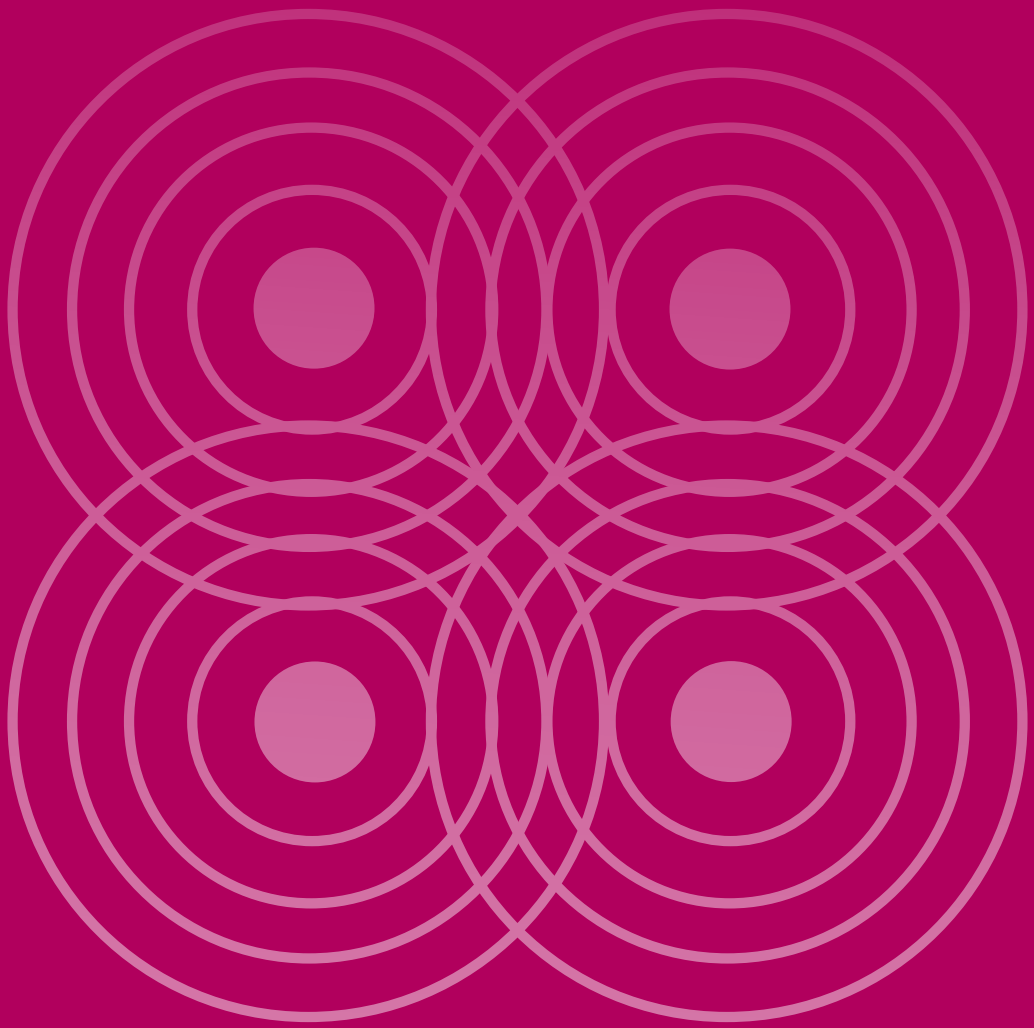
STRIVE
Tackling the structural drivers of HIV

INCORPORATING STRUCTURAL INTERVENTIONS IN COUNTRY HIV PROGRAMME PLANNING AND RESOURCE ALLOCATION

Report from an expert consultation convened by STRIVE and the HIV Modelling Consortium with support from the Global Fund to Fight AIDS, Tuberculosis and Malaria

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE
12 AND 13 DECEMBER 2016



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CONTENTS

TABLE OF FIGURES

1. EXECUTIVE SUMMARY

With increased interest in incorporating structural interventions in national HIV planning and investment, the STRIVE research consortium and the HIV Modelling Consortium convened a two-day expert meeting in London on 12 and 13 December 2016, with support from the Global Fund to Fight AIDS, Tuberculosis and Malaria. The consultation brought together 37 experts – mathematical modellers, epidemiologists, economists and policy-makers – from academia, civil society, bilateral development partners and multi-lateral organisations in order to:

- Review the state of the evidence on the effectiveness, costs and cost-effectiveness of a range of structural interventions;
- Investigate how these issues are currently addressed by available models, and identify limitations and potential improvements;
- Discuss alternative modelling solutions, notably treatment and prevention cascades;
- Learn from each other's approaches and from approaches used in country processes to model structural interventions;
- Generate recommendations about how models could better incorporate these interventions in the short term, and how this agenda should develop over time.

In preparation for the consultation, STRIVE developed and shared a briefing paper to ensure a common understanding of what HIV investment models are designed for and how they work, as well as how structural factors impact on HIV risk and service uptake and adherence, and what interventions have been found to be effective at addressing them.

Introductory presentations outlined HIV investment cases that have used modelling to prioritise and advocate for investments; the definition of and evidence for structural HIV interventions; and the use of models in programme planning. Key messages:

- → The achievement of ambitious 90-90-90 targets is likely to be constrained by a range of structural factors and barriers.
- → Currently, there are major challenges in acquiring data on 'critical enablers' (UNAIDS' term for structural drivers) and their associated costs, which makes them difficult to model.
- → The nature of structural interventions makes impact evaluations with HIV endpoints difficult to conduct and their impacts challenging to quantify.
- → Modellers will need to engage to a greater extent with technical experts in relevant areas to ensure model structure and model parameters reflect the current evidence base.

Two parallel frameworks – the established HIV treatment cascade, together with an emerging 'prevention cascade' – have the potential to capture the impact of structural factors on direct mechanisms for prevention and treatment. They may offer an alternative approach to frame, represent and model structural interventions. Key messages:

- → Biomedical interventions require behavioural and structural actions to achieve high effective coverage.
- → For any population group, the process of a biomedical intervention can be conceived of as a set of steps, presented as a 'prevention cascade', with three key determinants of coverage; demand, supply, and adherence.

- → Current models tend to reflect coverage of biomedical interventions as a model input, but do not address the interventions that would be likely to increase coverage.
- → Early evidence suggests that combined structural interventions are likely to have significant impacts on both HIV prevention and development outcomes.
- → The treatment cascade has been demonstrated to be an effective tool to compare rates of retention in care, particularly when there is heterogeneity amongst a population (e.g. people who inject drugs in prison versus those in the community).

Experts in each field presented a review of the current evidence base on the effectiveness and costs of key structural interventions:

- Intimate partner violence
- Schooling
- Stigma
- Human rights
- Female sex worker empowerment
- Alcohol

Key messages that relate to structural factors overall:

- → Structural factors function at a macro level, upstream of the proximal determinants of HIV risk.
- → The evidence for the direct impact of structural interventions on HIV incidence is generally weak.
- → Clear and strong evidence shows that structural interventions can increase uptake of biomedical interventions by acting on supply- and demand-side constraints and impacting on issues relating to adherence.
- → Limited cost data on structural interventions is available, generally from small-scale interventions in a wide range of different contexts, making it difficult to generalise or feed into a cost function.
- → It is unclear who should fund structural interventions, given their multiple HIV and non-HIV benefits, extending to broader health and development programmes. Assuming these interventions could be co-financed would require reflecting such cost-sharing in investment models by adjusting cost inputs.

Efforts have been made to incorporate structural factors and interventions into modelling design and analyses: presentations covered lessons from the South African investment case and two population-specific examples (sex-worker empowerment programmes and the effects of incarceration on HIV and HCV transmission).

Two models (Goals and Optima HIV) are used worldwide to inform HIV programming and resource allocation; representatives explained how these models work and how they currently incorporate structural interventions.

In order to go beyond generalisations, four smaller groups were formed to identify model improvements relevant for specific sub-populations and structural interventions, and options to integrate the evidence on structural interventions into models for adolescent girls and young women, sex workers, people who inject drugs and men and women on first-line ART.

Key messages in conclusion:

- On the basis of immediate endpoints, and how they are currently measured and modelled, structural interventions cannot compete with other HIV interventions, but there are likely to be other justifications for scaling them up further.
- Structural factors research should be reorganised by population groups to understand the impact that each structural factor exerts on a population group, and how each relates to one or more HIV endpoints.
- Modelling structural factors is a developing area, and there is a need to better understand which model structures can be used and their implications.

Participants discussed short-term improvements and their data and process requirements, as well as developing models for combination interventions with structural components. The final discussion focused on both short-term actions and longer-term ambitions.

SHORT-TERM RECOMMENDATIONS

- **Rethink whether mathematical models for decision-making should seek to incorporate multiple complex interventions**

  The HIV Modelling Consortium should organise a consultation to discuss: (1) future approaches to modelling for decision-making, specifically the feasibility of continuing to incorporate multiple interventions vs alternative, less complex approaches to identify the main epidemiological determinants to be tackled; (2) the potential value of integrating the cascade perspective into epidemiological models.

- **Re-organise data on structural interventions along the prevention/treatment cascade**

  STRIVE should combine and organise data on different structural drivers and interventions along the steps of the prevention and treatment cascades, in to understand and highlight which combinations of interventions are likely to have the largest effect on biomedical interventions. This would generate a framework to reorganise the data for other key population groups, as well as strengthening the case for the inclusion of adolescent female groups in investment models.

- **Establish an external review process to validate the quality of inputs and assumptions included in modelling**

  The Global Fund and UNAIDS should ensure a robust consultation process to evaluate model approaches. The HIV field needs a transparent and systematic process for technical experts to review, validate and synthesise evidence as the basis for selecting interventions to include in models used for decision-making.

LONGER-TERM RECOMMENDATIONS

- **Development of models**

  In future work to redesign models to test and model interventions, draw on insights from concepts of the cascade. In the context of the UN Sustainable Development Goals (SDGs), identify opportunities to integrate HIV modelling with broader SDG modelling initiatives and/ or model packages of interventions for specific populations such as adolescents.

- **Economics/co-financing**

  In cost inputs for structural interventions, account for potential additional non-HIV benefits and identify alternative funding streams to finance them. STRIVE may be well placed to clarify and provide guidance on financing and cost-sharing implications for different types of structural interventions.

The evidence presented at the meeting suggested that current approaches to resource allocation and priority setting do not adequately consider or model structural and other more complex interventions, despite the significant and growing evidence base on their impact on HIV service coverage and HIV-related outcomes. One way forward would be to re-organise the evidence base around the treatment and prevention cascades, and then to explore methods of integrating this into investment models, with this process guided by expert opinion. Rather than attempting to estimate the direct effect of structural interventions on HIV endpoints, the evidence may best be presented in terms of supply-side constraints, demand-side constraints and issues relating to adherence. In this way, structural interventions would not be conceived as exclusive to biomedical interventions, but instead as a vital part of the intervention package and a key enabler of the effectiveness of biomedical treatment and prevention.

Background to the consultation

The consultation was held against a backdrop of:

- Flat-lining international HIV financing,
- Heightened focus on prioritised investment approaches and roll-out of country investment cases,
- Growing global recognition of structural drivers in explaining high risk among adolescent girls and young women in sub-Saharan Africa (as witness large targeted investments, including PEPFAR's DREAMS initiative and the Global Fund's catalytic funding).

Policy-makers, funders and analysts all recognise their importance, but interventions that address structural drivers of risk and service uptake/adherence still tend to be excluded from resource allocation models and, therefore, under-prioritised in investment cases. This has largely been explained by the limited evidence available on their effectiveness for HIV endpoints and their low cost-effectiveness for the HIV budget. However, the evidence base has been growing and merits revisiting in light of renewed prioritisation efforts at national level.

Several trials have demonstrated the effectiveness of a range of biomedical interventions for HIV, and billions of dollars have been spent on improving access to these HIV prevention and treatment services. Yet, with current levels of uptake and adherence, there is a long way to go to reach ambitious global targets such as the 90-90-90(1) target set by UNAIDS.

Mathematical models of HIV have been used since the early days of the epidemic to improve understanding of the epidemic and help national policy-makers and international organisations develop effective strategies and design intervention packages. To date, models have been used predominantly to investigate the potential of biomedical technologies and behavioural interventions to reduce HIV incidence. However, there has been significant debate about how to incorporate structural factors and interventions into models, given that they could impact directly on HIV incidence as well as support access to treatment and prevention services.

To some extent, the process of model development has been restricted by a lack of both congruent communication between mathematical modellers and social scientists, and the opportunity to share more fully the evidence on structural factors and interventions – how and at what level these are understood to function.

The approach that current models take to incorporating structural interventions tends to be mechanistic. This typically involves searching for evidence of the extent to which a structural intervention may directly impact on HIV incidence via a proximal determinant of risk, such as condom use or increasing needle substitution amongst people who inject drugs. Yet, studies that can demonstrate direct impacts tend to be limited in number, with much stronger evidence on structural interventions instead showing effects on processes that enhance the effectiveness of biomedical programmes. For example, structural interventions may act to increase HIV testing and prevention measures, improve adherence to treatment and advance human rights, which support better outcomes for people living with, at risk of or affected by HIV. Such measures, termed 'critical enablers' by UNAIDS, are thought to be vitally important in the eventual elimination of HIV. However, their immediate impact on reducing HIV incidence and AIDS mortality may be lower, and their relative costs may be higher, when compared directly to biomedical interventions. Some successful trials have, however, demonstrated that such interventions can have both HIV and broader development benefits, raising questions around who should fund programmes that have dual impacts and thus how they should be factored into HIV resource allocation models that seek to optimise the use of HIV budgets.

2. INTRODUCTION TO INVESTMENT CASES, HIV MODELLING AND STRUCTURAL INTERVENTIONS

The first session underscored the policy importance of HIV models in the context of country investment cases, and provided brief introductions to HIV epidemiological and resource allocation models, as well as the role of structural drivers and interventions in HIV responses.

THE HIV INVESTMENT APPROACH

In 2012, UNAIDS launched the HIV strategic investment framework to guide countries in allocating limited resources for maximum impact. The framework has been utilised by national HIV planners and stakeholders to either orient their national strategic plan prioritisation or for the development of an investment case – a country-led, people-centred package of investment priorities that is based on a robust analysis of the epidemiology, the current response, recent scientific evidence and economic intelligence.

With the over-arching aim of optimising resource allocation to reduce HIV incidence and AIDS mortality, the framework proposes three categories of investment:

- Core basic programme interventions scaled up to reach the relevant populations and address epidemic dynamics;
- A set of critical interventions that facilitate programme implementation and create an enabling environment for achieving maximum impact;
- Support for synergies with wider health and development sectors related to AIDS (Figure 1).

Iris Semini presented on the application of the investment case approach in more than 25 countries across several regions, key findings to date, and selected challenges. She described examples from Namibia, Kenya, Malawi and Botswana, as well as making general comparisons across regions. Countries utilised the investment framework to respond to different questions, with the ultimate goal of building a long-term vision of impact of short-term and long-term investments. Several countries adopted tailored Fast Track targets through the application of the investment framework. Reviews of these country applications have suggested that the approach was useful to demonstrate the impact of investment choices and build commitment to the need for investment in the HIV response. The reviews also identified major gaps in funding for HIV prevention programmes and social enablers. Challenges for the future include making the case for additional investments, given the large treatment costs that absorb the bulk of HIV resources; and finding interventions that work for vulnerable populations, such as women and girls, with investments in critical enablers likely to be a key component. Yet, limited data on the impact of critical enablers on HIV incidence and AIDS mortality remains a key challenge and often leads to the exclusion of these interventions in the modelling exercise, thus often resulting in reduced investments.

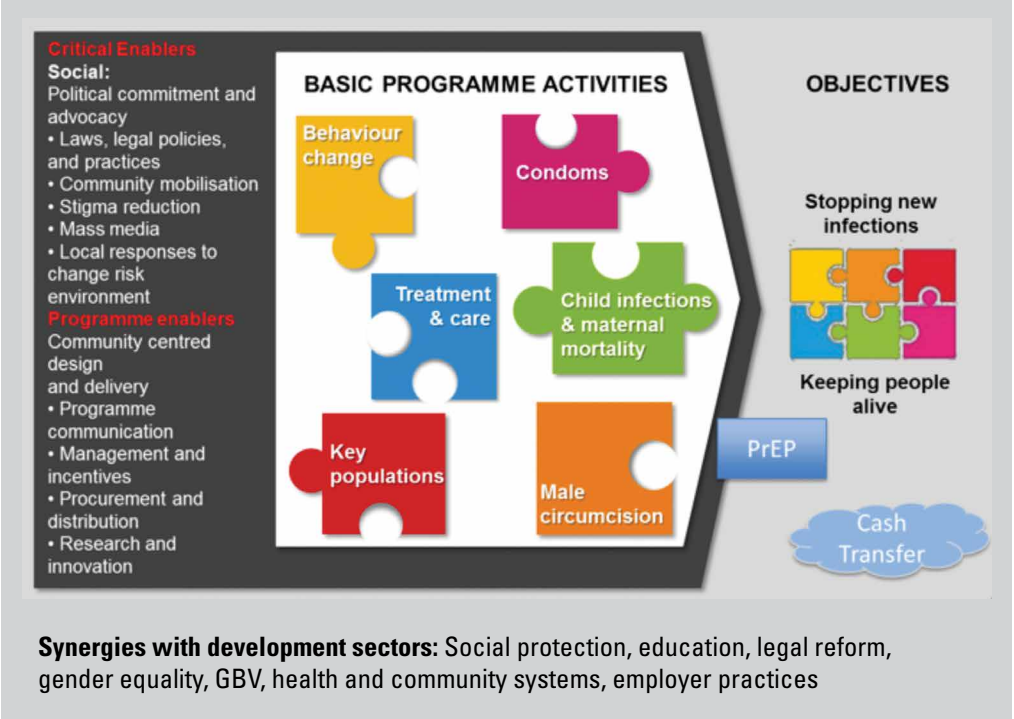


Figure 1: The UNAIDS HIV strategic investment framework to optimise resource allocation

AN EXAMPLE INVESTMENT CASE

John Stover presented the example of the investment case for HIV in Tanzania, describing in greater detail the methods used for estimating the annual cost of implementing such programmes to achieve universal access to HIV treatment, care and support, as well as estimating the potential future impact of the new investment strategy using the Goals Model. An overview of the different interventions was presented, along with key factors to consider (Figure 2).

INTERVENTIONS	FACTORS TO CONSIDER
HIV testing and counselling	Effectiveness
Care and treatment	Coverage
Voluntary medical male circumcision (VMMC)	Targets
Prevention of mother-to-child transmission (PMTCT)	Implementation analysis
Condom promotion	Programme package
Behaviour change comunications	Bottlenecks
Programmes for young women and girls	Critical enablers and synergies
Programmes for key populations	Technical efficiencies
PrEP/microbicides	Cost and cost-effectiveness

Figure 2: Review of interventions and factors to consider in their implementation

Several scenarios were tested with varying levels of technical efficiency, demonstrating that the highest number of infections were averted when maximum technical efficiencies were achieved (maximum achievement with improved levels of technical efficiency). This was reached at an additional $300 million cost, distributed across support programmes, medical services, blood safety, youth, people who inject drugs, men who have sex with men, sex workers, condoms, voluntary medical male circumcision (VMMC), prevention-of-mother-to-child transmission (PMTCT), HIV testing and ART.

The major conclusion emerging from this investment case example was the challenge of acquiring reliable data on the impact of critical enablers, and their associated costs, making it difficult to reliably incorporate these into a model.

THE EFFECTIVENESS OF STRUCTURAL INTERVENTIONS FOR HIV

Charlotte Watts introduced the importance of structural drivers in the context of public health interventions and HIV, and framed structural interventions as those aimed at addressing 'upstream' determinants of risk. The following challenges are encountered when assessing the impact of structural interventions:

- Their upstream nature makes rigorous impact studies with HIV incidence outcomes challenging;
- A limited number of ransomised controlled trials (RCTs) have sought to assess their impact on HIV incidence and other HIV outcomes;
- Structural interventions may impact on multiple drivers of HIV risk, with pathways of effect being particularly difficult to disentangle;
- Trials commonly focus on a limited number of outcomes, despite structural interventions impacting on multiple outcomes (Figure 3).

