

UNAIDS 2019
Meeting report

Shaping oral PrEP modelling for high-burden countries in sub- Saharan Africa

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This meeting report contains the opinions and contributions of multiple stakeholders.
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Summary

The UNAIDS/ World Health Organization (WHO) meeting, *Shaping oral PrEP modelling for high-burden countries in sub-Saharan Africa*, was held in Geneva in June 2018. Meeting participants represented a broad range of oral pre-exposure prophylaxis (PrEP) stakeholders. They considered the model outputs required to advance PrEP programmes, the data and assumptions used in models, and decision-making around “reasonable use” of resources for PrEP. The principles covered in these discussions can apply to other biomedical HIV prevention tools.

PrEP roll-out is progressing in several countries in sub-Saharan Africa, despite often weak data for decision-making. Programme priorities for PrEP programme planning were summarized as the following:

- Identifying groups at substantial HIV risk by behaviour and location.
- Making population size estimates of these groups.
- Defining the PrEP package for various populations.
- Integrating PrEP delivery with other health services.
- Estimating costs for PrEP delivery, differentiated by delivery channel, population and location.
- Linking PrEP coverage and uptake to the impact on the national and sub-national epidemics

To guide HIV resource allocation, models have been developed that include cost, impact, prevention alternatives, time frame and available resources. For optimal resource allocation, PrEP provision needs to be aligned to the risk of HIV infection, with rapid roll-out and service integration. Modelling approaches to the heterogeneity of the risk of infection in populations are improving, but data specific to key populations in sub-Saharan Africa are not yet systematically available. The extensive PrEP cost-effectiveness modelling will only be improved when better real-life data about uptake and adherence become available.

The following data on key populations and other priority populations were flagged as particularly weak:

- Subnational incidence data and other markers of HIV risk, disaggregated by age and behaviour.
- Real-life PrEP uptake and adherence data, and their association with the risk of HIV infection.
- Varying patterns of effective PrEP use (e.g. daily, event-driven or during seasons of risk).
- The feasible uptake and impact of other prevention methods.
- Cost of the PrEP packages and different service delivery models, including scale-up.
- Estimated costs to the user and willingness to pay.

The introduction of PrEP is anticipated to have explicit collateral effects through engaging individuals at high risk of HIV infection. These effects could include an increase in diagnosis and treatment of HIV and other sexually transmitted infections (STIs), and improved uptake of various primary health-care services. Collateral effects and costs of prevention programmes are not routinely evaluated in comparative cost-effectiveness exercises.

Mathematical models also lack the necessary data related to benefits, policy prioritization and choice that influence HIV prevention programme decisions, such as the following:

- Equity of service provision and prioritization of populations for reasons other than HIV risk.
- Unknowns, such as future preferences for PrEP formulation (e.g. oral, vaginal ring or long-acting injectable).
- Behavioural, structural and syndemic factors that affect HIV prevention uptake and continuation.

Economic evaluation approaches to combination HIV prevention (including PrEP) need to be standardized. Making the best use of models in HIV prevention will involve partnerships between programme planners, modellers, communities and funders working to address their well-defined questions. Country ownership of data and engagement of priority populations in programme monitoring and evaluation are key to achieving sustainable and effective prevention programmes. Investment now in data quality and implementation and behavioural research, will improve the quantification of parameters for future models.

Next steps

1. Continue to foster collaboration between stakeholders to set modelling priorities and improve the application of modelled guidance to PrEP programming and resource allocation.

Action: UNAIDS to explore ways to convene (virtually) Ministry of Health representatives, modellers (including economists) and all relevant international agencies to agree on some precise, setting-specific policy modelling questions for which data are available. UNAIDS will facilitate access to relevant data for the modelling to take place.

2. Prioritize the improvement of data for PrEP programme costing to strengthen future mathematical modelling.

Action: WHO will work with countries and other stakeholders (e.g., the Clinton Health Access Initiative [CHAI], OPTIONS and investment case modellers) on monitoring and costing of PrEP in combination prevention packages and to support best practices for PrEP costing.

