1 Denial, neglect, stigma and criminalisation: Notes on the global challenges to preventing HIV during anal sex

Summary

- There is increasing recognition that gay men and other men who have sex with men (MSM) throughout the world—in developed and developing countries alike—have very high, disproportionate rates of HIV.
- Gay men and other MSM in developing countries remain largely under-represented and often completely invisible in national HIV and AIDS strategies, epidemiology, surveillance, and research; and they are woefully under-served by prevention, care, support, and treatment programmes.
- Anal sex between men and women is under-recognised, under-researched and under-characterised, resulting in a pressing need to address the attendant HIV prevention issues.
- While rectal microbicide research efforts continue, other viable options should be pursued aggressively to prevent transmission of HIV and other sexually transmitted infections through anal intercourse and to promote better anal health. For example: provision of male and female condoms, water-based lubricants, and human papillomavirus (HPV) vaccination.

1.1 Code Red: HIV among gay men and other men who have sex with men

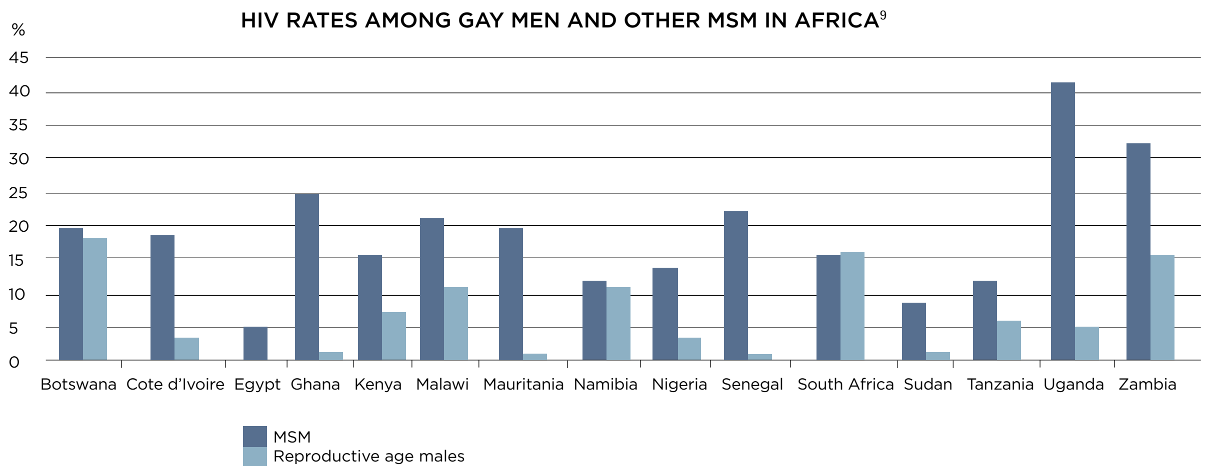
Globally, it is estimated that gay men and other men who have sex with men (MSM)* are 19 times more likely to be living with HIV compared with the general population.[1] In the AIDS 2008 Jonathan Mann Memorial Lecture on health and human rights, Saavedra, Izazea-Licea, and Beyrer stated:

> *"Gay, bisexual, and other MSM have been among the most affected populations by HIV since the AIDS pandemic was first identified in the 1980s. Evidence from a wide range of studies show that these men remain at the highest risk for HIV acquisition in both developed and developing countries, and that despite three decades of evidence of their vulnerability to HIV, they remain under-served and under-studied. Prevention strategies targeted to MSM are markedly under-funded in most countries, leading to limited access to health services including prevention, treatment, and care."*[2]

*Some men who engage in sexual activity with other men identify as gay or bisexual, while others do not. Therefore, IRMA uses the phrase "gay men and other men who have sex with men (MSM)."

As the research and literature on the global HIV pandemic among gay men and other MSM finally expands, we are getting a clearer picture of the high rates of HIV among gay men and other MSM from all corners of the globe.[3, 4] The evidence is compelling: gay men and other MSM are disproportionately affected by HIV. In many countries throughout Western Europe, North America, Latin America and the Caribbean, Southeast Asia, and sub-Saharan Africa, HIV prevalence rates among MSM are higher than among the general population of reproductive age adults.[5, 6, 7, 8] This remains true even in countries with generalised epidemics, such as in sub-Saharan Africa.

HIV RATES AMONG GAY MEN AND OTHER MSM IN AFRICA[9]



It is estimated that unprotected anal intercourse is 10 to 20 times more effective at transmitting HIV compared to unprotected vaginal intercourse.