The impact on multiple outcomes is key, because structural interventions may provide the opportunity to realise high value for money across sectors, if they are

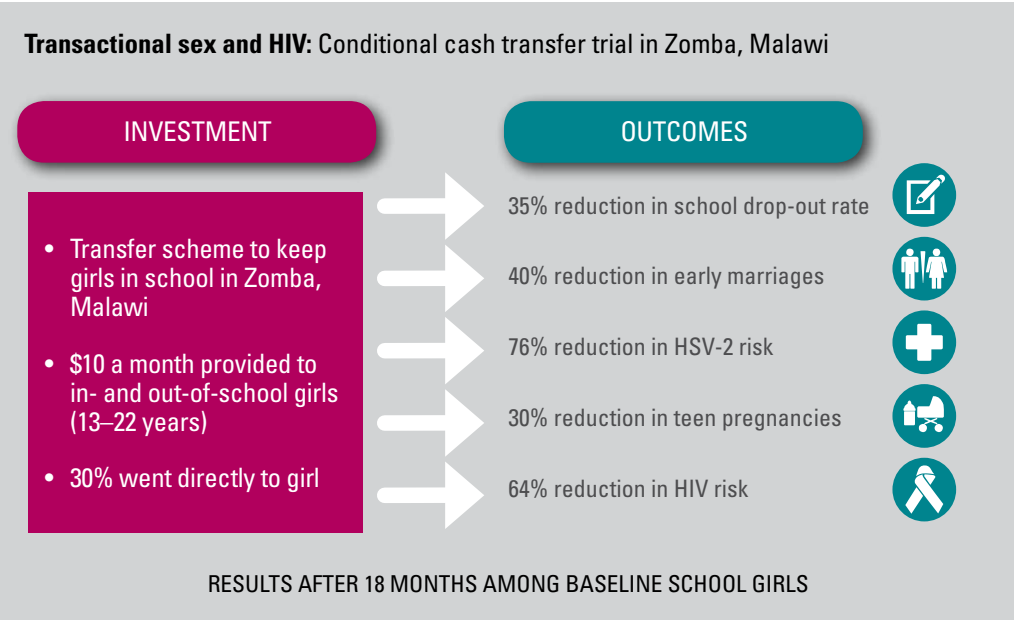


Figure 3: Structural interventions such as conditional cash transfers have benefits beyond HIV prevention, which include developmental outcomes

able to achieve development synergies. For example, cash transfer schemes aimed at keeping girls in school may reduce incidence of HIV and STIs, in addition to providing girls and young women with greater opportunities for education, training and employment, which further benefit the wider economy.

There is growing recognition that the ability to achieve international targets, such as the 90-90-90 targets, may be limited by a range of structural factors. Yet, the upstream nature of structural interventions make impact evaluations with HIV outcomes difficult to conduct and these outcomes difficult to quantify. As such, models need to meet the challenge of adequately capturing the multiple benefits of structural interventions.

MATHEMATICAL MODELS OF HIV FOR PROGRAMME PLANNING

Tim Hallett provided an introduction to HIV modelling and the use of models in programme planning. He highlighted the following key axes of differentiation between models:

- Their reliance on user-inputs versus default values;
- Being more or less mechanistic or granular in their representation of interventions;
- Their intended influence, being direct versus indirect, and qualitative versus quantitative.

The concept of "top-down" versus "bottom-up" modelling approaches was introduced. Top-down approaches tend to apply a relatively standardised model (e.g. GOALS) to facilitate multiple analyses across many settings. These models are adopted by UNAIDS, PEPFAR and The Global Fund to show what impact could be achieved by a recommended programme configuration and to set targets for key performance indicators. Bottom-up modelling approaches typically design a model to fit a particular population and research/policy question. The top-down approach will model the effect of a particular intervention as a change in a parameter (e.g. an effect on the average levels of condom use), whereas a "bottom-up" approach will try to model more of the pathway of impact (e.g. how does exposure to violence change over time, and how does this affect the distribution in risk amongst the population?). While potentially more nuanced and able to directly integrate more available data, the bottom-up approach requires more time and resources, making it difficult to apply and parameterise the model for a large number of contexts. Each approach therefore has advantages and disadvantages, and the key question for the community is how these models should be constructed and used.

Importantly, the question was raised of whether it would be feasible to expect any mathematical model of HIV to continually be adapted and extended to simulate the impact of an increasingly large set of complex interventions, as a means of choosing between specific "tactics" for programme delivery. Even now, the representation of interventions in HIV models is, by necessity, over-simplified, with limited description of the specifics of each of the interventions being modelled, and what variables, such as "coverage", mean in practice. A fundamental question was put to the meeting: do policy-makers need structural interventions to be included in models in order to decide whether to fund them? Moreover, the following two key problem statements were proposed:

- How to use the available data on all the actions that can affect HIV epidemics to best inform decision-making in HIV programming?
- How can the models in use today be adapted to better reflect the available data on some particular interventions?

As a potential solution to these statements, the prevention cascade was proposed as an approach to represent and capture alternative forms of intervention, including structural interventions. For each individual subgroup and intervention technology, coverage is 'unbundled' into several steps and constituent parts, representing supply-side constraints, demand-side constraints, adherence issues and efficacy. In this manner, structural, behavioural and biological processes exist as a holistic process along a pathway, not as mutually exclusive events (Figure 4). This would allow for the detailed mechanistic structure, the underlying drivers, and each step towards effective coverage to be more adequately represented and the available data to be synthesised accordingly.

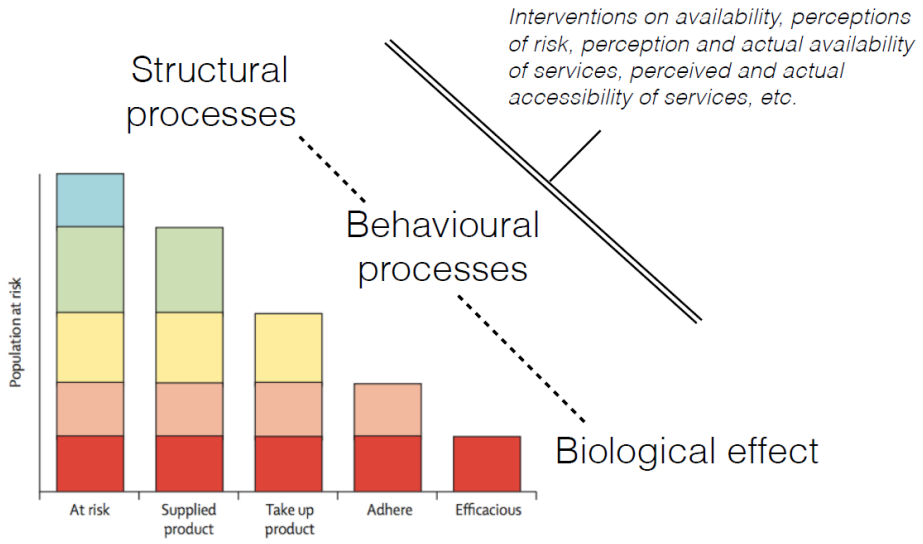


Figure 4: Representation of an HIV prevention cascade, which would be focused on an individual subgroup, with their corresponding supply-side, demand-side and adherence constraints – acting upstream of the biological effect

An emerging theme from this session was the risk of an over-reliance on models that could not necessarily consider the complexity of interventions and associated policy choices. In addition, the lack of clarity, data and tools to address technical efficiencies was highlighted, as well as the considerable time and resources required to ensure a better understanding of structural processes. Moreover, a specific financing concern was raised regarding which HIV and development programme budgets would accrue net gains from investments in social enablers and development synergies, and the resulting question of who should pay for them.

The session concluded with discussions relating to the importance of ensuring that in the process of model adaptation and use, modellers engage with technical experts in relevant areas to ensure that changes reflect current evidence. In future, the investment approach will need to focus on the acquisition of more granular data, optimising cases at sub-national level, with a particular focus on high transmission areas. This will require greater clarity on the pathways of impact of enablers and synergies, and their associated costs.

KEY MESSAGES

- The achievement of the ambitious 90-90-90 targets is likely to be constrained by a range of structural factors and barriers.
- Currently, there are major challenges in acquiring data on critical enablers and their associated costs, which makes them difficult to model.
- The nature of structural interventions makes impact evaluations with HIV endpoints difficult to conduct and their impacts challenging to quantify.
- HIV prevention and treatment cascades could provide an alternative approach to frame, represent and model structural interventions.
- Modellers will need to engage to a greater extent with technical experts in relevant areas to ensure model structure and model parameters reflect the current evidence base.

3. THE HIV PREVENTION CASCADE AS A TOOL TO MODEL STRUCTURAL INTERVENTIONS

This session introduced the potential use of the HIV prevention cascade as a tool through which to model structural interventions. First, James Hargreaves discussed how interventions could be mapped using the HIV prevention and treatment cascade framework, making reference to a recent Lancet paper(2) on this issue. Next, Sinead Delaney-Moretlwe summarised existing evidence on the extent to which four selected structural drivers impact on different parts of the HIV testing and treatment cascade.

PRIORITISING COMBINATION HIV PREVENTION INVESTMENTS

James Hargreaves focused on the prevention cascade and its relationship to structural interventions and resource allocation models. The initial discussion described current optimism around biomedical interventions, along with the limitations of converting efficacy to impact through high coverage and use; the pessimism around behavioural interventions, as a potential result of ambitious impact trials and perceived weakness in not addressing social determinants; and finally our confusion around structural interventions – what they are, how effective they are on HIV versus other hypothesised benefits, who should do them and finally who should pay for them. In conclusion, biomedical interventions were deemed necessary preventative measures, but requiring behavioural and structural actions to achieve increased coverage. For any particular biomedical or "direct mechanism" reaching a particular target population, the process can be conceived of as analogous "steps" to prevent infection. This is referred to more commonly as the "prevention cascade".

Specifying any particular prevention cascade would require addressing these six key steps:

Define coverage of direct mechanism

1. Define population – the denominator
2. Specify "direct mechanism(s)" of prevention
3. Operationalise a measure of "covered" – numerator for last bar

Define and measure the three determinants of coverage …

4. Relating to "demand"
5. Relating to "supply"
6. Relating to "capability to adhere"

The factors pertaining to determinants of demand, supply and capability to adhere to prevention are then defined as follows:

DETERMINANT OF DEMAND FOR HIV PREVENTION	
■ Perception of need for HIV prevention (i.e. risk) ■ Awareness of direct mechanism ■ Perceived social norm about direct mechanism ■ Positive attitude toward direct mechanism	"Demand" or "Motivation"
Determinants of supply	
■ Availability – geography, volume ■ Affordability – cost ■ Accessibility – service characteristics ■ Acceptability – service delivery characteristics	"Supply" or "Opportunity"
Determinants of capability to adhere	
■ Self-efficacy ■ Skills ■ Incentives and disincentives	"Adherence capability"

The prevention cascade can then be portrayed in the form of a cascade, with potential losses occurring at each step:

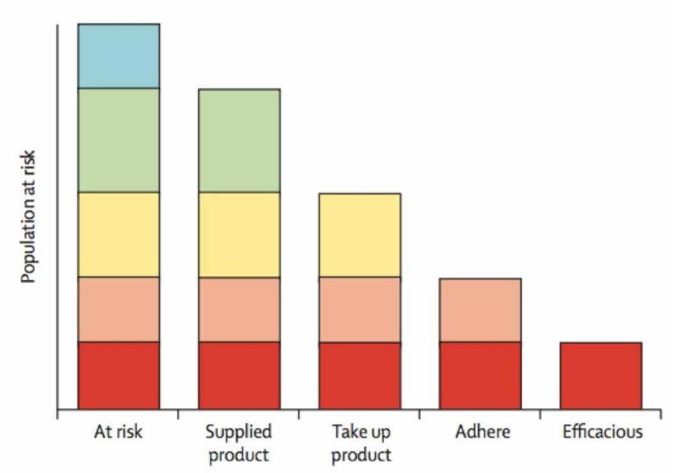


Figure 5: Intervention-centric prevention cascade, from Garnett et al. *Lancet HIV*, 2016: e297-306

A systematic review organised the current literature on HIV prevention interventions along the framework of those addressing demand-side factors, supply-side issues and adherence to prevention mechanisms(3). This highlighted the generally weak evidence of these processes to achieve lower HIV incidence, but their stronger effect on intermediate outcomes, such as increased condom use and HIV testing. Therefore, for many direct mechanisms over time, Hargreaves suggested that innovation was needed, and the greatest gains could be made where it is possible to successfully identify interventions that address capabilities to adhere. Many of the structural and social determinant interventions that the STRIVE consortium works on would fall here, although other "structural" interventions in the literature operate on supply-side issues. In addition, using the prevention cascade as a tool would align with the desire to work towards rational resource allocation to achieve prevention goals in modelling, by explicitly addressing the multiple ways in which coverage can be increased. Models generally reflect coverage of direct mechanisms of prevention, while not addressing the interventions that would likely be successful in achieving higher coverage gains. Using a prevention cascade framework within programme planning could help make explicit the need for interventions to address the demand, supply and adherence to the direct mechanisms of prevention (and treatment), delivered through relevant platforms and supported by policies, in order to increase their coverage. This approach has the potential to help frame scenarios in a practical and useful way, appropriately reflect the contribution of different types of interventions, identify what data are needed and aid in making better decisions in the face of imperfect models and data.

IMPACT OF STRUCTURAL FACTORS ON HIV CASCADES

Sinead Delany-Moretlwe summarised evidence from a recent review of the impact on HIV testing and the treatment cascade of the following four structural drivers: gender inequality and intimate partner violence, stigma, poverty and problematic alcohol use. Reviews were assessed for evidence of structural factors impacting testing, linkage to care, initiation of ART or PrEP, adherence or retention in care and impact on viral suppression or HIV infection.

For gender norms and violence, identified studies included associations with linkage to care, ART initiation and adherence and retention in care. There was some evidence that gender norms, violence or fear of violence reduced women's access to and decision to accept HIV testing, but the results were mixed. Intimate partner

violence (IPV) reduced ART initiation and use, contributing to poor treatment outcomes. There were no reviews for PrEP, but there was emerging evidence of similar patterns.

There were more consistent findings that stigma acted as a barrier to access and uptake of testing and linkage to care, and adherence and retention in care. There was less evidence of ART stigma being associated with poor PrEP adherence in placebo controlled trials, but evidence is emerging.

For socio-economic status, treatment initiation was influenced by travel time, distance, lack of consistency and co-ordination across services, and the limited involvement of the community in the programme planning process. In particular, for PMTCT, transport was frequently mentioned as a barrier. Poor adherence and retention in care were associated with housing instability, food insecurity and high transport costs and distance to accessing care.

Alcohol was shown to negatively impact on all steps of the treatment cascade, although evidence on the impact of alcohol use and HIV service utilization was variable. There was strong and consistent evidence that alcohol use undermined adherence and treatment outcomes, with worse outcomes for non-communicable diseases and co-morbidities.

The evidence from this session showed how several structural factors influence elements of the prevention and treatment cascade. When designing ART-based prevention interventions, it is crucial to identify evidence-based interventions that address structural factors and to test layered interventions that optimise ART benefits in populations at risk. It is clear that structural factors inhibit testing, access to services, uptake of ART/ART-based prevention and adherence. Yet, there is evidence that structural factors are amenable to interventions within programmatic timeframes. In order to have a significant impact on HIV prevention, evaluation of combined approaches will be required – with early evidence suggesting this is feasible and that combined interventions are likely to have impacts beyond HIV.

KEY MESSAGES

- Biomedical interventions – the mainstay of prevention – require behavioural and structural actions to achieve high effective coverage.
- For any population group, the process of a biomedical intervention can be conceived of as a set of steps, presented as a 'prevention cascade', with three key determinants of coverage; demand, supply, and capability to adhere.
- Current models generally tend to reflect coverage of biomedical interventions as a model input, but do not address the interventions that would likely be successful in achieving higher coverage gains.
- Early evidence suggests that structural interventions are likely to have significant impacts on both HIV prevention and development outcomes.

4. REVIEW OF THE EVIDENCE ON STRUCTURAL INTERVENTIONS

This session presented the current evidence on structural interventions, assessing both the evidence for their direct impact on HIV incidence as well as their impact on processes and interventions that support uptake and linkage to care. The session concluded with a review of the current economic data on these structural interventions and the implications for how they get financed.

INTIMATE PARTNER VIOLENCE

Lori Heise presented evidence on intimate partner violence (IPV), Gender inequality and gender-based violence were originally positioned within the UNAID's Investment Framework as a "development synergy", rather than as core component of HIV programming or as a "critical enabler" of such programming. This reflected the view that violence was most appropriately dealt with by the development sector rather than by the HIV field per se.

More recently, however, research has demonstrated that GBV has a closer relationship to HIV-related risks than originally anticipated. Violence by intimate partners, for example, has been linked to reduced uptake and adherence to HIV treatment and prevention methods such as PrEP. It also has been linked to increased risk of HIV acquisition through multiple pathways including increased sexual risk-taking on the part of women and men who were abused in childhood or adolescence; reduced ability on the part of women to negotiate safer sex; the HIV risk profile of violent men; and increased immune activation.

There is currently a strong evidence base on the prevalence and incidence of IPV in low and middle-income countries and on the links between IPV and HIV. These social problems share many common features:

- Both are endemic at high levels in many parts of the world, especially East and Southern Africa.
- Both are spatially distributed with "hotspots" and pockets of high and low exposure scattered in close proximity (Figure 6)
- Both disproportionately affect young women, especially in sub-Saharan Africa.
- Both share common "upstream" factors – such as insecure livelihoods, alcohol availability, and patriarchal gender norms – that drive downstream risk (Figure 7).

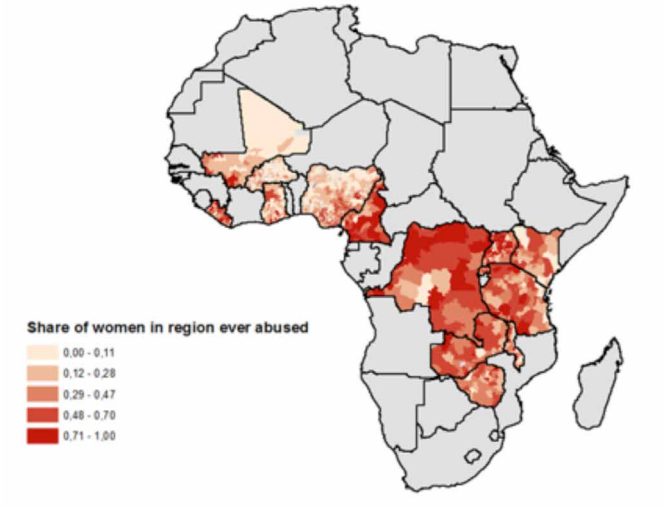


Figure 6: There is significant heterogeneity between and within countries of gender-based violence

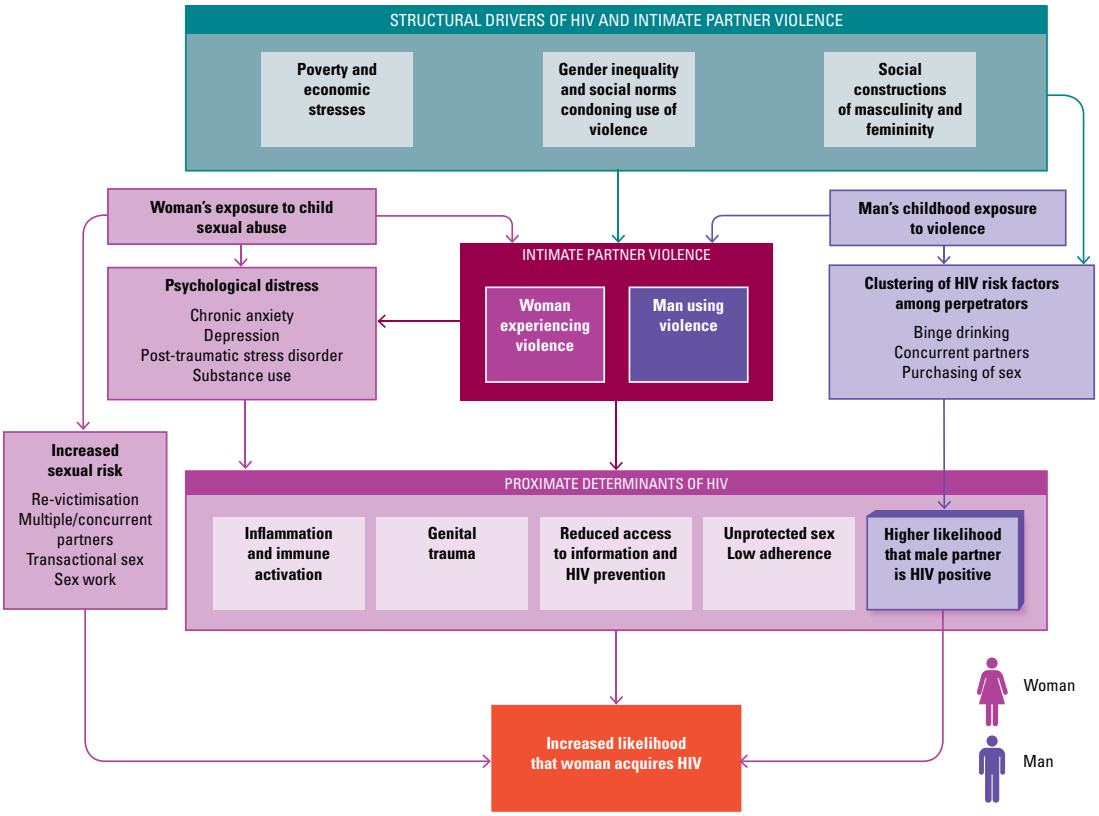


Figure 7: Evidence suggest that multiple pathways (structural, behavioural and biological) are associated with the link between violence against women and HIV

The current evidence of an association between IPV and HIV: This includes a meta-analysis of studies on women aged ≥15 years of age which established an association between HIV and IPV in 12 sub-Saharan African countries(4). However, in multi-variable analysis this association remains significant only in settings where more than 5% of the population are HIV positive. Therefore, while the degree of increased risk may be modest in certain settings, IPV can nonetheless have a substantial impact on population levels of HIV because the practice is highly prevalent, with existing cohort studies estimating the attributable fraction of HIV due to IPV to be between 12 and 22%.

