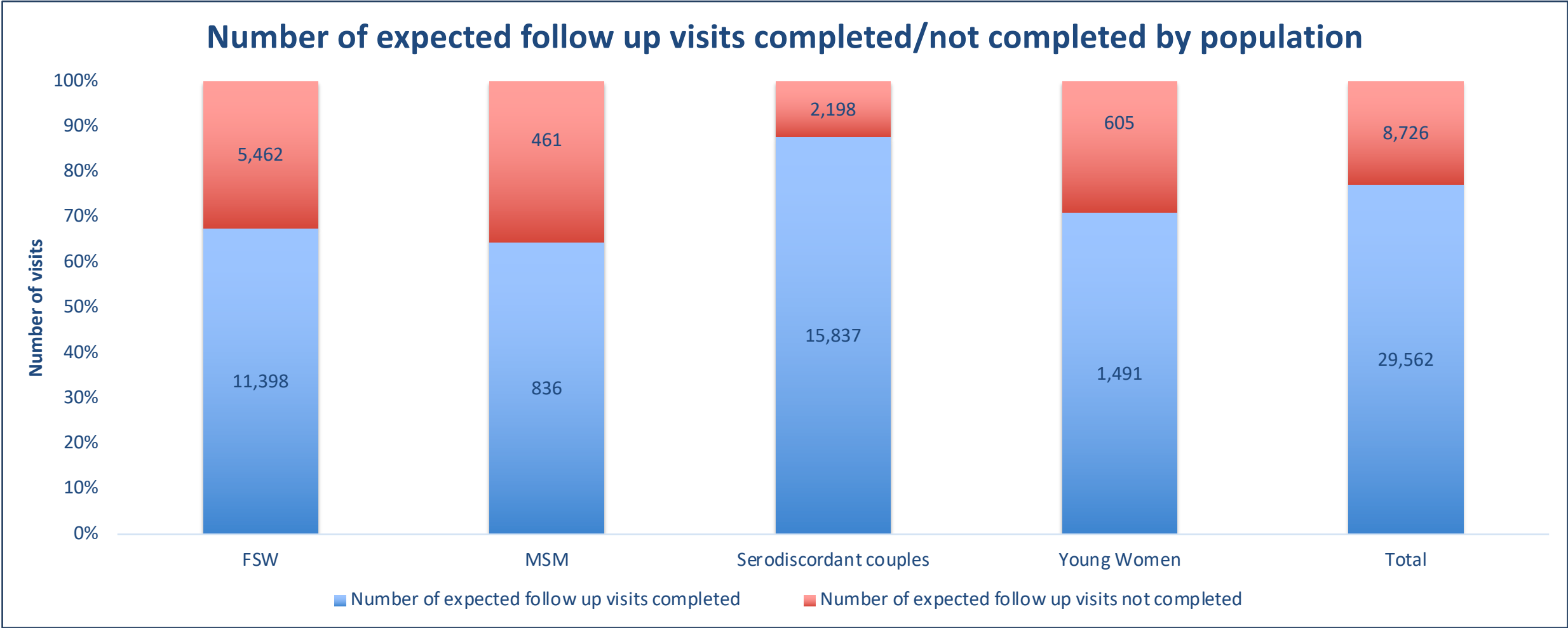
At least half of the expected study visits were completed in all projects



Project	Benin	India	Kenya LVCT	Kenya Partners	Nigeria	Senegal	South Africa	TOTAL
Percentage of expected visits completed	58%	71%	69%	88%	N/A	91%	55%	77%

- visits not completed if >1 month after last appointment
- visits were considered completed regardless of PrEP use

