

MALE CIRCUMCISION FOR HIV PREVENTION

MODELS TO INFORM FAST TRACKING VOLUNTARY MEDICAL MALE CIRCUMCISION IN HIV COMBINATION PREVENTION

23-24 MARCH 2016



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ACRONYMS

ART	antiretroviral treatment
ASM	Age Structured Mathematical (model)
DMPPT	Decision-Makers' Program Planning Tool
EIMC	early infant male circumcision
HIA	HIV infection averted
MC	male circumcision
MTCT	mother-to-child transmission
PEPFAR	President's Emergency Plan for AIDS Relief
PrEP	pre-exposure prophylaxis
SNU	subnational unit
STI	sexually transmitted infection
VMMC	voluntary medical male circumcision
WHO	World Health Organization
UNAIDS	Joint United Nations Programme on HIV/AIDS

EXECUTIVE SUMMARY

Since the WHO/UNAIDS recommendation in 2007 that medical male circumcision be considered an additional method of HIV prevention and should be rapidly scaled up in countries with low prevalence of circumcision and high prevalence of HIV, there has been considerable investment in implementing voluntary medical male circumcision (VMMC) programmes for HIV prevention in eastern and southern Africa. By end 2015, 11.7 million adolescent and adult males had undergone circumcision through these programmes. Initial projections of cost and impact of VMMC interventions were developed before the programmes were implemented at scale and based on best assumptions about the course of the HIV epidemic valid at the time of development (2007–2010). These projections need to be revised as circumcision scale-up has not been uniform between and within countries, with greater uptake among adolescent and younger men than men over age 30 years. Similarly, the future impact on HIV incidence and prevalence in focus countries must be projected according to current HIV epidemic estimates and expected declines in HIV incidence resulting from scaling up antiretroviral treatment (ART) to reach the 90–90–90 by 2020 and 95–95–95 by 2030 HIV testing and treatment targets.

In preparation for a new phase of VMMC interventions over the period through 2021, WHO and UNAIDS convened a small consultation of modellers and policy-makers to review and discuss different models and projections, and develop key messages to inform strategic directions over the next five years. The key conclusions and recommendations from the meeting are listed below.

- HIV incidence reduction targets and impact:
- The 9.1 million VMMCs conducted in the period 2008– 2014 will avert approximately one quarter of a million HIV infections by 2025.
- The VMMC programmes in priority countries in eastern and southern Africa are necessary to reach the 2020 and 2030 Fast Track prevention targets (under 500 000 and 200 000 annual new HIV infections by 2020 and 2030, respectively). The HIV testing and ART scale-up targets (90–90–90 by 2020 and 95–95–95 by 2030) are not sufficient by themselves to reach these overall targets.
- VMMC programmes are cost-saving in almost all priority VMMC countries when HIV treatment costs averted are considered.

- The impact of expanding circumcision to at least 90% of men will be even greater if the 90–90–90 targets for treatment expansion are not reached.
- While circumcision reduces a man's individual lifetime HIV risk, the indirect effect of preventing further HIV transmissions to women, their babies (vertical transmission) and from women to other men has an even greater impact on the population incidence, particularly for circumcisions performed at younger ages (under age 25 years).
- Prioritizing by age, risk group and geography:
- The greatest impact on HIV incidence in the next five years will be obtained in most countries by expanding circumcision coverage in the 20–24- and 25–29-year age strata, which correspond to the ages of highest HIV risk.
- Focusing on men at high HIV risk, as determined for example by having multiple sexual partners, will result in greatest impact and efficiency.
- The results of models that considered prioritizing by geography were mixed. There was a strong rationale for prioritizing by geography in a few countries – notably Kenya, Malawi and Tanzania – but most countries lacked sufficiently robust data to prioritize provinces or districts according to impact and cost-effectiveness of circumcision. In countries with clear geographic differences, particular regions or districts and major urban areas should be saturated with VMMC services before moving to other areas.

