PEOPLE'S RESEARCH AGENDA

Community & Advocacy Priorities in HIV Prevention Research and Development

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Meeting the Moment for HIV Prevention Justice

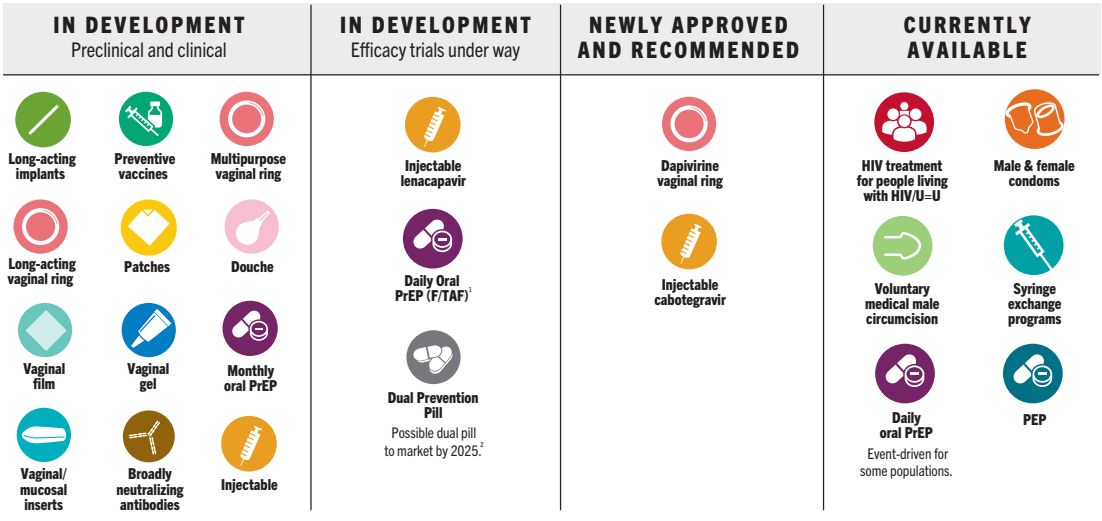
Why Develop a People's Research Agenda?

Over the past decade, biomedical HIV prevention has undergone a transformation. There are a range of new ARV-based prevention products approved and in delivery, with more in the pipeline, and a range of HIV vaccine and antibody studies have further identified the challenges and the opportunities in HIV prevention.

Even as new ARV-based PrEP options have entered the market, the majority of candidates are in upstream safety, dosing and immunogenicity trials, as shown in Figure 1.

There are insights into vaccine development from HIV, COVID-19 and other fields, and an ever-expanding understanding of the promise and pathway for broadly neutralizing antibodies (bnAbs). The products that have shown efficacy have different delivery mechanisms, levels of effectiveness, and durations of protection. There are more options than ever—with more to come. However, as options have proliferated,

FIGURE 1 **The HIV Prevention Pipeline**



[1] In Oct 2019, US FDA approved F/TAF for adults and adolescents who have no HIV risk from receptive vaginal sex; still in development for cisgender women.

[2] Efficacy trials for the Dual Prevention Pill (DPP) not required; bioequivalency of the two approved products (oral PrEP and oral contraceptive) when dosed together may be all that is required.

And in implementation science projects:
www.prepwatch.org/resources/implementation-study-tracker/

resources for research, implementation science and delivery have flattened or dwindled. With less or limited resources, the stakes for decisions about which products to develop and eventually deliver become even higher for funders, communities, policy makers and governments.

The People's Research Agenda (PRA) meets this high-stakes moment for HIV prevention with a clear, concise and collaboratively developed set of priorities for how prevention research should be conducted and what products should be developed. It is a living document to be used as a tool for communities to amplify their priorities and for funders, product developers and policy leaders to have close at hand—along with the communities who informed it—as crucial decisions are made about what to invest in, where and why.

The PRA is a contribution to the powerful civil society movement that has issued a clarion call for choice that meets the preferences and priorities of people impacted by and at risk of HIV. Developed through a multi-pronged consultative process, summarized in Figure 2, the PRA is designed to provide a concise yet comprehensive set of principles, priorities and product category considerations, so that no discussion about the future of HIV prevention research is held without consideration of the people's views and voice. In this way, the PRA seeks to meet the moment for HIV prevention justice and address the scientific and structural barriers that prevent people from accessing HIV prevention.

The People's Research Agenda exists in community with and was guided by the authors and constituents who developed other agendas including the *Choice Manifesto*, the *Global HIV Prevention Roadmap for Key Populations*, and *No Data No More*, the trans research agenda. The specificity and detail in these complementary documents is invaluable and essential. One measure of the value and impact of the PRA will be the extent to which the goals in these and other crucial documents are realized through application of the principles and processes described in the pages that follow.

A full-length PRA report will be released in December 2024, with additional infographics and information on how the first iteration of the PRA was developed, how to provide additional feedback on the priorities, and how together, we will know, if we're making progress.

