

ADVOCATE, TRANSLATE, CATALYZE

FOR HIV PREVENTION AND HEALTH EQUITY

DECEMBER 2021

World AIDS Day 2021—40 years into this pandemic and two years into the COVID-19 pandemic. And now AVAC has been engaging for 26 years!

This year, AVAC is reflecting not only on the many lessons of the year just past, but also on how to prepare for the increasingly complex challenges before us on the road to global health equity.

While 2020 demonstrated the enormous value of scientific collaboration, and how efficiently R&D can move with appropriate funding and political will, 2021 proved that even the world's best science is no match for the debilitating effects of poor health systems, bad communication, vaccine nationalism and persistent health inequity. Once again, real world experience showed that developing prevention options is only part of the answer. Delivering those tools equitably, with clear information and without stigma, is what translates innovation into impact—whether for COVID-19 vaccines or oral PrEP for HIV prevention.

The past year presented us all with extraordinary challenges. It was one of AVAC's busiest years ever, as we worked in partnership with many to help empower communities to address the multiple overlapping challenges of HIV and COVID-19, and to integrate HIV experience and knowledge into strategies for more effective pandemic preparedness and response (PPR).

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This was also a year of contrasts. While COVID-19 raged throughout 2021, limiting access to treatment, prevention and research for HIV and many other diseases, and illustrating the inadequacies of most of the world's health systems—HIV prevention research also entered its most dynamic period in decades.

Among the most hopeful developments, the movement for long-acting PrEP continued to mature in 2021. This year saw strong data on the safety and effectiveness of injectable Cabotegravir, along with the launch of the IMPOWER efficacy studies of once-monthly oral Islatravir and the PURPOSE efficacy studies of six-monthly injectable Lencapavir. And in a major and long-awaited advance for woman-controlled prevention, the <u>Dapivirine Vaginal Ring</u> received initial regulatory approval and was recommended as an additional prevention option by World Health Organization (WHO).



At the same time, a new potential avenue of prevention opened with results from the Antibody Mediated Prevention (AMP) studies, which evaluated whether the broadly neutralizing antibody (bNAb) VRC01 could protect against HIV infection. While the studies found that VRC01 did not reduce overall risk of acquiring HIV, it did protect some individuals from infection by strains of the virus that were particularly vulnerable or "sensitive" to the antibody. The data, while complex, are certain to inform future bNAb and vaccine studies.

Not all recent developments in the field were as hopeful, however. Following the discontinuation of the <u>Uhambo</u> vaccine study for lack of efficacy in 2020, the <u>Imbokodo</u> study also came to a disappointing conclusion in August. When viewed through the lens of the very high HIV incidence among women in both studies, these results demonstrated both the urgent, ongoing need to scale up the PrEP options available now, and the simultaneous need to reevaluate scientific approaches toward the development of safe and effective HIV vaccines.

This year also brought the acknowledgement that the world failed to meet the 2020 AIDS targets established by the UN. The development of ambitious new targets for 2025 was accompanied at the UN High Level Meeting on AIDS by an important recognition, in the clearest terms to date, that choices and combination prevention are "a cornerstone of an effective HIV response." While this focus on combination prevention raises hope for better progress toward this next round of targets, **turning** words and declarations into action will require bold new approaches to collective action.

The world also continued to grapple this year with critical questions of social justice, which are increasingly recognized as central to achieving global health equity. For AVAC, that process included an extensive Equity, Diversity and Inclusion (EDI) audit and the development of AVAC's EDI Statement. It commits us to taking concrete action to address the debilitating impact of neo-colonialism, racism, misogyny, homo/transphobia, discrimination and other forms of systemic oppression in global health; reversing the disproportionate impact of HIV on people who are disempowered, marginalized, criminalized and/or targeted by systemic racism and discrimination; and emphasizing in all aspects of our work the central need to achieve global health equity.