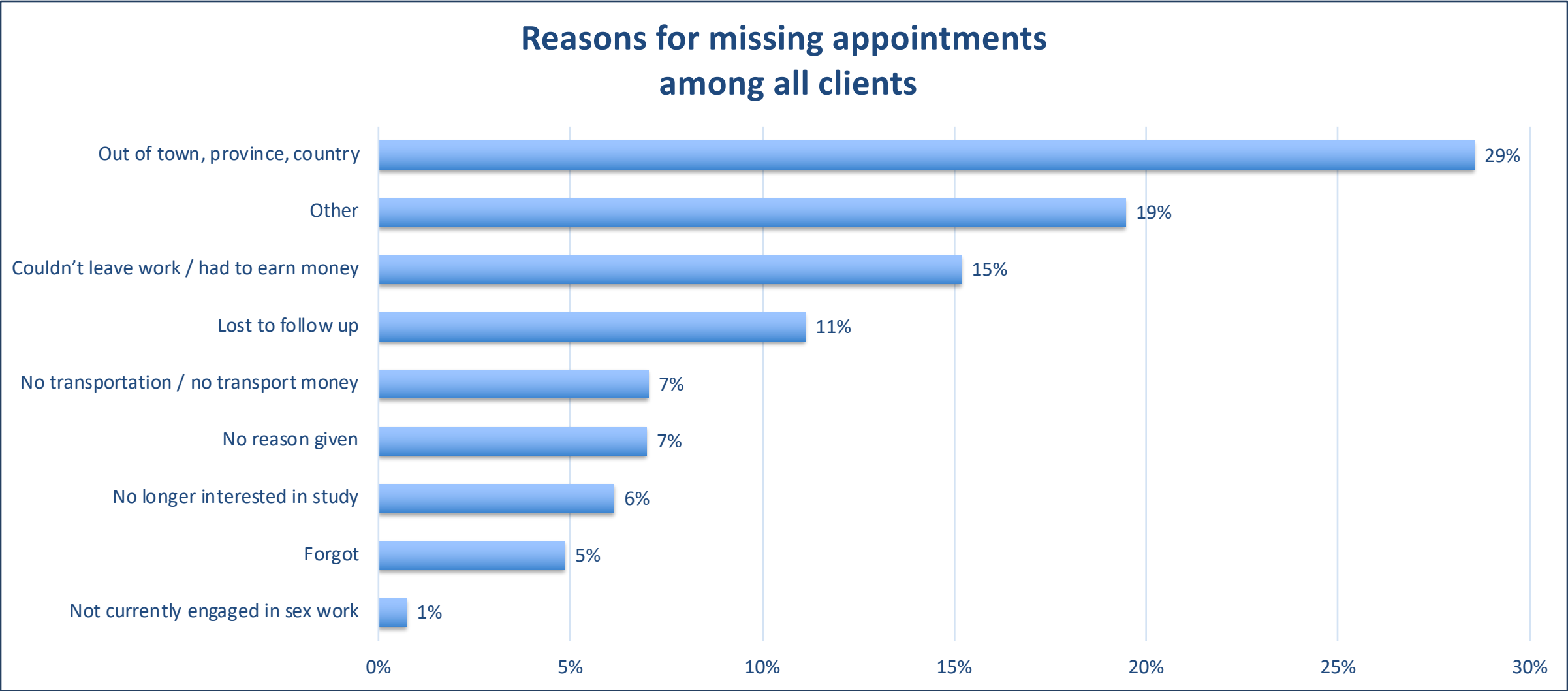
88% of expected study visits among SDCs were completed, and all populations completed two thirds of expected visits



Population group	FSW	MSM	SDC	YW	Total
Percentage of expected visits completed	68%	64%	88%	71%	77%

- visits not completed if >1 month after last appointment
- visits were considered completed regardless of PrEP use