KEY MESSAGES

- Any product that is approaching an efficacy trial cannot move forward without a clear access plan in place, and the trial must be conducted in parallel with considerations on access, pricing and manufacturing.
- New products should balance filling a gap in the prevention toolbox with additions to existing products that make them more accessible and streamline uptake (e.g. both longer and shorter intervals of dosing; multi-purpose products; novel formulations, mechanisms of action and/or delivery systems).
- Product development should move forward with greater focus and investment in social and behavioral science while being mindful of structural barriers such as stigma and discrimination, restrictive legal/social environments that impact access of services for priority populations and gender inequities.
- The field needs realistic Target Product Profiles (TPPs) for all product categories with urgency. This is especially true for vaccines and bnAbs; advocates recognize vaccines and bnAbs as having an important role to play for a sustainable end to the epidemic.
- There is excitement among advocates about the promise of Multi-Purpose Technologies (MPTs), but the regulatory pathway brings significant complexity. Regulators, researchers, advocates and other key stakeholders must collaborate to address potential barriers to MPT introduction.
- Significant time and energy across stakeholders should rightfully continue to be placed into making newly efficacious products accessible.

How was the PRA Developed?

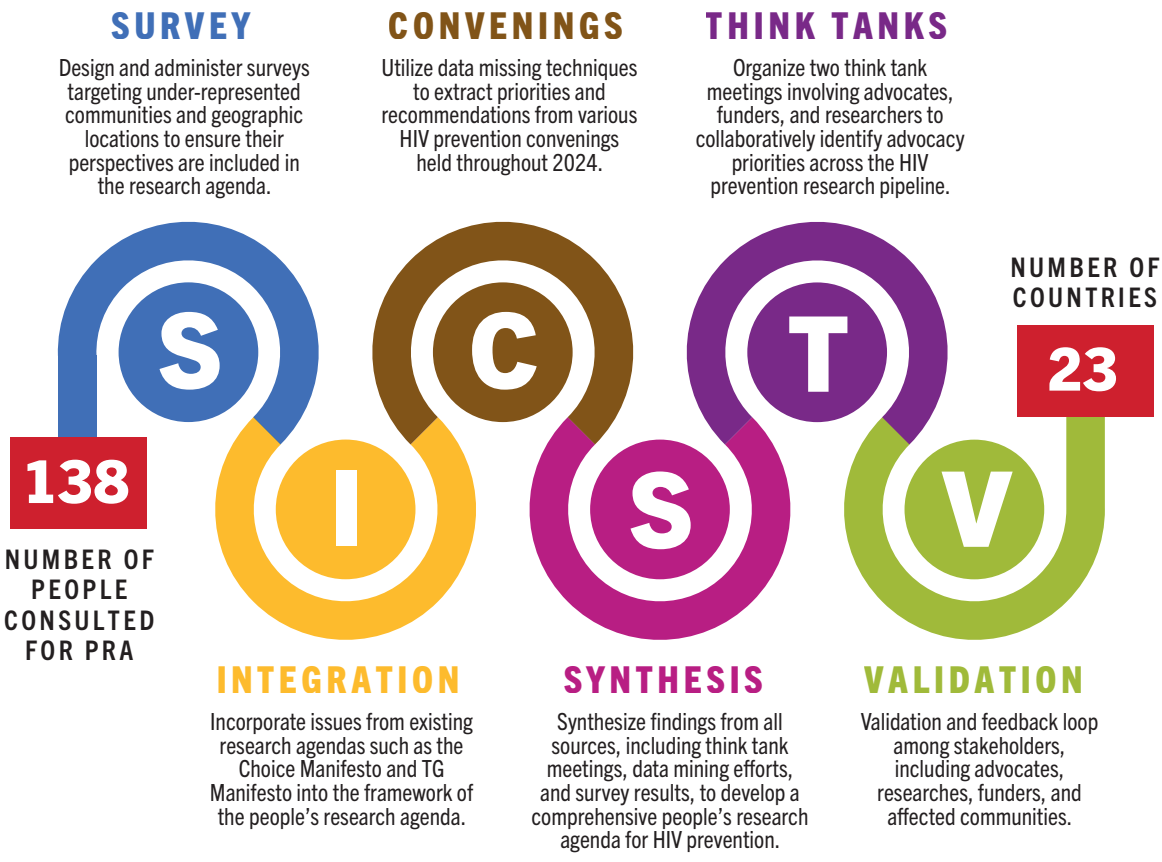
The People's Research Agenda is a living document developed through intentional consultative processes that used multiple modalities, including surveys, focus groups, convenings (see Figure 2), to gather insights about the processes and products needed to actualize HIV prevention justice. The process was centered on and led by people living with and at risk of HIV and evolved based on feedback received along the way.

In this summary of the People's Research Agenda, you'll find the PRA's core insights into the processes involved in HIV prevention research and implementation, and the types of products that should be developed through these processes. In other words: what needs to be prioritized for research, development and delivery, and how these and other phases of action should unfold as we move towards the 2030 global targets.