- Coverage or saturation targets are advised to be set by age strata (not uniformly for the entire 15-49-year age group) and established where possible at subnational levels. Progress towards coverage targets should also be monitored by age strata at the subnational level.
- Circumcision services should be provided to younger adolescents aged 10-14 years as the eventual impact of circumcision in this age stratum will be large. Experience with implementing VMMC programmes has shown that acceptability of circumcision varies by age and personal circumstances, and generating demand among older men is both difficult and costly.
- Sustaining high male circumcision coverage for long-term benefits:
- Ending AIDS as a public health threat by 2030 will reduce new HIV infections to near zero in most communities, but will not extinguish the epidemic entirely. Continued control strategies will be necessary to ensure that the HIV epidemic remains at low levels.
- At the height of the HIV epidemic, generalized and hyperendemic epidemics occurred only in countries and communities where circumcision prevalence was low. Maintaining a high prevalence of circumcision among sexually active men is a simple and affordable strategy to prevent any future resurgence of the HIV epidemic that might occur if treatment programmes cannot be sustained or drug-resistant HIV strains emerge. The benefits of such resilience will persist for many generations.
- Sustaining high circumcision coverage through adolescent and early infant male circumcision:
- As VMMC programmes reach higher coverage among men aged 15-29 years, coverage will need to be sustained by offering circumcision to annual cohorts of adolescent boys.
- Countries need to develop efficient and sustainable adolescent VMMC services that provide circumcision to boys who were too young to have been circumcised in the catch-up phase.
- Even in countries considering or preparing for the introduction of early infant male circumcision (EIMC) into programmes as their primary long-term circumcision strategy, an adolescent circumcision programme will be required until EIMC is sufficiently comprehensive that over 90% of infants are circumcised and boys circumcised as infants reach adolescence.

- There will be almost no impact of EIMC on the HIV epidemic until boys become sexually active and reach the age of highest HIV incidence 20–25 years later.
- Programme and research considerations:
- Rapid expansion of VMMC among males aged 1 5-29 years is necessary to achieve the 2020 HIV prevention target.
- Services should be provided to men aged 30 years and over who request circumcision, although generating demand in this age group is likely to continue to be difficult and costly.
- Efforts should be made to identify and circumcise men at high risk of heterosexual HIV infection irrespective of age, as these men have the greatest absolute reduction in risk following circumcision. Effective mechanisms must be established to refer high-risk, HIV-negative men identified through HIV testing services and programmes to circumcision services.
- The relative costs and efficiency in reaching VMMC coverage targets through different service delivery models (for example, outreach, mobile or fixed site) should be assessed and those models best suited to the local context prioritized.
- VMMC programmes are a unique opportunity and mechanism to link adolescent boys and young men to information and services related to sexual and reproductive health, sexuality education, preventing alcohol and drug misuse, and addressing gender norms that contribute to intimate partner violence and violence against women. More work is needed to improve training and information materials to deliver education and counselling in an age-appropriate and culturally sensitive manner.
- Funding is critically needed for the next few years to complete the catch-up phase in those countries where 80% coverage of the age group 15-49 years has not yet been achieved and to increase this to 90% coverage among those aged 10–29 years while countries transition to services that sustain high circumcision coverage for annual cohorts of adolescent boys.

BACKGROUND AND CONTEXT

Since the WHO/UNAIDS recommendation in 2007 that male circumcision be considered an additional method of HIV prevention and should be rapidly scaled up in countries with low prevalence of circumcision and high prevalence of HIV, there has been considerable investment in implementing VMMC programmes for HIV prevention in eastern and southern Africa.

By end 2015, 11.7 million adolescent and adult males had undergone circumcision through the newly created circumcision programmes.¹ A modelling study conducted in 2011 estimated that 20.3 million circumcisions were required to reach 80% circumcision coverage of the age group 15–49 years by the end of 2015 in 14 priority countries in eastern and southern Africa. The estimated total cost to perform this number of circumcisions between 2011 and 2015 and maintain 80% coverage through 2025 was US\$ 2.02 billion. This was projected to avert an estimated 3.36 million new HIV infections and result in a net saving of US\$ 16.5 billion due to HIV treatment and care costs averted.² Many of the assumptions on which this model was based have changed since 2011, most notably the slower than anticipated progress in scaling up circumcision, highly variable coverage between countries, heterogeneous proportions of men circumcised in different age groups, lower overall HIV incidence rates and lower annual costs for ART.

