

Quarterly Meeting of the Coalition to Accelerate Access to Long-Acting PrEP
Thursday, 11 April 2024
15:30-17:00 East Africa / 15:00 – 17:00 Thailand / 8:30-10am Eastern Standard Time
MEETING SUMMARY - shared on 19 April 2024

Agenda		
Start Time (EST)	Agenda Item	Organization / Presenter
8.30 - 8:35am	Welcome and Objectives	Mitchell Warren (Coalition Secretariat)
8.35 – 9.50am	Updates from stakeholder groups of Coalition to Accelerate Access to Long-Acting PrEP	
8.35 – 8:50am	Convenors	Mateo Prochazka Nunez (WHO)
8.50 – 9am	Civil Society Caucus	Kenneth Mwehonge (HEPS Uganda); Nicky Suwandi (KP Advisory Group)
9 – 9.10am	Donor Caucus	Ashley Vij (USAID); Sarah Hamm Rush (Gates Foundation)
9.10 – 9.20am	Ministries of Health	Lloyd Mulenga (Zambia)
9.20 – 9.40am	Implementation Science groups	Moses Kanya (Makerere University); Kristine Torjesen (FHI 360)
9.40 – 9.50 am	IP management, e.g. voluntary licensing	Sébastien Morin (MPP)
9.50 – 10am	Wrap up	Mitchell Warren (Coalition Secretariat)

MEETING OBJECTIVES

1. Recapitulate coalition goals and regather as a group for the first time since launch.
2. Launch the quarterly reporting framework.
3. Understand each coalition stakeholder groups priorities in LA PrEP and use this to update the list of priorities per product and more broadly.
4. Use this meeting as a first iteration to understand how future coalition meetings can be better used for cross-stakeholder collaboration within the Coalition.

UPDATES FROM STAKEHOLDER GROUPS

Convenors

- Provided an overview of Coalition structure and its priorities identified for 2024.
- To gather input from the group regarding these priorities, the group participated in a MentiMeter survey with the following question, “*Are there any missing priorities for the Coalition?*” Answers included:
 - Product-specific
 - CAB - Availability of generics CAB globally and rationalization of testing routes to access CAB.
 - DVR - Regulatory pathway for 3-month ring.
 - LEN – Transparency regarding planning for results, access, and generic manufacturing .
 - Pricing

- Need to prioritize LMIC's ability to pay as a key issue when talking with all product developers, including MICs. Coalition needs to indicate a roadmap to lower pricing.
- Access
 - Focus on programmatic plans for long-acting injectables, post study access, addressing regulatory bottlenecks and multi-country pilot plans.

Civil Society (CS) Caucus

- Provided an overview of the caucus, the selection of three representatives to facilitate the group, and the first CS Symposium in February 2024, during which developers and PEPFAR provided updates and responded to CS questions.
- The priorities for the CS Caucus were cited as:
 1. Advocacy efforts for specific products and funders
 2. Demands for price commitment, transparency, and cost reduction
 3. Engagement with generic manufacturers for lower prices
 4. Membership open to interested CSOs, particularly from Latin America

Donor Caucus

- Provided an overview of the caucus, its membership, and focus on technical discussions rather than decision-making.
- Key points regarding the caucus were clarified as:
 - Aiming to align priorities and understand each other's investments.
 - No decision-making power regarding funding, and focus on sharing technical and programmatic updates, fostering alignment.

Ministries of Health (represented in this call by Zambia)

- Professor Lloyd Mulenga provided the following highlights from the initial rollout of CAB:
 - Observed high uptake in certain regions, low uptake in main hospitals and smaller clinics. The strategy used includes government and private facilities in urban and rural areas.
 - Successes include robust filing systems to track information, demand creation, multidisciplinary team involvement.
 - Challenges include use of rapid tests before initiation of CAB, turnaround time for NAT testing, supply issues.
- Discussion
 - Eligibility for CAB is determined based on risk criteria, but confirming HIV negativity before initiating CAB is vital. This makes both rapid antibody testing and NAT testing necessary to ensure accuracy and safety, especially considering the delay in NAT testing results.
 - Thus far, no clients have expressed a desire to switch away from CAB to oral PrEP.

- Side effects were observed during the rollout, including injection site reactions and one case of elevated liver enzymes.
- Ongoing data analysis is needed to determine the necessity of rapid and NAT testing. The aim is to ensure accurate testing protocols while considering the challenges they may pose to implementation.