One way to understand the relative burden of HIV between gay men and other MSM on one hand, and the general population of reproductive age on the other, is to look at the adjusted odds ratio. In other words: how much more likely are gay men and other MSM to be HIV-positive than reproductive age adults in the same countries? One systematic review of global literature from 2000–2006 showed that in Latin America, gay men and other MSM were 33 times more likely to be HIV-positive compared to reproductive age adults. In Asia, they were more than 18 times more likely, and in Africa, they were 3.8 times more likely to be HIV-positive compared to reproductive age adults.[10, 11, 12] Similarly, in 2010 the U.S. Centers for Disease Control and Prevention (CDC) released an analysis of the relative burden of HIV among gay men and other MSM. It showed that in the U.S. they are 44 times more likely to be HIV-positive than other men, and 40 times more likely to be HIV-positive than women.[13]

HIV AMONG GAY MEN AND OTHER MSM COMPARED TO REPRODUCTIVE AGE ADULTS; ADJUSTED ODDS RATIOS BY REGION[14]

REGION	NUMBER OF COUNTRIES	ODDS RATIO
Americas	15	33.3
Asia	7	18.7
Eastern Europe	12	1.3
Africa	4	3.8

Yet, as Saavedra, Izazea-Licea, and Beyrer have pointed out:

> *"Global responses have not been commensurate to these realities. MSM remain under-studied, under-served, under-funded and frequently ignored or denied by governments. We must ask why."*[15]

It is unconscionable that nearly 30 years into the HIV pandemic, we are only beginning to have more robust data on the rates of HIV among gay men and other MSM in Africa and other parts of the developing world. As IRMA outlined in its 2008 report,[16] many factors conspire to perpetuate this silence, including the ongoing criminalisation and stigma attached to same-sex behaviour[17] and the resulting fact that gay men and other MSM remain hidden and ignored, languishing in the shadows of most public health interventions.

1.2 Far and away: Universal access to comprehensive services for gay men and other MSM

The Global HIV Prevention Working Group estimates that fewer than 10% of gay men and other MSM have access to appropriate behaviour change programmes to help reduce their risk of HIV infection.[18]

In its 2008 special report *MSM, HIV and the Road to Universal Access—How Far Have We Come?*[19] amfAR, the Foundation for AIDS Research, found a discouraging discrepancy between the epidemiological data and the global response. Out of 128 countries reporting in 2008 on the progress they have made in implementing the 2001 Declaration of Commitment on HIV/AIDS:

- Almost half the countries reported no data whatsoever on HIV among gay men and other MSM for any of the five requested indicators: prevalence of HIV infection, rates of HIV testing, HIV knowledge, condom use, and access to prevention programming.
- 62% of countries reported no HIV seroprevalence data among gay men and other MSM.

"In other words, almost two-thirds of the countries surveyed appear to have no information on the extent of HIV/AIDS among their MSM residents," according to amfAR.[20]

The HIV response in Africa has focussed largely on the dynamics of a "generalised epidemic," despite increasing evidence that there are specific groups at high risk for HIV, including gay men and other MSM. Even in a country like South Africa, where the HIV epidemic among gay men and other MSM preceded the generalised epidemic by several years, and where MSM are protected under the constitution and are included in the country's national strategy, current policies and programmes are generally unresponsive to the needs of gay men and other MSM.[21] An effective response requires that gay men and other MSM be included in surveillance, research, prevention, care, and treatment programmes. However, this is a considerable challenge in contexts where male-to-male sex is illegal, which is the case in 31 sub-Saharan African countries, including four countries where the death penalty is a possibility. Criminal, cultural, and religious barriers conspire to keep gay men and other MSM invisible.[22, 23]

"Like male and female condoms, male circumcision, prevention of mother to child transmission, and access to care and treatment, safe and effective vaginal microbicides, vaccines, PrEP, and rectal microbicides will be important tools in the prevention package we offer women and men at elevated risk."

Kim Eva Dickson
World Health Organisation
Geneva, Switzerland

Gay men and other MSM, including HIV-positive gay men, face criminal prosecution and violence in many countries. Several horrifying examples in 2008–2010 include:

- The Ugandan Parliament began to review a bill that included severe sentences: men who engaged in homosexual behaviour more than once, as well as HIV-positive men who engaged in homosexual sex, could be sentenced to death.
- Political leaders in many countries, including Poland, Gambia, Jamaica, and Uganda, made homophobic remarks, calling for the arrest, detention, and even killing of homosexuals.
- AIDS activists in Senegal were sentenced to eight years in prison for "unnatural acts" and "belonging to a criminal association."
- There were reports of gays in Iraq being tortured and killed by having their anuses glued shut and then force-fed diarrhea–inducing liquids.
- Inspired by religious leaders who were opposed to a gay wedding, a group of young people allegedly assaulted gay men in Kenya, calling for their death by fire.