Out of town travel was the most common reason for missing appointments



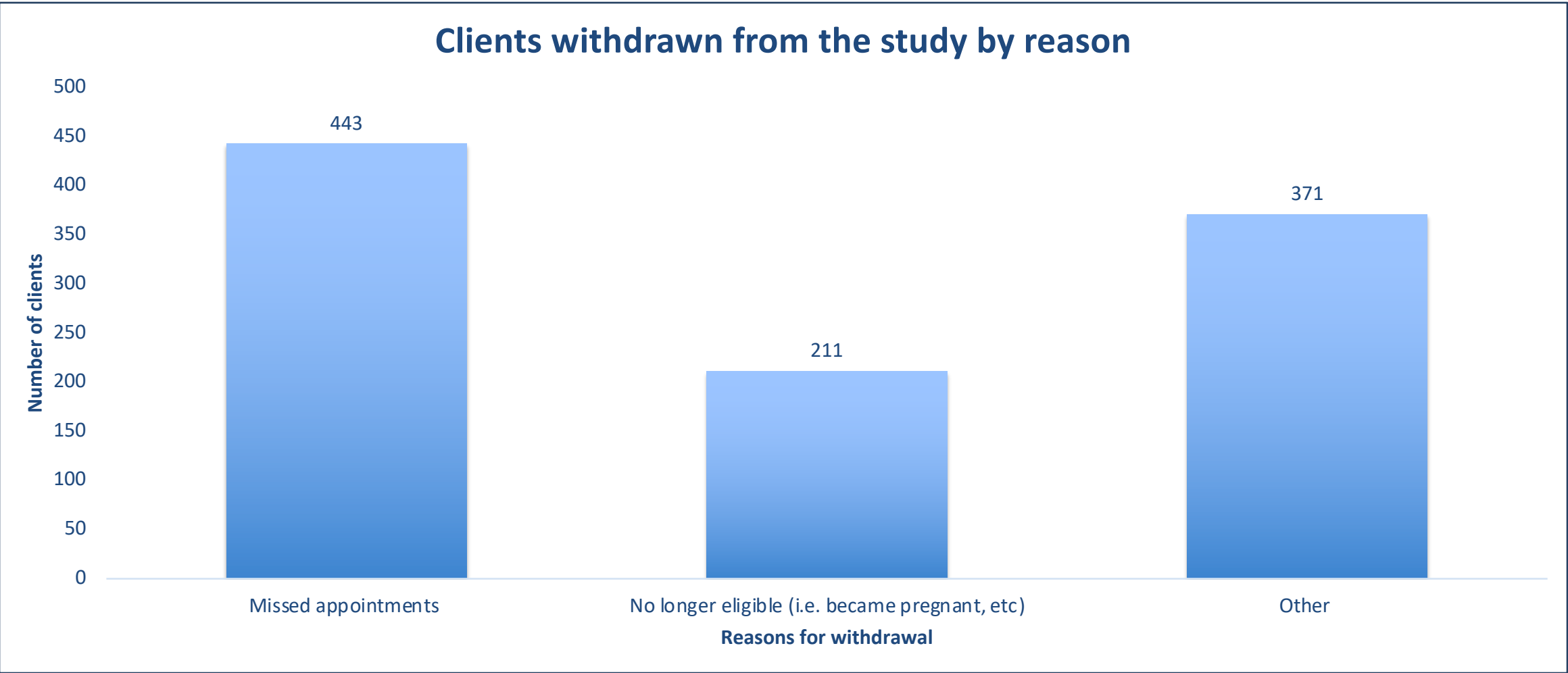
Data on “other” not collected or explained consistently across projects. It includes participants who did not answer their phones, and those who promised to come when contacted but did not come back for their appointments.

Reasons for Missing Appointments by Population Group

Population group	Most common reasons for missing appointments
Female sex workers	<ul style="list-style-type: none">• Out of town, province or country• Couldn't leave work/ had to earn money• Lost to follow up
Young women	<ul style="list-style-type: none">• Out of town, province or country• Forgetting appointment• No specific reason given
Men who have sex with men	<ul style="list-style-type: none">• No transportation/ no money for transport• Out of town, province or country• Forgetting appointment
Sero-discordant couples	<ul style="list-style-type: none">• Out of town, province or country• No longer interested in the study• Lost to follow up

Across populations and projects travel/migration was a main contributing factor to missed appointments. Many of the participants in SW projects in Africa were from other countries.