Like many of our colleagues, we at AVAC have been evaluating the lessons of 2021 and how we, and the field, can maximize our impact and best address the HIV and health equity challenges on the horizon. Those questions inspired the **most extensive planning process in AVAC's 25 year history**. It included a participatory review of our partnerships through AVAC's Partnership Scorecard; independent analyses of key AVAC programs, including the Coalition to Build Momentum, Power, Activism & Strategy (COMPASS) Africa and the AVAC Advocacy Fellows; a comprehensive EDI Audit; and a new strategic plan designed to ensure AVAC's growth, development and sustainability into the future.

Recognizing and building on the organization's strengths, AVAC is poised to deepen engagement at the global level and simultaneously work in service of country needs while strengthening the capacity of advocates and institutions. As such, AVAC will advance ethical development of and equitable access to innovative HIV prevention and related pandemic response options, while leveraging these practices to contribute more broadly to global health equity.

ADVOCATE, TRANSLATE, CATALYZE

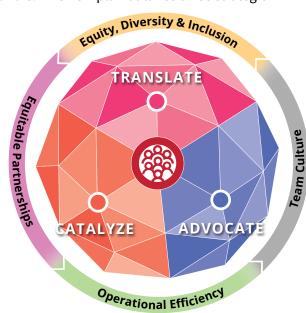
AVAC'S STRATEGIC PLAN 2022-2026

OUR VISION	A world without AIDS and with global health equity						
OUR MISSION	Accelerate ethical development of and global access to effective HIV prevention options, as part of a comprehensive and integrated pathway to global health equity						
VALUES	Inclusive	ople- itered	Rights- Based	Respectful	Transp	parent	Accountable
STRATEGIC PILLARS	TRANSLATE Bridging science and community through communication		ADVOCATE Mobilizing for inclusive and impactful programs, products, and policies		CATALYZE Cultivating and sustaining partnerships to spur advances in HIV prevention and nimbly apply those to emerging health needs and issues		
	communicatio	on					

This World AIDS Day we are pleased to release the resulting **AVAC Strategic Plan 2022-2026** and **Equity, Diversity and Inclusion Statement**, which together will guide our work and our partnerships in the years ahead.

AVAC's Strategic Plan 2022-2026 was developed through an inclusive and ambitious planning process that incorporated input from AVAC's staff, partners and donors. This new plan outlines three strategic pillars that will guide our work for the years ahead:

- TRANSLATE includes AVAC's work to bridge science and community by:
 - Amplifying the voices, perspectives and needs of affected communities among scientists, policy makers, industry leaders, product developers and the media.
 - Ensuring that research findings and emerging evidence are clearly and meaningfully shared with communities.
 - Supporting informed decision making and evidence-based advocacy by our partners.



- ADVOCATE includes AVAC's efforts to mobilize for inclusive, effective programs, products and policies by:
 - Fostering power-sharing and supporting the development of skilled, informed advocates.
 - Leveraging advocacy and communications to support country identified and driven priorities.
 - Enhancing transparency, driving resource efficiency and ensuring that policies and product access are inclusive and hold donors and decision makers to account.
- **CATALYZE** includes AVAC's efforts to cultivate and sustain balanced partnerships to advance HIV prevention and global health equity, including:
 - Convening and leveraging coalitions of communities, product developers, implementers and policy makers to advance and accelerate product development, introduction and access.
 - Facilitating ethical, inclusive and effective trial design and research that prioritize the needs, engagement and input of civil society.
 - Supporting cross-partner learning and collaborative action to enhance R&D implementation and advocacy.

AVAC's <u>EDI Statement</u> is an integral part of our way forward. Developed through a participatory process involving a diverse team of AVAC staff, board members and partners, the EDI Statement outlines our commitment to:

- Embed EDI in annual planning, establishing EDI goals and feedback mechanisms and measuring and rewarding EDI goal achievement.
- Increase diversity throughout AVAC, including at leadership levels, and working to create a culture where everyone feels safe, seen, heard, inspired and fulfilled.
- Assess the power dynamics of our partnerships and identify additional opportunities to increase the voices of those with lived experience and field expertise in AVAC plans and priorities.

