



MODULE 5

Advancing HIV Prevention through Market Systems and Innovation

Preamble

For the first time, a robust pipeline of prevention products promises to transform sexual and reproductive health for young women and girls. Yet, the experience of the last few decades of programming suggests that more caution than celebration is warranted. With few exceptions, the scale-up of essential sexual and reproductive health prevention technologies has remained slow and arduous, and securing funding persists as a barrier to wider scale adoption of promising technologies. The reasons for the poor utilization of new technologies are complex: inadequate orientation to the key needs and realities of target audiences; limited efforts to deliberately plan for scale-up; shortfalls in stewardship, management and partnership; a lack of evidence and analysis to prioritize innovation portfolios; and ineffective marketing of prevention products, to name only a few.

Multiple sectors – health, education, justice, welfare and markets – are failing to deliver for girls and young women their fundamental rights to sexual and reproductive health. Given these realities, a narrow focus on promoting new products and technologies is unlikely to yield the desired health and well-being outcomes for girls and young women at highest risk of HIV acquisition. An expansive approach to programmatic innovation must address the behavioural and structural enablers required to assure equitable access to new and established HIV prevention tools alike. To yield dividends for young women and girls, programme managers charged with implementing large-scale HIV prevention efforts must approach the introduction of new methods and solutions with an eye towards more effective problem solving, by forging effective collaborations between public sector, market systems and girls and young women themselves.

Existing HIV prevention and sexual health markets must embrace business model innovations, new service delivery approaches and innovative financing to address predictable bottlenecks in service delivery and operations. While actors at every level will serve crucial functions and may even facilitate key functions in availing prevention technologies to girls, the stewardship role must ultimately be held by the national authorities. This role includes articulating a vision for a healthy, sustainable market and developing supporting policies and activities to achieve that vision. Effective stewardship will entail active management of novel HIV prevention tools at all stages: from registration through to supply and deployment.

This module explores the role of innovation in improving outcomes for young women and girls, with the knowledge that each context is unique and that every intervention must be oriented to the specific needs and opportunities of this population.

Key Takeaways

- Assessing the entire ecosystem’s preparedness and ability to absorb new interventions can be an important investment to inform the innovation and scale-up journeys of HIV prevention initiatives – engaging the target audience could be particularly transformative, surfacing insights that are often hidden or ignored.
- Young women and girls directly affected by HIV can play a strong role in prioritization efforts, identifying game-changing innovations and championing new ideas, new ways of working and new solutions.
- Rigorous data and analysis can help to estimate the cost and impact of different product introduction and scale-up strategies, to determine strategies for prioritization and to identify how scale-up might be refined for impact.
- To effectively respond to the lived realities of young women and girls, programmes must coordinate an integrated approach that addresses the behavioural and structural enablers of health-seeking behaviour at numerous levels – individual, peer and societal – if uptake of biomedical prevention technologies is to be advanced.
- Public sector innovators and market systems must work in partnership to engage the crucial sectors that affect girls and young women’s lives, informed by a thorough understanding of the everyday realities faced by young women and girls.
- New financing models are required to support the operationalization and intentional replication of novel tools across contexts and ultimately at scale.
- Governments are ultimately responsible for overall innovation stewardship and particularly for defining clear partnership roles for key actors and stakeholders – whether within government or without, a market facilitator function should be clearly identified and supported to guide the successful integration and scale-up of appropriate prevention technologies.

5.1 Assess the Entire Ecosystem's Preparedness to Transform, Absorb and Scale up Innovations

Effective HIV prevention is inextricably linked to the health of the marketplace that delivers life-saving products and services to young women and girls. For example, a well-functioning health-care market with public and private sector participation requires manufacturers to produce high-quality products; distributors to deliver the necessary quantities; service providers to administer them correctly; communities to trust in the safety and efficacy of prevention products; and young women and girls to be educated and active participants in their own health. However, markets sometimes fall short. Developers may not anticipate enough demand to develop or finance a new product, manufacturers may not know how much to produce, and distributors may not see enough profit to justify delivery. The unfortunate reality is that a single breakdown in this complex system can keep life-saving products from those most in need.

Structured intervention can disrupt current practices or transform existing market structures, creating efficiencies that lead to better health outcomes. Actors at both ends of the market – producers and purchasers – may face high transaction costs, critical knowledge gaps or imbalanced risks that hamper their participation in the market and lead to market shortcomings. Countries, donors and procurers can use their purchasing power, financing, influence and access to technical expertise to address the root causes of market shortcomings and influence markets for improved health outcomes for young women and girls. Designed to be transformative, market-shaping interventions aim to reduce long-term demand and supply imbalances and reach a sustainable equilibrium.

Market-shaping actions can accelerate progress towards increasing access to and use of life-saving commodities by addressing previously insurmountable market barriers at scale. As these challenges are addressed, the market-shaping field requires additional coordination and leadership to uncover potentially transformational solutions (see '*Healthy Markets for Global Health: A Market-Shaping Primer*').

A variety of structural barriers have stunted the growth of new tools as they have come to market, including inadequate financing, regulatory and guideline obstacles, inefficient delivery of health services and a resistance to change in the community. To make progress with innovative solutions for HIV prevention, consider answering these questions:

- Where are the biggest issues?
- What are the root causes of these issues?

- What potential solutions can effectively address these root causes?
- Are these solutions accessible to the communities that need them most?
- Are these solutions affordable? Plausibly scalable? Sustainable?
- What is needed at the systems level for an innovative solution to be successful?