The 2009 report *Ensuring Universal Access to Comprehensive HIV Services for MSM in Asia and the Pacific*, also by amfAR, recommends a significant increase in the range of HIV-related programming for gay men and other MSM in the developing countries in this region. As in many parts of the developing world, non-governmental organisations provide the bulk of current services, and have little support to do so. It is perhaps not surprising that HIV prevention programmes reach an alarmingly low proportion of gay men and other MSM in the region (an average of 2% in 11 countries in 2005).[24] Accordingly, unless HIV prevention efforts improve, gay men and other MSM may soon account for the largest proportion of people living with HIV in Asia.[25]

1.3 First steps: The response to HIV among gay men and other MSM in developing countries

There are encouraging signs that issues concerning the rights and health needs of gay men and other MSM are starting to be recognised, studied, and addressed. However, much remains to be done.

At the 2006 International AIDS Conference (IAC) in Toronto, the Global Forum on MSM & HIV was created, drawing greater attention to the international crisis surrounding HIV and MSM. In 2008, *The Invisible Men: Gay Men and Other MSM in the Global HIV/AIDS Epidemic* was the theme of the Forum's ground-breaking satellite meeting at the IAC in Mexico City. From the heads of the United Nations (UN), the Joint UN Programme on HIV/AIDS (UNAIDS), and the World Health Organisation (WHO), to prominent leaders from various sectors, there followed repeated calls for an acute concentration on the HIV-related needs of gay men and other MSM. In impassioned speeches, homophobia was denounced as one of the key obstacles to stopping the epidemic.

"This obsessive homophobia... is totally absurd, and it's also cruel... I'm really more and more convinced that homophobia is one of the top five obstacles to really stopping this epidemic."

—Former UNAIDS Executive Director Peter Piot, *The Invisible Men: Gay Men and Other MSM in the Global HIV/AIDS Epidemic satellite*, 2008 IAC

"When the government of Senegal jails eight gay AIDS activists for no reason except homophobia, setting back the fight against AIDS, where are the scientific voices of condemnation? Right now, in the Caribbean, every country save the Bahamas has laws that criminalise homosexuality. We tiptoe round this twisted form of racism. We submit to ridiculous claims of cultural relativism.

"The Prime Minister of Jamaica, in the safety of Parliament, makes the most contemptible statements about gay men, leaving every elemental component of human rights in tatters, and he's never called to account ... not by the UN Human Rights Council, not by the G8, not by the G20, not by the Commonwealth ... only by the gay activists themselves.

"What is wrong with the international community? If this is how it behaves, it doesn't deserve the name 'community' at all.

"And if the political leadership lacks the courage to confront such outrageous slander, you shouldn't lack the courage. You're scientists. You know that it's a scientific reality that a certain percentage of the world's people are gay. So tell the political philistines to get over it and stop wreaking such damage. More, you know that an ugly homophobic culture is a threat to public health that inevitably serves to spread the virus ... I beg you to say so. The majesty of science is its influence."

—Stephen Lewis, Co-Director, AIDS-Free World, and Former United Nations Secretary-General's Special Envoy for HIV/AIDS in Africa (2001–2006). July 19, 2009, International AIDS Society Conference, Cape Town, South Africa

These sentiments continue to echo. Yet, however commendable, these words require tangible action.

The work on the ground is being waged by an increasing number of groups of gay men and other MSM in developing countries, and their allies. There are many examples of trailblazing organisations from all corners of the world providing HIV prevention care and support services to gay men and other MSM as they fight homophobia, violence, stigma, and discrimination in countries including Ghana, Ukraine, India,[26] Sudan,[27] Uganda,[28] Nigeria,[29] Laos,[30] Nepal,[31] and Peru.[32]

In late 2009, the Global Fund to Fight AIDS, Tuberculosis and Malaria announced that it had approved, in principle, a landmark U.S. $47 million grant for a community-strengthening programme aimed at reducing the rapid and alarming spread of HIV and AIDS among gay men and other MSM and among transgender people in South Asia. The grant proposal was submitted by Naz Foundation International (NFI), PSI (Population Services International), the United Nations Development Programme Regional Center based in Colombo (UNDPRCC), and the South Asian MSM and AIDS Network (SAMAN), a coalition of community-based organisations dedicated to MSM and HIV issues at the country level. The five-year project will encompass Afghanistan, Bangladesh, Bhutan, India, Nepal, Pakistan, and Sri Lanka. It is the first time the Global Fund will support a major regional project in Asia specifically addressing MSM, transgender people, and HIV.[33]