What can existing data tell us about pathways of influence? The current evidence suggests the potential existence of structural, behavioural and biological pathways linking violence against women with HIV (Figure 7). Despite the potential complexity of these, the most important driver of HIV risk among women is in fact the HIV status of her partner and there is a growing body of literature that suggests that men who abuse their partners share a clustering of other behaviours that make it more likely for them to be infected with HIV. These include having outside sexual partners, seeking sex with sex workers, engaging in high-risk sexual behaviour such as unprotected and anal sex, and binge drinking, as well as being more likely to report symptoms of STIs. Coupled with this are mental trauma and stress that are associated with up/down regulation of women's genital immune response. For example, higher rates of depression lead to lower T-cell function in women who experience chronic abuse, and post-traumatic stress disorder is associated with dysregulation of cortisol pathways.

Trials: To date, one trial has shown strong evidence in reducing IPV and HIV incidence. The SHARE (Safe Homes And Respect for Everyone) project was a community-based mobilisation to change norms around IPV and offer integrated violence and HIV prevention programming, with a screening and brief intervention

to address IPV in the context of HIV testing and counselling(5). A second trial, SASA!, showed positive results for shifts in attitudes towards supporting wife beating, reduction in past year occurrence of physical violence among women with a history or violence, number of concurrent outside partners among men and women's ability to refuse sex(6). Other trials (Figure 8) have shown positive behavioural change including reductions in the risk of violence.

POPULATION	DESCRIPTION	OUTCOME	EFFECT SIZE
Critical reflection and mobilisation			
SASA! Uganda	RCT of community mobilisation trial	IPV	52% reduction in IPV reported by women
IMAGE trial Uganda	RCT of participatory group training trial embedded in microfinance	IPV	55% reduction in past year IPV reported by women
SHARE trial Uganda	RCT of SASA! intervention with brief intervention as part of HIV testing	IPV and HIV	20% reduction in 12 month physical IPV; 18% reduction in 12 month sexual violence
Stepping Stones South Africa	RCT of group reflection and community activism	IPV	27% reduction in 12 month perpetration of sexual and/or physical violence by men
Economic empowerment			
WINGS Uganda	BRAC – cash transfers and microfinance training	IPV	

Figure 8: Example of trials that have shown a positive behavioural change, leading in most cases towards reductions in levels of violence

SCHOOLING

Audrey Pettifor presented a series of studies conducted in Africa on the relationship between HIV and education, with stronger effects seen in women than in men when heterosexual populations have been examined. To date, most of the studies have been rural or national studies and have focused on increasing schooling through waiving secondary school fees, waiving uniform fees, cash transfers and social protection schemes. Factors that influence the impact of interventions on schooling are likely to include the level of schooling at the start of the intervention and other interventions aiming to impact the outcome such as social protection measures which already exist.

In the context of education attainment and attendance, upstream factors – such as socioeconomic status, self-esteem, social networks and aspirations – are likely to play a significant role in influencing sexual behaviours and protection further downstream (Figure 9). There have been studies on attendance (all of which have been cross-sectional) as well as on attainment (where studies are more often longitudinal). In Botswana, each additional year of secondary schooling led to an absolute reduction in cumulative risk of HIV infection of 8.1% points relative to baseline, with effects larger for women than men(7). In Zambia, young women with more education were less likely to be HIV-infected than those with less education, and declines in infection rates from 1995–2003 were greatest in young women with the most education(8). In Uganda, HIV infection rates declined most rapidly over 10 years in young women with secondary school education(9); and in South Africa, participants were 7% less likely to become infected with HIV for each year of education they had completed(10).

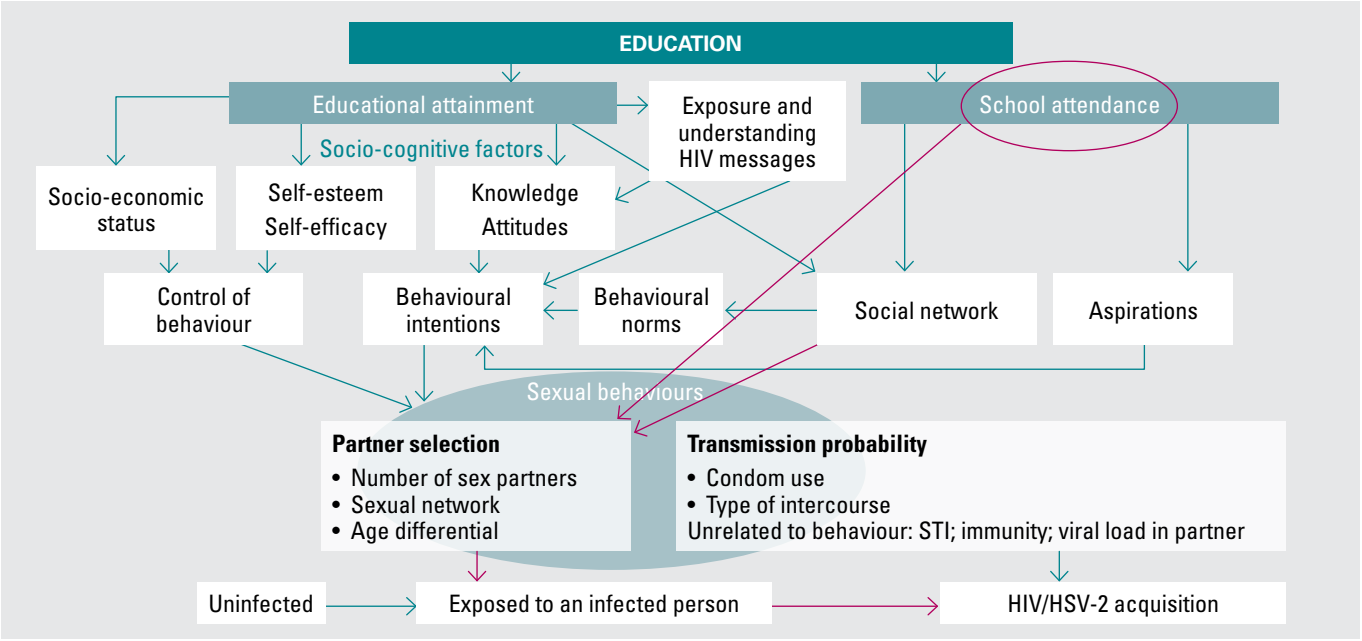


Figure 9: Potential pathways of change which may be influenced by greater attendance and greater attainment within schools. (Source: Adpated from Jukes 2008)

Two reviews of HIV and education indicate a protective association between higher education and HIV infection, particularly as epidemics mature(11). Among young women with one lifetime partner, those who had not completed high school were almost four times more likely to be HIV infected compared to those that had completed high school(12). Analyses of the HPTN068 cash transfer trial in South Africa found that adolescent girls and young women who attended school more often and did not drop out of school were less likely to acquire HIV and also less likely to have older partners and more partners. Therefore, there is sufficient evidence to suggest that greater levels of attendance and, particularly, attainment can have a positive effect on reducing HIV, particularly amongst women. Cash-transfer interventions are evidenced as an especially effective mechanism to increase attendance and retention in schools(13), although to date there is only low-quality evidence of the consistent effectiveness for reported biological or behavioural change outcomes in reducing HIV incidence. A study in Malawi showed that both conditional and unconditional cash transfers increased girls' school attendance and reduced HIV prevalence(14). However, trials of the impact of cash transfers on HIV incidence among adolescent girls in rural South Africa did not show an impact (HPTN068 Swa Koteka(15) and Caprisa studies). Compared to biomedical interventions, cash-transfer schemes are also significantly less cost-effective, when HIV is the only measured outcome (Figure 10).

	COST-EFFECTIVENESS RATIO (US$ PER INFECTION AVERTED)	STUDY YEAR
Medical male circumcision	$551; $1,096	Kahn et al (2006); Bärnighausen et al (2012)
Treatment as prevention (CD4 count ≥ 350 cells per µl)	$8,375	Bärnighausen et al (2012)
Pre-exposure prophylaxis	$12,500-20,000; $6,000-66,000	Pretorius et al (2010); Hallet et al (2011)
Secondary school		De Neve et al (2015)*

* This study; other benefits of schooling are not captured in the cost-effectiveness ration.

Figure 10: Cost-effectiveness ratio of secondary school and known HIV prevention interventions

Interventions that aim to increase school attendance and attainment have been shown to have a positive impact on both HIV and developmental outcomes, particularly through increasing young people's opportunities that lead to better prospects. Indeed, greater levels of attendance and attainment are also likely to have a positive impact on the more upstream distal factors which influence sexual behaviours and HIV risk, such as aspirations, self-esteem, and social economic status.

STIGMA

Anne Stangl presented evidence on stigma, describing how stigma and discrimination impact on demand-side access to treatment as well as prevention and adherence. HIV-related stigma and discrimination hamper efforts to prevent new HIV infections and to engage people living with HIV (PLHIV) in care and treatment(16-18). HIV-related stigma reduction is a key priority in PEPFAR's blueprint for achieving an AIDS-Free Generation and UNAIDS' HIV investment framework(19-21). Effective interventions to reduce HIV-related stigma and discrimination are crucial to the success of biomedical prevention(19, 20). A number of processes are hypothesised as being influenced by stigma and discrimination (Figure 11). If improved outcomes can be achieved, HIV incidence and HIV related morbidity and mortality can be expected to decline.

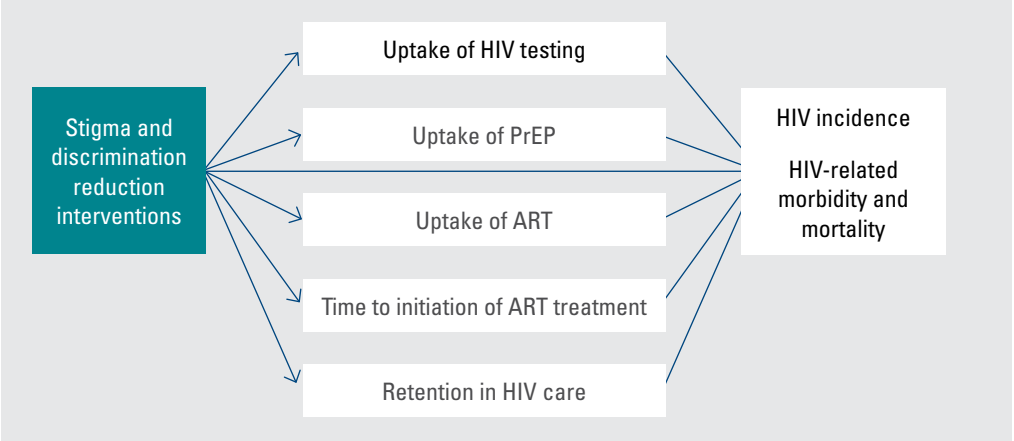


Figure 11: The perceived impact of stigma and discrimination reduction on HIV outcomes

A recent systematic review(22) included 48 studies, of which 87% were deemed to be of high quality. The studies included 14 different target populations in 28 countries, and covered information-based approaches, skills building, counselling and support, contact with affected groups, structural and biomedical interventions. Individual-level interventions were the most common (56%). However, the review demonstrated that the socio-ecological levels targeted by stigma reduction interventions have expanded to include all five levels of influence (community, individual, organisational, interpersonal and public policy) over the past decade, as well as combinations of these. This is particularly important as stigma is a social phenomenon that is reinforced by the communities and societies in which people live, so interventions to shift community and societal norms are as urgently needed as those that address individual attitudes and behaviours.

The stigmatization process can be interrupted or mitigated in two key areas (Figure 12). Interventions can: (1) reduce or remove the drivers and facilitators of HIV stigma (i.e. fear of HIV transmission through casual contact; stereotypes and prejudices about people living with HIV (PLHIV) and key populations, harmful laws and policies, etc.) and (2) address the harmful manifestations of stigma (i.e. support PLHIV to overcome internalised or experienced stigma and foster resilience,

reduce community perceptions about the level of stigma, etc.). It is ideal to design interventions that address both the drivers and manifestations concurrently across multiple socio-ecological levels. While several of the studies reviewed did present findings on multi-level interventions, most (67%) only targeted the drivers and facilitators of stigma.

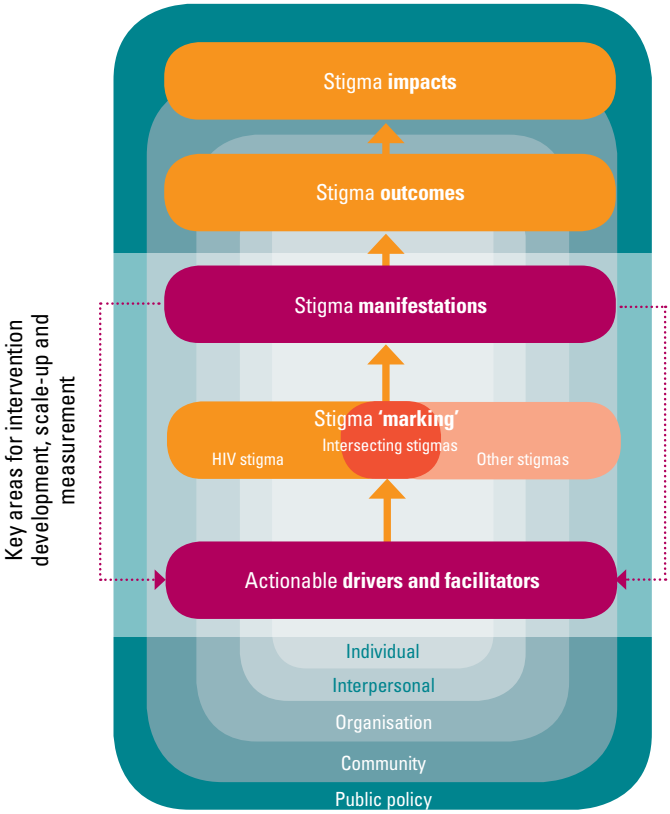


Figure 12: The pathway through which stigma operates

Key insights from STRIVE on successful interventions show considerable progress over the last decade regarding the expanded number, geography and complexity of interventions on stigma, with multiple studies that show reductions in HIV-related stigma which are of high quality. Although critical challenges and gaps remain, the current evidence is particularly strong for interventions involving students, health care workers and community members, and for interventions using structural and counselling based approaches. There is currently moderately strong but compelling evidence that stigma can be reduced. Evidence of the impact of stigma reduction on direct HIV measures such as incidence and mortality is relatively weak, but there is stronger evidence on behavioural factors, such as increased testing and retention on ART, which may influence HIV outcomes.

HUMAN RIGHTS

Anne Stangl and Joanne Csete presented evidence on the effectiveness of human rights interventions. There is now an international consensus on the importance of expanding access to human rights and incorporating principles of a rights-based approach as essential to ensuring the effectiveness of HIV responses. UNAIDS recommends seven key human rights programme areas that are critical for improving HIV outcomes, including reducing stigma and discrimination, HIV-related legal services, monitoring and reforming laws, rights literacy, sensitisation of law-makers, proper training of health-care providers on human rights and ethics and women's land and property rights. These and other factors directly or indirectly influence access to and utilisation of health services and thus affect both HIV incidence and mortality.

Figure 13 illustrates some of the key factors related to human rights that are likely to have an impact on both HIV incidence and HIV-related morbidity and mortality. These are mediated by factors such as gender inequality and gender-based violence; HIV-related stigma and discrimination in health services; a lack of privacy, confidentiality, and informed consent in health services; unjust criminalisation of minor drug offences, sex work and LGBTI persons – often with associated abusive policing; discriminatory neglect of services for prisoners; HIV laws and policies that undermine rights; and a lack of access to due process and legal services for affected populations.

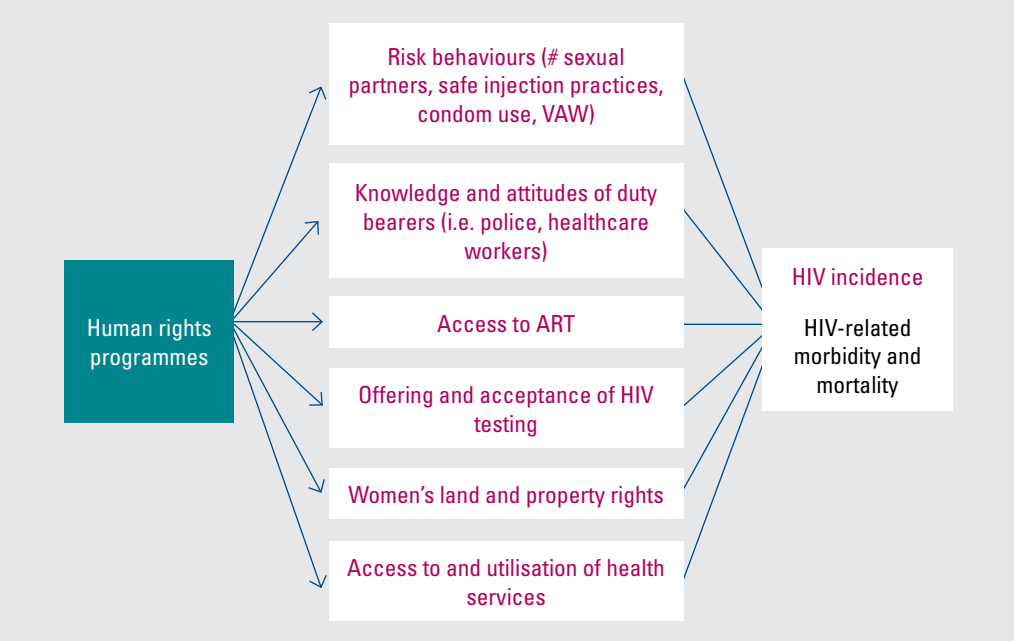


Figure 13: Human rights programmes that may impact upon HIV incidence and HIV-related morbidity and mortality

A recent systematic review identified 23 studies, of which 53% were deemed to be of high quality based on the Downs and Black checklist(23) and the Spencer guide(24). They included 15 target populations in 11 countries. The most common interventions were those focused on monitoring and reforming laws, policies and regulations, and studies addressing the sensitisation of law-makers and law enforcement agents towards HIV. Of these studies, 83% reported improvements in HIV-related health outcomes and 52% addressed more than two UNAIDS' human rights programme categories. Policy-level interventions were most common (53%), followed by community-level (18%), individual (9%) and organisational-level (5%). The remaining studies included a combination of two or more of these approaches. In addition to this systematic review, the Global Fund is conducting a programme review of existing evidence, which is in progress.