What is the real value to people's health and to public health of introducing new products that we cannot deliver to communities who need them?

— PRA Survey Participant

FIGURE 2 **Methodology: Development of People's Research Agenda**

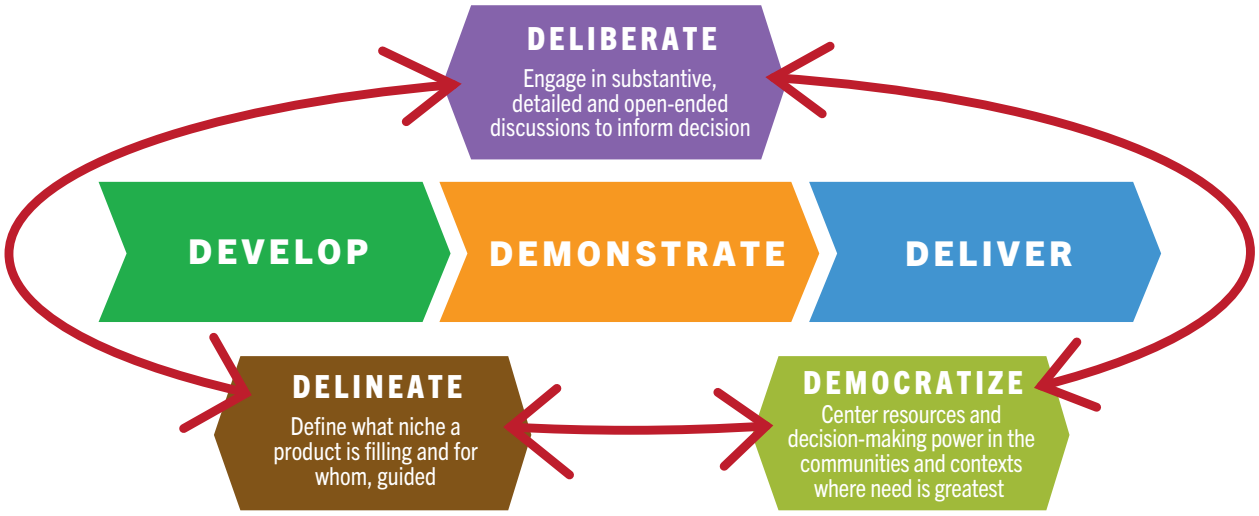


CORE COMPONENTS PART I

Strengthening Engagement Processes

The consultations that shaped the People's Research Agenda centered on what products are needed and how they should be selected, identified and introduced. Across diverse groups and identities, common themes emerged about the research processes needed for all products and in all communities.

FIGURE 3 **New dimensions to the "3D" pathway**



Connect with communities to **deliberate** on the products needed most.

Delineate the product preferences, structural barriers and sources of resilience in communities most at risk of HIV, to ensure choice and equity.

Democratize decision-making at every stage to build the trust and partnerships needed for a sustainable and effective HIV prevention landscape.

Elements of core actions have long been part of HIV prevention and treatment research since its inception, however they are not consistently included in product development pipeline schema. Unlike pipelines or pathways, which suggest linearity, the PRA dimensions are ongoing and cyclical. Many elements of the engagement process described in PRA consultations exist in different forms, and are key to the "Develop, Demonstrate, Deliver" advocacy pathway that AVAC and its partners have used for years to conceptualize the biomedical prevention research agenda. These new "Ds" are additive to this "3-D" agenda—and apply to other conceptualizations or frameworks for the research-to-rollout process.

Deliberate

Across the modalities used to solicit input for PRA, respondents talked about the need to involve impacted communities in the discussions that lead to decisions about which products to develop, which experimental trials to embark on, which products to perhaps not develop because there are existing comparable products on the market. This phase draws on all senses of the word—*thoughtful, well-advised, weighing facts and arguments with a view to a choice or decision.* This phase is grounded in and reflective of the Good Participatory Practice (GPP) guidelines which call for:

- **Involvement with communities during protocol development, trial design, and trial implementation;**
- **Meaningful engagement in planning for results dissemination, product introduction and access;**
- **Leadership from and deep listening to the people impacted by and in need of the product being studied.**

Priority actions identified in PRA dialogues for the "Deliberate" phase of action:

- Target Product Profiles (TPPs) informed by community input;
- Community involvement and engagement in decision-making in every stage of research, from preclinical research through to product introduction;
- Specific communication channels and materials designed to support deliberation including on community priorities that can guide investments into delivery mechanisms, product modalities, and populations to be involved in the trials.