3. Describe the likely collateral effects of PrEP programmes and explore ways of capturing them.

Action: UNAIDS will collate examples of the measurement of collateral effects and costs of PrEP introduction.

4. Evaluate the high-risk population size estimation tool presented in the meeting for use in strengthening target-setting at the local level.

Action: UNAIDS and WHO will work with countries ready and interested in the evaluation.

5. Develop and disseminate the conceptual framework of overlapping determinants for effective PrEP use, including objective HIV risk.

Action UNAIDS and WHO to develop the draft framework

6. Incorporate the meeting outcomes into the UNAIDS 2025 AIDS targets process and prevention policy debate. Continue to liaise with active partners to improve the way that primary prevention is represented in the modelling to end the epidemic.

Action: Ongoing via the UNAIDS Secretariat with multiple stakeholders.

Meeting agenda
Day 1:Background

Time	Presenters	Topic and discussion points
8:30		Coffee
Session 1: Setting the scene Chairperson: Katharine Kripke		
9:15	Tim Martineau Acting DXD, UNAIDS Gottfried Hirnschall Director, WHO	Welcome, opening remarks and introductions
9:30	Jessica Jones Bill & Melinda Gates Foundation	Feedback and action points from the previous PrEP modelling meeting, April 2018
9:45	Peter Godfrey-Faussett UNAIDS	Meeting objectives
10:00	Rachel Baggaley WHO	Where and how is PrEP accessed?
10:20	Mitchell Warren AVAC	Future PrEP formulations
10:40	Break	
11:10	Kelsey Case Imperial College, London	Review of PrEP modelling activities in sub-Saharan Africa
11:30	John Stover Avenir Health	Strengths and weaknesses of modelling the prevention package to guide HIV programme planning
11:50	Paul Revill University of York	The strengths and weaknesses of economic modelling and budget impact guidance for PrEP
12:10	Moderated discussion Kelsey Case Paul Revill John Stover	How can models best be used to guide prevention implementation and resource allocation at the country level? Spotlight on the gaps in modelling Moderator: Andrew Phillips

13:00	Lunch	
Session 2: Who are the models for? Chairperson: Julie Franks		
14:00	Delivette Castor USAID Discussion (20 minutes)	The principles of setting targets where data are incomplete Moderator: Jerry Jacobson
14:30	Irene Mukui Ministry of Health, Kenya Urbanus Kioko University of Nairobi Questions	Case studies: use of data in setting and costing PrEP targets
15:00	Break	
15:30	Hasina Subedar National Department of Health, South Africa Lise Jamieson HE2RO, South Africa Getrude Ncube Ministry of Health and Child Care, Zimbabwe Isaac Taramusi National AIDS Council, Zimbabwe Questions	Case studies: use of data in setting and costing PrEP targets
16:30	Moderated panel discussion with country programme presenters	What data are important for country PrEP programmes? Moderator: Peter Godfrey-Faussett
17:00	Peter Godfrey-Faussett	How has today moved us towards the meeting objectives?

Day 2: Data and models

Time	Presenters	Topic and discussion points
<p>Session 3: Best use of geographical, behaviour and network data to improve modelling for impact Chairperson: Kelsey Case</p>		
09:00	Rosalind Coleman UNAIDS	Update from yesterday; looking forward to today's agenda
<p>Geolocalized data</p>		
09:10	<p>Tim Hallett Imperial College, London</p> <p>Katharine Kripke Avenir Health</p> <p>Discussion (50 minutes)</p>	<p>Identifying to whom PrEP should be offered</p> <p>Balancing cost-effectiveness and impact when prioritizing PrEP service provision</p> <p>Moderator: Geoff Garnett</p>
10:40	Break	
<p>Behavioural and structural risk data</p>		
11:10	<p>Jerry Jacobson CDC consultant</p> <p>Connie Celum University of Washington</p> <p>Discussion (50 minutes)</p>	<p>Setting PrEP targets with key populations using localized behavioural data</p> <p>Prioritizing PrEP delivery in a generalized epidemic: is risk quantification a help or a hindrance?</p> <p>Moderator: Dawn Smith</p>
12:40	Lunch	
<p>Session 3 (continued) Chairperson: Ombeni Mwerinde</p>		
<p>Network data</p>		
13:40	<p>Pam Gumbi</p> <p>CAPRISA</p> <p>Iryna Zablotska Kirby Institute</p>	<p>Social network analysis in generalized epidemics to increase PrEP's impact</p> <p>Understanding the public health impact of PrEP from post-hoc demographic, network and other behaviour data</p>