Engaging young women and girls in the journey of innovation and scale-up can assist in the assessment of an entire ecosystem's preparedness and ability to transform to absorb new innovations, and then transition them to scale (see 'Module 4: Girl-centred Design'):

1. **Landscape analysis.** Identify, classify and evaluate key actors and stakeholders. This analysis will facilitate the understanding of the overall context, revealing new insights, creating a relevant user journey and prioritizing who to engage and when.
2. **Defining the problem.** Based on insights gained from landscape analysis, articulate the problem to be addressed and the value proposition of the specific innovation.
3. **Ideation.** Generate ideas to address the problem by engaging external experts and affected communities, and identifying overarching themes and opportunities to pursue. These creative solutions can be inspired by both new ideas and existing practices.
4. **Prototyping/field testing.** Engage young women and girls in prioritizing ideas for field testing. The first 'prototype' is the first time all parts of a solution are tested together to assess whether the intellectual concept behind an innovation has the potential to effectively address the problem statement. Identify any potential issues as all components are tested, analysed and refined.
5. **Transitioning to scale.** Further develop innovations that have demonstrated small-scale success and attract partners to help fill gaps in the ecosystem's capacity for scaling up .
6. **Scaling-up.** Replicate and/or adapt an innovation across large geographies and populations for transformational impact.
7. **Sustainable scale.** Wide-scale adoption of the operation of an innovation at the desired level of scale-up/exponential growth, sustained by an ecosystem of actors.

5.2 Ensure Traction and Optimize Transition to Scale with Innovative Financing

It is critically important to note that, while innovative tools, models and approaches exist within the realm of programming for young women and girls, achieving appreciable coverage at scale cannot be completed without adequate and predictable financing flows. A range of novel and innovative financing tools could allow solutions to be made

operational, intentionally replicated across contexts and ultimately taken to sustainable scale, demonstrating a significant impact and catalytic effect by:

- Fostering innovation
- Raising funds for programme delivery
- Increasing efficiency
- Supporting countries in transition and ensuring sustainability

Key innovative financing modalities are most effective when designed to complement funding models and government spending, boosting impact by enhancing the efficiency and impact of health programmes and increasing funding beyond traditional mechanisms at the global, regional and implementing country levels. These platforms include the following:

- **Consumer donations** empower millions of individuals to contribute to the cause of global health, raising funds when they purchase products or services, or creating grassroots fundraising mechanisms.
- **Philanthropic platforms** enable different types of investors, foundations, philanthropic leaders and others to pool their financial contributions to a cause. These pooled funding mechanisms aim to mobilize and distribute funds in a more coordinated and efficient way. Pooled fund investing is used to leverage expertise as well as financial resources to support health programmes.
- **Debt swaps** convert debt repayments into investments in health. Under individually negotiated debt swap agreements, an implementing country can agree to invest in programmes to fight diseases or strengthen health systems. In return, a creditor country cancels debt owed by the implementing country.
- **Blended finance** combines grants with other sources of financing, including investments from development finance institutions. Health programmes can be conditional on, or implemented in coordination with, investments from funding partners.
- **Results-based financing** is the disbursement of grant funds after pre-agreed results are achieved at specific milestones. One form of this financing is known as 'cash on delivery'.
- **Outcome-based financing** is the disbursement of funds after predefined outcomes are achieved, with the donor or private investor generally providing upfront financing to a programme implementer. If the pre-agreed outcomes of the programme are met, the investment is repaid, often with a financial return. This financing includes social impact bonds, which focus investments toward programmes that yield effective social outcomes in the fight against disease.



5.3 Use Rigorous Evidence and Analysis to Prioritize Innovation Portfolios

A broad spectrum of promising but uncoordinated initiatives exists to facilitate the development and scale-up of novel health and well-being solutions. Yet, few resources are available to comprehensively catalogue, assess and weigh the potential impact of these solutions, and there are few tools available to assess and prioritize the cost, acceptability, feasibility, scalability and potential impact of these solutions for the populations who need them most. On the other hand, an increasing number of therapeutic interventions of import to sexual and reproductive health (SRH) requires rationalization.

The need to assess which specific products and solutions bear the promise for impact at scale, and therefore warrant the investment of scarce resources, poses a special quandary for national authorities. Beyond the reliance on gold-standard metrics for assessing product efficacy, national prevention programmes would be well-served by explicit strategies to engage young women and girls in considering the following questions:

1. How might current programming benefit from new ways of applying, adapting, delivering or further developing an existing solution?
2. How sustainable is a given innovation or solution, and what is its potential to lead to long-lasting change?
3. What are innovative and cost-effective ways to expand, deepen and accelerate impact for young women and girls?
4. What innovative partnership models can enhance, deepen and align innovation to the burden of poor health and disease?
5. What are the best implementation and distribution modalities for deploying new and appropriate science or technology?
6. How can programmers prioritize, harness and develop ideas from young women, girls and other affected populations in the community, while involving them in implementation?

Networks of people living with and affected by HIV have always been at the forefront of the AIDS response. Young women and girls affected by HIV can play a strong role in prioritization efforts, identifying game-changing innovations and championing new ideas, new ways of working and new solutions. Rigorous data and analysis can further help to determine strategies for prioritizing which specific innovations to integrate, their cost, impact and scale-up modalities (see 'Module 4.2: Use Data to Understand Young Women's and Girls' HIV Vulnerability'). These strategic prioritization efforts should ensure that the introduction of any new innovations is aligned to the burden of new HIV infections,

while keeping the values, needs and preferences of young women and girls at the centre of innovative programming (see '*Module 4.1: Adopt a Human-centred Design Lens for Programme Design*').