> **The idea of spending so much time in R&D and then taking another 20 years figuring out how to move products to people is so much time wasted, and so many infections that could have been prevented if we moved quicker. We need to start thinking of not just designing the product, but also including questions around infrastructure, preference and cost at the earliest. The time from design to impact is unnecessariry long and it does not have to be.**
>
> — PRA Think Tank Participant

Delineate

Across the PRA consultative process, participants spoke about the need for clarity about which candidates are developed and why. They identified the need for clarity about why additional products might be developed for categories where several approved options exist, and for clarity about why products should be developed that may meet the needs of a specific population or groups. PRA respondents also spoke frequently of the need to support a choice-based approach, with different modes of delivery and duration of action. Such an approach would include different levels of efficacy and effectiveness and would be grounded in the reality that there is no single "perfect" product. The best solution is the best fit for a person on the day they are selecting an HIV prevention option. This kind of clarity comes from a careful, collaborative identification of what products are needed, and for whom. This is the work of delineation, which means *to mark, form or show the outline or border of.* Conversations that focus on delineation may look at the products that exist, the ones that are needed, the groups that are under-served by existing

choices, and more. The constituents who contributed to the PRA also called for a delineation of HIV prevention research as a global good, not an enterprise that is for a specific group of people. There are numerous examples of the ways that HIV prevention research has served broader, global objectives both in terms of scientific advancements, community engagement, understanding of user-centered design and community-led delivery and more.

Success by 2030 would be marked by a dramatic decrease in new HIV infections, the availability of effective and diverse prevention options, and the dismantling of barriers that have historically hindered the global response to HIV.

— PRA Survey Participant

Priority actions identified in PRA consultations for the "Delineate" phase of action:

- Approaches to trial design and product development guided by a deep, community-informed understanding of the structural and social determinants of health, which also determine whether and how biomedical tools are used. Products must fit communities' lived realities; access cannot come at the expense of human rights or cause risk to people whose identities or behaviors may be criminalized or stigmatized. These groups may also be excluded from or under-represented in research processes. To address this, spaces for dialogue and funding streams for sociobehavioral science within trials must be created so that structural barriers to trial participation are identified, removed, and pathways for equitable access are created.

- Investment in the investigations of the HIV prevention market and product landscape that proactively identify cost and access issues and opportunities and ensure that products in the pipeline meet needs identified in target product profiles. This analysis is particularly necessary for supporting sociobehavioral research, informed decisions about advancing a choice-based agenda in the context of resource constraints.

- Global consensus on and public recognition of the contributions (past, present and future) of HIV prevention research to broader health security and public health goals.

Democratize

Many of the PRA consultations were framed in a grounding principle that progress depends on attention to and redistribution of power. This includes the power to:

- **Decide which concepts are explored in preclinical trials, which advance to clinical and which effective products are delivered to the people that need them.**
- **Select populations to be involved in studies, demonstration projects and delivery.**
- **Manufacture specific products (infrastructure, expertise and intellectual property).**

To shift decision-making dynamics, impacted communities need to have a voice and vote (or a veto if needed) that counts. The "Democratize" phase reinforces this clarion call from PRA constituents: decisions must be made transparently, collaboratively and in contexts where all impacted stakeholders have a chance to influence the outcome. Democratizing does not mean reducing decisions to majority votes. Instead, it calls for a people-centered

process in which voices, values and visions are shared, weighed and used to shape equitable distribution of human, technical and financial resources. This decision-making process is supportive of and reinforced by the ongoing work of decolonization, the crucial ongoing work of uprooting of historical patterns and precedents, and their replacement with terms and conditions defined and led by the groups, countries and regions where extractive practices were located/ are ongoing.

Potential actions flowing from the Democratize phase:

- Creating and testing new approaches to selection and advancement of candidates that bring funders, product developers, country stakeholders and engaged communities together to take key decisions.
- Ensuring that people with lived experience with HIV have leadership roles in setting and monitoring implementation of prevention research agendas.
- Building high-burden countries' interests in regional manufacturing capacity, cost access considerations into decision making at the earliest stages of product development.
- Ensuring that data ownership and sharing agreements are transparently negotiated and agreed upon by all stakeholders, and that data from communities, i.e. from community-led monitoring, is valued and used by all stakeholders.

PEOPLE'S RESEARCH AGENDA PERSPECTIVES ON HIV PREVENTION CLINICAL TRIAL DESIGN

Clinical trials sit at the crossroads of the "what" and "how" of HIV prevention research. The PRA priorities for engagement described in this section should be applied to the clinical trials process as means of identifying and addressing the design issues that will arise in an increasingly complex prevention landscape. In addition to these cross-cutting actions, priorities emerged from an advocacy cohort from the African-based Clinical Trial Design Academy (CTDA). The CTDA identified specific challenges including how to evaluate additional products in the context of emerging, highly efficacious prevention products. Each of these choices, as well as decisions about trial populations and locations, will impact the design, duration, cost and size of future studies.