1.4 The D-List: The inadequate response to HIV among gay men and other MSM in high-income countries

Gay men and other MSM in high-income countries have always accounted for a high proportion of HIV cases. In many high-income countries, the number of new infections among gay men and other MSM has been increasing for over a decade,[34] along with rates of unprotected sex and sexually transmitted infections (STIs).[35] This may be partly due to the fact that even in these settings, prevention programmes all too often fail to prioritise populations at high risk for HIV—including gay men and other MSM, transgender people, persons who inject drugs, sex workers, prisoners, and immigrants. "The level of resources directed towards focussed prevention programmes for these groups is typically quite low, even in concentrated epidemics," according to UNAIDS.[36]

One notable example of this comes from the U.S. As mentioned previously, the CDC estimated that gay men and other MSM in the U.S. are 40 to 44 times more likely to be HIV-positive than other men and women. Despite this fact, according to information provided by the CDC at the 2009 National HIV Prevention Conference, a much smaller proportion of funding for some HIV prevention programmes is specifically targeted to gay men and other MSM, compared to other populations.. The CDC's Department of HIV/AIDS Prevention provides funding annually to 59 health departments across the country (50 states, D.C., Puerto Rico, U.S. Virgin Islands, and six large cities). In 2007, only 29% of this department's funding for health education/risk reduction programmes and 11% of funding for counselling, testing, and referral programmes was allocated to gay men and other MSM.[37] This is despite the fact that gay men and other MSM represent over half (53%) of new infections in the U.S.[38] While the programmes examined represent only a portion of U.S. funding for HIV prevention, they nonetheless provide a revealing, and sad, picture of priorities.

1.5 Where do we go from here? The response to HIV among gay men and other MSM

A report released by NAM* in 2009, *Appropriate prevention and care services for men who have sex with men and transgender people in resource-limited settings,*[39] provides a summary of the potential elements of a successful response to HIV, and is adapted here.

Strengthen the evidence base: One of the first steps required to respond to the epidemic in MSM is to improve the quality of the data used to inform and develop policy. For instance, MSM need to be included in regular HIV/AIDS surveillance; MSM-related questions should be included in population-based surveys; and the access of MSM to prevention and care should be monitored.

Prioritise the human rights environment: The UNAIDS *Action Framework on Universal Access for Men who Have Sex with Men and for Transgender People*[40] emphasises that improving "the human rights situation for men who have sex with men… [is] the cornerstone to an effective response to HIV." It recommends that "MSM… are appropriately addressed in national and local AIDS plans, that sufficient funding is budgeted for work, and that this work is planned and undertaken by suitably qualified and appropriate staff…"

Involve gay men and other MSM "in the planning, implementation, and review of HIV-related responses, including the support of nongovernmental and community-based organisations, including organisations of people living with HIV" as well as "training and sensitising health-care providers to avoid discriminating against, and ensure the provision of appropriate HIV-related services for, MSM…"

"With the current trend of increased HIV incidence through anal sex, rectal microbicides need to be a priority as a prevention option, especially for marginalised MSM."

Abdullrahman Orosanya Mohammed-Saheedi
IRMA-Nigeria Member
Lagos, Nigeria

*NAM is a community-based HIV information provider based in the UK.

Ensure access to effective prevention, treatment, and comprehensive care: The UNAIDS framework recommends that all interventions should be evidence-informed, developed with, and protect the rights of, MSM and transgender people and should include safe access to:

- Information and education about HIV and other STIs, and support for safer sex and safer drug use, through appropriate services;
- Condoms and water-based lubricants;
- Confidential, voluntary HIV counselling and testing;
- Detection and management of STIs through the provision of clinical services;
- Referral systems for legal, welfare, and health services, and access to appropriate services;
- Safer drug-use commodities and services;
- Appropriate antiretroviral and related treatments, where necessary, together with HIV care and support;
- Prevention and treatment of viral hepatitis;
- Referrals between prevention, care, and treatment services; and
- Services that address the HIV-related risks and needs of the female sexual partners of MSM.

Advocates, researchers, policy makers, and donors have the basis on which to build an effective response due to:

- The increasing amount of research in the past two years dedicated to gay men and other MSM throughout the developing world;
- The emergence and development of local and national groups addressing the needs of gay men and other MSM in developing countries;
- The renewed attention paid to the HIV epidemic among gay men and other MSM in high-income countries; and,
- The burgeoning focus on these issues at regional and international conferences and in the work of multilateral agencies such as WHO and UNAIDS.

"Rectal microbicides are incredibly important, and need to be developed."