Uncertainties in projecting the evolution of HIV incidence are compounded by the concerted effort by the global health community to end the AIDS epidemic as a global health threat by 2030, with ambitious targets to accelerate expansion of HIV testing and treatment coverage by 2020 and 2030. The UNAIDS Fast Track strategy aims for 90% of people to know their HIV status, 90% of those infected to be on ART, and 90% of those under treatment to be virally suppressed (90–90–90) by 2020, with coverage of each element of the treatment cascade increasing to 95% by 2030 (95–95–95). Corresponding prevention targets are to reduce the global number of annual new HIV infections to fewer than 500 000 by 2020 and fewer than 200 000 by 2030.³ Additional uncertainty about the future course of the HIV epidemic follows from the recommendation by WHO in November 2015 that oral pre-exposure prophylaxis (PrEP) be offered to all men and women at substantial risk of HIV infection.⁴ There are also uncertainties whether treatment scale-up will have the anticipated impact on new HIV infections as a result, for example, of lower than anticipated adherence or emergence of drug resistance to first and second line treatment regimens. Similarly for PrEP, the practicality, acceptability and sustainability of PrEP programmes beyond pilot and demonstration projects have yet to be established.

In developing the strategic directions on VMMC for the period through 2021, a reassessment was necessary of experiences to date with scaling up VMMC programmes - successes, challenges and impact. Similarly, there was a need to project the future impact of VMMC programmes on HIV incidence and prevalence in focus countries according to different strategies for increasing circumcision prevalence in key age groups and sustaining high circumcision prevalence into the future.

In March 2016, WHO and UNAIDS convened a meeting of modelling experts and policy-makers to: review recent modelling work; identify the implications of different models, including common themes and messages from findings; recommend approaches for future strategic directions; and note key research and evaluation needs. Specifically, the objectives of the meeting were to:

- 1. Review progress in the expansion of VMMC programmes through 2015, assess the impact of circumcisions performed to date and estimate future impact in the context of new HIV incidence data and projected expansions of treatment and other prevention programmes.
- 2. Share technical details of recently completed and ongoing modelling studies, including objectives, key questions and assumptions, parameters and their implications for interpreting model results and projections.
- 3. Discuss model results and key implications for global stakeholders on target-setting and prioritization by age, geography and/or risk group at country level.
- 4. Identify key communication messages on progress and impact, uncertainties and strategic directions on VMMC through 2021.
- 5. Identify whether VMMC has a continued role in HIV prevention in focus countries in eastern and southern Africa given the projected scale-up of ART and oral PrEP.
- 6. Agree on evaluation priorities such as the impact of VMMC in the context of HIV combination prevention and Fast Track goals, identify data needs and approaches for this evaluation.

The meeting agenda (see Annex A) covered a review of global HIV treatment and prevention targets, progress with scaling up VMMC programmes, different models to estimate impact and costs of VMMC programmes, the impact of targeting by age, geography and/or risk profile, EIMC and other strategies to sustain high circumcision prevalence, and key advocacy and communication messages arising from the modelling review. The meeting was attended by representatives from different teams that had developed models of VMMC impact and costs, international organizations and consultants (see full list of participants in Annex B).

In contrast to the scale-up of HIV treatment, progress in reducing HIV incidence had been disappointing with an estimated 8% reduction in HIV incidence over the period 2010–2014 among adults aged 15 years and over (see Figure 1).⁵ This reduction was considerably short of the 2015 target (50% reduction from 2010 incidence) or the trajectory necessary to reach the UNAIDS Fast Track targets of fewer than 500 000 new HIV infections annually by 2020 (75% reduction) and fewer than 200 000 by 2030 (90% reduction).³ There was hope that rapid expansion of ART,

regular HIV testing, promptly starting all newly diagnosed HIV-positive persons on treatment, and use of oral PrEP among HIV-negative people at substantial risk of HIV infection would have a large impact on HIV incidence. In this context, it was necessary to assess the role and impact of VMMC programmes in the 14 focus countries in eastern and southern Africa to determine whether they were still relevant and necessary.