Through this process, we also are re-committing to a robust Monitoring, Evaluation and Learning (MEL) strategy that will underpin AVAC's work across all three pillars, ensuring that we use data to monitor progress, make timely course corrections and capture impact.

DEVELOPING OPTIONS; DELIVERING CHOICES

We've also been looking outward, with recommendations for how the entire field must evolve to increase the pace and effectiveness of responses to HIV, COVID-19 and other health challenges; meet the next round of AIDS targets; prepare for future pandemics; advance global health equity; and address the structural and systemic obstacles to turning biomedical options into feasible prevention choices for real people.

Turning prevention options into feasible choices for people will be the focus of the upcoming *AVAC Report 2022: Developing Options; Delivering Choices*. AVAC's five key recommendations from that report are previewed here:

Deliver what we've got: Increase access to the HIV prevention we have now and plan for what's coming

To significantly impact the epidemic, the field must deliver the prevention options that people want, where, when and how they want them; integrate HIV with other vital health concerns; emphasize equitable access; and more systematically address the prevention-limiting impact of stigma, discrimination and misinformation. Strategies include:

- Training a broader range of prevention providers and employing task-shifting approaches that have been effective for treatment, but which have still not been widely used in prevention.
- **Integrating HIV prevention with health services** for other pressing needs that may be seen as equally or more urgent by the communities at greatest risk for HIV infection.
- Improving prevention procurement and coordination by increasing research on demand and delivery strategies and strengthening systems and tools to forecast prevention product demand, especially for next generation, long-acting prevention tools.
- Supporting and responding to community input, leadership and expertise, including building the capacity of local partners and governments to lead product delivery.
- **Sharing best practices**, particularly the learnings from PrEP delivery and support in major clinical trials and from innovative delivery models such as PrEP without prescription.
- **Developing an end-to-end approach to prevention** that includes prioritizing the perspectives of end users in product design, product delivery and how we talk about prevention.
- Increasing community awareness of HIV prevention and the options available, including placing prevention education and outreach into a broader HIV education context, using understandable language and addressing the concerns users say are most important to them.
- Building robust private and public sector support for global prevention research
 development and manufacturing, including technology transfer and investment to develop
 and support global manufacturing capacity, trial sites, labs and research and product delivery
 capacity in LMICs.

AVAC'S FIVE KEY RECOMMENDATIONS

- Deliver what we've got: Increase access to the HIV prevention we have now and plan for what's coming
- 2 Develop what we need: Adapt research to reflect the lessons of the past 18 months
- Center communities in the prevention response
- Change the HIV prevention architecture to drive better decision-making
- Imbed the AIDS
 response into the
 future of global health
 security and pandemic
 preparedness and
 response (PPR)

2 Develop what we need: Adapt research to reflect the lessons of the past 18 months

Years of research and community-led advocacy are producing vital lessons in product development, delivery and user preference. Utilizing these lessons to expand prevention options and choices should include:

Reevaluating approaches to HIV vaccine development. A safe and effective HIV vaccine remains the most essential prevention tool, and the cornerstone of efforts to end the epidemic. While the field focuses on new hypotheses driven by the results of the Uhambo, Imbokodo and AMP studies, and awaits the results of the Mosaico and PrEPVacc studies, it's time to recommit to diversity, creativity and collaboration in considering what comes next in the search for safe and effective HIV vaccines. With no other vaccine candidates on a clear track to licensure, the field must carefully consider how new developments, such as germline targeting approaches, should inform which hypotheses, products and delivery strategies advance as the search for a vaccine continues.

Learning from the COVID response. The COVID experience provides critical lessons that should inform the efforts of HIV advocates, researchers and funders to:

- Increase and diversify HIV prevention R&D funding.
- Support collaboration through pooled data and open-source research.
- Strengthen collaboration across labs, institutions and diseases.
- Conduct trials in parallel to produce more rapid results.
- Support advance purchase agreements and the early development of manufacturing capacity for promising prevention tools.