	Discussion (50 minutes)	Moderator: Katie Callahan
15:10	Group work, including break	Critique of models and their translation to programmes
16:30	Feedback from the groups and discussion	Moderator: Julie Franks ICAP
17.15	Peter Godfrey-Faussett	How has today moved us towards the meeting objectives?

Day 3: Implementing PrEP in HIV prevention programmes

Time	Presenters	Topic and discussion points
<p>Session 4: Getting practical: demand, delivery, capacity, costing and resource allocation</p> <p>Chairperson: Michelle Morrison</p>		
09:00	Rosalind Coleman UNAIDS	Update from yesterday; looking forward to today's agenda
09:10	Jeffrey Wambaya, ISHTAR Carolyn Njoroge KESWA Phindile Ngcobo CAPRISA Moderated discussion (30 minutes)	How can PrEP fit in with the HIV programmes for my community? Moderator: Michelle Rodolph
10:00	Daniel Were Jilinde PrEP Project, Kenya	Service delivery models and capacity requirements for PrEP provision integrated with other services

	<p>Katie Callahan CHAI</p> <p>Discussion (25 minutes)</p>	<p>The practicalities of costing PrEP in country programmes and estimating the collateral benefits of PrEP</p> <p>Moderator: Connie Celum</p>
10:45	Break	
11:15	<p>Delivette Castor</p> <p>Discussion (30 minutes)</p>	<p>Prioritization of PrEP when resources are limited</p> <p>Moderator: Shona Dalal</p>
12:00	All participants	<p>What is the pathway from current modelling to accelerated PrEP scale-up?</p> <p>Moderator: Rachel Baggaley</p>
12:45	Peter Godfrey-Faussett	Wrapping up and close

Themes and discussions

Summary of the meeting discussions in plenary and groups, informed by the presentations.

Data for modelling the impact of interventions

Modelling PrEP's effect on HIV transmission requires, at the very least, data on HIV incidence and on PrEP efficacy, coverage, uptake and adherence. Efficacy data are available for all populations, but other data are either insufficient at the subnational level or not well-characterized due to limited implementation experience.

Programme planners need more granular information on risk beyond high-level incidence. Drilling down into the distribution of risk within different incidence bands requires disaggregation of data by geographic locality, age and behaviour. Describing the distribution of risk is most important in populations where the overall incidence is low. Supplementary data on other biological or behavioural factors that influence transmission could include the use of other HIV prevention methods, viral load and STI prevalence.

Coverage, uptake and adherence influence the magnitude of any impact of PrEP, but data on them are not available for models. What is also needed is quantification of the relationship between the risk of HIV infection and PrEP uptake and adherence among different populations and in different contexts.

Improving data use for impact estimation

The recently developed Incidence Patterns Model (IPM) and geospatial HIVE-Map are examples of models designed to improve the description of population and geographic heterogeneity of incidence.¹ Work using IPM and Goals models in eastern and southern Africa confirm that countries vary with respect to the relative impact and cost-effectiveness of PrEP in different key and priority populations, including by subnational geographic region. This modelling has helped guide national programme decisions and identified groups where expanding PrEP coverage can be a good use of resources.