Figure 1 Estimated new annual HIV infections (UNAIDS, 2015)⁵



2015, 2020 and 2030 targets

VMMC programmes had been launched following strong evidence of efficacy and recommendations by WHO and UNAIDS in 2007 that countries with hyperendemic and generalized epidemics should scale up circumcision. Funding for VMMC programmes has been primarily from external sources -- the Government of the United States of America President's Emergency Plan for AIDS Relief (PEPFAR), the Bill and Melinda Gates Foundation, and more recently the Global Fund to Fight AIDS, Tuberculosis and Malaria. Countries had contributed variable amounts of domestic resources to support VMMC expansion, mainly through deployment of healthcare workers to support the programmes. There had been rapid expansion in the 14 priority countries from 2009 (see Figure 2), with 2.66 million circumcisions performed in 2013 and 3.24 million in 2014; however, the number of new circumcisions in 2015 was only 2.62 million.¹ While there remained substantial numbers of uncircumcised men in the age range 15-49 years, some countries had achieved at least

Figure 2 VMMC programme expansion in 14 priority countries: number of annual circumcisions by country 2008–2015 (adapted from WHO Progress Brief)¹



Year

80% circumcision prevalence among adults and others were reaching this level in specific age groups. Attention was beginning to turn in some countries towards VMMC programmes that were less intensive than the catch-up or emergency phase to adopt a more sustainable model of offering circumcision to smaller annual cohorts of adolescent boys or young men who entered the eligible age range for circumcision. This has provided an opportunity to link VMMC with other educational and preventive services, such as male sexual and reproductive health, supporting women's sexual and reproductive health and rights, the education sector, youth groups and traditional leaders. To date little hard evidence of the benefits and impact of linking VMMC with other services exists, or of the wider impact of VMMC on health and development issues beyond the primary effect of reducing HIV incidence and prevalence in communities where VMMC programmes have been implemented.

MODELS OF VMMC IMPACT AND COSTS

Early models

Several mathematical models of the impact of scaling up VMMC programmes were developed and published in the period 2006–2008, soon after the results from three randomized controlled trials of circumcision and HIV prevention were completed.

These models, all set in the context of HIV epidemics in eastern or southern Africa with HIV incidence in the range 1.2–4.5 infections per 100 person-years, were reviewed by a small expert group convened by UNAIDS, WHO and the South African Centre for Epidemiological Modelling and Analysis.⁶ The models found that there were large benefits in providing male circumcision among heterosexual men in low male circumcision, high HIV prevalence settings with one HIV infection being averted for every five to 15 male circumcisions performed, and costs to avert one HIV infection ranging from US\$ 150 to US\$ 900 over a 10-year time period. In addition, the modelling projected little impact of potential behavioural risk compensation following circumcision on population-level HIV incidence and a substantial indirect benefit for women from a reduced HIV prevalence in circumcised male partners.

This review was used as the basis for developing a compartmental deterministic model in Microsoft Excel to estimate the epidemiologic impact (HIV infections averted), cost and net savings associated with different scenarios for scaling up VMMC, referred to as the Decision-Makers' Program Planning Tool (DMPPT).² The model was populated with country-specific demographic and epidemiological data and used to explore different country-specific scale-up strategies. Under a common scale-up model of expanding circumcision prevalence to 80% among men aged 15-49 years within five years (2011–2015) and then maintaining this coverage rate for a further 10 years through 2025 in 13 of the priority countries or provinces, the model estimated that a total of 28.8 million circumcisions would need to be performed and these would avert 3.36 million HIV infections through 2025, approximately 8.6 circumcisions per HIV infection averted (HIA). Such a programme was estimated to cost US\$ 2 billion over the period 2011–2025 with an average cost of US\$ 809 per HIA. The discounted net savings due to ART and care costs averted were projected to be US\$ 16.5 billion over the same period. Results varied from country to country (for example, cost per HIA ranged from

US\$ 369 in Zimbabwe to US\$ 4096 in Rwanda) and were strongly determined by the country-specific HIV incidence. Detailed country-specific analyses were used to develop national circumcision scale-up plans, allocate financial resources and launch the VMMC programmes.

Limitations of the DMPPT model were that the population was disaggregated into only four age/sex groups (females aged 15-24 and 25-49 years, males aged 15-24 and 25-49 years), circumcision prevalence was assumed to increase linearly and uniformly throughout the two male age groups towards the specified target, and the unit cost of circumcision was the same for all men. Experience with implementing VMMC programmes showed that the uptake of circumcision was much greater in younger than older men, motivating older men to attend the VMMC service was more complex and costly, and a large proportion of circumcisions were performed in adolescent boys aged 10–14 years when VMMC programme resources were not being fully utilized for the priority age range 15–49 years. In addition, the first generation models had projected a stable HIV incidence or a gradual decline over a 15-year time period based on recent historical trends in the absence of a circumcision intervention. The models did not account for the potential impact on HIV incidence of expanding ART to the UNAIDS 90-90-90 target for 2020 and 95-95-95 target for 2030, or for expansion of other HIV prevention interventions such as oral PrEP.