Zeda Rosenberg
International Partnership
for Microbicides
Silver Spring, U.S.

An effective response to HIV among gay men and other MSM must address the biomedical, social, and political factors that are unique to these groups. The stigmatisation, demonisation, and persecution faced by gay men and other MSM in many parts of the world cannot be ignored. Planning for the development and eventual roll-out of rectal microbicides (RMs) must take these realities into account. Otherwise, even safe, effective, acceptable, and accessible RMs will be of little utility to the millions of men who need them. To achieve the goals presented in this section, we must ensure that all stakeholders—advocates, funders, policy makers, and researchers—are held accountable for tangible progress over the coming years.

1.6 Women and anal intercourse: An overlooked driver of the epidemic

By Kathleen Morrow (Brown University, IRMA Steering Committee member, U.S.)

Unprotected receptive anal sex is a high-risk behaviour when it comes to HIV transmission. What many often underestimate is the impact receptive anal sex may play in male-to-female and female-to-male transmission of the virus. The assumption is that women acquire HIV from penile-vaginal sex. In fact surveillance data do not make the distinction between vaginal or anal transmission among women who become infected with HIV. As a result, prevention programmes have not adequately addressed the risk of anal transmission in women.

Depending on which study you read, 20–75% of women report that they have engaged in receptive anal sex. In absolute numbers, conservative estimates indicate that globally up to seven times more women engage in receptive anal sex than men.[41] After all, women make up about half the population, while gay men and other MSM constitute a much smaller proportion.

While more studies have been published recently to support the need to know more about this phenomenon, there are still many questions to be thoroughly and comprehensively addressed:

- Are there differences in mechanisms of transmission between women and men who engage in receptive anal sex that warrant specific consideration?
- What is the prevalence of condom use for vaginal versus anal sex among women who engage in both behaviours? In other words, are women who have anal sex using condoms more often, less often, or with similar frequency when they engage in vaginal sex versus anal sex? Does engaging in receptive anal sex somehow make a woman more vulnerable to HIV infection? If so, what are the variables that moderate or mediate that effect?
- Do we know all we need to know about condoms and lube when it comes to anal sex? How does condom use (type of condom, e.g.) and/or lube use (type of lubricant, amount used, etc.) impact risk?
- What do we know about specific "routines" or "rituals" that are part of peoples' anal sex practices and how do those practices impact risk? Do hygiene behaviours associated with anal sex mediate risk? Douching? Enemas? What about hair plucking or shaving around the anus? What about anal bleaching? We have theories about these practices, but little scientific evidence.
- What better information could prevention science provide that would help people make better choices about whether and how to engage in anal sex?
- What attitudes, beliefs, and motivations could be targeted to increase safer anal sex practices among women and/or their sexual partners?
- What behavioural skills do we need to teach—or prevention products do we need to make available—to women who engage in anal sex to increase safer anal sex practices?
- What are the contextual models of anal sex initiation that impact risk? That is, what do we know about how women first come to engage in anal sex that may impact their risk? Does a woman's first anal sex act that is forced, coerced, or freely chosen impact her risk if she continues to engage in anal sex in the future?

- What about other anal sex contexts? How do the different sexual activities of women (and their partners) affect their levels of risk and which women are at greatest risk? How do we quantify and understand differences in risk as a function of sexual sequencing? How does commercial sex and the phenomenon that anal sex brings more money impact women's risk? What about the continuing belief systems around preserving virginity by engaging in anal sex? What about the impact of beliefs regarding pain versus pleasure in sexual encounters, and power and control?

We need a full spectrum of scientific research to be undertaken to address the physical and behavioural factors of HIV transmission that are unique to women who engage in anal sex. The enquiry must begin with basic science to better understand transmission and infection in the female rectum and continue on toward the development of RMs that take women's anal sex practices into account. We also must develop social and behavioural theory to devise intervention strategies for women and their partners that clearly and distinctly address the risks associated with anal sex.

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"In the evaluation of the first generation of vaginal microbicides, we may have underestimated the impact of HIV infections acquired from anal intercourse, which may have led to a substantial level of efficacy dilution. Although this certainly needs to be addressed in future vaginal microbicide trial designs, it also indicates the urgent need for a rectal microbicide in our goal of preventing the spread of HIV among women and men."

Benoit Masse
Statistical Center for HIV/AIDS Research
Seattle, U.S.