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¹ The IPM (based on Demographic Health Surveys, integrated biological and behavioural surveillance surveys and local survey data) uses HIV transmission likelihood to estimate incidence with geographical disaggregation in groups of people according to marital history, whether or not they are a member of a key population, whether they are the negative partner in a sero-different couple, and their male circumcision status (where applicable). IPM therefore allows consideration of previously unrepresented risk groups but does not consider age or viral load. The HIVE-Map model (based on survey and routine service delivery data) distributes new infections geographically based on the number of people living with HIV and levels of antiretroviral therapy coverage, but it does not capture any behavioural or structural determinants of incidence distribution.

Collaboration between external funders, modellers, programme planners and all those who collect data should lead to identification of data gaps and needs, and more efficient use of existing data. Community groups from key and priority populations should be engaged in data gathering and data use to enhance programme planning. A possible way to start would be for members of key populations to be supported to collect data relevant to transmission likelihood in order to improve local incidence and risk estimates. It is important to remember that experience, legitimacy and freedom of expression vary between community organizations, and that approaches to ensuring their participation should be shaped by the legislative and structural context in which they operate. Optimizing data security and transparency about data use is vital to maintaining trust and collaboration.

Economic evaluation of PrEP for resource allocation

The implementation of PrEP has been evaluated as a good use of resources for specific subgroups within key and priority populations. The identified groups all have high levels of HIV infection risk and may also have a high likelihood of onward transmission of HIV if they do become infected. Such groups include seronegative partners before viral suppression is reached for their partner living with HIV, male sex workers within a population of gay men and other men who have sex with men, adolescent girls and young women in places of very high HIV incidence, and young women beginning transactional sex in places where there is high prevalence of untreated HIV in male partners.

The resource-use evaluations considered the relative cost and impact of different components of prevention packages (including PrEP) that are provided through a standardized service and modelled in low-resource contexts.

Modelling of risk heterogeneity in populations will demonstrate the situations of greatest PrEP impact and find the settings where PrEP becomes cost-effective or cost-saving.

The existing model outcomes identify populations that *should* be given PrEP from an epidemiological and economic perspective. Additional criteria that countries will factor into pragmatic decisions about the good use of resources relate to identifying people who *would* take PrEP. These criteria could include predicted PrEP uptake patterns (based on programme experience and levels of demand), capacity to deliver PrEP in a stigma-free and convenient service, and the total budget available.

Although starting with populations that are easy to reach with PrEP will cost less, the gap to more marginalized populations will eventually need to be bridged. Finding and engaging people at high risk of HIV who are not currently using HIV-related services tends to be more costly.

Modelling can contribute to the debate on the strategic use of resources by specifically considering populations that are currently left behind and asking what it will take to end the HIV epidemic. Improving the range of populations considered in models will show more

clearly that the persistent and unaffordable HIV transmission cycle will only be broken through the engagement of key and most-affected populations. The extra costs can also be justified from the perspective of human rights and equity.

Challenges in cost-effectiveness evaluation of combination HIV prevention, including PrEP

Comparing different approaches to service provision

Various models of PrEP provision are being proposed, including decentralization of services with task shifting and PrEP provision differentiated by population. It is difficult to improve the modelling to compare programmes in the absence of real-life uptake, adherence and cost data. Only once PrEP is being used at scale, with adherence and costs better described, will we know its comparative cost-effectiveness in different situations.

Collateral effects and costs of PrEP provision

PrEP provision is likely to have a range of collateral effects and associated costs. The offer of PrEP through convenient and non-stigmatizing services can have an explicit additional effect of engaging individuals at high risk of HIV infection who have not found suitable prevention methods that they can use consistently. User-friendly services attract people with other health needs, including people for whom the risk of HIV is one element of a syndemic of health-related issues.

The integration of PrEP into comprehensive services could: increase uptake of testing, diagnosis and treatment of HIV and other STIs; improve interest in all HIV primary prevention strategies; and lead to better management of comorbidities (such as mental health problems). No clear pattern of changes in STI incidence related to PrEP has yet emerged and the effect of PrEP on the incidence of STIs should be monitored.

Capturing the collateral effects of PrEP provision and adjusting costs accordingly is not being done. Collateral effects are not routinely considered when evaluating any biomedical prevention service, although they may be important and vary between prevention options. The resource needs for demand creation and community support development also need to be transparently factored into all prevention programme resource needs estimates.

Comparative impact of PrEP and other HIV prevention, specifically for key and other priority populations

PrEP is intended as a prevention choice for people at high risk of HIV infection who do not or cannot use other methods of HIV prevention. Many modelling studies have assumed levels of uptake and impact of other highly cost-effective prevention interventions that may not be realistic for key and other priority populations. This includes the predicted uptake and prevention impact of antiretroviral therapy for people living with HIV among key and priority populations.

Data collection relevant to PrEP should be standardized, with assessment of all prevention methods, including evaluation of the likelihood that populations would use them. Choice experiments and other qualitative work with the populations concerned will be necessary to evaluate this.

PrEP, testing and antiretroviral therapy cost avoided

When comparing costs saved through prevention of an infection, the main saving is the avoidance of antiretroviral therapy. The modelled decrease in life expectancy from becoming infected with HIV has been estimated at almost zero if treatment to viral suppression is available. Therefore, the life-years gained from not becoming infected with HIV are minimal. A standardized approach is required for estimating the quality-adjusted life years (QALY) gained from preventing HIV infection.

Demand creation and HIV testing services are synergistic in identifying people earlier for either treatment or PrEP. The earlier in a period of risk that effective HIV prevention is adopted, the greater its cost effectiveness. Primary prevention examples of this principle include HIV-negative people at the start of a sero-different partnership or young women transitioning to sex work, or at the onset of a localized micro-epidemic.

Alignment of PrEP uptake and HIV risk for maximum cost-benefit

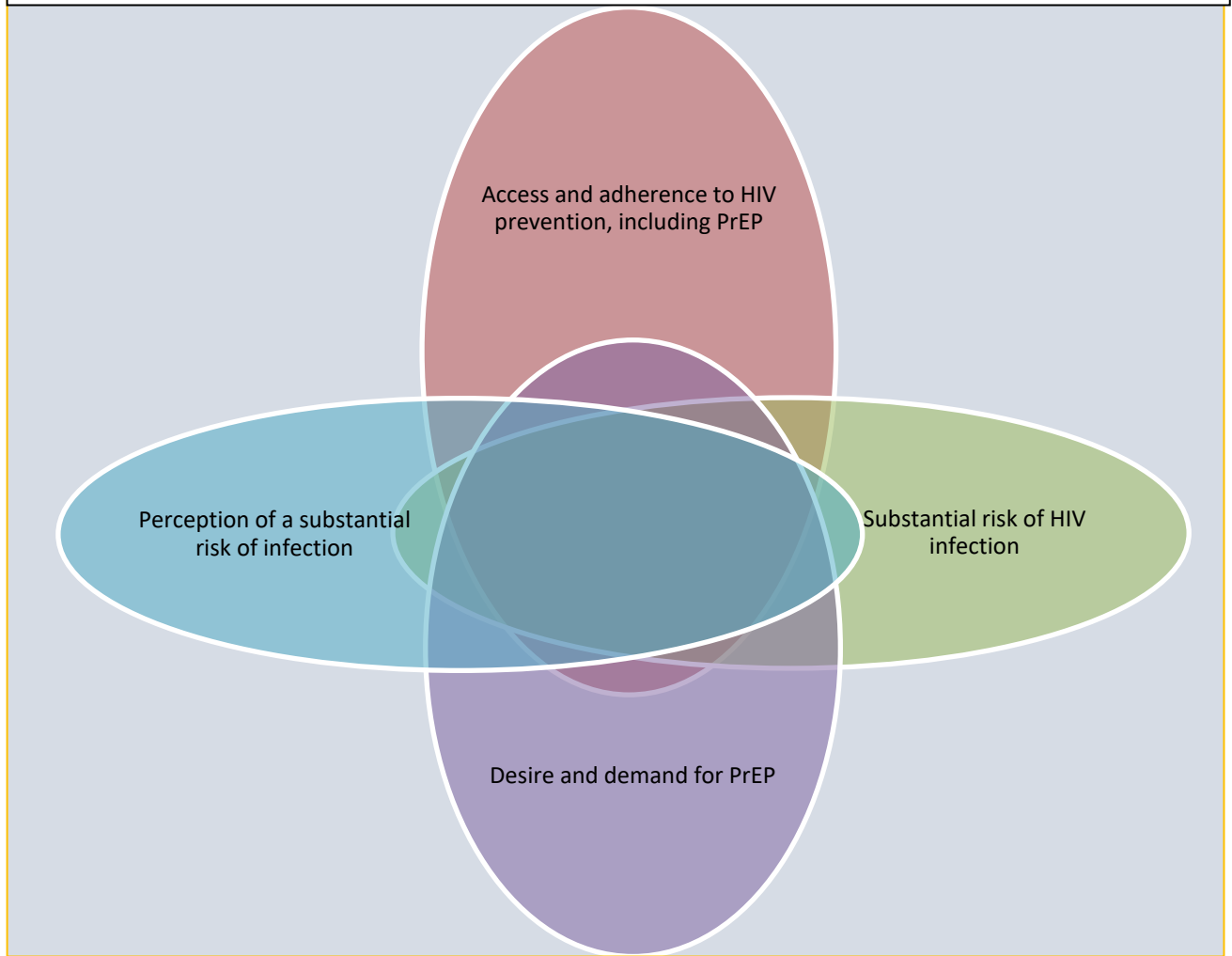
To maximize the benefits of a given investment, it is vital to align PrEP uptake and adherence as closely as possible to the individual's actual HIV risk. There is limited understanding of the interplay of individual-level factors that influence effective PrEP use and their alignment to the actual risk of HIV.