For example, the DREAMS Innovation Challenge noted that several partners failed to consider that the majority of girls they were trying to reach were young mothers whose childcare responsibilities could limit enrolment and/or who might need spousal support to participate. Others did not consider peer educators' transportation costs or the health fees associated with referred services. Flexible partners found ways to overcome some of these barriers and gaps, but engaging local girls and young women in the design and throughout implementation would have helped to identify and reconcile them far sooner (see '*The Dreams Innovation Challenge: Lessons in innovation for reducing adolescents' vulnerability to HIV*').

5.4 Coordinate an Integrated Approach that Combines Biomedical Prevention Technologies with Behavioural and Structural Enablers

Similar to initiatives targeting men who have sex with men (MSM), sex workers (SW) and other key populations with biomedical prevention technologies such as oral pre-exposure prophylaxis (PrEP), moral and religious objections create barriers to providing information to unmarried young women and girls on preventing the sexual transmission of HIV; this poses a tremendous challenge for rolling out PrEP among this group. Research also suggests that adolescent girls are among the groups least likely to adhere to PrEP.

Additionally, the most recent data indicate that only 15 per cent of females aged 15–19 years in sub-Saharan Africa have been tested for HIV in the past 12 months and received the result of the last test.

Young women and girls continue to fall into a major structural gap in the implementation of HIV prevention initiatives. Due to fear of backlash, policymakers are hesitant to explicitly name young women and girls in strategic prioritization – yet, across many settings, young women and girls continue to have the highest rate of HIV incidence. **They need and deserve a crisis intervention now.**

For young women and girls, agency and vulnerability are inextricably linked (see '*Module 4.2: Use Data to Understand Young Women's and Girls' HIV Vulnerability*'). Programmes cannot continue to do what has typically been done, which has been to implement

behavioural and biomedical interventions without structural interventions – because doing so has meant not working with the girls’ lived reality. Programme implementers are part of a robust community of partners committed to creating change, and examples of structural innovation and best practice can be observed and replicated across settings. For example, successful girl-affirming programmes inspired the start of the DREAMS initiative in sub-Saharan Africa; after a rigorous analysis of vulnerability, the United States President’s Emergency Plan for AIDS Relief (PEPFAR) integrated foundational structural determinants – including social protection, food and opportunity – into its HIV prevention programming. Utilizing a vulnerability analysis developed by the Population Council, DREAMS adapted this programming with success among girls aged 15–19 years. However, the project continued to face ongoing challenges among young women aged 20–24 years, as this older population specifically requires a bridge to employment (see ‘Module 4.6: Establish Girl-affirming Approaches’). Over time, DREAMS has committed to structural innovations that not only recognize the intersection of poverty and agency, but also put young women at the heart of their investment strategy. DREAMS girls – among the most vulnerable to structural factors linked to HIV acquisition – are benefiting from entrepreneurship skills training, starting their own businesses and being hired as community health workers and advocates against sexual violence.

Service delivery innovations – including social, behavioural and structural interventions – have the potential to further improve access to services and critical prevention commodities for young women and girls. For example, social and behavioural interventions promoting condoms (and their benefits beyond prevention) can pave the way to the acceptability and scale-up of innovations in barrier methods, such as the range of World Health Organization (WHO) pre-qualified female/internal condoms.

On the structural level, criminalization and age of consent often jeopardize access to SRH-related services. Effective structural interventions may change the environment in which people act, in order to influence their health behaviours. Programme managers must consider how the following structural dimensions may affect the access to, and the uptake, implementation and impact of innovation for HIV prevention among young women and girls:

- Policy, regulatory and/or legal change
- Changes to their enabling environment
- Shifts in harmful social norms
- Catalysing social and political change
- Empowering communities and groups

Biomedical HIV prevention – including innovations in treatment as prevention (TasP), PrEP and post-exposure prophylaxis (PEP) – represents a host of new options in discreet, user-

friendly HIV prevention methods that aim to address the needs of individual users (see Figure 3). Long-acting regimens, injectables, implants and multipurpose technologies strive to directly address the needs expressed by young women and girls; however, this does not mean that these options can always be readily accessed by those who need them most.

Figure 3: The prevention product development pipeline

	CURRENTLY AVAILABLE				IN REGULATORY REVIEW		IN DEVELOPMENT		NA – NOT INTENDED FOR LICENSURE	
										
	VMMC	Daily Oral TDF/FTC	Event-driven Oral TDF/FTC	Daily Oral TAF/FTC	Dapivirine Vaginal Ring	Injectable Cabotegravir	Dual Px Pill (TDF/FTC/COC)	Ad 26 Vaccine	Monthly Oral Islatravir	VRC 01 bNAb infusion
	2007 Recommended in 14 priority countries in E/SA since	2012 US approval; 2015 first African approvals	2019 WHO recommendation	2019 FDA partial approval; ±2024 for cisgender women	2020 positive EMA opinion; WHO guideline and abbreviated PQ review	±2021 Likely earliest approvals	±2022 Likely earliest approvals	±2024 Likely earliest approvals	±2024 Likely earliest approvals	±2024 Likely earliest approvals
Populations	Heterosexual men	All at risk	MSM	All except "those at risk via receptive vaginal sex"	Women	Women, MSM, TGW	Women	Studied in multiple populations	To be studied in multiple populations	Studied in multiple populations
Next steps	Re-energize post COVID restrictions	Scale up demand creation and support for continuation	Integrate as per guidelines	Efficacy trial in cisgender women in Africa start 2021	National regulatory approvals & product intro in 2021	Continue 084/01; regulatory submission in 2021	Bioequivalence studies	Efficacy trials continuing	Efficacy trials to start 2021	Multiple bNabs in development