1.7 En route to a safe, effective rectal microbicide: Maintaining anal health, preventing HIV and STIs

While RM research efforts continue, other potentially viable options should be pursued aggressively to prevent transmission of HIV and other STIs through anal intercourse (AI) and to promote better anal health. However, it is often confusing when trying to determine what we know—and what we don't know—about various prevention strategies, how they relate to anal sex, and the extent to which they are readily available. Are female condoms appropriate for anal sex? Does medical male circumcision reduce the risk of acquiring or transmitting HIV through AI? Can men benefit from vaccines against human papillomavirus (HPV)? Are water-based lubricants available? How are these tools made accessible?

1.7.1 Anal health

By Ross Cranston (University of Pittsburgh, IRMA Steering Committee member, U.S.)

As the RM development agenda moves forward, it would be a failure in the field of preventative sexual health to ignore the spectrum of disease that may present in the anal canal. Receptive AI is associated with an increased risk of anal fissure, fistula, ulceration, and abscess, in addition to STIs that are specific to the anal canal, such as herpes simplex virus and HPV. These inflammatory conditions already have been associated with an increased risk of HIV infection. All of these conditions have an impact on sexual function and quality of life, though they are mostly transient. They may also influence the use of a RM.

HPV infection is strongly linked to the development of cervical cancer. There has been considerable success with a cervical cancer prevention programme that includes screening women using Pap smears with follow-up colposcopy—a medical procedure that provides an illuminated magnified view of the cervix—if warranted by the severity of the Pap diagnosis. The cervix and anal canal are biologically similar, and HPV infection is also linked to the development of anal cancer. Since the 1980s, it has been recognised that MSM are at high risk of developing this condition. More recently, HIV-positive MSM have emerged as the highest risk group for anal cancer, with rates of up to 70 times those seen in the general population.

Techniques such as anal Pap testing and high-resolution anoscopy (HRA)—similar to cervical colposcopy—have been developed to identify the anal lesions that are most likely to progress to cancer. Such lesions can subsequently be removed. However, there are limitations. Anal Pap testing has limited specificity to diagnose pre-cancerous lesions and currently individuals with any type of anal Pap abnormality require assessment by HRA that is time-consuming, costly, and not widely available. Additionally, although current treatment methods are effective, new lesions commonly develop over time.

In part due to these issues, there are no international guidelines for the diagnosis and treatment of anal pre-cancer, which has resulted in considerable inertia in addressing the issue. While there is a strong research imperative to improve both anal Pap testing and current treatment methods, there remains a fundamental lack of awareness of these issues among gay men and other MSM, women who participate in AI, and their healthcare providers and advocates. There is a pressing need for more effective education, promotion of risk awareness, and advocacy for those at risk.

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1.7.2 HPV vaccination

By Ross Cranston (University of Pittsburgh, IRMA Steering Committee member, U.S.)

Human papillomavirus is one of the most common viral infections in humans. There are more than 100 different HPV types that cause a spectrum of disease that extends from hand and foot warts to anogenital dysplasias (abnormal precancerous cells) and cancers. Up to 75% of the general population is likely to be exposed to anogenital HPV infection in their lifetime.

Clinical trials have been conducted in young women using HPV vaccines against the HPV types most commonly associated with cancer of the cervix, vagina, vulva, penis, and anal canal (HPV 16 and 18), and the types that cause anogenital warts (HPV type 6 and 11). The results of these studies show that the vaccines provide extremely high rates of protection against new infections with these HPV types in women not previously exposed to these HPV types. Later studies also confirm prevention of HPV-associated cervical dysplasias related to these viruses in the same population.

While these findings are very encouraging, the studies show that the vaccine's effectiveness is reduced when women have been previously exposed to one or more of the HPV types contained in the vaccine. This indicates that the vaccine is best given *before* sexual exposure to HPV.

The HPV vaccine also has been studied in boys and has been shown to prevent genital warts. Further studies among HIV-positive boys, girls, men, and women have reported that the vaccine stimulates an anti-HPV immune response, but studies showing effectiveness to prevent infection or dysplasia have yet to be done.

By early 2010, Gardasil (sold in some countries as Silgard) had been approved in 119 countries, and Cervarix had been approved in nearly 100 countries. In many cases, they are approved for both girls and boys. However, in some cases—like the U.S. for example—public health authorities have not recommended the vaccines for boys, despite advocating its use in girls.

Such opinions have ramifications. They place men at risk for anogenital warts, which are frequently associated with psychological stress and discomfort associated with treatment. The consequences are especially significant for gay men and other MSM, who already are affected disproportionately by HPV-associated anal cancer. The absence of public health recommendations for the HPV vaccine in boys is a missed opportunity to prevent the consequences of this infection, including the development of anal cancer, particularly as widespread anal dysplasia (pre-cancer) screening for those already infected with HPV has yet to be defined and implemented.