Key considerations:

- Invest in continuous learning so that advocates and communities where research is planned are equipped to weigh in on complex and evolving trial designs and approaches.
- Novel trial designs using external controls are important in developing new prevention products. However, they must meet the rigorous standards of randomized controlled trials (RCTs) to ensure they provide reliable answers to key research questions without compromising quality.
- Trial designs must address the needs and concerns of highly impacted communities.
- Products moved into trials should be ones that fill community-informed gaps, such as improving upon existing prevention methods with innovations in cost, mode of delivery, duration or level of protection and other parameters.
- Participants should be supported to clearly understand how novel design elements, such as run-in or opt-out phases, may impact their involvement.
- Ensure that regulators are prepared to review and react to the data generated by future trials, especially if it is a novel design.

CORE COMPONENTS PART II

Products and Priorities

The PRA process was designed to gather participants' priorities for specific product categories. The process of seeking this input revealed challenges and opportunities that can be used to shape the implementation and iteration of the PRA, which is intended as a living, regularly revisited document.

One challenge centered on gathering detailed, specific inputs on some specific product categories. This is also an opportunity for skill-building and—sharing. Some HIV prevention advocates may be excited about delving into the science of immuno-modulating prevention, like vaccines and bnAbs, to think through the types of immune responses or product components that are most desirable. Others may be more interested in ensuring that the product—however it works—is affordable, accessible and clearly differentiated from other existing products. There is room and need for all levels of interest and expertise in shaping the pipeline—and the PRA calls for the processes that ensure this happens.

In addition to this key learning, PRA consultations offered up a range of ideas and insights into characteristics and considerations to shape the prevention pipeline. These are summarized below, along with a brief on the research, development and delivery contexts in which the conversations took place. The full PRA report, to be released in December 2024, will amplify and expand on these top-line findings.

HIV Vaccines

Context

At the time that PRA consultations took place, there were no ongoing HIV vaccine efficacy trials. In 2023, the Mosaico trial of an investigational HIV vaccine regimen tested among men who have sex with men (MSM) and transgender people was halted early after an independent data and safety monitoring board (DSMB) determined that the regimen was safe but did not provide protection against HIV acquisition. Also in 2023, PrEPVacc, a trial of two different vaccine candidates in the context of oral PrEP, halted immunizations at the recommendation of the trial's DSMB, for the same reason. The majority of candidates in development at present are in early clinical and pre-clinical phases. PRA contributors frequently referred to the rapid development and sluggish roll-out

AT A GLANCE

- **Support a choice-based prevention agenda with clear and realistic target product profiles** that reflect the current and future landscape of HIV prevention; including the availability of long-acting PrEP—and address access, cost and regional manufacturing priorities that emerged clearly during COVID-19. Balance filling a gap in the prevention toolbox with modifications on existing products that make them more accessible and streamline uptake.
- **Begin with the end in mind** by identifying and anticipating trial design issues (feasibility, cost, size, regulatory pathways) and implementation science questions so that the timeline from evidence to impact and to widespread access is as short as possible. Initiate access planning during efficacy trials to ensure expeditious rollout.
- **Center and invest in social and behavioral science** that explores end users' needs and preferences, informs target product profiles, and identifies and addresses social and structural barriers in HIV prevention.
- **Maintain advocacy across product categories to fill important gaps in a comprehensive HIV prevention toolbox.** There is promise in MPT R&D, but it first requires clarity around complex regulatory pathways. PRA conversations reflect intensive advocacy to make newly efficacious products accessible; however, vaccines, bnAbs, implants, and other products in early-phase development will play an important role for a sustainable end to the epidemic.

of COVID-19 vaccines, and the lessons learned about the speed with which new products can be brought to market, gross global inequities in access to these lifesaving tools, and the challenges with vaccine mis- and disinformation, and with changing messages about duration and level of protection, and need for boosters, that hampered uptake when vaccines were available.

Priorities

- Re-calibrate and secure field-wide alignment on clear, realistic target product profiles (TPPs) that reflect the evolving landscape of HIV prevention, including the availability of long-acting PrEP, and that appropriately address the dose, time to protection, duration and efficacy that would be needed to license an HIV vaccine that can deliver impact in the future.
- Incorporate key lessons from rapid development of COVID-19 vaccines particularly in relation to equity, community engagement and effective communication to address vaccine hesitancy.
- Build rapid, sustainable, distributive vaccine manufacturing capacity for clinical-grade vaccine candidates for trials and, in the long-term, for licensed vaccines.
- Clearly articulate the field-wide strategy around upstream HIV vaccine research, i.e., Experimental Medicine Vaccine Trials (EMVTs) or Discovery Medicine Trials, which test a scientific hypothesis in vaccine design, rather than an experimental vaccine for product development. Ensure communities and stakeholders understand the field-wide map of these trials and incremental milestones to ensure progress toward an ultimate vaccine.