More recent models addressed these limitations by allowing for more age strata and greater flexibility in unit costs and circumcision coverage by age. Some, but not all, have incorporated sharp reductions in projected HIV incidence.

DMPPT model version 2

Katharine Kripke, Avenir Health, described the DMPPT 2 model that was built to address some of the earlier shortcomings. As before, estimates of country or provincial population structure (UN Population Division, World Population Prospects 2012), non-AIDS mortality and HIV incidence (from Spectrum/AIM or Spectrum/Goals models) by age and sex were imported from external sources and used to estimate HIV incidence among circumcised and uncircumcised men. The model was set up for each country based on the official national HIV prevalence and incidence estimates and projected the effect of changing circumcision prevalence in different age groups compared with the base scenario of maintaining circumcision prevalence at preprogramme levels. The main analyses assessed the impact of scaling up circumcision to 80% over five years

Figure 3 Reduction in HIV incidence through provision of VMMC to males, by age group, in the years 2014–2050 (example from DMPPT 2 model applied to South Africa)⁷



in specific age strata, maintaining that prevalence into the future and projecting future HIV infections in the whole population (men and women). The relative contributions of saturating different age strata were compared with a scenario of no scale-up of circumcision over baseline (that is, maintaining circumcision prevalence at preprogramme levels). The approach is illustrated in Figure 3 for South Africa – in this example, the greatest relative short-term impact (within five years) (see point a in Figure 3) is achieved by circumcising men in the 20–24-, 25–29- and 30–34-year age groups, while the greatest relative long-term impact (within 15 years) (see point b in Figure 3) is achieved by circumcising the 15–19- and 20–24-year age groups. The greatest impact after 25 years is achieved by circumcising the youngest (10–14 year) age group.

While the DMPPT 2 model could compare the relative impact of different age-specific scale-up strategies, it was considered less reliable for projecting the absolute number of HIAs due to uncertainties in HIV incidence projections (a limitation common to all VMMC models). The DMPPT 2 model could not simulate variations in sexual mixing patterns by age potentially correlated with HIV prevalence or infectiousness, nor could it reflect rapid or non-uniform scale-up of ART or new PrEP prevention interventions.

In common with most mathematical models, further limitations of the DMPPT 2 model are that projections, particularly long-term projections, are highly sensitive to HIV incidence estimates and lack of data limits the ability to carry out useful subnational estimates. Moreover, the model does not reflect important programmatic considerations and experiences, such as the challenges of demand creation, the availability of resources, and additional benefits of VMMC such as linkages to educational programmes, other HIV prevention services and treatment programmes.

The DMPPT 2 model was used to explore the relative impact of age prioritization in Kenya, Lesotho, Malawi, Mozambique, Namibia, South Africa, Swaziland, Uganda and the United Republic of Tanzania; subnational geographic prioritization in Kenya, Malawi, Mozambique, South Africa, Uganda and the United Republic of Tanzania; and district-level targets in Kenya, Lesotho, Malawi, Mozambique, Swaziland, Uganda, the United Republic of Tanzania and Zimbabwe. The model was further used to assess the impact of circumcisions conducted to end 2015 in all 14 priority countries. Key output metrics included number of HIAs, reduction in HIV incidence, circumcisions per HIA, total programme cost, cost per HIA, treatment costs averted, and net savings.

Goals model

John Stover, Avenir Health, outlined the structure of the Goals model, which was designed to estimate the cost