1.7.3 Anal intercourse and female condoms: What's the deal?

By Cindra Feuer (AVAC, IRMA Steering Committee member, U.S.)

Unprotected AI is the sexual activity most associated with risk of HIV infection; therefore it's imperative that research be conducted to find new methods of protection. As we know, RM research is well on its way, but the female condom, already approved for vaginal use, has not been tested for efficacy in anal sex. However, there is evidence that female condoms, like male condoms, are indeed being used off-label during anal sex.

Is this a good thing or bad thing? Well, experts cannot say for certain until safety and efficacy studies are conducted, but because both male and female condoms work similarly as physical barriers, it's reasonable to assume that using a female condom anally is better than not using any protection at all. Male condoms were never tested anally either, but the lack of U.S. Food and Drug Administration (FDA) approval of male condoms for anal sex has never been problematic. This is because the penis-shrouding function of the male condom remains the same for both vaginal and anal sex. On the other hand, the female condom is designed specifically for insertion into the vagina, with a flexible inner ring that is secured to the cervix. This design may not transfer safely or effectively when used in the anus, underscoring the need for clarity through clinical trials.

Studies show that anywhere from 13%–21% of gay men and other MSM in the U.S. have used the female condom for AI. Unfortunately, because there is no definitive research, many health providers do not readily promote the female condom for AI.[42] This may be a lost opportunity. Additionally, the little information available to the public on the female condom, for example on government-run websites, is often inconsistent or vague.

The field needs to conduct new safety studies of the female condom and AI, as former ones were inconclusive. Clinical trials comparing the efficacy of the female condom to the male condom during AI are needed, as well as feasibility studies. Once the facts are determined, and safety and efficacy are demonstrated, marketing the female condom for AI must be widespread but also targeted to men, in addition to women, so perhaps a name change would be in order.

Until then, people desperate for protective options will continue to use the female condom during AI. Therefore, interim guidelines with clear, consistent information must be developed. The community must remain steadfast in advocating for research into new options for AI protection like microbicides and pre-exposure prophylaxis (PrEP), but a more immediate need is the evaluation of the existing female condom for its use in AI.

Adapting materials from *The Fenway Guide to LGBT Health*, the Chicago Female Condom Campaign has created recommendations for anal use that can be found on its website: www.ringonit.org. This site also features a link to an instructional video, created for a program in Burkina Faso, which demonstrates the proper use of a female condom between men.

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1.7.4 Medical male circumcision and anal intercourse

By Chris Beyrer (Johns Hopkins University, U.S.)
and Tim Farley (World Health Organisation, Switzerland)

Three randomised controlled trials of circumcision done in South Africa,[43] Uganda,[44] and Kenya[45] have shown that circumcised men were about 60% less likely to acquire HIV infection through unprotected vaginal intercourse than uncircumcised men.

These studies complement the wealth of data showing lower HIV prevalence rates in settings with high prevalence of male circumcision,[46, 47] as well as prospective studies showing a strong protective effect of circumcision on an individual's risk of acquiring HIV.[48]

The way circumcision works to reduce the risk of HIV infection is now fairly well understood. The moist inner aspect of the foreskin is like other mucosal membranes (for example the inside of the mouth, vagina, and rectum) with many cells which are targets for HIV infection. Once a man has been circumcised and the skin over the surgery site has fully healed, the remaining foreskin and the head of the penis become more keratinised—more like the shaft skin which is much more resistant to HIV infection.

Trial data have not shown that circumcision reduces the likelihood an HIV-positive man will transmit HIV to his HIV-negative partner through vaginal sex. In fact, the only trial to be completed suggested the opposite. This trial enrolled Ugandan married couples in which the husbands were HIV-positive and the wives were HIV-negative. The wives of the men who were circumcised in this trial were at somewhat greater risk of getting HIV than the women married to uncircumcised men. The increased risk may have occurred when couples started having sex again before the skin on the man's penis had fully healed—a process that is thought to take about six weeks.

Much less is known about the impact of circumcision on the risk of HIV infection following unprotected AI. This holds true for all persons engaging in AI, including women, gay men and other MSM. There has been no randomised controlled trial examining the impact of circumcision on the risk of HIV transmission during AI. This means that the only evidence for or against circumcision for gay men and other MSM, and for men who engage in AI with women, is from observational, not experimental, studies.

Since medical male circumcision reduces the risk of HIV acquisition during insertive vaginal intercourse, a similar effect may be hypothesised for insertive AI. However circumcision is not likely to reduce risk during receptive AI, among men or women. Many gay men and other MSM engage in both insertive and receptive AI. Since receptive AI is about 11 times riskier than insertive AI,[49] circumcision may have less benefit for gay men and other MSM than for men who only have vaginal sex with women, because their major risk is from receptive AI when not protected with a condom.