Antibody Mediated Prevention (AMP)

Context

Antibody mediated prevention (AMP) is also sometimes called passive immunization. In AMP strategies, a person receives antibodies that are designed to be potent against multiple types of HIV. There are no broadly neutralizing antibodies in efficacy trials at present; one bnAb, VRC 01, has shown a limited efficacy signal, with the candidate showing high levels of neutralization against a small subset of viruses that were highly susceptible to neutralization by this bNAb. Research efforts are focused on improving the potency, breadth and duration of protection afforded by AMP strategies. Most priorities and recommendations were applicable to both vaccines and bnAb fields, with limited distinction and little bnAb-specific recommendations. However, this should not be interpreted as a reason to deprioritize the category. Instead, it highlights the need for more information and engagement with advocates, emphasizing the importance of further investment in community engagement for this product category.

Priorities

- Develop clear, realistic TPPs that reflect the evolving landscape of HIV prevention, including the availability of long-acting PrEP, and that appropriately address the dose, delivery mechanism, duration and efficacy that would be needed to license an antibody cocktail that can deliver impact in the future.
- Maintain antibody research to inform vaccine design and possible HIV treatments irrespective of the ability to develop an actual antibody product that could move into efficacy trials and beyond.
- Strengthen a civil society stance on advancing bnAb candidates to clinical trials and, potentially, to market for both prevention and treatment, building on existing knowledge and research. One consideration discussed was the use-case of bnAbs for the prevention of HIV acquisition in infants. Given the complexity of administration via

infusion and the existence of highly effective long-acting and on-demand PrEP strategies amongst adults, efficacy trials of bnAbs for prevention may not be feasible, whereas impact on virologic control in people living with HIV could be more readily evaluated. These perspectives should also be considered around access issues such as estimating demand/market for a bnAb product, feasibility of manufacturing a combination antibody as an injectable product, and user and community acceptability.

- Hold researchers accountable to having a clear rationale for any development program of a bnAb product, which would include a robust GPP/stakeholder engagement plan, community consensus and support for the intended dose and delivery mechanism of the product to be tested (and ultimately manufactured and rolled out), post-trial commitments after any efficacy read-out, and other key issues.