Since the UN adopted a human-rights based approach in 2003, there has been significant improvement in human-rights based programmes to improve HIV-related health outcomes, which has been evidenced by STRIVE. However, despite both growing support and evidence for the inclusion of human rights interventions, important gaps remain in the evidence. Critical questions remain at the local, state and national levels regarding implementation and scale-up due to the evaluation of individual and public health benefits lagging behind. This lagging behind of evaluation is linked to the fact that community-based organisations providing basic services to criminalised and marginalised populations often have bare-bones budgets that do not allow for both service delivery and rigorous evaluation. In addition, there is very little data available on the cost and cost-effectiveness of

these types of interventions. In its first year, the Global Fund's five-year effort is seeking to support the scale-up of programmes to reduce human rights barriers to HIV services in selected countries and to monitor and cost that scale-up to generate model-ready data.

The overall evidence on human rights programmes provides weak but compelling evidence that human rights programmes can have a positive impact on determinants of health, HIV prevention behaviours and HIV incidence. The pathways of change are likely to be complex and context-specific. More research, such as the Global Fund initiative, is undoubtedly required to gain greater insight on the impact at local, state and national levels.

FEMALE SEX WORKERS

In this session, Tara Beattie presented evidence of the impact of empowerment interventions for female sex workers (FSWs), who are at disproportionately high risk of acquiring HIV(25). In 110 countries with available data, the prevalence of HIV infection is almost 12 times higher among FSWs than for the population as a whole, with prevalence at least 50-fold higher in four countries. Structural factors that place FSWs at an increased risk of HIV infection include violence experience, migration, food and housing insecurity and alcohol use. However, the mechanisms through which these exert an effect are often unclear. Figure 14 presents a conceptual framework for both distal and proximate drivers of HIV risk and vulnerability among FSW populations. The green circles show traditional interventions and the red circles represent structural interventions for which we have evidence of an effect.

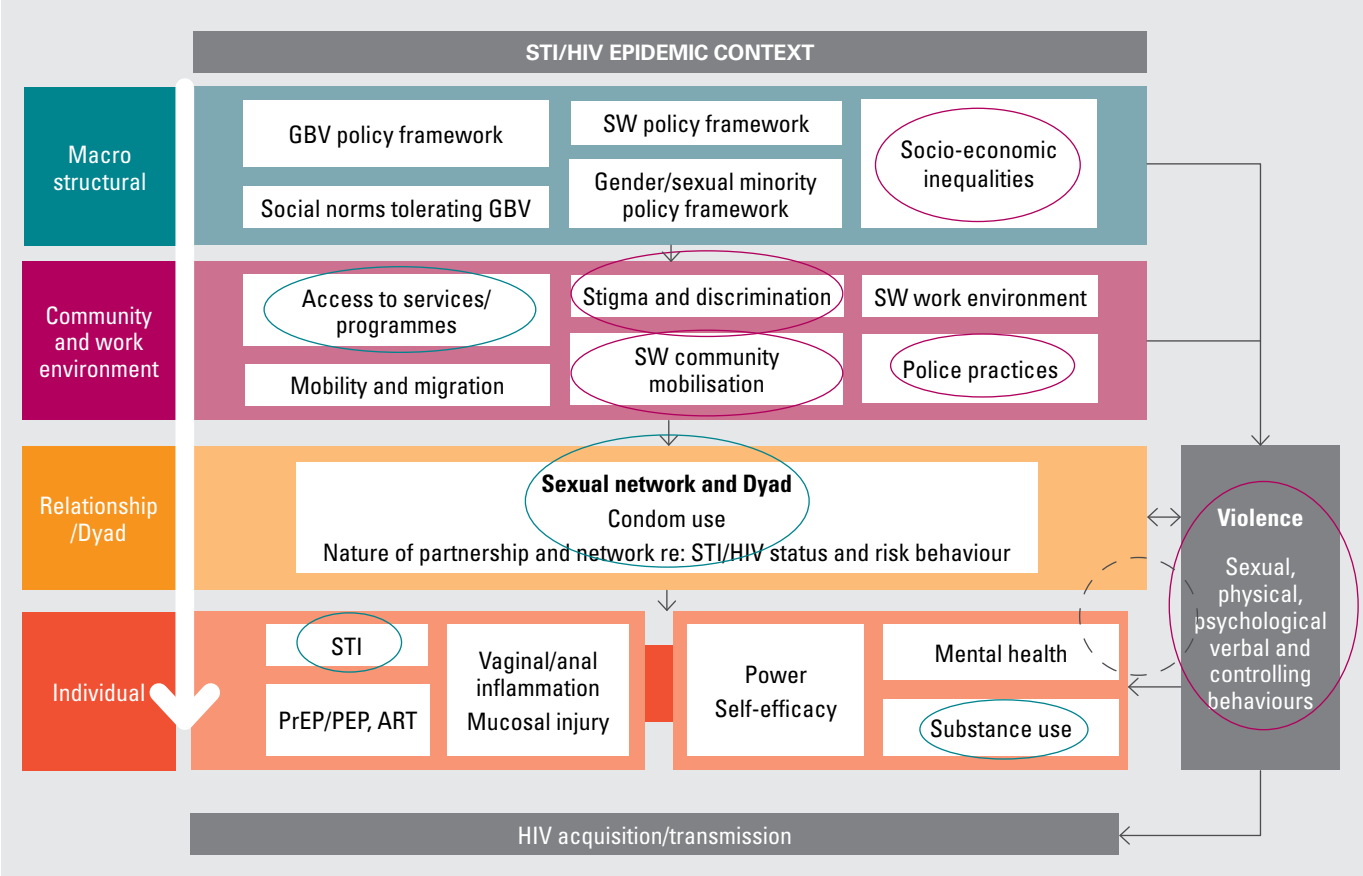


Figure 14: A conceptual framework for the distal and proximal drivers of HIV risk and vulnerability among sex worker populations. (Source: Decker, Beattie, Bhattacharjee, Shannon and Amin, *in prep*)

Sex worker empowerment: A sex worker community-empowerment-based HIV response is defined as "a process by which sex workers take collective ownership of programmes and services to achieve the most effective HIV responses and address social and structural barriers to their health and human rights(26)." Traditionally, FSW HIV prevention programming focused on peer education, condom distribution and STI testing and treatment but meta-analyses have demonstrated the limited impact of these stand-alone disease-focused approaches(27). In contrast, FSW community empowerment approaches are community-led, recognise sex work as work and seek to promote its legal status, and are committed to ensuring the health and human rights of FSWs as workers and as human beings. A community empowerment response to HIV is based on sex workers' experiences, insight and leadership. Thus it is a social movement in which FSWs come together as a community to develop internal cohesion, and then mobilise their collective power and resources to demand their human rights and entitlements(26). Community empowerment is therefore an overall approach rather than a set of specific activities. Intervention packages will differ, depending on the context and the needs of the local sex worker community, but often include biomedical (e.g. STI and HIV testing and treatment), behavioural (e.g. peer outreach; condom distribution) and structural components.

Figure 15 shows an example of the typical stages of empowerment. In this instance, empowerment is understood to be a social process, not focused on a given health or disease outcome, but rather one which seeks to challenge unequal power structures which inhibit the overall health and well-being of a given group(28). In this way, community empowerment is considered a structural intervention to address and alter social, political and material conditions surrounding sex work in a given setting.

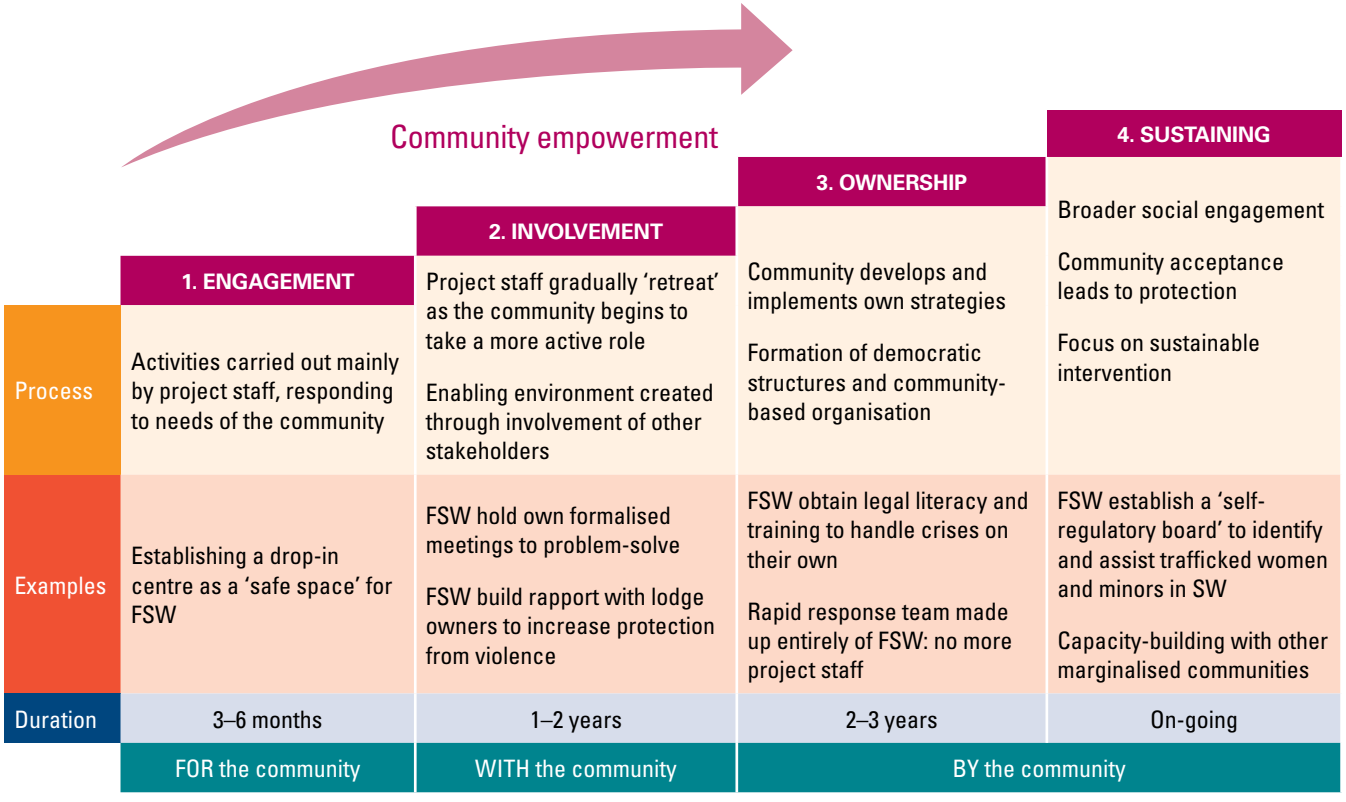


Figure 15: Stages of community empowerment in Ashodaya's model of implementing community-base structural interventions in Mysore, south India (Source: Moore et al. Community empowerment and involvement of female sex workers in targeted sexual and reproductive health interventions in Africa: a systematic review. *Global Health*. 10 Jun 2014. 10;10:47)

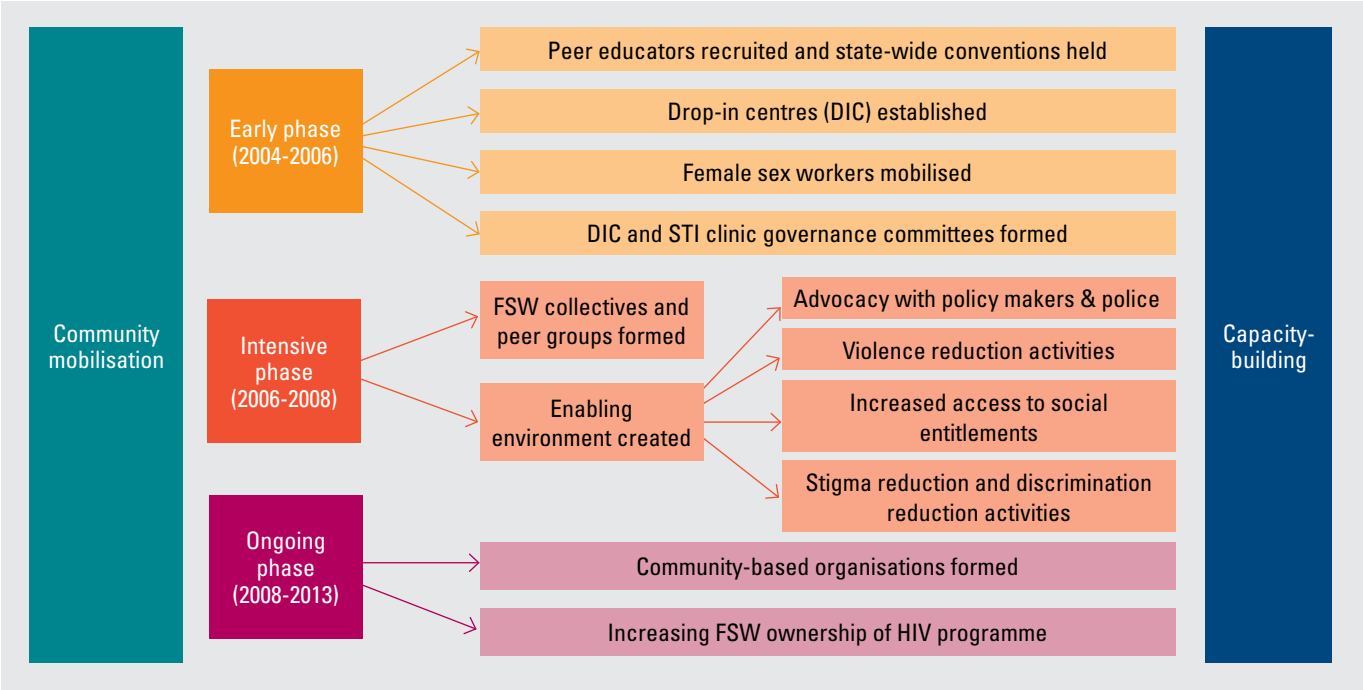


Figure 16: Community mobilisation activities of Karnataka Health Promotion Trust, south India

Evidence for the association between community empowerment and HIV: There is a significant amount of evidence for the association between community empowerment FSW interventions and HIV outcomes. A systematic review of 22 peer-reviewed articles (2003-Jan 2013) assessed the effectiveness of community empowerment-based interventions for HIV prevention in sex workers. It represented 30,325 participants from eight projects in three countries: India (17 articles), Brazil (four articles), and the Dominican Republic (one article, one table). Thirteen of the 22 articles were from the India Avahan programme, funded by the Bill & Melinda Gates Foundation. The meta-analysis showed positive outcomes for HIV prevalence, STI prevalence and condom use.

While more evidence is required, it is possible to hypothesise the pathways through which empowerment may have an impact (Figure 17), although these are likely to

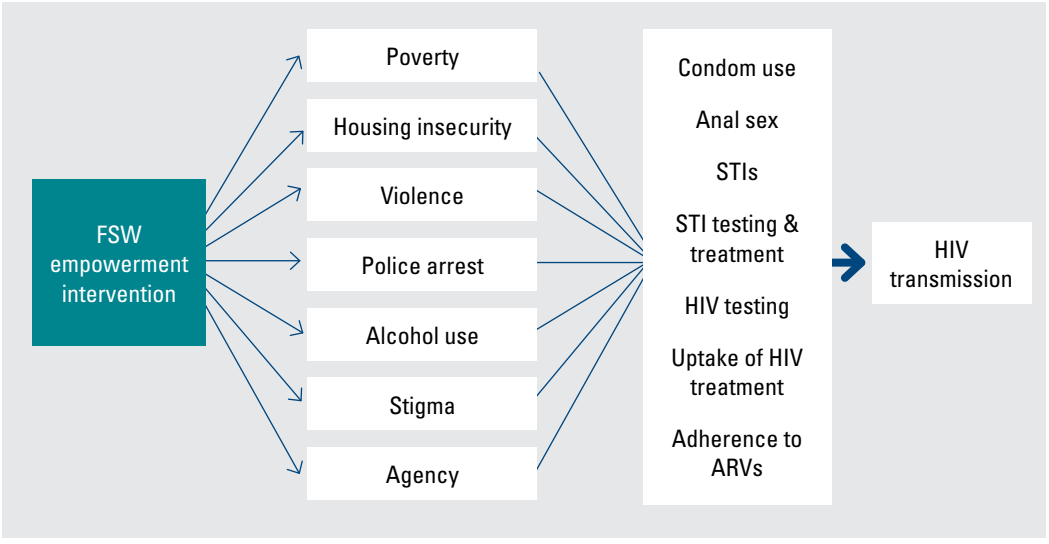


Figure 17: Conceptual pathway describing the pathways through which FSW empowerment interventions may indirectly and directly reduce HIV transmission

be complex. An economic evaluation of the India Avahan Project from Karnataka State suggested that the community mobilisation and empowerment component made an important contribution to the impact of the intervention and was highly cost-effective: when savings from ART were taken into account, investments in community mobilisation for FSWs were even cost saving(29).

Although cluster-RCT evidence is lacking, there is compelling evidence that FSW empowerment interventions can impact on condom use, STI prevalence and most likely HIV outcomes. WHO currently recommend this approach be implemented in multiple settings, increasing the need to capture its effects in the context of mathematical models. The discussion related to this session concluded that there was strong evidence supporting the inclusion of sex worker empowerment, and that the simplest way to do this would be to ensure that the unit costs of the intervention were adjusted accordingly. There was a lack of clarity about whether, in existing resource allocation models, sex worker interventions incorporate empowerment components or not – given that the specifics of the interventions being considered are often not well described.

Further research is needed to understand the impact of other factors on the pathways between FSW empowerment and HIV. A consolidation of evidence would be helpful in exploring the pathways through which FSW empowerment acts and the impact upon uptake of services which directly influence HIV transmission. Greater clarification is also required over the actual cost of such a programme, given its complexity and multiple components.

ALCOHOL

Katherine Fritz presented a review of the effectiveness of alcohol interventions for HIV-related behaviours and outcomes. Overall, 5.1 % of the global burden of disease and injury is attributable to alcohol, as measured in disability-adjusted life years (DALYs)(30). The association between alcohol use and HIV is complex and includes direct biological pathways as well as a range of more indirect behavioural pathways (Figure 18).

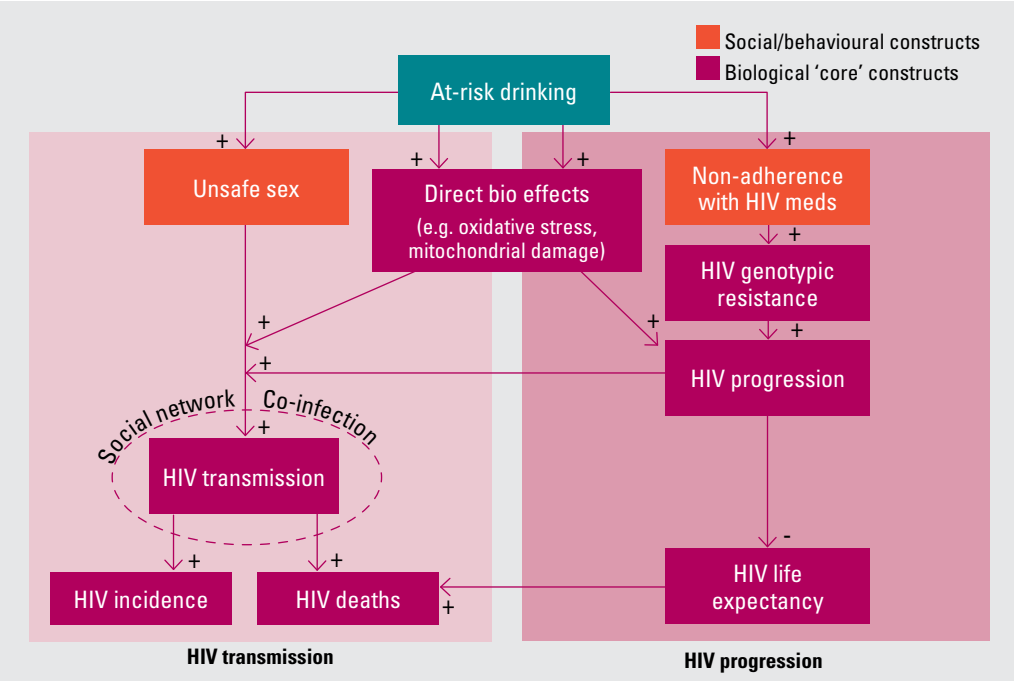


Figure 18: The complex association between alcohol use and HIV. (Source: adapted from Kendall Bryant NIAAA)

Evidence of an association between alcohol and HIV risk: A meta-analysis of 30 experimental studies reported stronger intentions to engage in riskier sexual activities for participants who consumed alcohol(31). Numerous systematic reviews showed a strong consistency and agreement in estimated effect measures across studies. One study in particular demonstrated a dose-response relationship in blood alcohol calculator of 0.1mg/L leading to a 2.7% increase in the likelihood of engaging in unprotected sex(32). Figure 20 summarises these studies.