Missed appointments the primary reason clients withdrew from projects



“Other” reasons include: death, seroconversion (N=16, all known to have stopped using PrEP), out of town/province/country, no longer interested in the study, gone back to country of origin

Patterns and reporting of stopping and restarting PrEP varied across the projects but was significant in some

- In total, six of the seven projects reported 2,162 episodes of stopping and 706 episodes of restarting*

Reasons for stopping included

- | | |
|---|-------------------------------------|
| – Partner successfully on ART | - Pregnant/trying to conceive |
| – Side effects | - No longer sexually active |
| – Partner request | - Moved back to country of origin |
| – No longer perceive self to be at risk | - Moved out of town/province |
| – Don't like taking pills daily | - No longer interested in the study |
| – Seroconversion* * | |

Reasons for restarting included

- Perceived self at risk
- Now able to take pill every day
- Change in partner and relationship status

* Figures do not include Benin

* * All seroconverters were known to have stopped taking PrEP

Conclusions

- Demonstration projects play an important role in bridging clinical evaluation and program implementation
- It is feasible to deliver PrEP beyond clinical trials and people at risk are willing to try it
- These projects helped lay the groundwork for other demonstration projects, and informed PrEP policy development, program implementation and scale up
- The range of projects can offer important lessons about how to deliver PrEP to individuals and populations at risk of HIV

Acknowledgements

- Thanks to the many people interviewed for this project for their thoughtful, frank and informative insights and analyses.
- We very much appreciate the feedback, information provided and hospitality of the Investigators and staff at all of the the BMGF-supported PrEP Demo Projects in familiarizing us with their projects and responding to our many questions during site visits, phone calls and emails.
- Staff at other key organizations working on national policies and programs, PrEP research and delivery, and the design and implementation of these demo projects also gave generously of their time in interviews and addressing follow up questions.
- Finally, thanks to the staff at BMGF for commissioning this project, and for their very helpful feedback and guidance throughout.

Annex: Select Details and Examples

Influence of Demo Projects

Built capacity in PrEP delivery within and across countries	<ul style="list-style-type: none"> Community of practice created across project teams through protocol development, exchanges and joint meetings Tools developed and made available to programs and on PrEPWatch.org including standard operating procedures and job aids, training materials, monitoring and evaluation, IEC materials Project researchers, staff and clients are champions and experts for PrEP nationally and internationally
Catalyzed and informed national policies and roll out	<ul style="list-style-type: none"> Project staff served on national technical and guideline committees Benin: <ul style="list-style-type: none"> Demo project results Influenced decision <i>not</i> to roll out PrEP for FSW given high cost, low uptake, limited impact Informed and accelerated implementation of national guidelines for early treatment in clinical practice South Africa <ul style="list-style-type: none"> Expanded from demo project to national roll out to FSWs and subsequently to MSM and to young women in tertiary educational institutions WHRI engaged local policymakers, Department of Health and SW organizations on PrEP, and supported 2016 guidelines on PrEP and ART in sex workers Kenya <ul style="list-style-type: none"> LVCT's work with diverse populations (MSM, FSW, YW) helped catalyze and support policymaker buy-in for roll out in diverse at risk populations despite challenges with retention Partners' work informed SDC guidance and staff are technical advisors working on roll out Nigeria <ul style="list-style-type: none"> Informed planned roll out in select states and populations supported by PEPFAR
Informed design and conduct of demo projects in other groups and settings	<ul style="list-style-type: none"> Benin: exploring demonstration project for PrEP in MSM Senegal: exploring PrEP demonstration project among FSWs in other geographic areas with high levels of sex work and migratory populations Kenya: informed many additional demo projects in other states Nigeria: informed support for additional demonstration projects in other states in the country