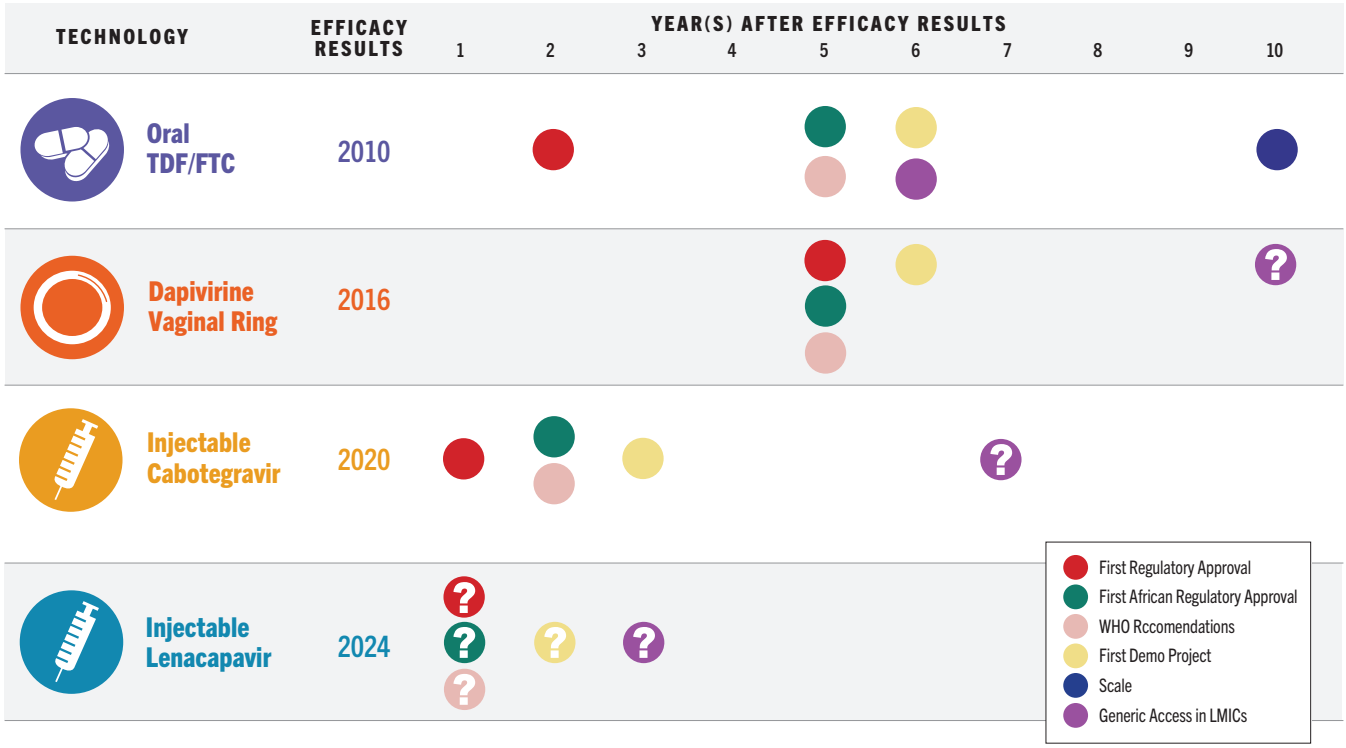
ARV-Based Prevention

Oral PrEP

Context

Daily-oral tenofovir based PrEP is the first ARV-based prevention method to be approved and is the most widely used worldwide, with daily dosing recommended for cisgender women and other people who have vaginal sex, and intermittent or on-demand dosing available as an additional option for cisgender men and other people who have anal sex or insertive penile or vaginal sex. There are a range of lessons learned about barriers and facilitators to oral PrEP initiation and continuation for individuals, and about program design innovations such as telemedicine, use of HIV-self testing and community-based peer support, that can help people start and stay on oral PrEP for as long as they would like to. A once monthly pill, MK-8527, is an investigational antiretroviral drug that is currently being studied as a potential PrEP product in a phase II clinical trial, with plans to move into an efficacy program in 2025.

FIGURE 4 **Moving a Product to the "Real World": We must shorten the timelines between regulatory approvals and scale-up to advance HIV prevention**



Priorities

- Product developers and researchers should prioritize products with varied dosing schedules including weekly, monthly and on-demand.
- Funders should prioritize investment in additional and robust research for on-demand oral PrEP among cis-gender women.
- Program implementers and funders should continue to explore options to increase uptake of approved products through different packaging, pill sizes and colors.
- Issues of continuation should continue to be investigated, and user-controlled methods should not be abandoned. Continuous data collection is needed to inform research of daily and on-demand options.
- Integrate social and behavioral science to understand the role of stigma and discrimination in preventing access to HIV prevention services and develop strategies to overcome these challenges. Focus on the barriers and facilitators to the uptake of HIV prevention methods, with a particular emphasis on involving communities in the research process to ensure strategies are culturally relevant, and acceptable to promote uptake.

Dapivirine Vaginal Ring

Context

During the period in which the PRA consultations took place, advocates saw some progress in the campaign to expand access to the dapivirine vaginal ring, including the announcement, in July 2024, that the Global Fund to Fight AIDS, Tuberculosis and Malaria would procure 150,000 rings for distribution in countries implementing Global Fund grants. This effort reflected the tireless advocacy of cisgender women of diverse identities to secure access to this discrete, user-controlled product that fills an otherwise empty niche in HIV prevention. Resistance to widespread DVR introduction reflected the relatively low effectiveness of the product, compared to long-acting injectables or daily oral PrEP taken as prescribed. However, advocates for choice emphasized that user preference should dictate what is available, not solely the effectiveness profile or continuation burden of the product—or the preferences of funders and implementers.

Priorities

- Continue to learn more about the barriers and facilitators to correct and consistent use of the DVR, investing in user-centered design to inform messages, packaging and peer support to optimize impact.
- Use DVR introduction as an opportunity to learn about and lay the groundwork for future ring-based multipurpose prevention technologies (see next section).
- Tackle structural and social determinants affecting uptake of dapivirine ring among young women.

Long-acting Injectable Pre-exposure Prophylaxis (PrEP)

Context

PRA consultations took place over a period of time when oral PrEP uptake had significantly improved, reaching over 7 million new users by mid-2024 – a major milestone since its approval twelve years ago. Additionally, the dapivirine vaginal ring (DVR) and injectable cabotegravir (CAB) were being introduced in an increasing number of countries.As the PRA consultations concluded, two trials of six-monthly injectable lenacapivir (LEN), also showed extremely high levels of protection. The recent experience with CAB introduction includes challenges with expanding access to and

uptake of CAB in highly impacted communities in both high- and low-income countries. News of LEN efficacy came with excitement alongside concerns and questions about the licensing, cost and pricing, and broad geographic access to this new product.

Priorities

- Support choice through implementation science on when and why people switch between methods to better understand preferences, patterns of use, discontinuation and re-initiation. Attention should be paid to understanding when people discontinue because a product with the desired profile is not available.
- Evaluate the role of modifications and/or adaptations to existing products, including as part of MPTs, self-administration of ARV-based methods that currently require a health provider to administer, or alternate dosing schedules attainable by changing formulation (e.g. 4-monthly CAB for PrEP, 3-monthly ring).
- Ensure equitable access to current and future products, proactively addressing price, cost, licensing and other product-related drivers of resource needs, as well as the health system related needs including, but not limited to, provider training, implementation science, demand creation and community engagement.
- Develop target product profiles for additional ARV-based prevention methods that fill gaps and prioritize alternate delivery system, formulations, etc., for example monthly oral, sub-cutaneous delivery for self-administration, microneedles or patch-based delivery, vaginal and rectal inserts, longer-acting injections and on-demand dosing schedules that are not presently available, guided by community-articulated needs and preferences.
- Invest in ambitious, integrated approaches to product introduction, particularly for LEN, that investigate multiple implementation science questions in a finite number of large studies, shortening the time from pilot to public health impact.
- Develop country-level frameworks for piloting and scaling new methods, including earlier discussions with countries during the research phase.