Programme experience indicates that, where knowledge of PrEP is good, there are quantifiable associations between HIV risk and desire for PrEP, as well as between access to PrEP, uptake of PrEP and effective adherence. A conceptual framework of the overlapping determinants of individual HIV prevention uptake could be constructed (a simplified outline appears in the figure). Development of this conceptual framework would involve identifying and evaluating the influences on each of the factors that could be amenable to intervention.

Programme development should aim to make the central *sweet spot*—where all determinants overlap—as large as possible; this would achieve the greatest programmatic impact. Imbalance between the four determinants represent apoints to intervene.

Figure

Simplified conceptual framework of the determinants of primary HIV prevention uptake, including PrEP



From modelling results to country programmes

It is crucial to determine how to target PrEP provision to achieve an impact on the epidemic that could not feasibly be achieved by investment in other primary prevention methods while controlling costs.

Setting coverage targets to guide programme planning and budgeting

Estimating the total number of people at substantial risk of HIV infection is a first step in setting the coverage target for PrEP. A guide level of 3% annual incidence has been suggested as identifying substantial risk, calculated as the level of incidence at which PrEP becomes a cost-saving compared to the antiretroviral therapy costs for the infections prevented.

The 3% guide level is not a magic number that alone will determine the reasonable use of resources: The prevention impact could be increased if uptake was broadened to populations with a lower HIV risk, but at rapidly increasing cost. What the guide level of 3% does achieve, however, is to illustrate that PrEP is intended for people at very high risk of infection, and that the incident risk is one important factor in PrEP target guidance and budget-setting.

Accurate population size estimation of those at substantial risk becomes more important as the heterogeneity of risk in the population increases. A prototype priority population-size estimate tool was presented. It uses the background risk of HIV transmission to estimate the number of condomless sex acts required to increase the individual risk of HIV infection to an incidence threshold (e.g., 3%). The tool is intended for local use, so the population size of people likely to reach the incidence threshold would come from bio-behavioural survey data of numbers of condomless sex acts.