Incremental Analysis model

Nicole Fraser, World Bank, summarized the Incremental Analysis model developed to analyse the effect of circumcising one individual at a specific age and quantify outcomes in terms of current investments. The model was based on the Actuarial Society of South Africa's 2008 AIDS and Demographic model, which was a compartmental HIV disease progression and transmission model embedded in a demographic model. Compartments included sex, HIV risk group according to sexual activity (not sexually active, low level of risk, high risk [for example, a person with a sexually transmitted infection (STI)], intense risk [for example, a sex worker]) and age in one-year strata. For each risk group, individual sexual activity was characterized by assumptions on number of new partners per year, number of contacts per partner, and the distribution of partners by risk group. The model focused on heterosexual intercourse only and assumed that those below age 15 years or over 60 years were not at risk. Individuals aged 16-24 years could move in or out of higher sexual risk groups, but the risk group remained fixed for those aged 25 years or more. The model was adapted to include the impact of circumcision on HIV transmission dynamics and reflected existing circumcision prevalence. Instead of considering the impact of scaling up circumcision throughout the population, the model estimated the impact of a single circumcision performed at a specified age in 2013 and projected forward through 2058 (45 years), considering the benefit of lower HIV risk to the individual as well as benefits due to secondary or higher order transmissions averted. In addition to output metrics computed in other models, the Incremental Analysis approach also computed metrics such as amortization period and financial rate of return, which are more familiar to financial analysts and policy-makers. As with other models, there was no adaptation to evolving HIV incidence other than through the impact of the VMMC programme. The model was intended to compare the impact of circumcision at different ages and was, thus, not able to

Age Structured Mathematical model

Maaya Sundaram, Bill and Melinda Gates Foundation, described the methodology of the Age Structured Mathematical (ASM) model developed in collaboration with Laith Abu-Raddad and Susan Awad, Weill Cornell Medical College Qatar, to compare the short- and longterm impact of preferentially scaling up circumcision in different age strata and/or subnational geographical areas, examining also the impact of EIMC. The primary measure used to compare different scenarios was the number of circumcisions per HIA. The ASM model is a population-level, deterministic, compartmental model of heterosexual HIV transmission consisting of coupled nonlinear differential equations that stratify the population into compartments according to sex, circumcision status, age (five-year strata: 0–4 years, 5–9 years, ... 95–99 years), sexual risk (six levels from lowest [general population] to highest [female sex workers and their male clients]), HIV status, and stage of infection (three levels: acute, chronic and advanced). The model was populated with demographic data and projections from the UN Population Division, and country-specific historical HIV prevalence data for 1990-2011 from UNAIDS. Behavioural and circumcision prevalence data from past demographic and health surveys were used to estimate HIV incidence. The model included the option of varying unit circumcision costs by age to reflect additional costs incurred to identify and motivate older men to volunteer for circumcision. The model included the impact of secondary and higher order transmissions prevented by circumcision, but did not provide the option to include a marked future change in HIV incidence. As with other models discussed, the model was primarily directed at comparing the relative costs, impact and efficiency of different scale-up scenarios, and was not designed to estimate absolute costs or impact with any great accuracy.

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Subnational Units model

Stephanie Davis, Centers for Disease Control and Prevention, Atlanta, presented the Subnational Units (SNU) model designed to explore the impact of VMMC scale-up in the context of non-uniform ART expansion in Tanzania and Zimbabwe. This model was motivated by PEPFAR's plans to prioritize high HIV burden SNUs and/or populations in order to reach the 90-90-90 testing, treatment and viral suppression targets and 80% circumcision coverage. It was not clear if the priority SNUs for rapid ART scale-up (those with highest HIV prevalence) were also optimal for prioritizing VMMC scale-up (those with highest HIV incidence in men), nor whether VMMC impact might be lower in SNUs that had high treatment coverage. The model provided a framework for exploring the marginal impact of VMMC in situations where there was slower than planned ART scale-up and, conversely, the marginal impact of ART scale-up where VMMC scale-up was slower than planned.

Discussion

All models presented adopted a similar approach to estimating the impact of VMMC programmes on the HIV epidemic. The DMPPT 2, Incremental Analysis and ASM models projected either that HIV incidence remained at current levels notwithstanding the impact of circumcision, or assumed that recent historical trends continued. The Goals and SNU models made explicit assumptions about ART scale-up and were designed to explore the separate and joint impact of scaling up several HIV prevention interventions simultaneously.

All models necessarily involved simplifications of the complex dynamics and structural drivers of the HIV epidemic, but nevertheless were able to provide insights into how best to allocate resources and implement HIV policies that were simultaneously feasible and costeffective, without necessarily being optimal. While further refinements to the models were easy to propose, many model enhancements were limited by the availability of sufficiently detailed data, such as HIV incidence by sexual risk groups, the sizes of different risk groups or the level of partner mixing.