The epidemiology shows that this is likely to be the case. Observational studies on circumcision and HIV risks among gay men and other MSM populations haven't shown the same consistency that led to the African circumcision trials. Some U.S. studies have found a higher risk of HIV infection among uncircumcised men,[50] suggesting that circumcision was protective.[51] But another study found no protection for men reporting unprotected insertive AI.[52] In a study completed in Peru and Ecuador,[53] gay men and other MSM reporting only insertive AI showed a trend for lower HIV prevalence among circumcised men, though power was limited. An Australian study showed no overall difference in HIV incidence between circumcised and uncircumcised MSM.[54] However, it was the first study to demonstrate a significantly lower risk of HIV acquisition in circumcised compared with uncircumcised gay men and other MSM who reported a preference for the insertive position during unprotected AI.[55] A report from a recently completed HIV vaccine trial similarly suggested a lower incidence of HIV following unprotected insertive AI among circumcised compared with uncircumcised men, but the reductions were not statistically significant. This is due in part to the small proportion of uncircumcised men—only 14%—in the study.[56]

Although the data from observational studies in gay men and other MSM are not as clear as for heterosexual men, the biologic basis for reduced HIV risk following unprotected insertive AI is similar. However, a gold standard, randomised controlled trial of circumcision among exclusively or predominantly insertive gay men and other MSM in different settings and countries may be difficult

to conduct. A trial may be feasible—ethically and logistically—in some populations of gay men and other MSM with high HIV incidence where predominantly or exclusively insertive sub-groups can be identified. Possible settings for such trials include Peru, some South African groups of gay men and other MSM, India, and Thailand.

The policy implications of data showing a lower risk of HIV acquisition by circumcised men following unprotected insertive AI, even once confirmed, are not clear. The mainstay of HIV and STI risk reduction for both insertive and receptive AI is consistent condom use. Promoting medical male circumcision among gay men and other MSM would only reduce the risk of HIV infection during unprotected insertive AI with a partner known to be HIV-positive, or a partner whose HIV status is not known. The question is how frequently that occurs compared with other acts of intercourse, and whether the frequency of such acts can be reduced through promoting condom use and knowledge of HIV status. Many gay men and other MSM already use condoms strategically, with higher rates of condom use during intercourse between partners who are serodiscordant (where one partner is HIV-positive, and the other partner is HIV-negative) or where one partner's HIV status is not known.[57] Circumcised gay men and other MSM are probably at lower risk of HIV infection than uncircumcised men, but the difference in risk is likely small and almost irrelevant unless the risk of HIV from unprotected receptive AI can be reduced or eliminated.

1.7.5 Availability of lubricants

By Jim Pickett (AIDS Foundation of Chicago, IRMA Chair, U.S.)
and Chris Beyrer (Johns Hopkins University, U.S.)

At the IRMA-sponsored satellite session held prior to the 2009 International AIDS Society Conference in Cape Town, South Africa, Dr. Chris Beyrer of Johns Hopkins Bloomberg School of Public Health presented pioneering data on the epidemiology of HIV among gay men and other MSM in Africa and the implications for RM (presentation available here www.rectalmicrobicides.org/community.php).

After contextualising the challenges faced by African gay men and other MSM—including criminalisation, stigma, human rights abuses, lack of access to prevention and care, and limited HIV surveillance—Beyrer provided data from over a dozen countries, revealing high burdens of HIV among gay men and other MSM. AI was common, he reported, as was the use of lubricant.

However, according to Beyrer, the majority of African gay men and other MSM are not using water-based lube—which is compatible with condoms—primarily due to lack of access. For instance, in a 2008 study of gay men and other MSM in Namibia, Botswana, and Malawi, 12.9% of the men who indicated they always used condoms reported using water-based lubricant. Unfortunately, as high as 38.8% of those reporting always wearing condoms used petroleum-based lubricant (which degrades condoms), saliva, or no lubricant at all. While the research on lubricant use among this population suggests that a lube-based RM will be highly acceptable, the current lack of education around and access to water-based lubricant must be addressed immediately.

Many men and women use sexual lubricants during AI, yet we know very little about their relative safety for rectal use. Obtaining data on the relative safety of products used as sexual lubricants for anal sex would be valuable for public health reasons. For example, this data could be used to promote use of safer lubes, while discouraging use of lubes that are less safe. Section 2.11 of this report describes the current state of research and Section 4.4 describes IRMA advocacy for more data on the safety of lubricants for rectal use.