Design clinical trials to address the changing prevention paradigm. As the HIV prevention standard of care diversifies and improves, clinical trials design becomes increasingly challenging. AVAC's Trial Design Academy has been convening researchers, statisticians, regulators and advocates to explore how trial design challenges could be addressed through strategies such as external controls and recency assays. New ethics guidance for prevention trials from both the HPTN and UNAIDS/WHO provide important frameworks to consider, and new trials that are just launching from both Merck and Gilead provide real-time case studies in how to design and implement new trial designs. As clinical trials grow in complexity, advocacy for and engagement with trial designs are more important than ever.

3 Center communities in the prevention response

Generating deeper, more consistent community engagement in prevention requires restructuring community engagement. Community input must move beyond "consultation" on specific questions or challenges to a deeper, more sustained engagement that supports the full navigation of challenges from research to rollout, in all their complexity. Taking community engagement to the critical next level requires:

 Strengthening HIV community engagement mechanisms by addressing their independence and the potential impact of paid participation, and by improving linkages between trial-specific engagement and broader civil society engagement on HIV issues.

- **Enhancing leadership** and knowledge and supporting skills-strengthening for advocates and communities in shaping research and delivery agendas.
- Amplifying key population (KP)-led partners, platforms and priorities, including facilitating leadership, advocacy and organizational capacity strengthening for KP-led CSOs and networks and prioritizing research to understand how products work in different populations.
- **Prioritizing responses to stigma** by including clear indicators of the impact of stigma in every rollout program and prioritizing access to care for all key populations.
- Using human-centered design (HCD) and participatory research methodologies to inform research, product development, product introduction and program design. Key indicators of effective HCD should be included at every stage of the R&D process, not just at product introduction. Simplified, people-centered PrEP delivery models should be used to inform every aspect of new product rollout.

4 Change the HIV prevention architecture to drive better decision-making

Resource allocations for prevention are often made in an uncoordinated fashion by individual governments, funders and programs, and are neither sufficiently managed nor strategically allocated to reverse the pandemic. The lack of clear, reliable data also makes it virtually impossible to allocate prevention resources for greatest impact. HIV prevention needs a decision-making process for which products to develop, test and deploy that is longer-term in its approach and more responsive to the latest developments in research and product use. Improving the HIV prevention architecture should include:

- **Increasing transparency** by disaggregating data on investments and interventions (Potential models include PEPFAR data on DREAMS and VMMC data).
- **Supporting more holistic analyses** of the best treatment and prevention spend for health impact in each community, and of which products should be prevention priorities.
- Improving information-sharing through a rigorous, well-vetted platform for best practices.
- Facilitating collaborative decision-making between governments, funders, researchers, community and industry.

AVAC is supporting the efforts of the UN-led Global Prevention Coalition (GPC) and its partners to address these issues. We remain hopeful that the GPC's forthcoming Roadmap to 2025 will address these issues and provide a platform to build robust accountability measures to meet the next round of AIDS targets.

Imbed the AIDS response into the future of global health security and pandemic preparedness and response (PPR)

The certainty of more complex and challenging health crises on the horizon demands public health approaches that focus on health systems strengthening, better integrate key health priorities including HIV, TB, malaria, sexual and reproductive health and non-communicable diseases and lay effective groundwork for addressing emerging health priorities in the future.

To expand on the synergies between HIV and PPR, efforts to build a global pandemic response capacity should leverage the organizational capacities and reach of PEPFAR and GFATM to:

- **Center communities** in PPR planning, research and implementation.
- Re-focus on equity in all aspects of PPR.
- Strengthen health systems as a critical step toward achieving universal health coverage.
- Integrate health services to address critical, overlapping health needs, such as HIV prevention and treatment, sexual and reproductive health services, pre- and ante-natal services, TB and malaria prevention and treatment and others.
- **Improve efforts to counter misinformation**, which must be recognized as a fundamental driver of health inequity and poor outcomes.
- Leverage HIV platforms, systems and investments to strengthen health systems and PPR, while also ensuring that PPR supports and advances the HIV response.

Much more on these recommendations will come in the upcoming *Developing Options; Delivering Choices* report.