Interventions to reduce the HIV risks associated with alcohol use may occur at the individual or community level with different entry points and mechanisms used to achieve the desired outcome (Figure 19).

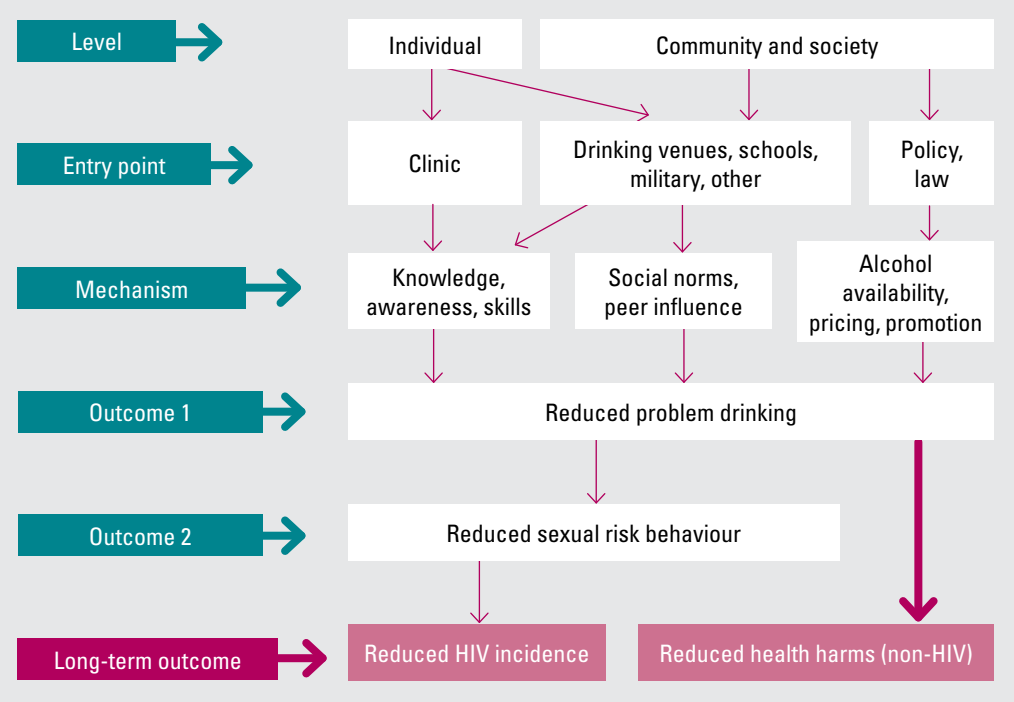


Figure 19: Intervention pathways preventing transmission of HIV

NUMBER OF STUDIES	ENTRY POINT	POPULATIONS	ALCOHOL USE IN SEXUAL CONTEXTS	COUNTRIES
4 RCTs 1 quasi-experimental	Clinic	At-risk populations, general population	2	South Africa, Russia, Uganda, Zambia
2 RCTs	Drinking venues	General population (men, women)	2	South Africa, Zimbabwe
3 RCTs 1 quasi-experimental	Schools	Girls, boys	2	South Africa, Namibia
2 RCTs	Military	General population (men, women)	2	Angola, Nigeria
6 RCTs 1 quasi-experimental	General community	FSW, at risk populations, general population	4	South Africa

Figure 20: Interventions to prevent alcohol-related HIV transmission

Clinic-based interventions: Out of a total of five clinic-based interventions, two reduced alcohol use in sexual contacts (two did not report), three increased condom use (one did not report) and two reduced alcohol use (one did not, and one did not report).

Military interventions: Of the two interventions, one reduced alcohol consumption before sex (one did not). The relevant study was carried out in Angola and showed a 25% reduction in alcohol consumption before sex at three-month follow-up, but reductions were not significant after six months. Both studies increased condom use, with a 10% increase in vaginal sex at three-months, and 11% at six-months compared to controls. However, neither reported on alcohol use reduction.

General community interventions: These totalled seven, of which three reduced alcohol in sexual context (two did not, two did not report); four studies showed an increase in protected sex (two did not, one did not report); and three studies reported a reduction in alcohol use (one study had mixed results, one showed no effect, and one did not report).

Interventions on men who have sex with men (MSM): Among MSM, the use of alcohol and other sex-enhancing substances such as stimulants, amyl nitrites and erectile dysfunction medications is associated with greater odds of engaging in condomless anal intercourse (CAI). Intent-to-treat analyses indicated that only one intervention reduced both CAI and substance use, highlighting the point that behavioural interventions may achieve decreases in CAI in the context of active substance use (33).

Despite strong evidence of an association, the challenge remains finding effective intervention approaches. There is currently limited evidence of sustained effects past three-months, with mixed evidence on general community, school and bar-based approaches. Finally, no research has been conducted to examine the effects of alcohol policy or legal interventions on HIV sexual risk behaviour.

Currently, the 'best buy' policy interventions to reduce alcohol-related harm are to:

- **Regulate production**, wholesaling and serving of alcoholic beverages that places reasonable limitations on the distribution of alcohol and the operation of alcohol outlets in accordance with cultural norms;
- **Reduce the impact of marketing**, particularly on young people and adolescents;
- **Use pricing policies** to reduce underage drinking, to halt progression towards drinking large volumes of alcohol and/or episodes of heavy drinking, and to influence consumers' preferences.

Alcohol and the treatment cascade: There is evidence to suggest that alcohol is an impediment to all phases of the treatment cascade including diagnosis, linkage to care, engagement with/retention in medical care, treatment with ART and the ability to achieve a suppressed viral load. In a series of recent studies, HIV-positive drinkers on HAART were twice as likely to have CD4 counts <500 cells/mL and four times less likely to achieve a positive virologic response to medication as compared with non-drinkers.

There is considerable potential for integrating alcohol risk-reduction strategies into the standard HIV prevention repertoire, along with ART/PrEP, condom promotion, harm reduction with sex workers and prevention with youth and key populations.

A dose-response relationship has also been shown between binge drinkers and non-binge drinkers to engage in unprotected sex. Multiple RCT studies and some quasi-experimental studies have been carried out at different entry points, which

include the clinic setting, drinking venues, schools, military, general community and amongst different populations. The evidence has shown mixed results for alcohol use in sexual contacts, reductions in unprotected sex, increasing condom use and reducing alcohol use.

Despite strong evidence of an association, challenges remain in finding effective intervention approaches, with limited evidence of sustained effects past three months. Supply-side interventions may help though have not been evaluated on HIV outcomes. However, policies such as regulating alcohol production, reducing the impact of marketing and pricing policies to reduce under-age drinking have been shown to reduce hazardous drinking and its ramifications (such as car crashes). There is some evidence to show alcohol's impact on the treatment cascade by lowering receipt of HIV testing, delaying access to treatment, lowering retention in care, non-adherence and even accelerated disease progression.

COSTS AND COST-EFFECTIVENESS OF STRUCTURAL INTERVENTIONS

This session, led by Michelle Remme and Anna Vassall, assessed current knowledge on the costs and cost-effectiveness of structural interventions for HIV. The existing evidence includes a systematic review of gender-responsive interventions(34), which identified 11 interventions with economic data, in six countries. These were nearly all single studies conducted in one context, and

	INTERVENTION	COUNTRY	COST	CER
Critical enablers (HIV+)	Male involvement PMTCT	Kenya	-	1
	Gender empowerment and collectivisation for FSW	India	-	1
	Female condom promotion for FSW	Kenya	-	1
	Expanded female condom distribution and promotion in general population	South Africa, Brazil	-	1
	Gender-transformative participatory sessions with men and boys	Brazil	1	-
	GBV messages in HIV mass media campaigns	South Africa	-	1
Dev syn (DEV+)	Gender/HIV training with microfinance	South Africa	-	1
	PEP in post-rape services	South Africa, Kenya	2	1
	Sugar daddy talks	Kenya	-	1
Dev syn (DEV)	Cash transfers for school girls	Malawi	-	1
	School support for orphan girls	Zimbabwe	-	1
	Free school uniforms	Kenya	-	1

NEW EMERGING STUDIES	STUDY	COUNTRY	EMPIRICAL/ MODELLED	COST/EE
Secondary schooling	De Neve et al, 2015	Botswana	Empirical	CEA
Cash transfers for girls (HPTN068)	Cabera et al, *in prep*	South Africa	Empirical	Cost
Community mobilisation for IPV and HIV (SASA!)	Michaels-Igbokwe et al, 2015	Uganda	Empirical	CEA
Alcohol intervention for PLHIV	Kessle et al, 2015	East Africa	Modelling	CEA
Stigma reduction	Brent 2016	USA	Modelling	CBA
Combination prevention with stigma reduction for MSM	Colchero et al, 2016	Mexico	Empirical	CEA

Figure 21: Past and current structural intervention studies that include cost-effectiveness analysis

they were predominantly from South Africa and Kenya. Since this publication, additional empirical and modelling studies have also emerged for some of the interventions discussed in the previous session, but overall the evidence base remains very limited (Figure 21).

A study currently in preparation reviews specifically the costs and cost-effectiveness of ART adherence-enhancing interventions in low- and middle-income countries (Figure 22). There is significantly more economic evidence on interventions that provide adherence support, in-kind support or an enabling programmatic environment for people living with HIV on ART, both in terms of their costs and cost-effectiveness in different settings.

	INTERVENTION	COUNTRY	COST	CER
Adherence support	Case management and adherence counselling	Ethiopia, Ukraine, Brazil, Côte d'Ivoire, Nicaragua, Malawi	3	3
	Community-based adherence support/accompaniment	Rwanda, Uganda, South Africa, Peru, Zambia	8	1
	Adherence clubs	South Africa, Malawi		2
	Directly-observed treatment by CHW	Cambodia	1	
	M-Health	India, Kenya, Brazil, Malawi	3	1
In-kind support	Nutrition support	Rwanda, South Africa, Zambia, Mozambique, Uganda, East Africa, Côte d'Ivoire	5	3
	Education support	Uganda		1
	Transportation stipends	South Africa	1	
Programme enablers	Facility size and staffing profile	South Africa		1
	Integration of ART and methadone	Vietnam		1

Figure 22: Summary table of adherence-enhancing interventions (Source: Osman et al, *in prep*)

While this evidence is useful to inform decisions regarding which interventions should be included in HIV models, as well as what range of cost inputs to consider, there are several challenges with the use and interpretation of this evidence base. Firstly, the interventions or strategies being evaluated are not always clearly defined or truly comparable between studies. Secondly, costing studies tend to focus on estimating unit costs, which represent a point estimate in a cost function and are likely to vary with scale and scope of intervention. While cost functions would be more meaningful for modelling, there is limited evidence from which to derive them. Also, since most costs are based only on small-scale or pilot studies, there is an additional concern around generalisability. Structural interventions and their costs may be particularly dependent on context. Since certain structural interventions only operate at the community level, their expansion pathway can be more difficult to define. Finally, delivery platforms need to be considered more explicitly when thinking about costs and scale-up. For example, there may be significant potential for efficiency gains from economies of scope for interventions delivered on large non-health platforms with high fixed costs, such as cash transfers, but such shared costs will be difficult to disentangle (and possibly share across HIV and non-HIV payers).

The Global Health Cost Consortium: The GHCC has been created in order to establish new methods and standards for cost data collection, compilation and reporting. Its aim is to use data analytics to estimate location-adjusted benchmark costs for use in resource needs estimates, investment planning and efficiency improvement. In addition, the GHCC is developing advocacy and communication tools and incentives to increase appropriate use of cost data in policy and planning.

The overall aim will be to improve the impact of the tuberculosis (TB) and HIV response within available resources by influencing resource allocation and funding by systematically improving the quality, timing, local relevance, interpretation and use of cost information on HIV/AIDS and TB. Strategic aims are to improve the interpretation and use of cost information in resource needs estimates, investment planning and efficiency improvement, and to improve availability, quality, timing and relevance of cost data related to TB/HIV services. The process involves stakeholder groups and a technical advisory panel made up of producers of cost data (individuals conducting cost studies in lower and middle income countries), users of cost data (PEPFAR, GFATM, WHO, MOH, NICE International, iDSI), experts and practitioners (academic institutions, other funded initiatives), Economic Reference Groups of HIV/AIDS, TB and HIV modelling consortia.

The expected outputs from the GHCC will be:

- Repository of unit cost data
- Tools to utilise unit cost data
- Interactive data visualisation tools
- Links to primary data
- Reference case
- Repository of data collection tools/guides
- Training resources – online videos, links to key courses etc.

Funding structural interventions: A major challenge in funding structural HIV interventions is deciding who should fund them, which is likely to differ based on how the interventions are delivered. Structural intervention components that are added on to existing HIV programmatic platforms (HIV+) – such as community mobilisation for sex workers – and that demonstrate an incremental effect over and above the basic HIV programme are more likely to be accepted as being within the remit of the HIV budget. Likewise, HIV-specific intervention components that are added on to development programmatic platforms – such as an HIV and gender training component for microfinance beneficiaries (DEV+) – would most likely have to be funded by the HIV budget. However, a development programme without HIV-specific components, but with HIV impact, may require some form of cost-sharing between the HIV budget and the budgets of other benefitting sectors (Figure 23).

HIV		DEVELOPMENT	
HIV	**HIV+**	**DEV**	**DEV+**
E.g. Programmes for female sex workers	E.g. Community mobilisation and gender empowerment US$ 19-21 per FSW US$ 13-19 per DALY averted (India)	E.g. Cash transfers for school girls US$ 92-231 per girl US$ 212-912 per DALY averted (Malawi)	E.g. IMAGE combined MF and gender training US$ 15 per participant US$ 2,733 per IPV-related DALY averted (South Africa)

Figure 23: Additional structural intervention components may be adding on to existing HIV and development programmatic platforms, with the option of a cost-sharing arrangement. (Source: Remme et al, *JIAS*, 2014)

Indeed, there is obvious overlap in funding needs with some development programmes tackling the social drivers of HIV, but having other health and development primary objectives and being funded and implemented by other payers. However, with shrinking HIV funding and pressure for sustainable financing, development interventions with multiple outcomes present an opportunity. The

HIV sector is reluctant to undertake such interventions as they are often expected to have low HIV-specific cost-effectiveness, with greater benefits accruing to other sectors.

Part of this financing challenge relates to the decision frame being considered. Are HIV models aiming to optimise HIV outcomes subject to a budget constraint only, or are they also constrained by the implementation platforms of the HIV/health sector? If the former, then there is a need to find approaches to determine when HIV money would be more efficiently spent contributing to other health or development programmes without a distinct HIV component but with demonstrated HIV impact.

Four options were presented for modelling these interventions:

- Models could include their costs, but exclude their impact: this is often done to include upstream programme components without corresponding evidence of impact, but does imply that these components become cost burdens without apparent benefit, and may therefore be more readily cut out of the package.
- Models could exclude their costs, but include their impact, especially if they are likely to be implemented anyway by other sectors and thus form part of the external context of HIV programmes.
- Models could include part of their costs, and include part of their impact, as noted above for the HIV+ and DEV+ type interventions.
- Models could include part of the intervention costs, and include their full HIV impact, assuming the HIV budget would co-finance the intervention with other benefiting sectors (so-called cross-sectoral co-financing).

For the latter, the argument was made for considering multiple non-HIV outcomes and payers for structural interventions, which would imply adjusting cost inputs, based on a co-financing approach, and potentially more efficient financing outcomes. However, in practice, this would also require cross-sectoral engagement to ensure that such co-financing would be viable and operationalised.

KEY MESSAGES

- Structural factors function at a more macro level, upstream of the proximal determinants of HIV risk.
- The evidence for a direct impact of structural interventions on HIV incidence is generally weak.
- There is clear and strong evidence that structural interventions can increase uptake of biomedical interventions by acting on supply- and demand-side constraints and impacting on issues relating to adherence.
- Limited cost data on structural interventions is available, and it is generally from small-scale interventions in a wide range of different contexts, making it difficult to generalise or feed into a generalisable cost function.
- It is unclear who should fund structural interventions, given their multiple HIV and non-HIV benefits that extend to broader health and development programmes. Assuming these interventions could be co-financed would require reflecting such cost-sharing in investment models by adjusting cost inputs.

5. INCORPORATING STRUCTURAL INTERVENTIONS INTO EXISTING MODELS AND INVESTMENT CASES

This session began with the example of South Africa's HIV investment case, which sought to assess the optimal mix of HIV interventions in terms of allocative efficiency within the context of a national priority-setting process. Two more modelling presentations covered current models that included structural interventions, assessing models for FSW and decriminalisation of drug use among people who inject drugs (PWIDs).

STRUCTURAL FACTORS AND THE SOUTH AFRICAN HIV INVESTMENT CASE

Gesine Meyer-Rath presented on the South African HIV investment case and how the process dealt with structural factors. The key analytical questions that the investment case addressed included:

- What is the current spending on HIV?
- How much does it cost to fund the current HIV programme in the medium to long term?
- What is the optimal mix of interventions in terms of allocative efficiency?

Evidence concerning the effectiveness of biomedical and behavioural interventions against HIV and structural factors was gathered and assessed through a review process (Figure 24). Structural factors consisted of "efficiency factors" affecting the uptake of efficiency of one intervention only, and structural and programme enablers and development synergies thought to affect more than one intervention. The key objective was to find good quality evidence that could be included in an existing model of the South African HIV epidemic, the Thembisa model.

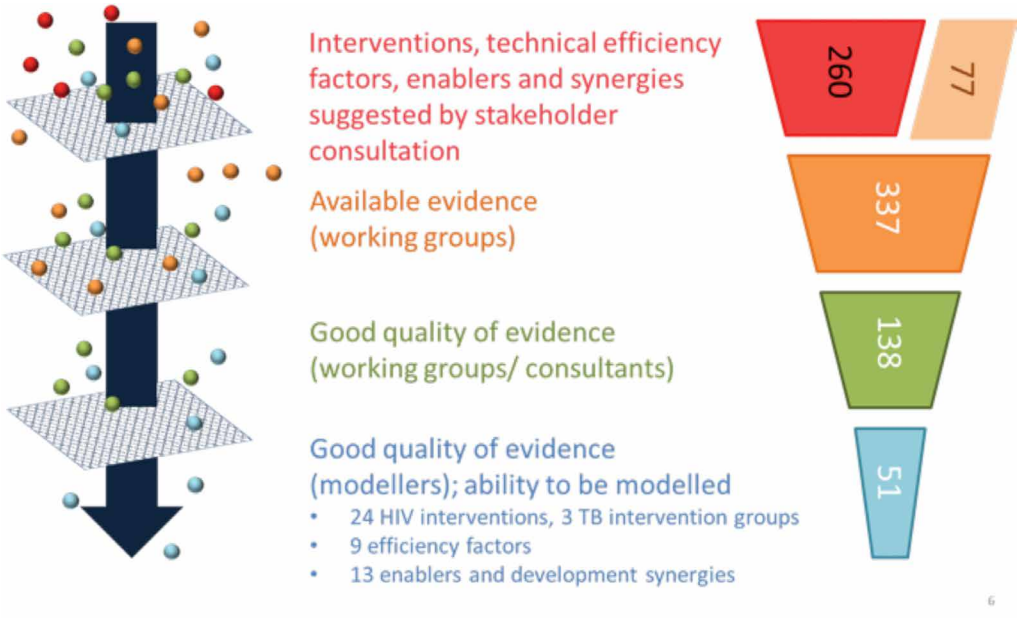


Figure 24: Review process to assess evidence concerning the effectiveness of biomedical and behavioural interventions against HIV and structural factors

The process involved modelling the cost and epidemiological impact of each intervention on the entire HIV programme and assessing the incremental cost per life year saved. In a second step, interventions were ranked by cost effectiveness using a novel optimisation technique that iteratively added the most cost-effective intervention onto a rolling baseline and then re-evaluating the cost-effectiveness of all other interventions incremental to the new baseline. The process allowed diminishing returns to be accounted for, which led to lower incremental effectiveness and higher incremental cost-effectiveness ratios (ICERs) throughout. The process then compared different scenarios for epidemiological impact, cost effectiveness and affordability against the baseline.