Combining such an approach with other population size estimation methods would enable triangulation and validation of results. It remains to be seen if generalizable trends will emerge for the proportions of different priority populations that are at high risk, including in different types of epidemics.

Avoidance of stigma and attracting people for PrEP

The target-setting process should not be visible in public-facing PrEP health promotion. The risk-based approach does not necessarily engage people with less access to health care or those for whom the message of being at-risk does not resonate. For example, younger women at the fringes of transactional sex do not self-identify as sex workers but may have the highest HIV incidence.

PrEP demand creation that focuses too much on risk can slow roll-out and reinforce stigma. Advertising PrEP as a healthy choice that responds to people's needs, and promoting it through channels that are appropriate to the respective population is more attractive. Important figures—such as faith-based leaders, politicians and opinion formers—need to be included in health promotion. Separate messages can be more focused towards (and shaped by) health-care workers and key and other priority populations.

The role of external funders in PrEP target-setting and evaluation

Normative guidance and external funding have been the supranational factors that have led to the inclusion of PrEP in HIV programmes. Bottlenecks persist at the policy, regulatory and service levels that slow the process of PrEP implementation. Perception from countries was that external PrEP coverage targets have been set, resources allocated, and evaluation designed by external funders who do not always coordinate within countries. External targets have sometimes been set without sufficient attention to service capacity, demand creation and community engagement. This undermines country ownership of programmes and rarely engages the populations for whom PrEP is intended.

External funding could be used to strengthen data collection processes, including for use in funding applications. A long-term view of programme development—which avoids a make-or-break evaluation of immature programmes—will give programmes the opportunity to reach their full potential. This is one of the important lessons learned from the introduction of voluntary medical male circumcision (VMMC).

Although much of the current funding for PrEP in low- and middle-income countries is from external sources, country and community ownership of programmatic responses and data is needed if new interventions are to be sustainable and effective.

Sustainability and the future

Models should project far enough into the future (to 2030 or further) to capture the full consequences of current prevention activity and investment. Mathematical modelling of the impact of different interventions demonstrates that primary prevention will be essential for ending the HIV epidemic.

Governments intend to expand PrEP in sustainable HIV prevention programmes through integration with other health services, differentiated service delivery, improved community involvement and diversification of funding. More guidance is needed on prevention investment relevant to such programmatic directions.

Programmatic results are showing wide variation in the uptake and effect of PrEP between different populations, with the greatest impact seen in concentrated and highly socialized populations of gay men and other men who have sex with men. The modelling challenge remains to define the role of PrEP and other components of effective prevention packages for future populations and their varied prevention needs.

Predicted changes in pricing of antiretroviral medicines—as well as the anticipated impact of increased treatment to viral suppression—both need to be factored into the future cost-saving and cost-effectiveness estimations for PrEP. The trade-off between cost-effectiveness and impact will be influenced by the changing cost of delivery of primary prevention. New PrEP delivery methods such as the vaginal ring or long-acting formulations also need to be incorporated.

Any development of PrEP-related resistance to antiretroviral medicines associated with PrEP that is disproportionate to the resistance averted through avoiding treatment exposure will require a re-evaluation of PrEP recruitment and adherence patterns.

Conclusions

Optimizing the use of data for primary prevention programme planning and evaluation and guiding budgetary decisions is an immediate priority for programme planners. Research priorities relate to options for prevention scale-up and strategies to achieve maximum impact on the HIV epidemic. While external funding is available, there is an urgent need to conduct the modelling, costing and implementation research that is relevant to PrEP and all primary prevention interventions.

An agreed country policy objective for PrEP in combination prevention will guide data collection and strengthen programmatic decisions. Specific modelling questions should be clearly defined through collaboration between programme managers, mathematical modellers and international agencies. Then data requirements can be identified, and models can be constructed, that respond to country needs and strengthen programme decisions.

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