Implementation Science Groups (represented in this call my SEARCH and MOSAIC)

- Dr. Moses Kamya at Makerere University presented on the SEARCH trial:
 - Over half of participants used CAB during the study, with 42% of CAB users having not used any prevention product prior. PEP was used by 2% of participants, and 28% used at least two different products during the follow-up period.
 - Outcomes: Average coverage in the intervention group was 69.7%, compared to 13.3% in the control group, with a significant difference of 56.4%. Seven adults seroconverted in the standard of care arm, while zero seroconverted in the intervention arm, resulting in an overall incidence rate of 0% in the intervention group compared to 1.8% in the control group.
 - Conclusion: People desired product options, chose different options, and changed over time. The person-centered choice model was highly effective, recommending wider access to CAB to increase biomedical coverage. “Choice was king.”
 - Discussion
 - It was confirmed that those who chose CAB in the intervention arm of the study are still on CAB. However, those in standard of care have not yet received CAB and the study team is hoping to get more supply this year, which will allow them to provide CAB to those individuals.
 - Study participants could switch between products at any point during follow up depending on their preference and circumstances. There was no defined timeline for switching.
- Dr. Kristine Torjesen at FHI 360 and MOSAIC updated on the overall status of implement science studies in the field.
 - Eleven studies are currently fielded, primarily in Africa and some in the US and Brazil. Studies offer a choice between oral PrEP, DVR, and CAB, or just oral PrEP and CAB.
 - Early Learnings:
 - There is demand for both oral PrEP, DVR, and injectable CAB. Client choices vary and change over time, emphasizing the importance of choice and ongoing support.
 - Provider training and job aids are essential for successful implementation.
 - Uncertainty remains around HIV testing algorithms for CAB rollout, requiring more data for informed decision-making.

- Concerns raised about participants' access to products after studies end, emphasizing the need for post-access support. There's currently limited programmatic access to CAB in Africa, with no access in Asia and Latin America.
- Discussion
 - Emphasized the need for commitment from donor partners to ensure continued product availability after studies conclude.
 - Emphasized the need for more data to inform decisions in this area. Stresses the importance of ongoing investigation and data generation to address testing algorithm concerns.
 - There has been strong advocacy from community stakeholders in Kenya asking the government to accelerate approval of and access to CAB PrEP. There's hope that regulatory approval will be granted soon by the Kenya Poisons and Pharmacy Board once they complete their review of the dossier submitted by ViiV.

IP Management/Voluntary Licensing

- MPP shared a detailed timeline for CAB's development and estimates for generic entry into the market, emphasizing the importance of each step and potential variations in timelines.
- Discussed efforts to expedite regulatory approval for generics in India and the importance of stakeholder engagement in building anticipation for the arrival of generics.
- Discussion:
 - Estimates CAB generic entry in the second half of 2026 or early 2027 earliest.
 - Pricing may vary but assures accessibility through negotiation and procurement mechanisms, including funding mechanisms like the Global Fund or PEPFAR.
 - Increasing demand will require effort from everyone (from donors to users and communities). If generics see business, they will prioritize further, and increase their manufacturing plans, this can accelerate access and lower prices too.
 - Indian regulations necessitate local trials for drugs approved abroad. Efforts are being made to utilize a provision allowing waivers for drugs addressing life-threatening diseases, especially since the three licensed manufacturers are based in India.

Conclusion

- This was the inaugural quarterly Coalition meeting, and subsequent updates will happen in the middle of the month following the close of each quarter,
- The secretariat will look to possibly convene gatherings at AIDS 2024 in Munich in July and R4P 2024 in Lima in October for those in attendance to meet in person.
- The first draft quarterly report and summary are online [here](#) and will be updated each quarter.

APPENDIX**Participant List (TOTAL: 65)**

Conveners				
Anne-Isabelle Cameron	Ashneil Jain	Carlos Passarelli	Chris Obermeyer	Heather Ingold
Heather-Marie Schmidt	Mateo Prochazka Nunez	Paula Munderi	Robyn Eakle	Trista Bingham
Civil Society/ Advocates				
Cedric Pulliam	Cindra Feuer	Henry Sakala	Kenneth Mwehonge	Leora Pillay
Morgane Ahmar	Nicky Suwandi	Ulanda Mtamba	Yvette Raphael	
Donors				
Ashley Vij	Elo Otobo	Emily Dorward	Gillian Leitch	Hema Srinivasan
Liesl Page-Shipp	Richard Borain	Sarah Hamm Rush	Shirley Chen	Taryn Barker
Yogan Pillay				
Ministries of Health				
Davies Kampamba	Ireen Bwalya	Lloyd Mulenga	Tatianna Alencar	
Implementers				
Beatriz Grinsztejn	Catherine Martin	Chimika Phiri	Danielle Resar	Elizabeth Irungu
Francois Venter	Jason Reed	Jessica Burry	Katie Schwartz	Kevin K'Orimba
Kristine Torjesen	Linda-Gail Bekker	Marcos Benedetti	Moses Kamyra	Nittaya Phanuphak
Patriciah Jeckonia	Rose Wilcher	Saiqa Mullick	Sara Allinder	Tina Chisenga
Viviana Rivas	Vusile Butler			
IP Management				
Esteban Burrone	Lobna Gaayeb	Sandra Nobre	Sébastien Morin	
Secretariat				
Kalob Gossett	Mitchell Warren	Navita Jain	Saira George Carballo	Wawira Nyagah