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To scale up access to biomedical HIV prevention, structural innovation and critical actions by community-based organizations, health-care providers and the broader health system are necessary. Biomedical HIV prevention creates new opportunities to reduce the alarming HIV health inequities that exist among young women and girls; however, effectively expanding access to treatment and prevention services requires an understanding of the enabling environment and unique needs, values and barriers to care they experience (see 'Module 4.1: Adopt a Human-centred Design Lens for Programme Design'). For young women and girls, structural interventions in biomedical HIV prevention initiatives can:

- Clarify issues around privacy, confidentiality, guardian consent requirements, and inconsistencies in other legal frameworks with regard to providing biomedical HIV prevention options to youth
- Educate communities about laws that affect the sexual health of young people
- Ensure dissemination of clear, accurate and evidence-based information to combat rumours, myths and misconceptions in the current programming context
- Mitigate backlash against implementers in the provision of biomedical HIV prevention options and information to young women and girls
- Identify and share best practices for addressing consent, confidentiality, cost and additional barriers for biomedical HIV prevention options
- Augment resources dedicated to reaching young women and girls who would benefit from biomedical HIV prevention options, and support them in staying in care and adhering to treatment

- Disseminate HIV prevention information through youth-serving organizations
- Build support for comprehensive health education and the integration of biomedical HIV prevention information into health education curricula and programming.

While scaling up access to all the treatment and prevention options that currently exist is essential, it is not sufficient. There remains a critical need for additional options and for orienting these to the key needs and realities of young women and girls. Although implementers need to programme for them, very few implementers design specifically for and with young women and girls. The biomedical prevention pipeline – which includes the newly pre-qualified dapivirine-releasing monthly intravaginal ring, dual-purpose technologies combining oral contraceptives and antiretroviral drugs for prevention, long-acting injectables, and HIV self-testing, among other products – has the potential to directly address the needs expressed by this population. However, the implementation of new biomedical innovations for HIV prevention will only be successful and sustainable among young women and girls within a context that combines the provision of prevention products with education and gender-empowerment (see '*Global Consultation on Lessons from Sexual and Reproductive Health Programming to Catalyse HIV Prevention for Adolescent Girls and Young Women*').

5.5 Innovation and Market Systems Management Must Have a Clear Public Sector Steward

Innovation and market-shaping comprise a spectrum of actions taking place within different sectors, but there are certain critical functions that only governments can provide – including the role of formulating policy, which is necessary for innovations to be absorbed (see '*Module 9.1: Promote Legal, Policy and Regulatory Environments that Create Girl- and Women-friendly Opportunity Structures*'). Policies lead directly to impact, and demonstrating impact makes the case for increased investment and transition to sustainable scale.

Governments are ultimately responsible for overall innovation stewardship and, particularly, for defining clear partnership roles for key actors and stakeholders. Aspects of this crucial stewardship role include:

- Formulating policies and regulatory framework for innovation
- Articulating a vision for a healthy, sustainable market
- Setting guidelines and standards of practice
- Ensuring policies are carried through and enforced at the national, district and site levels

- Defining clear partnership roles and delegating responsibilities among key actors and stakeholders, while communicating relevant market and technical information to them
- Coordinating innovation activities among ministries, key actors and stakeholders
- Integrating innovation and technology into existing health information systems and tracking (see 'Module 9.3: Engender Institutions to Work for Young Women and Adolescent Girls')
- Championing new product/programme introduction and uptake
- Assisting producers in finding markets for new products
- Advocacy, to help young women and girls find appropriate products
- Safeguarding the interests of the most vulnerable, marginalized and hard-to-reach populations – including young women and girls with disabilities and those living in marginalized communities
- Anticipating and addressing demand, backlash, resistance and any negative unintended consequences to implementing innovative solutions for young women and girls
- Clinical trials, research and development
- New product registration
- Planning, forecasting, and creating demand
- Financing and assessing impact

However, the key actions for advancing innovation with HIV prevention require not only political support, but also resources and expertise. Therefore, strategic partnerships between the government, private sector, donors, multilateral agencies, academia and implementing partners within civil society are crucial to accelerating progress and achieving results for young women and girls. Each of the following actors plays a pivotal role in the innovation journey:

- **Private sector.** Scaling up effective HIV prevention requires not only that innovative prevention technology reaches those who need it, but also that there is a political and financial will to make prevention a priority. In this regard, corporate partners can play a critical role in influencing governments' commitment; this includes the informal market, a thriving entity that often fills the gaps with innovative services and product where government action has lagged. Intentional public–private partnerships can help to increase impact and could address issues in: supply chain management (e.g. warehouses and distributors); traditional and non-traditional community engagement (e.g. data services and the mobile/technological sector); and the types of messages used to market and promote innovative solutions. Leveraging the principles of behavioural economics, human-centred design and

other methodologies long-used by industry to market their products can increase innovation uptake and reach (see 'Module 4: Girl-centred Design').

- **Donors.** While development assistance ('aid') plays an important role in the provision of health services in developing countries, their provision remains a quintessential

Private sector methodologies have delivered many important insights. These include the understanding that young women are far less concerned about HIV and much more concerned about pregnancy and that they are less interested in conversations about risk and more about love, relationships, romance and security.

Private sector partnerships allow the creation and delivery of relevant messages that meet people where they are in their lives. As certain actors and stakeholders are uncomfortable talking to young women and girls about their SRH, innovation in how and what messages are communicated can lead scientific innovation to have actual impact.

task of national governments. Donors cannot be a substitute for strong national health systems in the long run, as prioritization based on global public goods will not reflect national health priorities. They can, however, support the broader health system with initial investments in the development of promising products, and bridge funding to bring innovations to wide scale. Donors can impact the investing space by sharing knowledge with local stakeholders and by helping to create ownership among young women and girls over innovative solutions.

