UNAIDS 2025

Consultation on the Projected Impact and Cost-Effectiveness of Long-Acting Injectable Lenacapavir as Pre-Exposure Prophylaxis

A meeting in collaboration with the Gates Foundation

Disclaimer This meeting report contains the opinions and contributions of multiple stakeholders. The content does not necessarily reflect the position of UNAIDS.

Contents

Summary and key messages

Background

- UNAIDS and the Gates Foundation convened a meeting on 5-6 June, 2025 to consider mathematical modelling evidence on the anticipated epidemiologic impact and cost-efficiency of long-acting injectable lenacapavir (LEN) for HIV prevention in low- and middle-income countries.

Key messages

- Even with countries reaching 95-95-95 goals for testing, treatment, and viral suppression, there remains ongoing new HIV infections which can be averted by primary prevention.
- Pre-Exposure Prophylaxis (PrEP) programs, including LEN, can contribute to reducing incidence.
- LEN programmes will be a cost-effective use of health resources if they are able to identify and deliver LEN to people at the greatest risk of acquiring HIV infection.

Consensus on priority questions

- Delivering 6 million person-years of protection with LEN in the first three years of product introduction could avert up to 100,000 new HIV infections.
    - Although an important impact on averting some global new infections in the next three years, the main objective of the accelerated introduction is to establish a foundation for a more substantial and impactful long-term market for LEN as part of an HIV prevention portfolio to accelerate and sustain declining new HIV infections over several decades.
- With higher volumes, 5% total population coverage of LEN could avert 20-35% of anticipated new HIV infections, while or 20% total population coverage could avert 50% of new infections.
- LEN could be cost-saving compared to avoided costs of lifelong ART through averted infections at a total price of approximately $40-60 per person per year (commodities and delivery), when delivered to populations with expected HIV incidence of greater than 1% per year in the absence of LEN.
- Meeting participants emphasized the message that LEN has the potential to be a key component to achieving and sustaining the end of the epidemic.

Recommendations and next steps

- A roadmap should be developed to help countries and funders decide if, where, and how to implement LEN programs and what modelling tools can assist them.
    - This should include a user’s guide on how to use each of the current modelling tools and what are the key attributes of each model or tool.

Background

UNAIDS and the Gates Foundation convened a meeting from 5-6 June 2025 to consider mathematical modelling evidence on the anticipated impact and cost-efficiency of lenacapavir (LEN) rollout in low- and middle-income countries. Participants were comprised of pre-exposure prophylaxis (PrEP) program implementers, national program managers, mathematical modelling researchers, international funders, and civil society representatives. The purpose of the meeting was to establish consensus expectations on the three broad questions about (1) the potential impact of LEN, (2) focus locations and populations for LEN rollout, and (3) the cost-effectiveness of LEN.

Topic prioritization among 12 potential questions was determined through a pre-meeting survey questions circulated to country program managers, policymakers, and the civil society caucus of the long-acting PrEP coalition. Questions proposed were those that could be answered by modelling. Participants were asked to rank the following questions in order of importance, with 1 being the most important and 12 being the least important:

1. What would be the realistic number of infections averted over a 3-year period, if different volumes (50,000 to 2,000,000 person-years) of long-acting injectable PrEP (LAI PrEP) were allocated across 5 early adopter countries?
2. What is the long-term impact (over 20 years) of a short-term investment in LAI PrEP, if provision ceases after 3 years?
3. How many person-years of long-acting injectable PrEP would be needed to avert 50% of new infections compared to baseline by X year?
4. What volume of LAI PrEP would be needed to offset potential reductions in treatment coverage due to international funding disruptions?
5. What is the benefit of switching to LEN from long-acting injectable cabotegravir (CAB-LA) in terms of impact?
6. Which strategies of prioritizing LAI PrEP require the lowest number needed to treat while maximizing impact (e.g., key populations, pregnant/breastfeeding women, spatial allocation)?
7. In which geographies and/or populations does LAI PrEP make the most impact on HIV incidence and/or new infections?
8. What is the optimal way to offer choice among multiple PrEP modalities (e.g., oral, CAB-LA and LEN) for different populations?
9. What is the budget impact of providing 50,000 to 2,000,000 person-years of over 3-years? What would be affordability for governments/programs in the future?
10. At what price point would it be more cost-effective for governments to invest in LAI PrEP, compared to other existing prevention methods?
11. In what scenarios should local governments consider spending domestic resources on LAI PrEP vs. other broader health considerations after donor-funded LAI PrEP stops?
12. How does cost-effectiveness vary as a LAI PrEP program expands and becomes less targeted?

Participants' ranking of the questions are shown in Table 1, with two additional questions suggested through open responses:

- What is the point of return to investment based on different expected prices of LEN?
- What is the potential benefit of shifting from oral PrEP to the long-acting injection – is it financially and epidemiologically worthy?

Five prioritized questions (questions 1, 3, 4, 6, and 10), including at least one question from each of the three key topics for the meeting (impact, focus populations, and cost-effectiveness), were circulated to modellers to address in advance from ongoing modelling work to build consensus around answers.

Questions from countries about LEN implementation

At the start of the meeting national programme managers and a representative of communities affected by HIV from South Africa, Zambia, and Thailand shared their key questions about LEN implementation to frame how modelling could be most useful for informing country decision-making. These questions included:

- With limited resources and constrained budgets, what is the investment case for introducing LEN?
- At what price point would LEN be cost-saving for governments?
- What are the projected infections averted and cost-efficiency with different volumes of LEN?
- How can LEN use be prioritized for high-risk groups without creating stigma? For example if it is rolled out as a programme that is focused on key populations, willl that have implications for uptake. While this is not easily answered from modeling it is equally important to ensure the best outcomes for people at risk of HIV.
- How do we decide which HIV prevention products are best suited for an individual country's needs?
- How do we minimize disruption to current interventions, given changes in the international funding landscape, while introducing a new product?
- What can communities do to reach those populations in greatest need of LEN?

Participants agreed that each of these questions are very important but also recognized some of the questions are more applicable to implementation science research or other methods, rather than mathematical modelling, but were important to reflect on during the discussions.

Existing modelling evidence on LEN impact and cost-efficiency

Two studies using the EMOD-HIV model investigated the impact and maximum price per dose for LEN in South Africa, Western Kenya, and Zimbabwe. One study by Wu *et al.* found that LEN could avert 12-21% of new infections over 10 years when scaled up among key populations. The maximum price per dose at which LEN would be cost-effective relative to a willingness-to-pay threshold of $500 per DALY averted – when isolated to the price of the drug only and assuming two doses per year – would be $106 in South Africa, $21 in Zimbabwe, and $17 in western Kenya. A second EMOD-HIV study including the fully-loaded cost of delivering LEN, including commodities and delivery costs, found that the per-dose price of LEN could only be up to $53 in South Africa, $15 in Zimbabwe, and $8 in western Kenya.

A study using the Thembisa model for South Africa found that LEN could avert 27-41% of new infections over 20 years, with moderate to high uptake among key populations. The study estimated that LEN could cost a maximum of $225 PPPY to be cost-effective compared to expanded oral PrEP. LEN was projected to have a greater impact than both expanded oral PrEP and long-acting injectable cabotegravir due to its higher effectiveness, assumed increased uptake, and assumed longer duration of effective use.

A study by Yeo *et al*. of the cost-effectiveness of different types of PrEP in Zimbabwe found that long-acting injectable PrEP would be the most cost-efficient type of PrEP to scale up, with an incremental cost-effectiveness ratio (ICER) of ~$1,000 per DALY averted when used among female sex workers (FSW).

In both models, the cost per DALY averted increased when total adult population coverage increased. Expanded use of LEN resulted in a higher total impact on infections averted, but less efficiently.

Potential impact with current commodity commitments

The Global Fund and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) publicly announced in December 2024, in conjunction with the Children's Investment Fund Foundation (CIFF) and the Gates Foundation, an intention to provide access to LEN for at least 2 million person-years of protection over three years. Modellers were asked to consider the impact of providing 1 million, 2 million and 6 million person-years (PY) of LEN over three years, when delivered strategically to populations and locations with high HIV incidence risk (Table 2). Two modelling groups provided estimates for this question, using the following models:

- EMOD-HIV, an agent-based model, analyzed results in South Africa and Zimbabwe
- Goals, a deterministic compartmental model, analyzed results in South Africa, the Philippines, and Eswatini

The Goals scenarios (for South Africa, the Philippines, and Eswatini) assumed that up to 50% of the delivery would be to key populations, with the remaining volume delivered to medium-risk populations, regardless of total volume. The EMOD scenarios for South Africa assumed that LEN would be offered initially to women using the Vaginal and Oral Interventions to Control the Epidemic (VOICE) score, a risk scoring tool to identify individuals at high risk of acquiring HIV based on behavioral and demographic characteristics. In South Africa, LEN was assumed to be offered to women only with a VOICE score ≥6 for a volume of 1 million PY, women only with a VOICE score ≥5 for a volume of 2 million PY, and women with a VOICE score ≥5 and men with more than one partner for a volume of 6 million PY. In Zimbabwe, LEN was assumed to be offered to women with a VOICE score ≥1 and men with more than one partner for a volume of 1 million PY and all sexually active women for volumes of 2 and 6 million PY.

Table 2: HIV infections averted with varying volumes of lenacapavir over a 3-year period, when provided strategically to example locations and high-incidence populations

	Lenacapavir Volume Over 3 Years		
	1 million PY	**2 million PY**	**6 million PY**
South Africa	22,000 - 38,000	29,000 - 47,000	60,000 - 73,000
Zimbabwe	9,000	11,000	18,000
Philippines	17,000	33,000	53,000
South Africa + Philippines + Eswatini	41,000	57,000	103,000

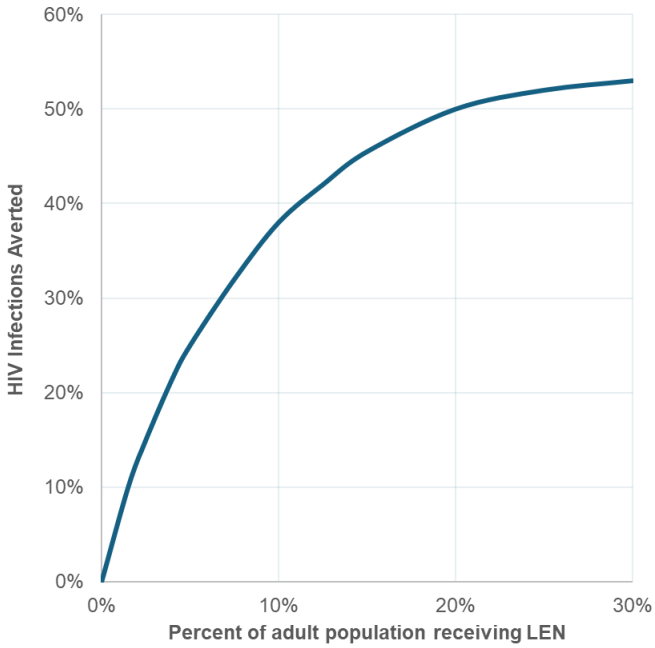
PY = person-years. Ranges represent results from multiple models (EMOD-HIV and Goals).

The number of infections averted over three years varied substantially based on volume and location, with all settings exhibiting diminishing efficiency as the volume of LEN increased. In Zimbabwe, impact was limited by a smaller total number of high-risk individuals, compared to other locations. The greatest impact was achieved when the volume of LEN was distributed to three high-incidence settings (South Africa, the Philippines, and Eswatini), with over 40% more infections averted in the highest volume scenario compared to any single country alone. Overall, providing 1 to 6 million person-years of LEN over three years would avert a small proportion of the total 3.8 million new HIV infections expected to occur over that period; effective initial implementation is a critical step to build a substantial and impactful market for LEN as part of a sustained HIV prevention portfolio to sustain global targets.

Potential impact of LEN with varying coverage and volume

Modellers were asked to assess how the percentage of infections averted varied as population coverage increased to understand what coverage and volume would be needed to avert a given proportion of infections across different settings (Figure 1).

Figure 2. Expected HIV infections averted with increasing population coverage of LEN in a generalized epidemic



Source. Illustrative heuristic informed by simulation results from EMOD model.

Across different types of epidemics (e.g., a high incidence generalized epidemic like South Africa, a moderate incidence generalized epidemic like western Kenya, and a high incidence concentrated epidemic like the Philippines):

- In a concentrated epidemic, providing LEN to 60% of the highest risk key populations (equivalent to 2% total adult population coverage) could avert 45% of new infections
    - Key populations (men who have sex with men [MSM], transgender women, sex workers, and people who inject drugs [PWID]) make up 3% of the total population in the Philippines and comprise ~80% of new infections
    - 60% key population coverage (2% population coverage) equal to about 1.1 million adults aged 15-49 in the Philippines
- In a generalized epidemic, providing LEN to about 5% of the adult population and prioritizing to those at highest risk by geographic location and individual risk characteristics could avert 25-35% of new infections
    - 5% population coverage or about 1.4 million adults aged 15-49 in South Africa, 1.5 million adults aged 15-49 in Kenya, and 400,000 adults aged 15-49 in Zimbabwe
- In a generalized epidemic, providing LEN to 20% of the adult population and prioritizing by location and behavior would avert 50-70% of new infections

- 20% population coverage or about 5.6 million adults aged 15-49 in South Africa, about 6 million adults aged 15-49 in Kenya, and 1.6 million adults aged 15-49 in Zimbabwe

When LEN is delivered to a small proportion of the population identified as those with the highest risk of acquiring HIV infection, the efficiency is higher in terms of the share of infections averted relative to the size of the population covered. A larger impact on averting infections can be achieved when a higher proportion of the population is reached, but with diminishing efficiency (i.e., there are higher numbers needed to cover with LEN per infection averted) because a large share of total HIV infections occur in large population groups in individuals without distinctive acquisition risk. In a concentrated epidemic, achieving a high proportion of infections averted requires only modest coverage among the total population if coverage is high within key populations (such as MSM, FSW, and PWID) where most infections occur. However, reaching and delivering LEN to a high proportion of such populations may be challenging, particularly in locations without strong existing HIV prevention programs.

Individuals at low risk of HIV acquisition are not assumed to have high LEN uptake and the selection of where to make it available will largely depend on the prevalence of unsuppressed HIV in the geographic location as well as individual risk factors.

Price thresholds for LEN to provide net savings on future treatment costs

Providing LEN could be cost-saving compared to averted lifelong ART costs if the total price (including commodities and delivery costs) is between $40-60 per person per year (PPPY) and when delivered to populations with incidence of greater than 1% (Table 3). If the price of delivering LEN fell below $40 PPPY, LEN use could be expanded to populations and locations with lower incidence. The price of LEN would have to remain <$100 PPPY to remain cost-saving even at incidence levels of greater than 2.5%. These are average figures based on aggregated estimates across multiple low- and middle-income countries and these price thresholds may vary by setting according to the local health system costs of delivering lifelong ART.

The potential savings from averted future HIV treatment costs (including drugs, hospitalizations, and health system costs) would only be fully realized several decades from now, compared to current budget investments to scale-up LEN. This means that health system financers would need to choose to increase health spending now to invest in LEN in order to accrue potential future health savings through reduced HIV burden.

Table 3: Cost of lenacapavir per person year, including both commodity and delivery costs, to be cost-saving at a lifetime cost of antiretroviral therapy (ART) of $5,000

	Estimated unit cost (US$) of LEN provision per person year				
Incidence rate per 100 uninfected persons	$20	$40	$60	$80	$100
0.01	$20,000	$40,000	$60,000	$80,000	$100,000
0.02	$10,000	$20,000	$30,000	$40,000	$50,000
0.03	$6,667	$13,333	$20,000	$26,667	$33,333
0.04	$5,000	$10,000	$15,000	$20,000	$25,000
0.05	$4,000	$8,000	$12,000	$16,000	$20,000
0.10	$2,000	$4,000	$6,000	$8,000	$10,000
0.15	$1,333	$2,667	$4,000	$5,333	$6,667
0.20	$1,000	$2,000	$3,000	$4,000	$5,000
0.25	$800	$1,600	$2,400	$3,200	$4,000
0.30	$667	$1,333	$2,000	$2,667	$3,333

Source: UNAIDS and Avenir Health June 2025

Notes: Green shading indicates cost-savings because the cost of providing LEN is lower than the future ART costs; analysis excludes the non-financial benefits of not acquiring HIV. The future ART costs are based on averages of low and middle income countries and would be different for countries paying other amounts for ART.

Globally, about 16% of total new infections in 2026 are anticipated to occur in locations and populations with incidence rate >1% and this proportion will decrease over time according to overall progress at reducing new HIV infections through combination prevention. As incidence declines, the populations and locations in which LEN programs would represent good value for money to the health system are expected to shrink consequently as well, indicating that an earlier investment would yield greater impact and would be more likely to be cost-efficient, but LEN programmes may need to narrow their future scope or find ways to continue to further drive down prices more rapidly than reductions in incidence to retain good value.

These thresholds represent a solely financial analysis of costs to the health system based on expected discounted future care and treatment costs. It does not consider value generated to improved health outcomes (e.g. productivity or wellbeing gains) accrued from averted infections.

Other important considerations

Participants noted several important considerations that require further clarity, either from research or from modellers conducting analyses:

- The cost and importance of the loading dose for individuals initiating LEN for prevention

- Models have thus far not included the cost of providing the oral loading dose of LEN, which may constitute around one-third of the total cost of providing LEN, particularly if individuals limit use to one year or less.
    - One study of LEN pricing found that an oral lead-in course could cost $127 for 4 tablets at current prices, which might fall to $20 for 4 tablets with generic pricing.
    - If used by an individual for ≤1 year, the loading dose cost could account for ~20-50% of the overall LEN provision cost.
    - Individuals may need to retake the loading dose if a follow-up visit is more than two weeks late.
- Participants discussed potential alternatives, including offering oral PrEP or the possibility of removing the loading dose completely. It was noted that for maximising population impact, dramatically or reducing the cost of the loading dose could potentially increase the total number able to be protected by Len by up to 30-50%.

- Uncertainty surrounding service delivery costs included in models, including the need for further research on:
    - Total costs, which may vary by service delivery model
    - Variability of risk of HIV acquisition in the target population
- The realized risk in client populations, both through program delivery and self-selection
- How to convey key messages about LEN implementation for different audiences

Modelling tools for LEN implementation planning

Multiple models and tools were considered as planning tools for country implementers and international funders to plan for LEN rollout, including the Goals model, PrEP-it, and a Gates Foundation model using sub-national HIV incidence data from the UNAIDS Naomi model. In addition, Unitaid is supporting Wits Reproductive Health and HIV Institute (RHI) and the Clinton Health Access Initiative (CHAI) to support countries' introduction of LEN, in collaboration with other partners. Through this support, partners will provide technical assistance for new product introduction and can produce resources adapted to specific country needs that complement existing forecasting tools. (Table 4).

Table 4: Models and tools considered during the consultation, including key features, advantages, and limitations of each. PrEP-it = Pre-Exposure Prophylaxis Implementation planning, monitoring, and evaluation Tool

Model/Tool	Key Features & Advantages	Limitations
Goals	• Deterministic model of HIV transmission to address key questions for strategic planning • Applied worldwide for UNAIDS Global AIDS Strategy, national strategic plans, investment cases and Global Fund applications	• Not fully age-structured • Limited network dynamics

	• Most countries have already received training for how to use the model	• Large number of country files means less attention to each • No sub-national estimates
PrEP-it	• Decision-making and analysis tool for target setting, cost forecasting, estimating impact, and commodity forecasting • Can be applied at the national, sub-national, donor, implementer or site level and for multiple PrEP methods • Currently supports 48 countries	• Doesn't model incidence over time or secondary transmission indirect effects • Doesn't address every planning need for PrEP programs
Gates Foundation simple model	• Simple equations to estimate impact, cost-effectiveness, and budget impact of HIV prevention interventions • Allows for multiple interventions and heterogeneity in risk	• Doesn't include the complexity of dynamic models, including lack of indirect effects of preventing an infection • Costs and health metrics are averages across populations
Naomi	• Bayesian small-area estimation model that provides sub-national estimates of HIV incidence, prevalence, and ART coverage • Stratified by sex and 5-year age group • Provides short-term projections for program planning • Webtool used annually by 43 countries	• Extrapolates spatial incidence from prevalence of viraemia • Complex and computationally intensive to run • Direct measures of HIV incidence at small areas impractical • Is a model input for programmatic decision-making
Unitaid-supported forecasting tools	• Checklist of key product-specific supply chain considerations • Simple, adaptable quantification tool to allow for country-specific inputs and accounting for current stock for supply chain forecasting • Unitaid and partners working on the global forecast for manufacturers' engagement (especially with generics), building on in-country projections	• Tools in ongoing development • Specific to individual country needs

Participants agreed that:

- Different stages in the process of LEN implementation will require different tools
- Models may not be able to include certain elements that may be helpful for country implementation decisions (e.g., health-system readiness and upfront costs) and should therefore be used alongside other tools or addressed with research instead of modelling

- Countries that have tools that meet their needs should move forward with those (e.g., South Africa) but there is a need for other countries to have easy-to-use tools to guide decision-making

Recommendations and next steps

Participants emphasized that LEN has the potential to be a key component to achieving and sustaining an end to the HIV epidemic. Even once countries reach 95-95-95 goals for testing, treatment, and viral suppression, there will continue to be ongoing HIV infections which can be reduced through primary prevention.

The meeting also reached consensus that a roadmap should be developed to help countries and funders decide if, where, and how to implement LEN programs as part of comprehensive and integrated prevention programming and what modelling tools can assist them in answering planning questions. As part of the roadmap, current modelling tools should have a user's guide on how to use the tools and what key attributes each model has, including:

- A summary of what each model can do for country planning (e.g., national or sub-national incidence estimates, cost-effectiveness, budget impact, etc.)
- Short guidance on how to use each tool in a given setting

Meeting agenda

Consultation on the Projected Impact and Cost-Effectiveness of Lenacapavir as Pre-Exposure Prophylaxis

5-6 June 2025, London, England

Day 1: Existing model evidence on Lenacapavir implementation questions

Time	Session	Speaker(s)
Chair: Mary Mahy, UNAIDS – Setting the scene		
9:00	Welcome from Gates Foundation	**Geoff Garnett** *Gates Foundation*
9:05	Welcome from UNAIDS	**Mary Mahy** *UNAIDS*
9:10	Goals of the meeting	**Izukanji Sikazwe** *CIDRZ*
9:30	Questions from national programme managers and community members on LEN implementation	**Hasina Subedar** *MOH South Africa* **Lloyd Mulenga** *MOH Zambia* **Midnight Poonkasetwattana** *APCOM*
10:00	Overview of existing models including LEN	**Britta Jewell** *Consultant*
10:30	*Coffee break*	
Chair: Geoff Garnett, Gates Foundation – Answering critical questions on LEN		
10:45	**Session 1: Epidemiologic impact of LEN** Question(s) for consensus: • Assuming supply and scale-up are not constrained, how does the percentage of infections averted vary with the percentage of the population reached with LEN, relative to baseline in one year? • What would be the number of infections averted if different volumes (50,000 to 2,000,000 person-years) of LEN are allocated over 3 years across 5 early-adopter countries, for both the short-term (3 years) and long-term (20 years)? • Which countries should be prioritized for early adoption?	
12:15	*Lunch*	
13:15	**Session 2: Populations for LEN implementation** Question(s) for consensus: • Which strategies of prioritizing LEN require the lowest number needed to treat (e.g., key populations, pregnant/breastfeeding women, spatial allocation)? • What volume of LEN would be needed to offset increases in new infections due to potential reductions in treatment coverage, resulting from international funding disruptions?	
14:45	*Coffee break*	
15:00	**Session 3: Health economics & cost-effectiveness** Question(s) for consensus: • At what price point would it be cost-saving for governments to invest in LEN, compared to (i) long-term ART costs and (ii) scaled-up oral PrEP?	

16:30	Summary and next steps	**Jeff Imai-Eaton** *Harvard University*
17:00	*Close*	

Day 2: Developing a country planning tool & consensus statements

Time	Session	Speaker(s)
Chair: Izukanji Sikazwe, CIDRZ – Developing a country planning tool		
9:00	Welcome back	**Jeff Imai-Eaton** *Harvard University*
9:05	Round robin on potential models for country planning tool	**John Stover** *Avenir Health* **Rob Glaubius** *Avenir Health* **Geoff Garnett** *Gates Foundation* **Jeff Imai-Eaton** *Harvard University* **Annie Cameron** *CHAI tools*
9:05	Characteristics of country planning tools for LEN	**Ruth Kamau** *Kenya NASCOP*
10:30	*Coffee break*	
10:45	Round robin (continued)	
11:30	Working groups to focus on key elements of country planning tool for (i) impact, (ii), focus populations, (iii) cost-effectiveness	
12:30	*Lunch*	
13:30	Report back and group discussion on recommended features and requirements for country modelling tool	
Chair: Jeff Imai-Eaton, Harvard University – Recommendations for consensus statements		
15:00	Group discussion on recommendations for consensus statements & implementation guidance	
16:30	Summary and next steps	**Izukanji Sikazwe** *CIDRZ*
17:00	*Close*	

Participants

Adam Akullian	Gates Foundation
Clemens Benedikt	UNAIDS
Anna Bershtyn	New York University
Annie Cameron	UNITAID
Shona Dalal	WHO
Heber Davila Rivera	PAHO
Mark Dybul	Georgetown University
Geoff Garnett	Gates Foundation
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