Meanwhile, our thanks this World AIDS Day to everyone who helped make our new Strategic Plan and EDI Statement possible and informed our thinking about the future. Together, they position AVAC to work with partners to address the challenges and opportunities ahead in HIV prevention and global health equity more effectively, efficiently and sustainably. In doing so, we commit to continue to build on our core values of putting people and communities at the center of our work, promoting rights-based approaches to care, ensuring that AVAC programs are ethically designed and delivered and fostering a team culture based on respect, inclusion, collaboration, transparency, continual learning and investing in our staff and partners.

As always, we thank you for your support of AVAC in the past, and look forward to joining you in meeting the many challenges ahead.

SOME OF THE ISSUES WE'LL BE WATCHING IN 2022

John Nkengasong takes the reigns at PEPFAR.

The historic appointment indicates that PEPFAR will continue to play a major role in HIV prevention and treatment worldwide. As the first person of African origin to head PEPFAR, and as a leader, in efforts to strengthen global pandemic preparedness and response strategies, John Nkengasong has the tools and experience to address the many challenges confronting PEPFAR. His success will require the ongoing support and engagement of government and advocates around the world.

PEPFAR and the Global Fund respond to COVID-19.

The two largest, best-funded and most experienced pandemic response organizations, PEPFAR and the Global Fund, both emerged from the response to HIV. As efforts to position the world for the next pandemic continue, we'll be working to ensure that the systems and expertise developed through years of HIV research, experience and advocacy are appropriately utilized to maximize responses to current and future pandemics, and to ensure that health equity is a cornerstone of those efforts.

Long-acting Cabotegravir (CAB-LA) for PrEP. U.S. FDA approval of the PrEP injection, which is administered once every two months, is expected in early 2022. Long-acting PrEP will open important new doors in HIV prevention, but also presents challenges for health systems and users adjusting to new PrEP delivery systems and schedules. A critical focus for AVAC will be closing the time gap in CAB-LA approval between wealthy counties and LMICs, and working to ensure that rollout of the new prevention option is much more equitable than what the world has experienced for COVID-19 vaccines.

The Dapivirine Ring rollout. Whether 2022 becomes the "year of the ring" will depend on the effective and equitable roll-out of this critically important woman-controlled HIV prevention option. Will approval mean availability for the ring (and cabotegravir PrEP), and will governments and health systems implement the user-focused programs that can make these prevention options real choices for people?

Will VMMC get back on track? Voluntary medical male circumcision is one of the safest, most effective and most affordable HIV prevention options available. Yet uptake rates for VMMC remain low, and the most recent Resource Tracking Funding Report found that funders provided only US\$ 6 million for VMMC in 2020, a 37% decrease over the previous year. While multiple factors contribute to low and declining VMMC uptake, efforts to "re-boot" access to and information about the procedure should be a key HIV prevention focus for 2022.

The challenge of combination prevention studies.

The PURPOSE 1, PURPOSE 2, IMPOWER -22 and IMPOWER-24 studies of new long-acting PrEP options will be the first major HIV prevention studies to take place following the anticipated approvals of the dapivirine ring and injectable cabotegravir for PrEP. Whether and how these studies make the new prevention options available for participants, how the trials adjust to address an increasingly complex prevention picture and how well they enroll a diverse pool of participants will be key focal points in the year ahead.

Defining the road to 2025. Ambitious targets for increasing global access to HIV prevention and treatment, and for reducing punitive laws and policies, stigma and discrimination and gender violence were established this year. The road map toward *achieving* those targets, however, is still to come. AVAC is supporting the efforts of the UN-led Global Prevention Coalition (GPC) and we'll be watching that process closely to ensure that the roadmap contains real, actionable strategies and robust accountability measures to achieve the targets.

The vaccine research agenda. With no vaccine candidates on a clear track to licensure, but with new hypotheses driven by results of the Uhambo, Imbokodo and AMP studies, the field must carefully consider how new developments should inform which hypotheses, products and delivery strategies advance as the search for a vaccine, the most essential prevention tool, continues.