- **Multilateral agencies.** Partnerships with multilateral health, development and humanitarian agencies allow for countries to be better supported in accelerating progress towards health-related goals. Multilateral organizations can facilitate linkages to governments and catalyse the development of guidelines and standards to support health actors to advance social innovations and integrate research in their process.
- **Academia.** Partnerships with academia play a pivotal role in determining the future of medical science, increasing the scale and pace of discovery by supporting innovative solutions and encouraging governments to facilitate further research. This research is critical to furthering innovation and attracting international investment and flexible partnerships, including those with the private sector – such collaborations help all partners to accelerate the development of innovative solutions.
- **Civil society.** Civil society actors, such as non-governmental organizations and networks for women and girls, play a pivotal role in advocating access to life-saving, preventive and protective new options while ensuring their equitable and judicious use. Essential to every stage of the innovation journey, these networks have clear roles in prioritization, advocacy, strategic engagement, monitoring and feedback

(see 'Module 5.3: Use Rigorous Evidence, Data and Analysis to Prioritize Innovation Portfolios').

- **Market facilitators.** Market facilitation is an innovative intervention approach being adopted by development organizations with the potential to catalyse broad-scale market growth. Market facilitators work to stimulate markets, encouraging them to evolve in a way that increasingly involves and benefits both the producers and the businesses, without becoming a part of the market themselves. They seek to catalyse ongoing pro-poor market improvement, while keeping ownership firmly among market actors and avoiding dependency. Market facilitators can come from the private sector, academia or specific governmental agencies.

Additional market-shaping strategies can define how partnerships contribute to health outcomes and facilitate healthier global markets for innovative solutions. Market-shaping efforts can be guided by:

- Ensuring continued availability and affordability for young women and girls
- Promoting consistent quality standards
- Supporting efforts to stimulate innovation
- Accelerating adoption of new and/or cost-effective products
- Preparing for country transition and long-term market viability
- Strengthening key foundational elements for market-shaping

5.6 Public Innovators and Market Systems Must Collaborate to Engage the Critical Sectors that Shape the Lives of Girls and Young Women

Endeavours to transition innovations to scale must operate in a multipronged fashion to achieve a scale and depth that catalyses new results. This is not dissimilar to the concepts behind combination or high-impact prevention: a set of strategically selected interventions that matches the needs of young women and girls, delivered at the scale required to make an impact. It means doing less of certain things and far more of others. It means making tough decisions and measuring impact. Above all, it means moving with clarity and speed. When a best practice emerges in one area, programme managers must be equipped to take those results and determine how to scale them up across programming – this will help to take innovation to scale more quickly and lift some of the enormous burden currently placed on young women and girls.

Since oral PrEP was first approved by the US Food and Drug Administration in 2012, 928,750 initiations have been achieved (as of December 2020), falling short of the global target

of 3 million. Uptake of PrEP has been explosive in a few contexts, driven by engaged key populations communities. Nevertheless, the global pace of adoption is still too slow, and uptake of PrEP continues to lag globally behind global targets. Programming must pivot more quickly, based on the evidence and implementation experience of front-runner communities. Small-scale pilots and demonstration projects are not indicative of how to deliver programming at scale – more aggressive cross-sectoral partnerships are needed to create the pipelines to deliver the next generation of innovative solutions. As the next generation of innovative solutions arrives – products such as the newly pre-qualified vaginal ring, the dual pill, dual injection and dual implant (see *Figure 1*) – cross-sectoral collaborations must allow innovation to move beyond a product-by-product model to a system-by-system approach, with young women and girls at the centre.

Civil society-led advocacy plays an equally important role in market-shaping, particularly in facilitating and brokering innovations (see '*Module 5.1: Assess the Entire Ecosystem's Preparedness to Transform, Absorb and Scale up Innovations*'). Greater engagement of young women and girls in HIV prevention strategy and innovation is necessary, or else we risk continuing to ignore the need for action on the underlying structural drivers and social context of the HIV epidemic.

A common agenda has been proposed as a framework to galvanize the key stakeholders of women-led prevention and to streamline collective efforts (see '*Common Agenda for the Dapivirine Vaginal Ring*').

Promising Directions: Game changers to optimize HIV prevention portfolios

Agile methodologies. Stakeholders in HIV prevention now use agile methodologies (originally designed for the software industry) when developing products and services, due to their highly collaborative and more efficient nature. Agile methodologies – such as scrum teams, design sprints and hackathons – can also be combined with other methodologies to create hybrid solutions:

- **Scrum** is a framework that helps teams work together to deliver a product increment, which is the body of work produced at the end of a development period. Scrum encourages a high level of communication, allowing scrum teams to learn through experiences, self-organize while working to solve a problem and reflect on their successes and challenges in order to continuously improve.
- **Design sprints** are a thinking methodology used to solve complex problems through co-creation, rapid prototyping and qualitative testing with targeted users.
- **Hackathons** are events, usually hosted by a tech company or organization, during which programmers collaborate closely on a project for a short period of time. Hackathon participants work rapidly and often without sleep to achieve their end goal, as the events typically last for only 24 hours or over a weekend.
- **Innovation challenges** are a compelling, competitive method of developing innovative concepts and solutions, during which participants are asked to generate ideas for improving products, processes, services or user experiences. Through ongoing feedback, updates and opportunities for collaboration, participants continue to be highly engaged as the challenge progresses. This game-style format enables participants to play an active role in selecting a winning idea, fostering a strong culture of innovation.