> **[What remains important is...] developing longer-acting systemic options like implants or injectables, shorter-acting non-systemic methods such as on-demand PrEP, and novel delivery modes like vaginal rings or microneedle patches. These innovations must address varying preferences, improve adherence, and ensure accessibility across diverse populations.**
>
> — PRA Think Tank Participant

Multi-Purpose Prevention Technologies (MPTs)

Context

The PRA consultations took place in the context of enormous enthusiasm for multi-purpose prevention technologies (MPTs). Much of this enthusiasm builds on renewed energy and calls from advocates to address high rates of STIs and integrate SRH services. Today, there are limited MPTs on the market, including the male and female condom and possibly soon, the dual prevention pill (DPP) which combines oral PrEP for HIV with oral contraceptives. Most MPT candidates are in early phase trials. While these candidates are years from widespread availability, the current

excitement and demand reflects the existence of multiple products and delivery mechanisms that could be used to provide various forms of MPTs. This includes synchronized injectable schedules for long-acting PrEP and contraception, a vaginal ring that delivers protection against HIV, other STIs and pregnancy, and other formulations, such as films, gels and implants.

Priorities

- Clarify complex regulatory pathways for co-formulation of pre-approved products and for novel products. Engage with regulators early and often to breakdown silos across disease areas, and to identify knowledge gaps between researchers and regulators around future requirements for MPT efficacy trials.
- Invest in products that can move quickly to market—i.e. those that combine existing products that have already received regulatory approvals. This is particularly important as the regulatory processes for different indications (HIV prevention, contraception, STI prevention) can be quite different.
- Accelerate work on products that meet community priorities including self-administration, enhancement of sexual pleasure, on-demand and intermittent dosing schedules.
- Delineate the populations that need, and do not have, MPTs and ensure that the pipeline reflects their needs, for example cisgender men who have sex with women, transgender people, woman and other people who can become pregnant at various stages of their reproductive lives, including peri- and post-menopause.
- Balance diversity (e.g. new delivery systems, long and short-acting, systemic and non-systemic, pre- and post-coital) to improve use, appeal and accessibility with the scientific constraints associated with delivery mechanisms. For example, there are several rings in development, but this is on account of the capacity for rings to carry multiple indication products.

CRITICAL CONSIDERATIONS ACROSS THE ENTIRE PREVENTION PIPELINE

- Close the gaps and lost time across the R&D lifecycle to ensure no time is lost between each step—from pre-clinical to first-in-human; between each clinical phase; from efficacy to introduction to impact.
- Support community-led and -informed prioritization within and across product categories and in the development, monitoring and updating of TPPs.
- Ensure regulatory agencies in resource-limited settings are able to review, support and accelerate first-in-human trials; bio-equivalence, PK and bridging studies; novel efficacy trial designs; and implementation science.
- Expand and accelerate links and collaborations between product developers, implementation scientists and advocates.
- Build sustainable, distributive manufacturing capacity.
- Facilitate real-time learning across product categories, as well as from other disease areas—e.g. COVID-19, TB, emerging pathogens, SRHR, etc.

CALL TO ACTION

The People's Research Agenda reflects the priorities and vision of more than 130 advocates from more than 20 countries. Across diverse identities and life experiences, this collective is united by the conviction that HIV prevention research is essential, and that continued progress depends on strong, clear community leadership. The PRA seeks to support this leadership by summarizing the vision for how products should be developed and what these products should look like. The nature of the process the PRA recommends makes this a living document. As we deliberate, delineate and democratize research decision-making processes together with policymakers, scientists, healthcare providers, funders and impacted communities, we will identify new priorities, new challenges and new opportunities, to inform new and updated agendas.

We invite you to join us in this crucial work by endorsing and engaging with the agenda. Take time to consider how the processes described can be incorporated into your work, how the priorities for products can shape discussions. Gather in multi-stakeholder groups—scientists, activists, implementers, users of products, and listen in order to learn, set shared priorities and move forward together.

We particularly call on funders and implementers to publicly endorse and use this document as a framework for crucial decisions unfolding in the coming years about where to invest and what to set aside.

Working together, with courage and curiosity, to implement this Agenda, we know we will achieve breakthroughs that reduce suffering and save lives.

Annex 1: List of Resources

The HIV Prevention Pipeline infographic

The Lens on LEN: The basics on injectable lenacapavir as PrEP primer

PxPulse podcast: An HIV Vaccine: Looking into the Future with Nina Russell

HIV prevention for the next decade: Appropriate, person-centred, prioritised, effective, combination prevention

HIV Prevention Resource Tracking Dashboard

HIV Prevention Clinical Trials Map

PEPFAR U.S. President's Emergency Plan for AIDS Relief
USAID FROM THE AMERICAN PEOPLE
CASPR COALITION TO ACCELERATE & SUPPORT PREVENTION RESEARCH
AVAC Advocacy. Access. Equity.

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