The review of current spending between 2011 and 2013 showed an increase in overall spending, with approximately 14% of the total budget allocated to those social enablers that ended up being included in the investment case. The results from the modelling showed the optimal package of programmes, under both a constrained and unconstrained environment (Figure 25), compared to the baseline scenario, with a significant impact on incidence if budgets were re-allocated according to the results of the optimisation.

	INTERVENTION	ICER (USD/LYS)
Constrained optimisation	Condom availability	Cost saving
	Male medical circumcision	Cost saving
	ART at current guidelines	84
	PMCT	103
	Universal treatment	187
	Infant testing at 6 weeks	193
	SBCC campaign 1 *(HCT, reduction in MSP)*	547
Unconstrained optimisation	SBCC campaign 2 *(condoms)*	872
	General population HCT	932
	SBCC campaign 3 *(condoms, HCT, MMC)*	1,374
	HCT for sex workers	2,004
	Infant testing at birth	2,207
	PrEP for sex workers	7,476
	HCT for adolescents	15,307
	PrEP for young women	19,993
	Early infant male circumcision	68,969,435

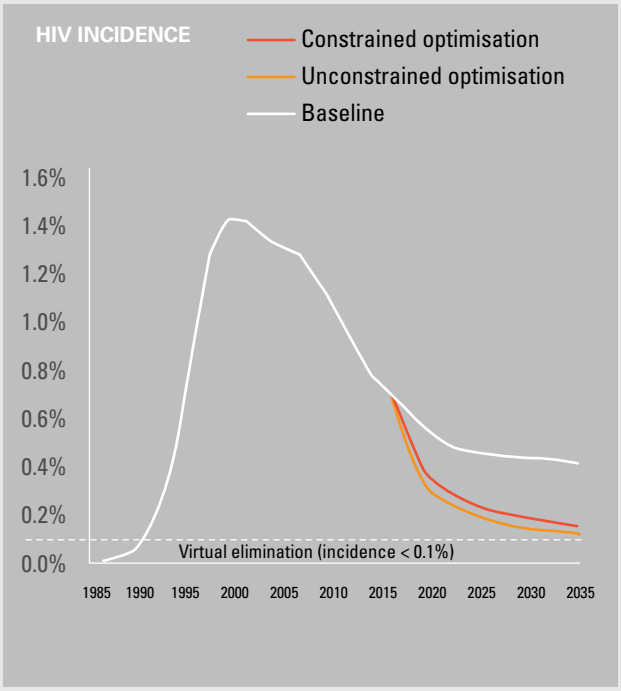


Figure 25: Results from the modelling analysis comparing a baseline scenario to constrained and unconstrained environments

Critical enablers were also included in the analysis, based on literature regarding their effectiveness +/- costs. However, even when only the fraction of their cost that was assumed to be borne by the HIV budget was included, they were much less cost effective than behavioural and biomedical interventions. In fact, apart from adherence clubs and community-based testing interventions, all deemed efficiency factors rather than programme enablers, most enablers were twice to 10 times as expensive per life-year saved as the full package of interventions under the unconstrained optimisation scenario (Figure 26). In summary, the results showed that critical enablers are not able to compete with other interventions on the basis of HIV endpoints, though there might of course be other reasons why they need to be scaled up further.

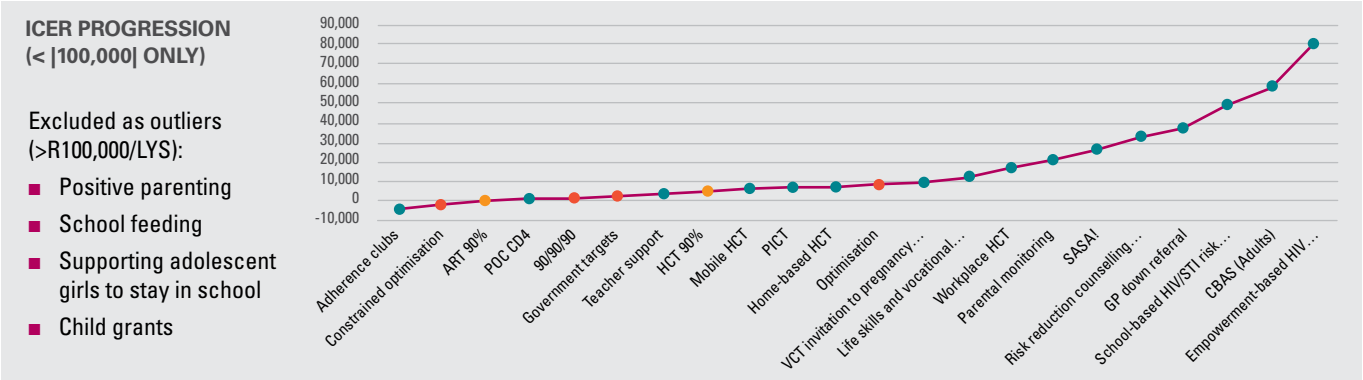


Figure 26: Critical enablers were not able to compete with other interventions on the base of HIV endpoints

To better understand the potential role critical enablers could play, an expert group conducted an additional review of evidence on the existing list of enablers and solicited new evidence. based on a more explicit and rigorous procedure: using a GRADE algorithm for RCTs or observational studies, and agreeing on a percentage cost that could be feasibly covered by the department of health. This generated a revised list of enablers with good evidence (Figure 27). Additional cost effectiveness analysis of these interventions is under way.

GENDER-BASED INTERVENTIONS	ALCOHOL
■ Community-based **GBV intervention** (SASA!) ■ **Changing gender norms of scouts** (Path 2012) ■ **IPV and HIV prevention** (Wagman 2015)	■ Risk reduction for **alcohol and substance abuse users** (Kalichman 2007) ■ **Empowerment-based HIV intervention designed to reduce sexual risk, substance abuse**, etc. (Wechsberg 2008)
EDUCATION	**SOCIAL PROTECTION**
■ Supporting **orphan girls** to stay in school (Cho 2011) ■ **School-based HIV/STI risk** reduction (Jemmott 2010) ■ Education through providing **HIV risk information on teenage sexual behaviour** (Dupas 2011) ■ **School-based sex education** (Fonner 2014)	■ **Life skills** and vocational training for out-of-school adolescent girls (Bandiera 2012) ■ **Teacher support, parent monitoring, school feeding, and positive parenting** (Cluver PC)
STIGMA REDUCTION AND OTHER	**CASH TRANSFERS AND MICROFINANCE**
■ Providing information on the public benefits of ART (Derksen 2015) ■ **Lottery-based incentivisation for maintenance of negative STI status** (Bjorkman-Nyqvist 2013) ■ Social services intervention (Bateganya 2015)	■ **State-provided cash transfers** (Cluver 2013) ■ Cash transfers **conditional on school attendance** (Baird 2012) ■ Combined microfinance and training (Pronyk 2008) ■ Incentivising FSW to leave SW (Odek 2009) ■ Microfinance, water pumps and education in sustainable farming practices (Weiser 2015)

Figure 27: Revised list of critical enablers

Key lessons learned from this exercise were:

1. There is *not* no evidence, and *no* need to cost structural factors by simply adding a % mark-up. There are very few studies (especially from South Africa) with a valid impact on an HIV endpoint that can be linked into an HIV transmission model.

2. Enablers fall short of other interventions' cost effectiveness. This is only a problem if they continue to compete for HIV funding from the same sources, which is why co-financing will have to play a significant role.

3. How to avoid double-counting effects in modelling. Current methods, including multiplying impacts or applying impacts consecutively on mutually exclusive fractions of a population, do not avoid the problem of diminishing marginal returns as the available evidence tends to report impacts of disparate structural factors or interventions on the same outcome in the same population. The solution to this may lie in study designs that evaluate the role of a number of structural factors in the same population.

The recommendation from this work was to reorganise the research on structural factors by population and to understand the different impact each structural factor exerts on a population group, and how each relates to one or more HIV endpoints (Figure 28).

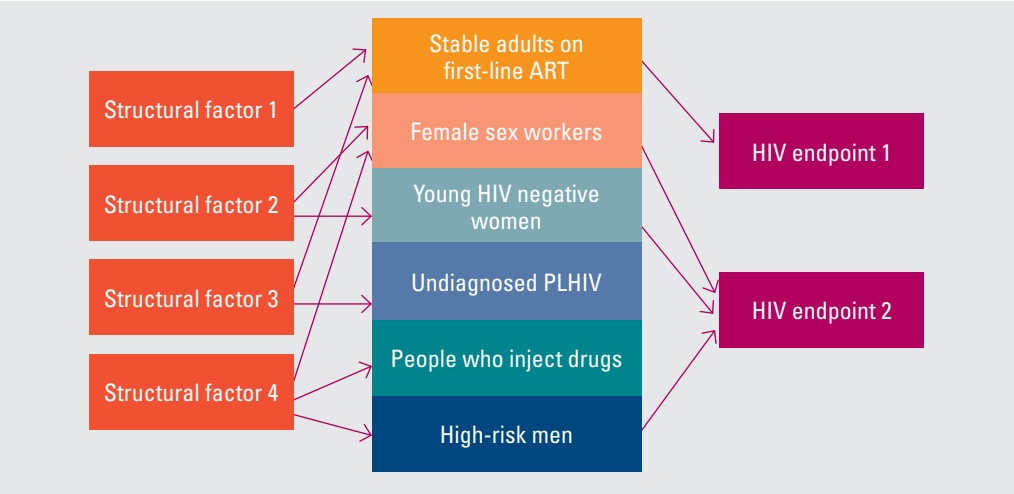


Figure 28: A key recommendation was to reorganise the work on structural factors by population, to enable a better understanding of the different impact that structural factors exert on a population group

MODELLING FSW EMPOWERMENT PROGRAMMES

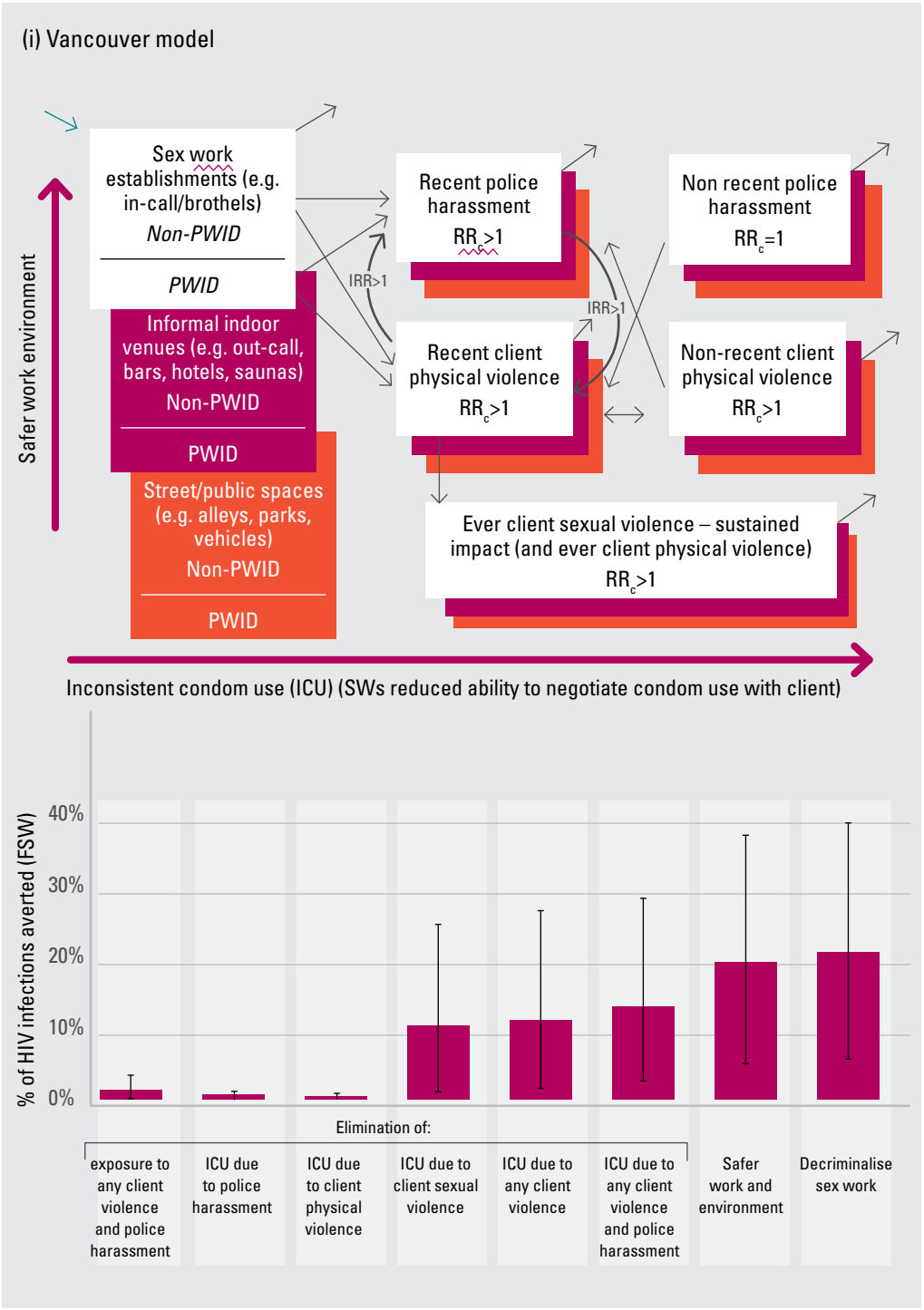
Michael Pickles presented two approaches to modelling FSW empowerment programmes. Sex worker empowerment is described as "a process by which sex workers take collective ownership of programmes and services to achieve the most effective HIV responses and address social and structural barriers to their health and human rights"(35). However, in the context of different intervention settings and populations it may describe a specified range of activities, which change over time, with varying levels of intensity dependent on the setting and different time points throughout the duration of the intervention. This results in differences in levels of effectiveness between settings and assumes that other supply/demand side issues are met.

The differences between top-down interventions (intervention modelled as change in a parameter) and bottom-up interventions (model more of the pathway, not just the direct risk) were described and two examples presented. The bottom-up approach example assessed modelling the effects of violence reduction and decriminalisation of sex work. The over-arching aim was to model the effects of elimination of different types of violence, and decriminalisation on HIV infections in sex workers in three geographically diverse settings (Vancouver, Mombasa and Bellary).

The model stratified FSWs by their experiences of violence, and how condom use varies (i.e. those who experienced sexual violence use condoms less). The model allows for FSWs to transition between different states of violence. The FSWs are

also subdivided by typology into brothel-based, street-based and home-based. The model structure therefore varied based on context (Figure 29), and was guided by data availability. In this example, FSWs in Vancouver (i) are more likely to also inject drugs, while binge drinking was a risk factor in Mombasa (ii).

When results between settings were compared, there were significant differences in the effectiveness of certain interventions, indicating the importance of context-specific model structures (Figure 29).



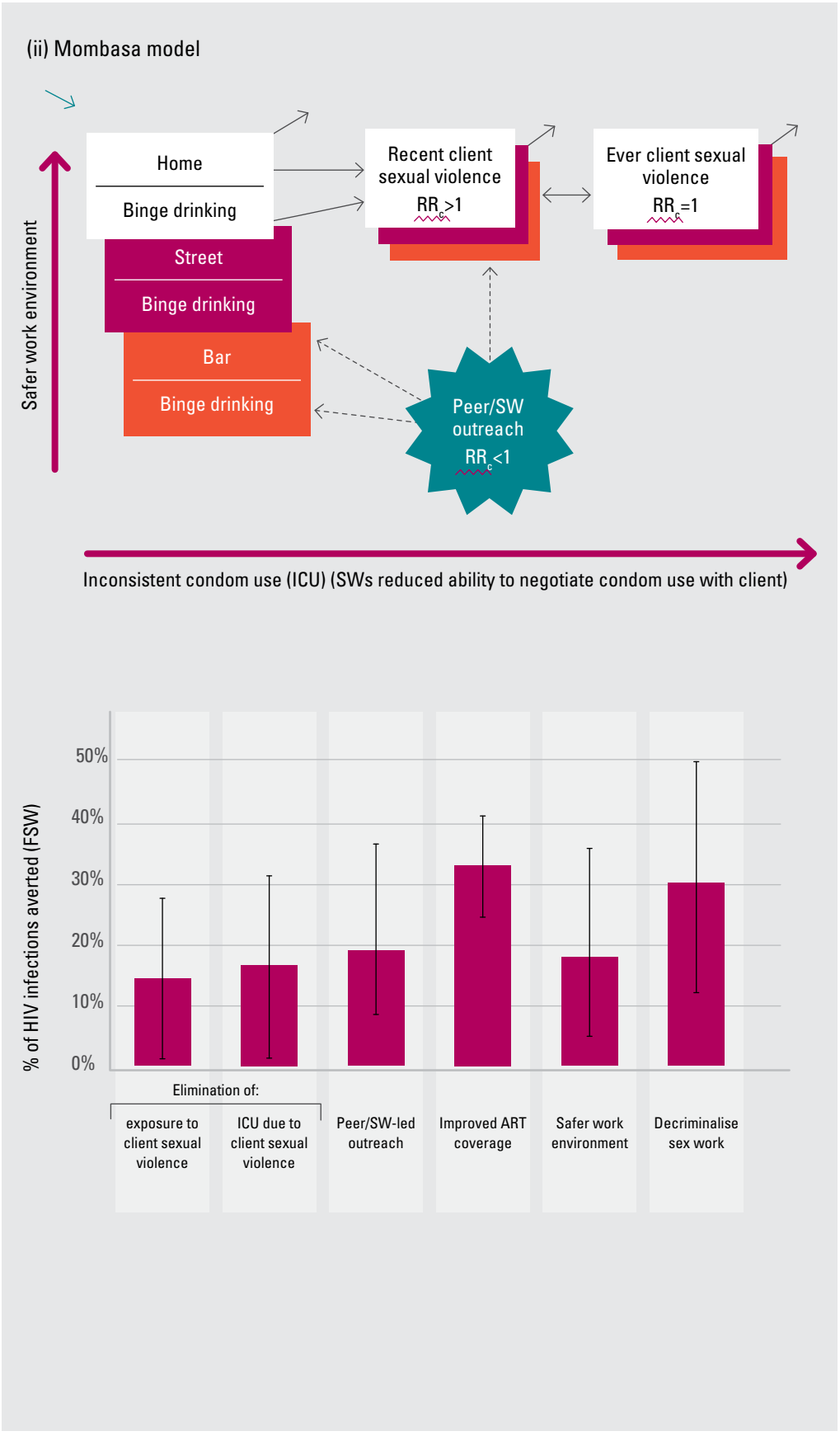


Figure 29: Comparison of model structure for Vancouver (i) and Mombasa (ii), and corresponding model results

The top-down modelling approach used the example of modelling the impact and cost-effectiveness of community mobilisation as part of the Avahan India AIDS initiative. The aim was to assess the incremental impact and cost-effectiveness of the community mobilisation and empowerment activities in Avahan and address the question of whether community empowerment should be a core part of FSW interventions. Avahan aimed to create a standardised intervention with the same basic mix of components in every site and standardised training (with local variation where needed). The intervention was carried out in >80 districts in India (and evaluated in 22), with the mix of activities in each setting changing over time.

Community mobilisation was modelled by dividing the FSWs into groups based on their levels of condom use ("always", "sometimes" and "never), with FSWs having the ability to change groups due to the intervention. Challenges associated with parameterising the model included the complexity of a large package of intervention activities, and how to uniquely capture the effect of community mobilisation alone, as opposed to in conjunction with other services. This was achieved by calculating an odds ratio for condom use with occasional clients, adjusted for confounders, with a proportional difference in the odds ratio representing changes in consistent condom use due to community mobilisation. A key finding was that having multiple time points suggested the effect of community mobilisation remained similar over time, despite activities changing. This may suggest that, during intensive programmes, over time other issues (e.g. supply of condoms) were also addressed.