- **Incubators** help to nurture innovative concepts, providing the resources for participants to reflect on and further develop these ideas so that they may be transformed into viable, sustainable solutions.
- **Accelerators**, born from the phenomenon of incubators, match stakeholders and implementers with experts in the field. Through mentorship, these experts help participants to develop the core skills needed to generate and grow innovative solutions into successful initiatives.

Case Study: The first ever youth acceptability study on the female (internal) condom in Uruguay

The project's overall objective was to design and implement a pilot experience for the promotion of the female (internal) condom (FC2) among Uruguayan youth and teens over 15 years of age, with the understanding that the approach to SRH among teenagers calls for specific design and implementation in which various innovation and adaptations – ranging from methodology to communications – must be considered. The project was supported by United Nations Population Fund (UNFPA) Uruguay, the Ministry of Public Health Uruguay and the Female Health Company. It was carried out between February and December 2018 by a technical team from **Iniciativas Sanitarias** (International Planned Parenthood Federation) under the supervision of an advisory committee in the region.

During project design, consultations with teenagers revealed that health centres were not the main source of information about protection and birth control methods for youth. Education centres and the community – in particular, peers as key influencers – proved to be the most impactful promotion agents, making the FC2 more widely known and reaffirming it as an option for teenagers.

Young people remained at the centre of the process, from design through implementation and evaluation – co-creating an approach that 'naturalized' the FC2 as part of the birth control and protection methods available to teenagers.

This approach included:

1. Generating an initial approach towards understanding opinions, practices and behaviours in adolescents and youth regarding the FC2, and identifying factors that enable and hinder its use within that age group
2. Defining messages, communication materials and tools (digital and on paper) relating to the FC2 aimed at adolescents and young people, considering the specificities of this population (codes, aesthetics, format and support)
3. Training health-care teams and educational staff on the features of the FC2, and its promotion and use among youth
4. Implementing training activities on sexual and reproductive health and



rights (SRHR), protection and birth control methods, and the FC2 for teenagers and youth

5. Defining recommendations for guiding the future design of strategies to promote the FC2 among teenagers and youth, in accordance with public policies related to SRH

Based on empirical evidence, two main barriers to accessing the FC2 were identified: distribution logistics and reluctance by some health professionals to proactively include female (internal) condoms in advice about protection and birth control methods. It is clear that, for the FC2 to become a protection and birth control option for teenagers, it is necessary to guarantee access and to develop tailored information and dissemination campaigns, in addition to implementing a strong training strategy for health-care teams.

Study population

- The total number of teenagers and youth surveyed during the study was 212, with 96 males and 116 females.
- Their average age was 16.4 years; most were aged 12–14 years (38.3 per cent) and 15–16 years (23.5 per cent).

Evaluation

- All individuals contacted for the follow-up provided an assessment on the method, which proved quite positive: 79 per cent of the adolescents stated that they considered it a good or very good method.
- Among those who actually used it, the assessment maintains the same positive ratio: 80 per cent stated that the FC2 was good or very good. As evidenced in the previous follow-up experiences, the main reason for not using it was the absence of sexual relations during the period monitored.
- The assessment by gender shows that 89 per cent of the males and 75 per cent of the females said that the method was good or very good.
- When asked if they would use it in the future, the main answer was yes (40 per cent) maybe on some occasion, while 27 per cent did not know and 24 per cent stated it was possible. Only 9 per cent said they would not use it. This indicates that with counselling and training, the FC2 could be

perceived as an effective option to prevent HIV, other sexually transmitted infections and unintended pregnancy among youth.

Summary

The teenagers who used the FC2 offered a positive assessment, with 80 per cent stating that the method was good or very good. Forty per cent of FC2 users asserted that they would continue using it in the future, and 24 per cent expressed that continued use was a possibility. Consistent with previous studies, the main reason for not using FC2 was the absence of sexual intercourse during the study's monitoring period (55 per cent).



HIGHLIGHTED IMPLEMENTER RESOURCES

5.1 Assess the Entire Ecosystem's Preparedness to Transform, Absorb and Scale up Innovations

Making the Case for Investing in Menstrual Health and Hygiene

Population Services International (PSI), PSI-Europe, The Case for Her, WASH United, and Simavi, Global Menstrual Collective; 2021; English

https://menstrualhygieneday.org/wp-content/uploads/2021/01/Making-the-Case-for-Investing-in-MHH-Report_Final.pdf

This report is a comprehensive guide for both why and how to invest in menstrual health and hygiene for the economic, educational and health benefits of women and girls in low- and middle-income countries around the world. It contains key recommendations at the community, organizational, national and global levels to effectively catalyse funding. These are presented alongside an overview of current progress and critical gaps, and barriers to investment.

Building Businesses for Girl Impact: Insights from Spring Accelerator

Spring Accelerator; 2019; English

www.springaccelerator.org/knowledge/building-businesses-for-girl-impact-insights-from-spring-accelerator

This report covers learning from 75 SPRING social businesses in nine South Asian and East African countries, together reaching over 2.5 million girls in 5 years. The lessons are compiled so that other accelerators, programmes, donors and ecosystem-builders can build on their experiences to better support businesses to innovate for impact.

Healthy Markets for Global Health: A Market Shaping Primer

US Agency for International Development (USAID) Center for Accelerating Innovation and Impact (CII); 2018; English

www.usaid.gov/sites/default/files/documents/1864/healthymarkets_primer_updated_2018.pdf

This Market Shaping Primer shares guidance gleaned from the field on the role market shaping can play in advancing the goals and objectives of global health. It seeks to synthesize these key principles into a flexible framework that can inform future market-shaping interventions across health sectors.

Scaling Innovation for Every Child

Accone, Tanya; United Nations Children's Fund (UNICEF); 2019; English

www.unicef.org/innovation/media/4551/file

This paper captures the strategies, models and critical success factors that emerged from 1,600-plus days of scaling up innovations for children across 90 countries by UNICEF's Global Innovation Centre.

5.2 Ensure Traction and Optimize Transition to Scale with Innovative Financing

Transition To Scale

Grand Challenge Canada; 2010; English

www.grandchallenges.ca/programs/transition-to-scale/

Grand Challenges Canada's Transition To Scale programme supports innovators from Canada and from low- and middle-income countries who are positioned to take their bold ideas to big impact in the area of global health. Through the programme, Grand Challenges Canada brokers smart partnerships that mobilize private capital and domestic public resources to generate scalable and sustainable solutions that deliver measurable social impact.



Financing for Scaled Impact

Clark, Catherine, Kimberly Langsam, Ellen Martin and Erin Worsham; Scaling Pathways; Innovation Investment Alliance, Skoll Foundation, and CASE at Duke; 2018; English

https://static.globalinnovationexchange.org/s3fs-public/asset/document/Scaling%20Pathways_Financing%20for%20Scaled%20Impact_0.pdf?goHK759iyLqBu2JoQoGwbaoGOI9j5Klw

The Scaling Pathways Series explores the strategies that leading social enterprises have taken to scale up their social impact. The Series includes Pivoting to Impact, highlighting critical lessons learned across geographies and sectors for enterprises and funders trying to unlock impact at scale; in-depth case studies, chronicling individual social enterprises' journeys to scale up; and theme studies, distilling insights and advice from a sample of social enterprises

Sharpening our Vision, Increasing our Velocity: Gender-Smart Investing Summit

Drakeman, Cynthia L., and Suzanne Biegrl; 2018; English

<https://www.gendersmartinvesting.com/2018-global-summit>

The report summarizes the themes, topics and takeaways unearthed over the course of the 2018 Gender-Smart Investing Summit. For attendees, it is a useful resource and reminder of key ideas and connections that inspired them to action on the day. For the wider community or those just beginning to realize the potential of gender-smart investing, it is a demonstration of the breadth, sophistication and diversity in the field.

5.3 Use Rigorous Evidence, Data and Analysis to Prioritize Innovation Portfolios

The PrEP Implementation Tool (PrEP-it)

Optimizing Prevention Technology Introduction on Schedule (OPTIONS) Consortium, Health Policy Plus (HP+) project and Efficiency and Accountability Technical Assistance to Partners II (EATAP-II) project; 2019; English

PrEP-it Excel worksheet: https://www.avenirhealth.org/download/software/PrEP-IT_v1_example.xlsx

PrEP-it frequently asked questions: https://www.prepwatch.org/wp-content/uploads/2019/11/PrEP-it_FAQ.pdf

PrEP-it user guide version 1.0: https://www.prepwatch.org/wp-content/uploads/2019/11/PrEP-it_UserGuide_sept24_2019.pdf

PrEP-it video tutorials: <https://prepwatch.org/prep-it-video-tutorials/>

Governments, donors and other stakeholders in countries at the forefront of PrEP delivery have encountered several programmatic challenges, such as difficulty in setting targets, tracking the continuum of PrEP delivery and estimating programme costs and impact. In response, the authors developed a Microsoft Excel-based tool called PrEP-it for oral PrEP implementation planning, monitoring and evaluation. PrEP-it assists with planning and monitoring via six primary functions: assessing site-level capacity and bottlenecks; tracking monthly initiation and continuation rates; national or subnational target-setting; forecasting drug supply needs; estimating programme costs; and estimating projected impact based on either programme targets or past performance.

The Dreams Innovation Challenge: Lessons in innovation for reducing adolescents' vulnerability to HIV

Fabel, Liz; DREAMS; 2019; English

https://publications.jsi.com/JSIInternet/Inc/Common/_download_pub.cfm?id=22907&lid=3

The DREAMS Innovation Challenge was launched to advance the PEPFAR's commitment to reducing HIV. Funded by the United States Department of State, Office of the Global AIDS Coordinator, and managed by JSI Research & Training Institute, the challenge spurred new partnerships and approaches in a multidimensional response to HIV prevention for adolescent girls and young women aged 15–24 years in sub-Saharan Africa in six focus areas: strengthening the capacity of communities to deliver services; keeping girls in secondary school; linking men to services; supporting PrEP; providing a bridge to employment; and applying data to increase impact.



GSMA mHealth Gender Toolkit: Key principles and tips for reaching women

GSM Association (GSMA); 2017; English

www.gsma.com/mobilefordevelopment/wp-content/uploads/2017/09/GSMA_mHealthGenderToolkit_2-08-17.pdf

This toolkit is a reference guide for mHealth value-added service providers and partners to help improve their services by making them more gender-inclusive and to reach more female users. The toolkit is designed to be read either as one whole document or as stand-alone sections if preferred.

Stanford Social Innovation Review: The next step for human-centred design in global public health

Johnson, Tracy, Jaspal S. Sandhu and Nikki Tyler; 2019; English

https://ssir.org/articles/entry/the_next_step_for_human_centered_design_in_global_public_health#

As human-centred design in global public health enters its adolescence, the authors offer a guide to help practitioners break through their misperceptions of people's needs to prescribe real solutions.

5.4 Coordinate an Integrated Approach that Combines Biomedical Prevention Technologies with Behavioural and Structural Enablers

Global Consultation on Lessons from Sexual and Reproductive Health Programming to Catalyse HIV Prevention for Adolescent Girls and Young Women

WHO; 2016; English

www.who.int/reproductivehealth/topics/linkages/WHO_Meeting_Rpt_HIV_Prevention_AGYW.pdf?ua=1

A global consultation was convened by the WHO Department of Reproductive Health and Research in April 2016 to review the factors contributing to achievements and challenges in improving the SRHR of adolescent girls and young women, especially those living in settings with high HIV incidence, and to identify elements of SRH interventions that make HIV prevention programmes more effective in reaching adolescent girls and young women in order to inform global policy, including the operational plan of the Global Strategy for Women's, Children's and Adolescents' Health. Examples of successful interventions were presented, and speakers and meeting participants explored the reasons for their success through questions and discussion, focusing in particular on the 'nuts and bolts' of the benefits of linking SRHR and HIV. A dynamic mix of participants included a balanced combination of experts in adolescent SRH and SRHR policies and programming; experts in HIV prevention research; youth advocates, aged 19–24 years, from a range of backgrounds and diverse settings in Africa, the Americas, Asia and Europe; and representatives and experts from key global health institutions, donor organizations and United Nations agencies.

An Advocates' Primer on Long-acting Injectable Cabotegravir for PrEP: Understanding the initial results of HPTN 083

AVAC; 2020; English

www.avac.org/advocates-primer-long-acting-injectable-prep

In 2020, the world learned new data from HPTN 083, a study of long-acting injectable cabotegravir (CAB-LA) for HIV prevention. This report summarizes the findings, unanswered questions and next steps for the development and introduction of CAB-LA.

5.5 Innovation and Market Systems Management Must Have a Clear Public Sector Steward

Sourcing & Management of Health Products: Market Shaping Strategy

The Global Fund; 2015; English

www.theglobalfund.org/en/sourcing-management/market-shaping-strategy/

The market-shaping strategy (2016–2021) defines how the Global Fund’s partnership can contribute to health outcomes by leveraging its position to facilitate healthier global markets for health products – today and in the future. The strategy details the Global Fund’s vision, principles, strategic objectives and more.

The Evolution and Future of HIV Prevention Technology: An HIV policy primer

McCarten-Gibbs, Margaret V., and Sara M. Allinder; Center for Strategic and International Studies; 2019;

English

www.csis.org/analysis/evolution-and-future-hiv-prevention-technology-hiv-policy-primer

This paper serves as a primer on the evolution of HIV prevention efforts, innovative new technologies and the outstanding barriers that keep critical tools from reaching those who would most benefit.

5.6 Public Innovators and Market Systems Must Collaborate to Engage the Critical Sectors that Shape the Lives of Girls and Young Women

Five Ways to Design Tech with Girls for Girls

Girl Effect & UNICEF; 2019; English

www.girleffect.org/stories/five-ways-design-tech-with-girls-for-girls

This blog presents five of the best practices the authors identified to help practitioners ensure that girls are not left behind in the digital world.

Technology, e-Health and HIV Programming

Avert; 2020; English

www.avert.org/technology-e-health-and-hiv-programming

This resource presents information on why e-health is important, how it is being used, the benefits for consumers and clinicians, barriers and limitations, and factors for successful project implementation.

Stanford Social Innovation Review: Marrying empathy and science to spread impact

Rao, Aarthi, Sandi McCoy, Jenny Liu and Lauren Hunter; 2019; English

https://ssir.org/articles/entry/marrying_empathy_and_science_to_spread_impact

A public health innovation shows that innovators can accelerate the diffusion of products with social impact by pairing design thinking and behavioural science.



PrEP Communications Accelerator

Optimizing Preventions Technology Introduction On Schedule (OPTIONS); 2016; English

<https://accelerator.prepwatch.org/about/>

This is a free, interactive digital resource that supports national governments, programme implementers and health practitioners to develop marketing and communications that drive demand for PrEP in sub-Saharan Africa. Both easy to use and information-rich, the accelerator offers tested guidance throughout the life cycle of a PrEP communications campaign and can be applicable across all PrEP formulations.

The accelerator also includes information about creating an enabling environment for PrEP with communications for the general population. The goal is not to encourage the use of PrEP by everyone, but rather to educate the whole population about PrEP and create general positive awareness for this HIV prevention method. Creating a supportive environment for PrEP is vital to its success.

Stronger Health Advocates, Greater Health Impacts: Markets matter advocacy guide

Path; 2017; English

https://path.azureedge.net/media/documents/APP_markets_matter_guide.pdf

This guide aims to make understanding markets easier and provides information and tools to support advocacy with policymakers and other key decision makers. It is designed primarily for experienced health-issue advocates who are new to thinking about markets. They will be able to deepen their public health impact by including a market perspective in their advocacy work and ensuring that health equity, choice and access are effectively reflected and realized.

Community Innovations

United Nations Programme on HIV/AIDS; 2020; English, French

www.unaids.org/en/resources/documents/2020/community-innovations

This publication is intended to spark interest, inquiry and discussion around community innovations. It draws on the response to the AIDS epidemic – a prime example of disruptive community innovations, not only in the health sector but also with far-reaching implications for nearly every aspect of people's lives – to show that innovation is about enabling communities to have the space, freedom and support to initiate and make changes for themselves.

Common Agenda for the Dapivirine Vaginal Ring

OPTIONS Consortium, International Partnerships for Microbicides and USAID/PEPFAR; 2019; English

<https://www.prepwatch.org/resource/common-agenda-dapivirine-ring/>

The common agenda is a shared guide for stakeholders working on the introduction of the dapivirine vaginal ring (DVR) and aims to keep stakeholders informed and engaged in a coordinated, efficient and transparent planning process for DVR introduction leading to scale-up with the goal of streamlining and accelerating collective efforts.

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