Feasibility, Recruitment, Product Characteristics

	Observations from Demo Projects	Suggestions for PrEP Implementation
Feasibility of PrEP Delivery	<ul style="list-style-type: none"> Despite challenges demonstration projects revealed that delivering PrEP to specific key population groups with additional support in areas such as counseling and peer counseling, risk assessment, community outreach, support groups, provider training, logistics and laboratory and supporting effective use is feasible 	<ul style="list-style-type: none"> Continue to identify which program components are most effective in identifying and initiating people at risk, and in supporting their continued use of PrEP
Community awareness/ Recruitment	<ul style="list-style-type: none"> Recruitment challenging despite multiple methods used Projects with established relationships with study communities and target populations were more successful in recruitment In some projects, outreach and sensitization were started too close to project initiation 	<ul style="list-style-type: none"> Sustain campaigns and information beyond “launch” Develop and make available materials in local languages Draw on MOH for credibility
Influence on product characteristics on effective use	<ul style="list-style-type: none"> Difficulty/unwillingness to adhere to daily pill Stigma associated with identifiable ARVs Noise from pill bottles <ul style="list-style-type: none"> Used cotton in bottle, envelopes, other strategies Tablet too big MEMS cap unpopular with clients and staff <ul style="list-style-type: none"> Large, unwieldy; difficult to manage and carry 	<ul style="list-style-type: none"> Ring, injectable or implant may (or may not) address concerns about daily pill taking Explore branding for PrEP separate and distinct from ARVs for PrEP Develop appealing, attractive, discreet packaging

Anticipating and Addressing Implementation Challenges

	Observations from Demo Projects	Suggestions for Future Demo Projects
Anticipating and addressing Implementation Challenges	<p>Implementation challenges led to delays and difficulties for many of the projects</p> <ul style="list-style-type: none"> • <i>Managerial</i>: Delays in protocol development and approval, data cleaning and analysis • <i>Logistical</i>: Delay of drug delivery and availability; duty on <i>Truvada</i> • <i>Communications</i>: Demonstration projects occupy an unfamiliar space; they are not clinical trials but the drug does not have regulatory approval. Study teams found it challenging to convey the concept of a demonstration project to regulatory and ethical review bodies, policymakers, participants, and communities • <i>Consumer</i> <ul style="list-style-type: none"> • mobility of target populations • Clients changing their minds, responding to external pressures, fear of side effects, unwilling to take pills daily • Uncertainty and/or mistrust in PrEP as a new intervention • <i>Political</i>: Civil unrest and disruptions affected recruitment and retention • <i>Geographic</i>: Some efforts to work in “typical” sites/communities were too difficult for a new intervention 	<ul style="list-style-type: none"> • Include experts in planning and product introduction, and representatives of study populations, as part of project design team • Invest in robust community engagement • Ensure that projects can be nimble in responding to external circumstances through, for example, expanding recruitment and follow up to other facilities • Compile experience with informed consent and community education to develop clear description of demonstration projects for diverse stakeholders

Key Insights by Population

Female Sex Workers	<ul style="list-style-type: none"> • Mobile and dynamic population; programs should be designed to allow individual FSWs to access PrEP in different sites • Shifting risk profile based on work, location, relationships; services should be prepared for FSWs to cycle on and off PrEP • Projects with FSWs generally had close connections with communities or NGOs through prior programs, services, or research. These relationships seemed to help with initiation and retention in some cases (India) but less so in others (SA).
Young Women	<ul style="list-style-type: none"> • Continuation, effective use, and follow up very challenging. Additional demo projects and programs exploring how best to deliver PrEP to YW in different settings. • Important role of partners, parents, and community in facilitating or hindering PrEP programs and access for YW <ul style="list-style-type: none"> • Community resistance to young women on PrEP due to concerns including “promiscuity” and young women’s sexual agency; also wanted programs for young men • Many felt they needed to inform or have permission from partners, parents and others • Some parents, community health volunteers, leaders supported PrEP recognizing YW HIV risk • Volunteer health workers and peers important in mobilization • Private, non judgmental and sensitive service settings and providers are key to PrEP delivery for YW • YW only included in one project in two settings, making it difficult to draw conclusions
Men who have sex with men	<ul style="list-style-type: none"> • Only included in one project in two settings making it difficult to draw conclusions; other settings (Benin, India) exploring PrEP delivery for MSM • Effective use and follow up were very challenging • Welcoming, supportive service environment critical to ensure sensitive and private PrEP delivery; high level of trust in LVCT site • Peers important for mobilization and building trust
Serodiscordant Couples	<ul style="list-style-type: none"> • Important target group with known risk, relatively straightforward to identify and recruit • Partners playing key role in building capacity for SDC services in Kenya • Relevance of SDC experience to other populations limited given clearly defined population and known risk; defined and limited term for PrEP use (6 mos)