In summary, a bottom-up approach faces challenges associated with variations in model structure between settings, and difficulties in parameterising transitions between states. However, such an approach may highlight important issues on the causal pathway. A top-down approach is simpler and can be used with existing models. As demonstrated, "parameterising" empowerment is difficult, particularly since programmes differ in the content, geographically and over time. Implementation is also likely to vary depending on the status of relationships with the FSW community, and local structural factors that affect FSWs. Casual pathway analysis is likely to be necessary, along with the use of local, time-varying parameters.

Modelling structural factors is a developing area, and there is a need to start to understand which structures can and cannot be used and the resulting implications. There is also a need to ensure that parameters function in a way that is assumed to be representative – ensuring that 'switching off a structural parameter' really represents what happens when an intervention is applied.

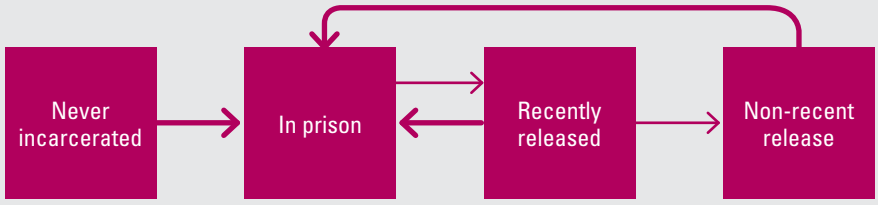
MODELLING THE EFFECTS OF INCARCERATION AND INJECTING DRUGS ON HIV AND HCV TRANSMISSION

Peter Vickerman presented an example of modelling HIV and HCV transmission amongst people who inject drugs (PWID) and the role of incarceration. Levels of incarceration amongst drug users are high, and many inmates are themselves drug users with 10–48% of men, and 30–60% of female inmates globally reporting illicit drug use in the previous month before prison. Levels of re-offending are particularly high, and model estimates suggest 40% of recently released PWID are re-admitted within a year. HIV prevalence is generally 2–16 times higher in prison than in the general population, and it is unclear whether this is due to the increased risk in prison, after release, or both – with an alternative theory being that higher-risk PWID get arrested more. A prison environment, with a limited supply of drugs, should mean PWID typically inject less frequently. However, in the absence of clean needle exchange programmes, there may be a limited number of clean needles resulting in more syringe sharing. To date, there is limited evidence to compare HIV

incidence amongst PWID in prison versus those in the community. However, there is preliminary evidence to suggest a greater relative risk (1.73, 1.22-2.25 95%CI) following release from prison, which diminishes over time. Evidence shows more individuals sharing needles and injecting more frequently, with some evidence to suggest lower rates of opioid substitution (OST) and needle substitution programme (NSP) use. Structural factors such as homelessness, unemployment, disruption to social networks and inadequate family support may also contribute.

Most of the evidence on the associated risk of incarceration comes from community survey data, with insufficient data on in-prison risk. Figure 30, shows the model structure and the associated processes for estimating risk. The model was used to project the contribution of incarceration to HIV transmission, the impact of preventing further incarceration of PWIDs and the impact of introducing OST into prisons (both with and without retention following release). Results will follow at a later date.

Challenges: There are several data challenges, which include an inability to determine causality because of only cross-sectional data being currently available. More longitudinal data or analyses are required to enable follow up from community to prison and back into the community. There is also a need to better understand the mechanism of effect, i.e. the interaction with interventions and structural factors which exist which may be crucially important for causation and understanding required interventions.



Calibrate model in Bayesian framework to fit to:

1. Incarceration data (% ever in prison and number of times) against injecting duration – to give rate of initial incarceration and rate of re-incarceration
2. HIV/HCV prevalence in each group while
   - Use behaviour or incidence data as priors for difference in risk by incarceration states

Figure 30: Model structure and strategy for estimating risk amongst the prison population

Additional challenges include potential high rates of attrition in longitudinal studies because of short sentences, and continual transition of inmates between prison wings. There are also increased ethical considerations related to conducting research in prisons compared to communities, and there is likely to be under-reported drug use due to a fear of retribution. Finally, studies of single prisons are unlikely to be representative of all prisoners, as prisons may vary by gender, sentence lengths, security and crime.

Current interventions within prisons are limited, with only eight countries having NSP in prison, compared to 82 in the community. However, OST is available in nearly 40 countries (Figure 31), although coverage is often low and frequently not available in every prison within a country, with strict enrolment criteria. Nonetheless, the HIV Care Cascade shows that retention on ART tends to be higher in prison compared to the national average and after release. This is likely the result of greater support (Figure 32).

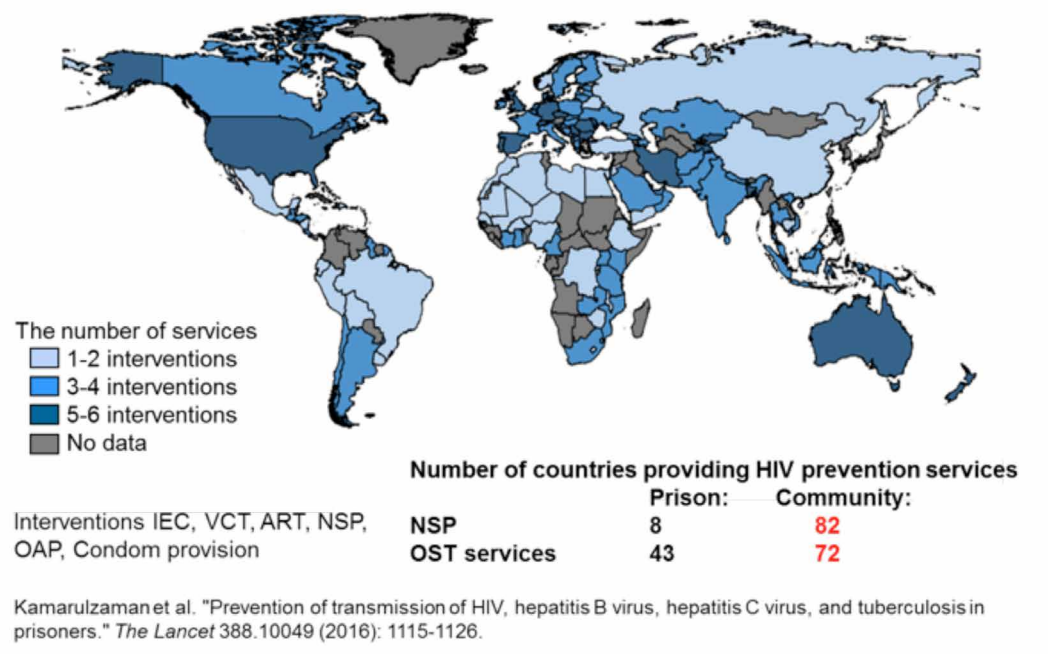


Figure 31: Provision of HIV, HCV and HBV interventions in prison by country from 2008 to 2015

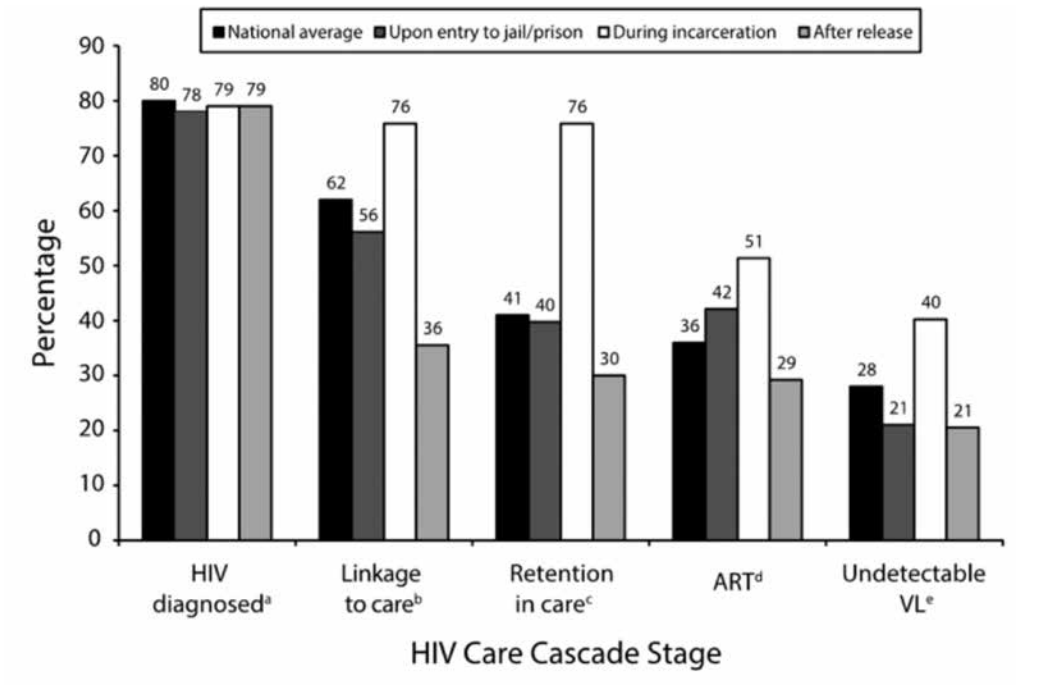


Figure 32: Decline in HIV Care Cascade following release from prison in the United States and Canada, (Source: Iroh, P. A., Mayo, H. and Nijhawan, A. E. (2015). The HIV Care Cascade Before, During, and After Incarceration: A Systematic Review and Data Synthesis. *American Journal of Public Health*, 105(7))

In summary, PWID account for 30% of new HIV infections outside sub-Saharan Africa. Eastern Europe and central Asia are the only areas with HIV infection rates increasing, with half of all new infections due to PWIDs. For HIV-positive PWID who are incarcerated, structural barriers to accessing treatment and retention in treatment programmes are likely to be greater; following their release from prison, they face high levels of unemployment, housing insecurity and a lack of social support in many countries. This is reflected in the care cascade (Figure 32),

where linkage to care, retention and adherence levels are consistently lower than the national average. Additional data, as well as patterns of transmission, will be essential to guide future modelling. There is a crucial need for more research in this area with these initial analyses suggesting prison settings and the transition back to the community could contribute significantly to both HIV and HCV in this vulnerable group. The prison setting provides a direct means to reach this group for treatment interventions, with a need for strong structural programmes supporting continuity of care after release.

KEY MESSAGES

- On the basis of immediate endpoints, and how they are currently measured and modelled, structural interventions cannot compete with other HIV interventions, but there are likely to be other justifications for scaling them up further.
- Structural factors research should be reorganised by population groups to understand the impact that each structural factor exerts on a population group, and how each relates to one or more HIV endpoints.
- Modelling structural factors is a developing area, and there is a need to better understand which model structures can be used and their implications.
- The treatment cascade has been demonstrated to be an effective tool to compare rates of retention in care, particularly when there is heterogeneity amongst a population (e.g. PWID in prison versus those in the community). This could be an important lesson for HIV prevention.

6. UNDERSTANDING THE ROLE OF STRUCTURAL INTERVENTIONS IN HIV INVESTMENT MODELS AND AREAS FOR IMPROVEMENT

In this session, two presentations were given on the structure of the Goals and Optima models, assessing the criteria for inclusion of current interventions in the models, adaptation of the models and future challenges. This provided an opportunity to compare an impact-matrix approach using default values (Goals) with an approach where the onus is on the local teams to input interventions and data, yet still continuing to have default values for certain parameters (Optima).

MODELLING STRUCTURAL INTERVENTIONS IN THE GOALS MODEL

Lori Bollinger presented a summary of the Goals model, explaining the overall structure and process and explaining how structural interventions have been incorporated. The structure of the Goals model divides the population into risk groups and uses information about the behaviour of each group to estimate transmission. Two types of interventions can affect transmission: biomedical interventions (condoms, male circumcision, ART) that directly affect transmission, and behavioural change interventions, which affect behaviours associated with risk (Figure 33).

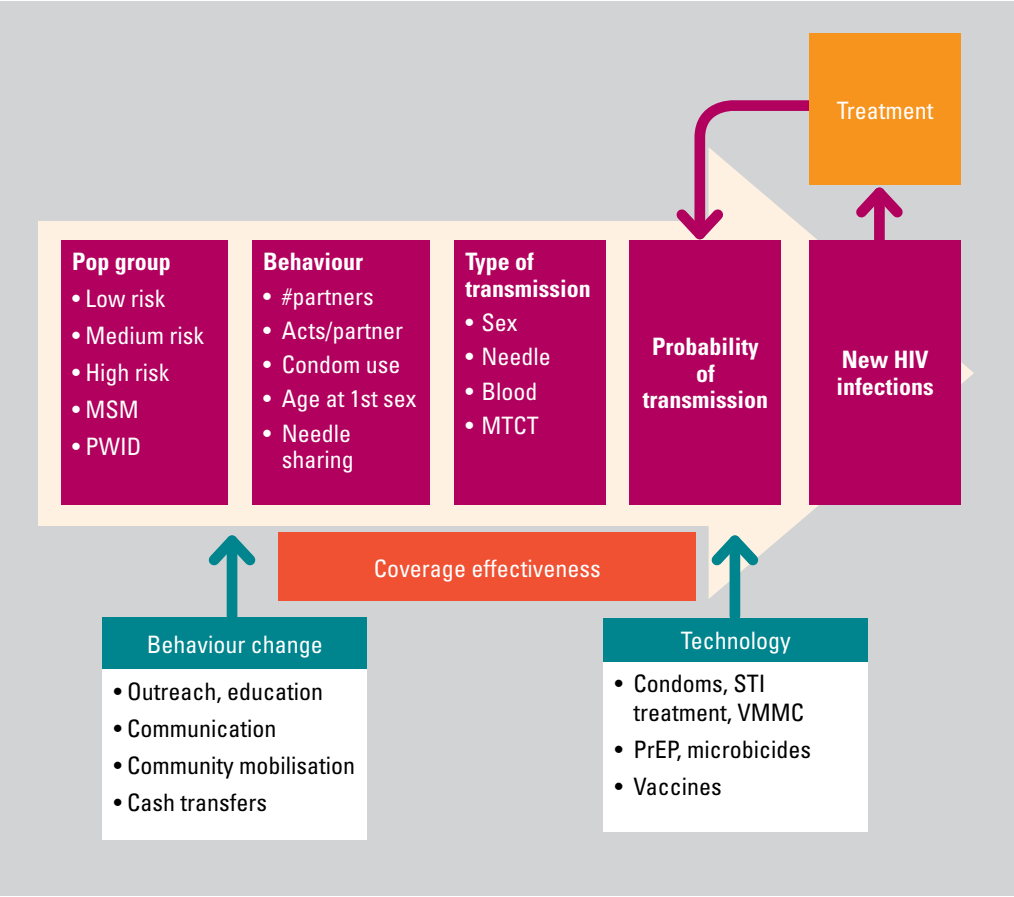


Figure 33: The Goals Model

The impact matrix is a key feature of the Goals model. It provides default values of the impact for a set of recommended interventions based on summaries of all the available studies that meet the quality standard. The interventions target a set of outcomes, which include condom use, number of partners, age at first sex and needle sharing for PWIDs. Upper and lower quartile versions of the matrix contribute to estimating the uncertainty in the outputs. Users have the option to change the default values at any time. Costs and impact are included if the intervention is in the behavioural impact matrix, or biomedical impact matrix. Costs are also included at a macro level for creating an enabling environment (e.g. stigma, human rights), where they can be entered as an absolute number or percentage.

The structure of the overall model has adapted over time, often in association with emerging policy initiatives, and as a result of Avenir Health's involvement with the aids2031 Costs and Financing Working Group. Structural interventions were first included in 2007, and have evolved to become part of the "enabling environment" of interventions within the UNAIDS framework. Among additional changes is the inclusion of cash transfers. With emerging evidence from the SHARE trial, programmes for preventing violence against women could soon be included too. There may be an option in future to add an intervention that specifies impacts by risk group and by outcome.

There are a couple of caveats that relate to the results generated by the model. Firstly, much of the work relates to advocacy efforts but not to actual budget allocations. Secondly, before the group is able to make recommendations on including further structural interventions, impact and actual costs need to be identified.

The Goals model is used extensively for policy purposes. Greater consolidation of evidence in the future will continue to improve model outputs.

STRUCTURAL INTERVENTIONS WITHIN OPTIMA HIV

Robyn Stuart presented on how structural interventions had been incorporated into Optima HIV. A software package and modelling tool, Optima HIV is designed to help countries allocate funds for HIV in a way that will result in maximal impact on the epidemic. It consists of four components:

- A mathematical model of HIV transmission/progression
- A programme/costing module for defining the HIV response
- A framework for defining the objectives and constraints of the response
- A mathematical optimisation algorithm that can determine, for any budget envelope, the optimal allocation of funds

The stages of the analysis are intended to determine which investment combination leads to the optimal outcome (Figure 34).

In order to model direct programmes, the model requires evidence of impact on one of the inputs to the epidemic model – sex acts, condoms, etc. – in addition to efficacy of protection, cost data (budgeted total cost or total spending data) and data on current coverage of the intervention. Programme definitions are flexible, unlike in Goals. The steps for defining a programme and identifying its effect are:

1. Determine the target population for the programme, and determine which proximal determinants of HIV the programme aims to affect.
2. Determine any supply- and demand-side constraints to coverage and uptake of the programme.
3. Determine how individuals reached by the programme will be affected.

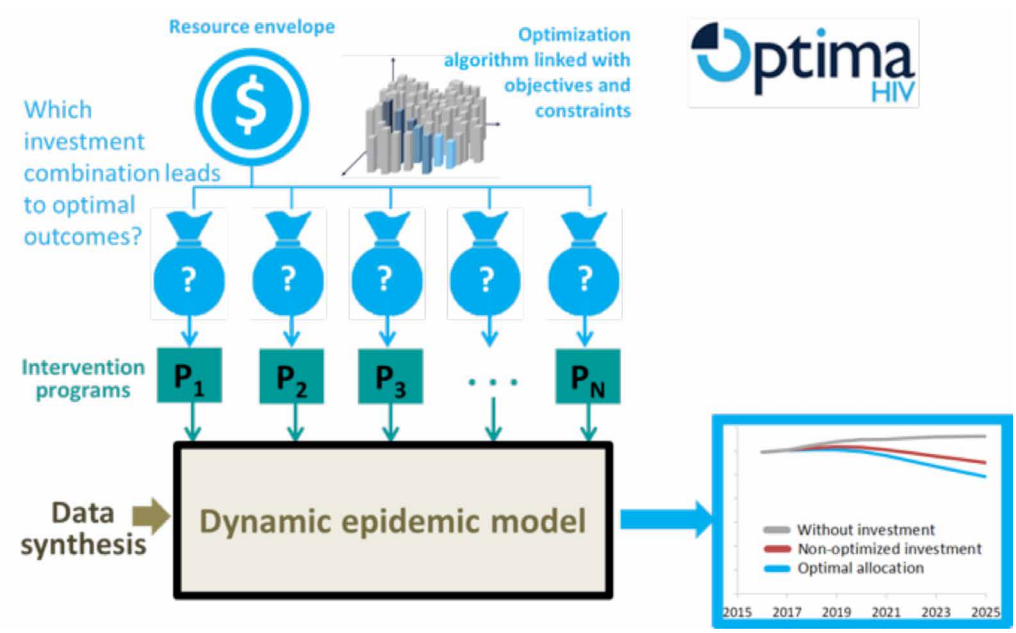


Figure 34: Schematic representation of Optima HIV

These steps are depicted in Figure 35. Based on these steps cost functions for each programme are derived (Figure 36).

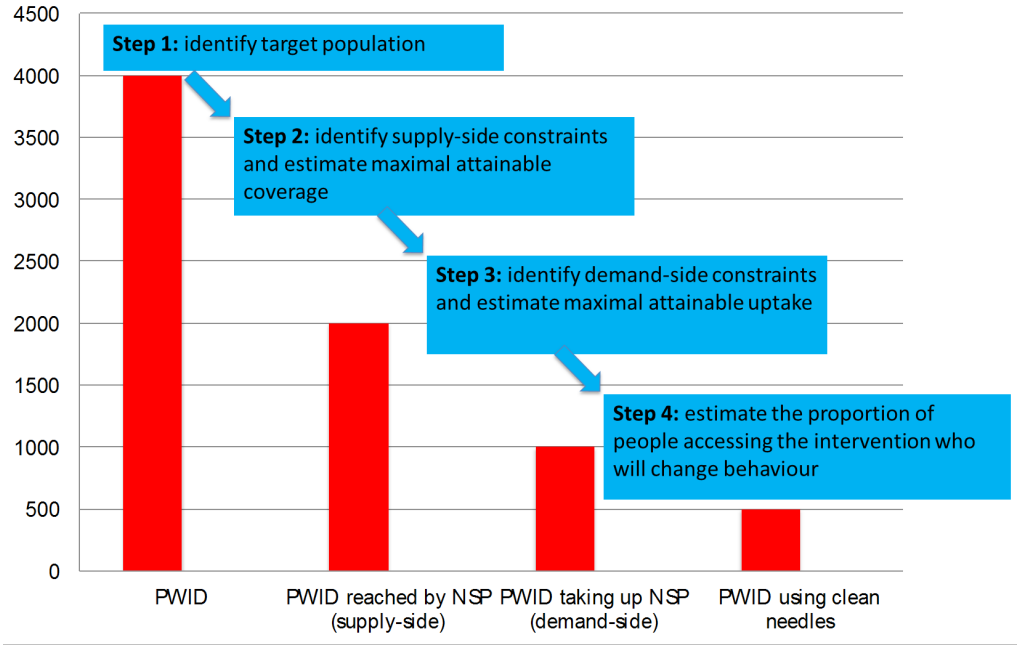


Figure 35: Optima HIV steps for defining a programme and identifying its effect

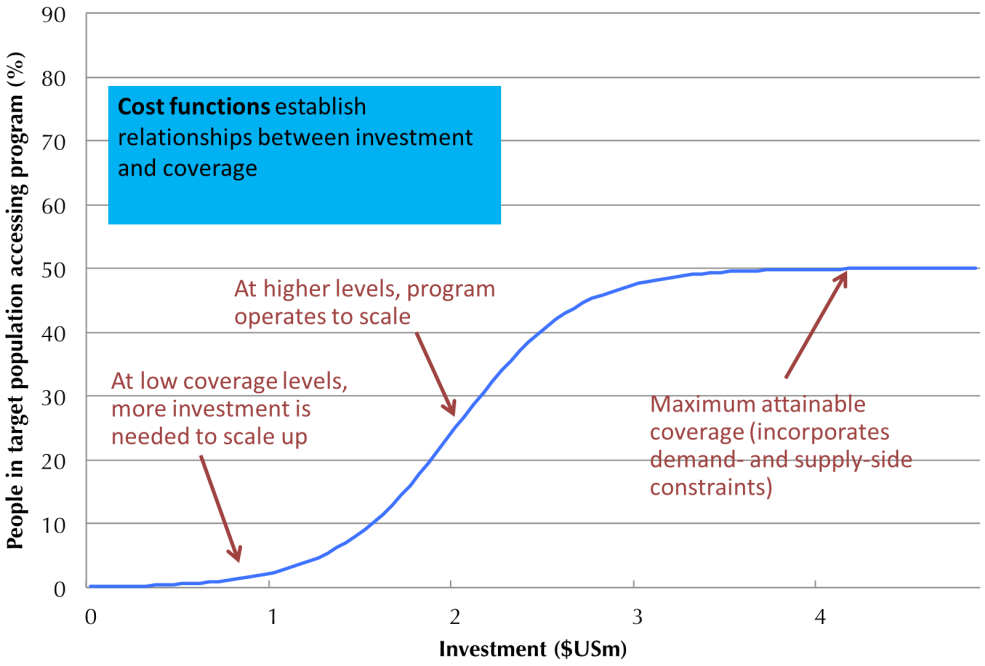


Figure 36: Cost functions are derived based on the individual programmes

Indirect programmes affect the target population, coverage and uptake of direct programmes (Figure 37). As with direct programmes, modelling indirect programmes requires evidence of impact, cost data and data on current coverage of the intervention.

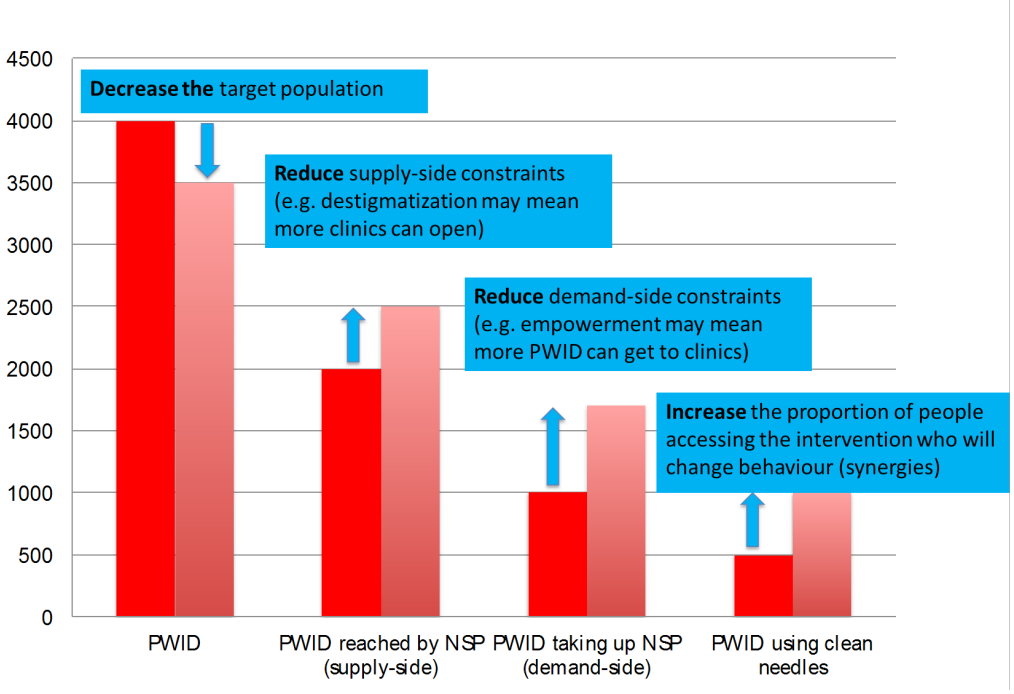


Figure 37: Impact of indirect programmes on the supply-side constraints, demand-side constraints, and adherence outcomes of direct programmes

Increasing investment in indirect programmes affects the cost functions for direct programmes by reducing demand- and supply-side constraints, resulting in higher coverage of direct programmes at any given investment level. Therefore, investments in structural interventions lead to reductions in barriers to both delivery and uptake of direct programmes and increased coverage of direct programmes. The impact of direct programmes affects behavioural and clinical outcomes, and therefore the epidemiology of the HIV epidemic.

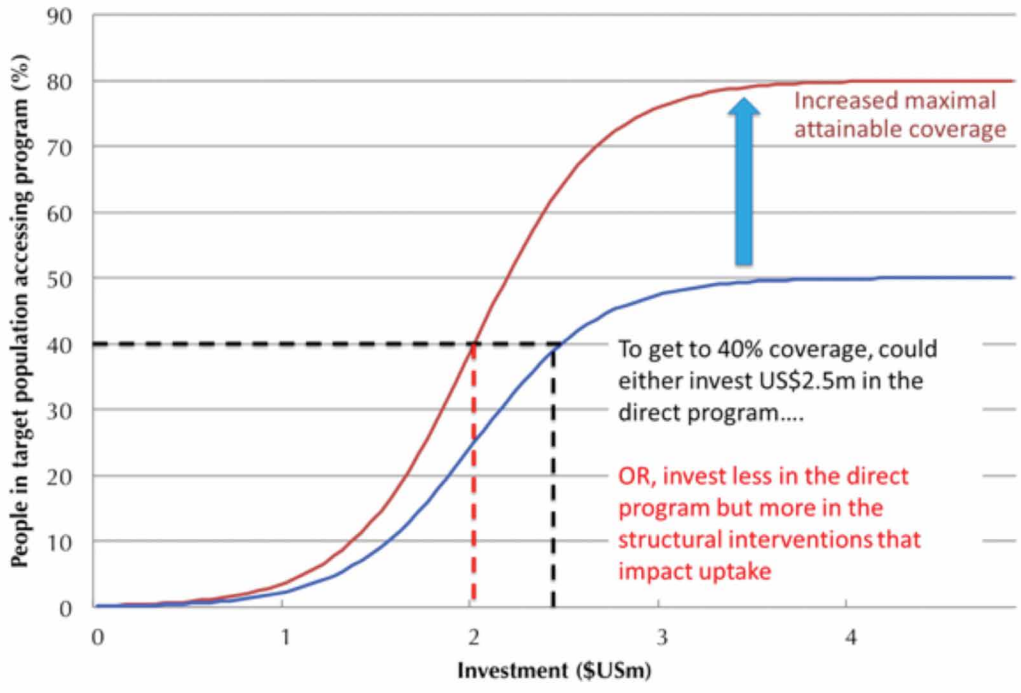


Figure 38: Increasing investment in indirect programmes affects the cost functions for direct programmes. Reduced demand- and supply-side constraints mean higher coverage of direct programmes at any given investment level

Co-financing of interventions has also been considered in studies that have used Optima HIV. For certain interventions, it may be possible to calculate the share of overall benefits that go towards the HIV sector. The question of whether HIV budgets should finance the entirety of interventions that also bring benefits to other sectors is not simple to resolve, however. The answer is dependent on the economic framework as well as the willingness to pay.

In summary, to date many approaches have been tried for programmes that affect proximal determinants, but there is evidence to suggest that indirect programmes could significantly raise the 'cap' on the saturation levels currently evidenced for direct programmes. The approach needs to be context-specific. To model structural interventions effectively, more impact data is needed from different contexts.

7. RECOMMENDATIONS

The evidence presented at this meeting suggested that current approaches to resource allocation and priority setting do not adequately consider or model structural and other more complex interventions. Yet there is a significant and growing body of evidence on the effectiveness of a range of structural interventions on HIV service coverage and HIV-related outcomes that is not fully reflected in current HIV investment models. A major conclusion was to conduct a comprehensive review and re-order the current evidence in line with the HIV treatment and prevention cascades, and to then explore methods of integrating this into investment models, through a process guided by expert opinion.

SHORT-TERM RECOMMENDATIONS

→ **Rethink whether mathematical models for decision-making should seek to incorporate multiple complex interventions**

The HIV Modelling Consortium should organise a consultation to discuss: (1) future approaches to modelling for decision-making, specifically tackling the issue of how feasible it will be to continue to incorporate multiple interventions, and whether there may be alternative, less complex approaches, which focus primarily on identifying the main epidemiological determinants that need to be tackled; (2) the potential value of integrating the cascade perspective into epidemiological models.

→ **Re-organise data on structural interventions along the prevention/treatment cascade**

With the increasing body of evidence now available, it would be useful if the data from different structural drivers could be combined and organised, so that it links more explicitly with the different steps of the prevention and treatment cascades. This would facilitate a better understanding of how different structural factors may work in combination to affect different parts of the cascade and so highlight which combinations of interventions are likely to have the largest effect. STRIVE is well placed to lead on this work, by doing a review to re-orient the evidence across a range of structural drivers and interventions, which impact upon biomedical interventions.

An initial review of the feasibility of this approach could be conducted using existing resources, considering adolescent girls for example. A series of steps would include identifying biomedical interventions offered to this population, differentiated by treatment and prevention; accessing available data on the supply-side, demand-side and adherence estimates in the cascade specific to this group; identifying structural intervention studies with outcomes that impact upon the components of the cascade; and understanding what additional data would be needed to fill current gaps in the evidence. This work would generate a framework to reorganise the data for other key population groups, as well as strengthening the case for the inclusion of adolescent female groups in investment models by estimating both their protective benefit from HIV, as well as additional investment benefits for this population.

→ **Establish an external review process to validate the quality of inputs and assumptions included in modelling**

A transparent and systematic process for evidence synthesis is required for the selection of interventions to put into models that are used for decision-making. The Global Fund and UNAIDS should ensure that a robust consultation process is in place to evaluate model approaches and that data inputs have had external review and validation from appropriate technical experts.

LONGER-TERM RECOMMENDATIONS

→ **Development of models**

Future conceptual work and thinking on how to redesign models to test and model interventions should seek to draw upon insights from a bottom-up approach with top-down thinking and concepts of the cascade. Moreover, in the context of the SDGs, it may become more important to identify opportunities to integrate HIV modelling with broader SDG modelling initiatives, or efforts to model packages of interventions for adolescents, for example.

→ **Economics/co-financing**

Cost inputs for structural interventions should account for their potential additional non-HIV benefits and the existence of other funding streams with those non-HIV objectives. There will be a need to clarify and provide guidance on financing and cost-sharing implications for different types of structural interventions, i.e. whether these represent components of HIV programmes or non-HIV programmes. This work could be led by STRIVE.

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PARTICIPANTS

John Stover
Director, Modelling and analysis
Avenir Health, Connecticut, USA
JStover@avenirhealth.org

Lori Bollinger
Vice President
Avenir Health, Connecticut, USA
LBollinger@avenirhealth.org

Chutima Suraratdecha
Senior Economist
Lead Health Economics and Finance Team,
Division of Global Health and TB,
US Centers for Disease Control and Prevention, USA
yhp3@cdc.gov

Joanne Csete
Adjunct Associate Professor
Department of Population and Family Health,
Mailman School of Public Health. Colombia University, USA
jc1188@cumc.columbia.edu

Charlotte Watts
Director of Research and Evidence Division
Professor of Social and Mathematical Epidemiology
Department for International Development, UK
London School of Hygiene & Tropical Medicine, UK
Charlotte.Watts@lshtm.ac.uk

Jay Bagaria
Health Advisor
Global Funds Department, Department for International Development, UK
J-Bagaria@dfid.gov.uk

Tjin Lim
Deputy Programme Manager for The Global Fund
Global Funds Department, Department for International Development, UK
T-Lim@dfid.gov.uk

Heather Doyle
Senior Coordinator, Gender Strategy
Investment and Impact Division, The Global Fund,
Geneva, Switzerland
Heather.Doyle@theglobalfund.org

Hannah Grant
Allocation Model Manager
Strategy and Policy Hub, The Global Fund,
Geneva, Switzerland
Hannah.Grant@theglobalfund.org

Kate Thomson
Head, Community Rights and Gender
The Global Fund. Geneva, Switzerland
Kate.Thomson@theglobalfund.org

Gesine Meyer-Rath
Assistant Professor
Center for Global Health and Development,
Boston University, USA
Health Economics and Epidemiological Research Office,
Wits Health Consortium, University of Witwatersrand, SA
Gesine@bu.edu

Anne Stangl
Senior Behavioural Scientist
International Research on Women, USA
astangl@icrw.org

Katherine Fritz
Senior Research Advisor
International Research on Women, USA
kfritz@icrw.org

Tim Hallett
Professor of Global Health
School of Public Health, Imperial College London, UK
tbhallett@gmail.com

Marie-Claude Boily
Professor of Mathematical Epidemiology
Department of Infectious Disease,
Imperial College London, UK
marieclaude.boily@gmail.com

Mike Pickles
Research Fellow
Department of Infectious Disease Epidemiology,
Imperial College London, UK
m.pickles@imperial.ac.uk

Sarah-Jane Anderson
Research Associate
Applied HIV Epidemiology Research Group, Imperial College London, UK
sarah-jane.anderson@imperial.ac.uk

Anna Vassall
Professor Health Economics
Department of Global Health and Development, London School of Hygiene & Tropical Medicine, UK
Anna.Vassall@lshtm.ac.uk

Michelle Remme
Assistant Professor in Health Economics
Department of Global Health and Development, London School of Hygiene & Tropical Medicine, UK
Michelle.Remme@lshtm.ac.uk

James Hargreaves
Professor in Epidemiology and Evaluation
Department of Social Epidemiology and Evaluation, London School of Hygiene & Tropical Medicine, UK
James.hargreaves@lshtm.ac.uk

Holly Prudden
Consultant/Honorary Research Fellow
Independent Consultant, HIV modelling and social epidemiology, UK
Holly.prudden@lshtm.ac.uk

Graham Medley
Professor of Infectious Disease Modelling
Department of Global Health and Development, London School of Hygiene & Tropical Medicine, UK
Graham.Medley@lshtm.ac.uk

Lori Heise
Associate Professor and co-Research Director of STRIVE
Department of Global Health and Development, London School of Hygiene & Tropical Medicine, UK
Lori.heise@lshtm.ac.uk

Tara Beattie
Assistant Professor in Social Epidemiology
Department of Global Health and Development, London School of Hygiene & Tropical Medicine, UK
Tara.Beattie@lshtm.ac.uk

Fern Terris-Prestholt
Associate Professor in Economics of HIV
Department of Global Health and Development,
London School of Hygiene & Tropical Medicine, UK
Fern.Terris-Prestholt@lshtm.ac.uk

Zindoga Mukandavire
Assistant Professor in Mathematical Modelling of HIV
Department of Global Health and Development,
London School of Hygiene & Tropical Medicine, UK
Zindoga.Mukandavire@lshtm.ac.uk

Saidi Kapiga
Scientific Director
Professor in Epidemiology and International Health
Mwanza Intervention Trials Unit, Tanzania.
London School of Hygiene & Tropical Medicine, UK
Saidi.Kapiga@lshtm.ac.uk

Robyn Stuart
Postdoctoral Researcher
Optima Team
Statistics and Probability Theory Group,
University of Copenhagen, Denmark
Robyn@optimamodel.com

Paul Hewett
Senior Associate
Population Council, Washington DC, USA
Phewett@popcouncil.org

Nazneen Damji
Policy Advisor
Gender, Health and HIV, UN Women
Nazneen.damji@unwomen.org

Iris Semini
Senior Regional Investment and Efficiency Advisor
Regional Support Team, Eastern and Southern Africa UNAIDS, Geneva
Seminii@unaids.org

Victoria Bendaud
Technical Officer
Strategic Information & Monitoring Division, UNAIDS, Geneva
Bendaudv@unaids.org

Audrey Pettifor (via Skype)
Associate Professor of Epidemiology
Gillings School of Public Health, University of North Carolina, USA
Apettif@email.unc.edu

Peter Vickerman
Professor of Infectious Disease Modelling
School of Social and Community Medicine, University of Bristol, UK
Peter.Vickerman@bristol.ac.uk

Beth Woods
Research Fellow Centre for Health Economics
University of York, UK
beth.woods@york.ac.uk

David Wilson
Director
Global AIDS Programme, The World Bank, USA
dwilson@worldbank.org

Sinead Delany-Moretlwe
Associate Professor and Director
Wits Reproductive Health Institute, University of the Witwatersrand, South Africa
sdelany@wrhi.ac.za

A growing evidence base demonstrates that structural interventions can have significant impact on HIV service coverage and HIV-related outcomes. With the growing interest in incorporating such interventions in national HIV planning and investment, the STRIVE research consortium and the HIV Modelling Consortium convened a two-day expert meeting at the London School of Hygiene & Tropical Medicine on 12 and 13 December 2016. With support from the Global Fund to Fight AIDS, Tuberculosis and Malaria, the consultation brought together 37 experts – mathematical modellers, epidemiologists, economists and policy-makers – from academia, civil society, bilateral development partners and multi-lateral organisations. The meeting was designed to:

- Review the state of the evidence on the effectiveness, costs and cost-effectiveness of a range of structural interventions;
- Investigate how these issues are currently addressed by available models, and identify limitations and potential improvements;
- Discuss alternative modelling solutions, notably treatment and prevention cascades;
- Learn from each other's approaches and from approaches used in country processes to model structural interventions;
- Generate recommendations about how models could better incorporate these interventions in the short term, and how this agenda should develop over time.

ABOUT STRIVE

A multi-year research consortium, STRIVE is led from the London School of Hygiene & Tropical Medicine with partners in India, South Africa, Tanzania, Uganda and the United States. Leading researchers in many disciplines – from biomedical trials to social science, epidemiology to anthropology, mathematical modelling to economics – head cross-partner working groups on crucial structural drivers of HIV risk:

Broadly, STRIVE:

- assesses how structural factors including stigma and violence impact on the treatment and prevention cascades
- designs, pilots, evaluates and analyses "upstream" structural interventions that yield multiple development benefits
- refines a new co-financing model and works with UNDP and African governments to test this approach in practice
- studies structural factors affecting young people's HIV vulnerability, including alcohol, and tests combination interventions for adolescent girls in India, South Africa and Tanzania

STRIVE
Tackling the structural drivers of HIV

The Global Fund
To Fight AIDS, Tuberculosis and Malaria

HIV Modelling Consortium

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE