## **Chapter 3. Prevention for Women**

In this era of great strides forward in treatment, it is important not to lose sight of the continued need to undertake a range of interventions to prevent HIV transmission. An estimated 2.7 million people newly acquired HIV infection in 2010, as they did for each of the years 2009, 2008 and 2007, down from 3.1 million people in 2002 (WHO et al., 2011b). However, even with all this encouraging news, for every one person initiated on ART, there were two new HIV infections in 2010 (Zachariah et al., 2011). The goal of programs and national policies should be both to reduce the annual number of deaths by continued access to effective treatment and to reduce the annual number of new infections by effective HIV prevention (Over, 2011). Despite the many documented successes of prevention

"A quarter of a century of AIDS responses has created a huge body of knowledge about HIV transmission and how to prevent it, yet every day, around the world, nearly 7,000 people become infected with the virus. Prevention work takes the longest time, is largely outside of health services, and has no 'quick win.' If not tackled, prevention work will also continue to undermine all the other gains" (Piot et al., 2008: 845, 857).

"HIV is seen as a woman's disease in our community" – Member of a breastfeeding support group, Kenya, (cited in Fleischman, 2011)

programs, in 2007 fewer than 10% of individuals at risk worldwide received key prevention services (Merson et al., 2008). With more than half of new infections among women, and the largest proportion among young women (WHO et al., 2011b), programs for women and girls must be at the forefront of expanding prevention efforts.

### Prevention Efforts Can Succeed and Must Be Scaled Up

Encouragingly, "the discourse on HIV prevention now includes the possibility that the epidemic can be stopped" (Padian et al., 2011b: 269). In addition to the many successful prevention efforts over the past decade, greater access to treatment and breakthroughs in the role of treatment as a prevention strategy have the potential to change the course of the epidemic. At the same time, "HIV prevention is neither simple nor simplistic" (Coates et al., 2008: 670) and "no single, stand-alone HIV prevention intervention offers a 'magic bullet'" (Kurth et al., 2011: 63). Furthermore, "no major multicomponent package of interventions has been launched in a full-scale, community-level randomized trial to assess impact on HIV seroincidence" (Kurth et al., 2011: 63). At the same time, "established methods such as condoms and behavioral change have never been scaled up to saturation level" (Katsidzira and Hakim, 2011: 1122) even though scaling up proven interventions is critical (Dieffenbach and Fauci, 2011). Even blood safety, long known as a critical component of HIV prevention, is insufficiently scaled up thirty years after the first HIV infections (WHO et al., 2011a; WHO et al., 2011b). Modeling has shown that prevention interventions have been more effective the sooner they are rolled out (Johnson

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and White, 2011). While prevention efforts can succeed, there is a "need to continually evaluate and update knowledge on HIV transmission and what works in prevention so as to better inform and reinforce policy making and implementation" (Wamai et al., 2011: para 4).

### Behavior Change is Possible

There is "growing evidence that, across a wide range of settings, people can and do alter their sexual and drug-use practices in response to the spread of HIV" (Bingenheimer and Geronimus, 2009: 193). In Kenya, the prevalence has stabilized at about 7% from a high of 13.4% in 2000, less than ten years ago (Siringi, 2010). In Rwanda, HIV prevalence decreased from 13% in 2000 to 3% in 2007 (Pose and Samuels, 2011). Also in Rwanda, reported condom use has increased to nearly 75% among men; fewer than 11% of men and 2% of women had multiple partners; and boys have delayed sexual debut (UNAIDS, 2011b). In Thailand, the HIV incidence was 150,000 in 1991 and since then the number of newly acquired HIV cases has decreased. This decline was correlated with implementation of the national HIV/AIDS programs (Park et al., 2010). HIV prevalence declined substantially – to 1% in 2010 – following a decline in incidence in Zimbabwe, (Hargrove et al., 2011) and it is likely that even in rural areas, the decline in HIV prevalence and incidence was due to HIV prevention activities (Gregson et al., 2011a) as the numbers of condoms distributed increased from 21.5 million in 1990 to 90 million by 2009. The proportion of condoms sold (rather than distributed at no cost) increased from 1% in 1990 to 70% in 2008 (Hargrove et al., 2011). In addition, the proportion of males aged 15 to 19 who reported having ever had sex declined from 33% in 1994 to 27% in 2005 and men's reduction of nonregular partners went from 57% in 1999 to 47% in 2005. The percent of sexually experienced men who reported paying for sex in the past year fell from 7.2% in 1999 to 3.6% in 2005 (Gregson et al., 2010a).

In South Africa, the incidence rate among young women aged 15 to 24 had a statistically significant decline of 60% from 2002 to 2008; however 2.2% of HIV-negative young women aged 15 to 24 became HIV-positive during the last year (Rehle et al., 2010). Condom use increased significantly among both men and women between 2002 to 2008, from 31% to 65% (Rehle et al., 2010). Cuba has managed to maintain a low adult HIV prevalence of 0.1% in 2009 (WHO et al., 2011b). In Brazil, adult HIV prevalence never reached 1% due to a well-coordinated response, protection of human rights, and large evidence-informed programs focused on sex workers, MSM and PWID (WHO et al., 2011b). In Cambodia, the prevalence of HIV infection has declined from 2% among people aged 15 to 49 in 1998 to a projected 0.7% in 2010 (WHO et al., 2011b). Declines in HIV incidence exceeded what would be expected from natural saturation of infection, "suggesting that programmatic approaches may be having an effect" (AIDS2031 Consortium, 2010: 51).

<sup>&</sup>lt;sup>1</sup> Attributing prevention efforts as a direct cause of HIV prevalence decline is speculative. If HIV prevention programs are implemented when HIV epidemics are at or near their peak, the subsequent decrease in prevalence might be incorrectly attributed to prevention programs (Chin and Bennett, 2007). Gay, J., Croce-Galis, M., Hardee, K. 2012. What Works for Women and Girls: Evidence for HIV/AIDS Interventions. 2nd edition. Washington DC: Futures Group, Health Policy Project. www.whatworksforwomen.org

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## A Range of Prevention Interventions Are Needed

Sexual behaviors and the sharing of injection equipment that cause most HIV infections worldwide occur due to a variety of motivations (e.g., reproduction, desire, peer pressure, desire to please, access to material goods, gender norms, coercion, etc.). Epidemiological studies have shown that multi-partner sex, paid sex and STIs are important risk factors in the AIDS epidemic, no matter what stage of the epidemic (Chen et al., 2007b). Sustaining behavioral change among individuals, couples, families, peer groups, networks, institutions and/or communities is no easy task, but can occur through educational, motivational, peer-group, skills-building or community normative approaches (Coates et al., 2008). "To be most effective, behavior change programs need to ...both...[change] behaviors in HIV-negative partners to reduce their risk of HIV acquisition and [change] behaviors of HIV-positive partners to reduce their risk of onward transmission" (Ross, 2010: S5). [See Treatment as Prevention and Treatment: Staying Healthy and Reducing Transmission]

It is critical to make explicit the interdependency of behavioral and biological mechanisms for HIV prevention (Bingenheimer and Geronimus, 2009). "The value of prevention with antiretroviral drugs for individuals with and without HIV has emphasized the overlap of treatment and prevention, and reinforces the need for integrated strategies for epidemic control. No longer is it acceptable to consider expenditures for treatment and prevention separately; the challenges for sustainably financing epidemic control apply equally to both" (Padian et al., 2011a: 274).

### Prevention Efforts Must Be Tailored

Behavior change (e.g. condom use, partner reduction, use of clean needles) needs to be promoted through a variety of means, including structural changes, such as changes in legal and gender norms, and promoting girl's education and employment opportunities. [See Strengthening the Enabling Environment] In countries in which 10–30% of the population is living with HIV, generalized interventions for women may be warranted. In other countries, specific key populations of women have much higher levels of HIV prevalence and need to be the focus of prevention efforts. [See Prevention for Key Affected Populations] However, HIV prevention programs for women who fall outside of "most-at-risk populations" are often lacking (Silverman, 2010). Young women require special attention. "...Our current 'prevention toolbox' is woefully inadequate for preventing HIV infection in young women who cannot negotiate monogamy and/or condom use with their sexual partner" (Abdool Karim and Humphries, 2010: 1). [See Prevention for Young People]

Focusing on Key Affected Groups Can Leave Out Other Women Also at Risk for HIV Acquisition

"When HIV programmes largely focus on sex work, drug use and male-to-male sex, it contributes to low HIV risk perceptions in the general population. Intimate partners are often left out and there is [a] lack of couple communication about sexual matters"

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(UNAIDS, 2009e: 15). One study found very limited communication concerning sexual matters between married Indian couples, in part, because bedrooms are shared with other family members and women, in particular, had no one with whom they could discuss sex (Marlow et al., 2010). Married women may not realize or have any control over their partners' extramarital sexual relationships [See also Partner Reduction] More prevention interventions are needed on a universal level so that everyone—including married women, for example, who may not realize their level of risk—can communicate with their partners and protect themselves.

## Alcohol Use Puts Women and Men at Higher Risk for HIV Acquisition

Alcohol use inhibits judgment and can lead to unprotected sex and violence. A review of 73 articles representing research conducted in 19 different sub-Saharan countries published between 1992 and 2008 found that HIV seropositivity and high-risk sexual behavior was correlated with alcohol use, with the odds for HIV infection between 1.5 and three times higher for individuals who consume alcohol and for women who have male partners who consume alcohol (Woolf-King and Maisto, 2010). Others have also found an association between HIV and alcohol consumption (Baliunas et al., 2010; Thomas and Lungu, 2010; Singh et al., 2011). Among girls 15 to 19 years of age, the riskiest sexual behaviors in one study in Zimbabwe found took place at venues affiliated with alcohol, and therefore should be the target of HIV prevention efforts (Singh et al., 2010). "Women are at risk of alcohol-related sexual risk behavior in multiple ways" (Fritz et al., 2010). A study of 12 focus group discussions in rural Uganda in 2002 found that both men and women viewed men's alcohol use as related to rape; agreeing with the assumption that women who accept alcohol from men will agree to have sex (Wolff et al., 2006). Men are more likely than women to consume alcohol and to consume alcohol in sexual situations and women whose partners regularly consume alcohol are more likely to be HIV-positive (Woolf-King and Maisto, 2011).

A review of peer-reviewed literature from 1980 to 2008 found inconsistent associations between alcohol use by female sex workers with HIV (Li et al., 2010b). Studies in Indonesia, China and Mexico found alcohol use common prior to sexual intercourse by female sex workers, as well as by clients, and associated with unprotected sex (Safika et al., 2011; Wang et al., 2010; de la Torre et al., 2010). However, female sex workers in a study in India have stated that they avoid alcohol prior to sex in order to reduce the risk of violence, but male migrant workers used alcohol to "be bold enough" to go to sex workers. As one male migrant worker put it: "if I don't drink nothing works out" (Rodriguez et al., 2010: S139.). Another study in India also found no association between alcohol and condom use by HIV-positive female sex workers, but did find an association between HIV-positive male clients, alcohol use and inconsistent condom use (Samet et al., 2010).

A cross-sectional study of 2,920 patients in West Africa found that antiretroviral adherence was reduced for those who had high levels of hazardous alcohol consumption

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(6.1% of men and 1.6% of women), recommending programs to address alcoholism (Jaquet et al., 2010). "Numerous studies have examined the intersection between alcohol and other drug use and HIV risk behaviors... and have shown that alcohol and other drug use is related to sexual risk behaviors... However, there is a paucity of recent literature examining existing HIV interventions that focus specifically on this relationship" (Browne and Weshsberg, 2010:207-208). A study in Thailand found that health care costs were associated with alcohol consumption in 42 diseases, including HIV, as alcohol consumption is associated with unsafe sex (Neramitpitagkul et al., 2009). Alcohol use also impacts adherence to antiretroviral therapy (Altice et al., 2010) and is associated with HIV disease progression (Shuper et al., 2010).

## Anal Intercourse Poses High Risks for Women and Men

Within a serodiscordant relationship, certain sexual behavior is inherently more risky for women. Anal sex increases risk of HIV acquisition and is practiced by heterosexual couples as well as MSM. A study in South Africa found that 14% of men and 10% of women reported anal intercourse (Kalichman et al., 2009 cited in Boily et al., 2009b). "Anal intercourse within heterosexual relationships is not an uncommon practice but is often underreported" (Baggaley et al., 2010: 1049). Most studies of heterosexual couples have found an increased male-to-female transmission risk among couples practicing anal intercourse, even if only occasionally. A systematic review and meta-analysis found no significant difference between per act risk of acquiring HIV through unprotected anal intercourse for heterosexuals and MSM. A woman who has unprotected receptive anal intercourse is 35 times more likely to acquire HIV than through oral-genital intercourse. Anal intercourse "may substantially increase HIV transmission risk even if the infected partner is receiving HAART" (Baggaley et al., 2010: 1048).

More Research is Needed on the Risk of HIV Acquisition and Transmission During Menstruation

In addition, some articles have suggested that sex during menses may increase the risk for both HIV acquisition and HIV transmission (Lurie et al., 2010; Royce et al., 1997) and it is surprising that not enough research has been conducted on this issue 30 years later to provide a definitive answer.

### Timely Access to Post-Exposure Prophylaxis (PEP) is Needed

There is significant evidence from animal transmission models, perinatal HIV transmission studies, observational studies, studies of post-exposure prophylaxis (PEP) in health care workers, and meta-analyses indicating that PEP is effective in reducing HIV transmission (CDCb, 1998; Bell, 1997; Young et al., 2007 cited in Siika et al., 2009). Health providers who have an occupational exposure to HIV need access to PEP. Gender-based violence increases the risk of HIV and rape survivors also need timely access to PEP. [See Strengthening the Enabling Environment: Addressing Violence Against Women]. Although the efficacy of post-rape antiretroviral prophylaxis has not been determined, zidovudine reduces the transmission of HIV after needle stick injury by 81%

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(Cardo et al., 1997; Petra Study Team, 2002 cited in Carries et al., 2007). "As such, there is current consensus that HIV prophylaxis should be provided immediately after an exposure where there is judged to be risk of HIV acquisition" (Siika et al., 2009: 48). In observational nonrandomized studies of zidovudine/lamivudine in 480 initially seronegative cases of heterosexual rape in South Africa, there was one seroconversion, and that occurred in an individual who did not initiate PEP until 96 hours after exposure, instead of the required 72 hours (Chirstofides et al., 2006; Bryant et al., 2009 cited in Weber et al., 2010). Because PEP is now the standard of care, it would be unethical to conduct a randomized clinical trial and it is highly unlikely such a trial would ever be conducted (Weber et al., 2010). For PEP, triple antiretroviral therapy is recommended for 28 days to be used in an HIV-negative person after high risk HIV exposure so that should prophylaxis fail and the person acquires HIV, there will be only a negligible risk of antiretroviral resistance developing (Weber et al., 2010).

## Some Women Are Overlooked in Prevention Programming

Older women and women with disabilities also need attention in HIV prevention programming but are often neglected (Rohleder et al., 2010). Additional research is necessary to discern the major risks facing these women and to evaluate interventions addressing those risks.

### Women Over the Age of 50

Women past the age of childbearing are often ignored in HIV prevention (Conde et al., 2009). In parts of southern Africa, older adults in heterosexual relationships account for a large share of new infections, but few programs address their needs (UNAIDS.

"Grandmothers are too often and incorrectly assumed to be sexually inactive..." (Sepulveda et al., 2007).

2011a). In sub-Saharan Africa in 2007, an estimated three million people over the age of 50 were living with HIV, accounting for approximately 14% of infections (Atun and Bataringaya, 2011; Negin and Cumming, 2010). HIV prevention and education efforts are needed for people over the age of 50. A WHO review of HIV in developing countries found that "sexual activity of older individuals in the developing world is barely researched. Many older individuals everywhere are sexually active" (Schmid et al., 2009: 162). A study in hospital of 706 cataract surgery patients over age 50 in Ethiopia found an HIV seroprevalence of 5% (35 out of 706) (Kassu et al., 2004). In Brazil, of 51,255 AIDS cases reported from 1982 to 2006, 2,668 AIDS cases were among those ages 50 or older. A study in South Africa found that of 100 women aged 50 to 80 years of age, few had adequate knowledge of how HIV is transmitted (Rauf et al., 2010). "Elderly grandmothers...appear to be forgotten in terms of their need for HIV/AIDS prevention information and education" (Sepulveda et al., 2007). Due to ARV therapy, more HIVpositive women are reaching menopause. Interventions for post-menopausal HIVnegative women, such as evaluation of cardiovascular risk, osteoporosis, etc. are also believed to benefit women living with HIV (Conde et al., 2009).

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#### Women With Disabilities

WHO estimates that one in ten people in the world lives with some kind of disability (WHO cited in Hanass-Hancock and Nixon, 2009). As of 2011, approximately 110 million people globally experience very significant disability and these people are at equal or higher risk of HIV acquisition. Women and girls with disabilities are often at increased risk of HIV acquisition (IDDC, 2012). Women with disabilities are also at risk for HIV but are often overlooked in HIV prevention strategies. "...The field of HIV and disability remains largely overlooked" (Heidari and Kippax, 2009: para 1). A systematic review of 36 studies in Cameroon, Ethiopia, Lesotho, Rwanda, Mozambique, Malawi, Swaziland, Uganda, Kenya, Nigeria, Zimbabwe and South Africa concerning disability and HIV/AIDS found that people with disabilities lacked access to information, testing and treatment and despite popular misconceptions, are sexually active and therefore there is a real need for disability specific HIV prevention programs (Hanass-Hancock, 2009).

Studies have also shown that adolescents with disabilities are also sexually active (Groce et al., 20003 cited in Hanass-Hancock and Nixon, 2009). LVCT (formerly Liverpool VCT) in Kenya has launched a program to provide HIV services to deaf people (Taegtmeyer et al., 2009 cited in Hanass-Hancock and Nixon, 2009). Another study in Cameroon found that those who were hearing impaired had rates of HIV similar to the general population, as well as risk factors such as early sexual debut and low condom use but with no HIV prevention activities tailored to their needs (Touka et al., 2010). A study in Uganda found that women with disabilities reported difficulties in accessing HIV/AIDS services (Chireshe et al., 2010). Those with disabilities also experience stigma and a lack of recognition of their sexual activity. People living with HIV also experience disability and HAART can cause disabling side-effects (Elliott et al., 2009), and therefore people living with HIV need protection against discrimination. A resource library -HEARD (Health Economics and HIV/AIDS Research Division) - in South Africa with a good practices on disability and HIV can be found http://www.heard.org.za/african-leadership/disability/good-practice-overview.

Overall, very little evidence is available regarding what works specifically for women over the age of fifty and disabled women and much more research and evaluated programming is necessary.

## Critical Prevention Approaches Under Development

Scientists are working to develop "new, potent biomedical prevention tools that can be integrated with – and enhance – currently available prevention approaches" (Dieffenbach and Fauci, 2011: 1). A number of biomedical prevention technologies are currently in clinical trials to assess their safety and effectiveness. These include vaccines, microbicides and the use of ART as prophylaxis, also referred to as pre-exposure prophylaxis or PrEP. While results from vaccine studies and microbicides "suggest the possibility of the eventual development of new prevention technologies, much work will be required before these early results can be translated into widely used products" (IOM,

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2011: 25). The goal of developing PrEP, microbicides and a vaccine will be to expand the range of prevention options (AVAC, 2010).

### Vaccine Development Continues to be a Priority

Substantial reductions in incidence of over 50% will only occur with the introduction of a vaccine or curative treatment (Hecht et al., 2010: 1256). "The development of a safe and effective vaccine has long been a major goal of prevention research. If developed, a vaccine would be a cornerstone of an integrated HIV prevention strategy" (Dieffenbach and Fauci, 2011: 4). An ideal vaccine would be feasible for widespread use in low-income settings, confer lifelong immunity, protect against all routes of HIV transmission and work against diverse strains; however, the limited efficacy of early HIV vaccines means that they would, once developed and available for use, need to be used as a complementary tool with existing prevention strategies (AIDS2031 Consortium, 2010). In 2012, Bill Gates wrote: "It is still possible to have a vaccine within 12 years, but it will take some luck and better planning" (Gates, 2012: 13). "It is, however, widely accepted, that a fully efficacious vaccine providing durable (years) protection against HIV would have the biggest impact on HIV incidence" (Shattock et al., 2011: 42). "A vaccine would be a great equalizer, presumably protecting men and women indistinguishably" (Padian et al., 2011: 275).

While recent trials have been promising, an HIV vaccine is yet to be licensed. A vaccine can have special benefits for women. An effective vaccine would provide women autonomy to protect themselves against HIV acquisition. A trial of an HIV vaccine with 16,402 healthy men and women ages 18 to 30 in Thailand found a vaccine efficacy of 31.2 percent, a modest efficacy, with less HIV acquisition among women than men among those on the vaccine as compared to placebo. The vaccine efficacy may have been greater in persons at lower risk of HIV acquisition. "... After the exclusion of the subjects who were infected with HIV-1 before vaccination, the modified intention-to-treat analysis showed a significant, though modest, reduction in the rate of HIV-1 infection, as compared with placebo" (Rerks-Ngram et al., 2009: 8-9). Additional efforts are underway to assess effects of additional doses and to determine whether this vaccine could be effective in Africa (UNAIDS, 2011b). Others have argued that the results from the Rerks-Ngram et al., 2009 trial do not represent significance, as "the low HIV incidence among this sample of the general population limited study power sufficiently so that both the strict intent-to-treat and per protocol analyses yielded a nonsignficant 26% reduction in HIV incidence and even the significant efficacy documented in the modified intent-totreat analysis had such a wide confidence interval that questions have been raised about the interpretability of the results" (Padian et al., 2010: 624). Others have argued that even a vaccine with 30% efficacy (Rerks-Ngram et al., 2009) could avert 44% of all HIV infections over the next 20 years in Thailand and 35% of all HIV infections in South Africa (Kaldor and Wilson, 2010) and have a significant public health benefit (Abbas, 2011). Even a vaccine with rapidly waning protection covering 60% of the population in South Africa could prevent three million new infections between 2020 and 2030, or about

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36% of expected infection and require only 39 people to be vaccinated for every infection averted (Andersson and Stover, 2011).

As some vaccine experts note, however: "It is misleading to say that a vaccine is the solution" as even once a vaccine is invented ...in five to ten years hence, "the AIDS epidemic will be with us for many years." It is unlikely that the first generation of vaccines will be 100 percent effective. "We remain cautiously optimistic that a substantial increase in our understanding of HIV infection and disease will lead to creative ideas about how to design an effective vaccine" (Johnston and Fauci, 2008: 890). However, "scientists agree that with no prospect of an effective vaccine to curb the HIV/AIDS pandemic in the foreseeable future, expanding the repertoire of prevention tools is all the more important" (Stephenson, 2008: 1529). Once developed and distributed, partially effective vaccines could be combined with all existing HIV technologies plus microbicides and PrEP (Excler et al., 2011; Shattock et al., 2011).

PReP or Oral Pre-exposure Prophylaxis is a Promising Potential Strategy

"Promising results from recent trials of oral and topical pre-exposure prophylaxis (PrEP) have bolstered hopes that antiretroviral (ARV) based methods will be a cornerstone of HIV prevention efforts in the future. Nevertheless, it is clear that in the near term, there will be no HIV prevention panacea" (Padian et al., 2011: Para 1). A randomized controlled study with 4,758 HIV serodiscordant couples in Kenya and Uganda showed that when used as pre-exposure prophylaxis (PrEP) by the HIV-negative partner, daily tenofovir (TDF, or brand name Viread), an antiretroviral drug, was 67% effective and daily TDF combined with emtricitabine (FTC) (or TDF/FTC, brand name with Truvada (another antiretroviral drug) was 75% effective in preventing HIV acquisition. "Both study medications significantly reduced HIV risk in both men and women" (Baeten et al., 2012). A PrEP with TDF/FTC study in Botswana with 1,200 men and women, of whom 45% were women, had an efficacy rate of 63%, with no increased adverse or safety for those on PrEP compared to placebo (Birnkrant, 2011). However, another PrEP trial with TDF/FTC and another with oral TDF among women in a number of African countries were stopped as roughly equivalent numbers of women acquired HIV among those receiving PrEP as those that did not. It is not yet understood why PrEP has worked in some populations and not others, although drug adherence may have been an issue where PrEP has not been shown to be effective (Van Damme et al., 2012; Microbicides Trial Network, 2012 cited in Cohen et al., 2012). In May 2012, the United States' Food and Drug Administration's Antiviral Drugs Advisory Committee (ADAC) voted by a large majority in favor of recommending Truvada as PrEP (pre-exposure prophylaxis) for men who have sex with men, and for an approval for use by the HIV-negative partner in serodiscordant couples (FDA.gov/advisorycommittees). The FDA is expected to decide by September of 2012. Trials are also underway to assess PrEP in key affected populations in resource-limited settings and further research is awaited.

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The use of PrEP is not without concern. Questions remain: Will people take more risks with PrEP if they think they are protected? Would those on PrEP who seroconvert and become HIV-positive have their treatment options limited by antiretroviral resistance? What about drug resistance if PrEP is given to someone who is HIV-positive but not yet diagnosed as HIV-positive (Wainberg, 2011)? "Concerns remain that using the same ARV drugs for treatment and prophylaxis may exacerbate circulating drug resistance if efficacy is only partial" (Shattuck et al., 2011: 43), though studies to date have not shown increased resistance (Warren, 2012) as long as PrEP is initiated after confirmed HIV negative status (Warren, 2012). Some of these same hypothetical concerns have also been raised with male circumcision, microbicides and vaccines — especially risk compensation/behavioral disinhibition (Baeten, 2012).

In countries where those who meet national and international guidelines for access to treatment have difficulty accessing treatment, concerns have been raised as to the use of antiretroviral drugs for PrEP instead of for treatment. Experts have advised "the global community should adopt as its first priority extending life for the greatest number of people" (AIDS2031, 2010: xiv). But modeling has shown that pre-exposure prophylaxis could avert as many as 30% of new infections in targeted age groups of women at highest risk of infection in South Africa, however, once access to antiretroviral therapy has been scaled up, cost-effectiveness of PrEP would decrease rapidly (Pretorius et al., 2010). Scaling up antiretroviral therapy is preferable as ARVs are both a treatment and a prevention strategy. It would be critical to counsel continued condom use for those on PrEP. [See also Treatment]

Frequent HIV testing is needed for those using PrEP (Cohen, 2011a). "PrEP involves dosing...uninfected individuals with costly medications ...success...also [depends] on levels of risk compensation" (Leibowitz et al., 2011: 984). Clearly, PrEP is not for all populations and all settings (Liebowitz, 2011). Willingness of an HIV-negative person who feels at risk to access and use PrEP is also a question. A study posed a hypothetical question to 181 HIV-discordant couples in Kenya. HIV-positive partners were more likely to want to access ARVs for prevention and HIV-negative partners were more likely to want to access PrEP, with participants tending to choose "the prevention option they would control" (Heffron et al., 2012b). Modeling in Zambia and South Africa found that treatment of those who are HIV-positive was more cost-effective than providing PrEP. However, PrEP could be cost-saving if accessed by those at greatest risk of HIV acquisition (Alistar et al., 2012; Nichols et al., 2012). Programmatic and resource decisions on treatment and prevention will need to be strategically designed and optimized for local conditions.

Microbicides or Topical Pre-exposure Prophylaxis Are Not Yet Ready for Roll-Out "Available HIV prevention strategies provide few options for young women who are at high risk of infection, but who are unable to convince their partner to be faithful or use condoms, underscoring the urgent need for a women-initiated HIV prevention

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technology" (Abdool Karim et al., 2011a: 279). Microbicides, a female-controlled technology, refer to a variety of topically applied products and hold great promise for women to be able to protect themselves from HIV, other STIs (Global Campaign for Microbicides, 2007), and unwanted pregnancy. While women have expressed a need for methods that can be used without the knowledge and consent of their male partners (Mantell et al., 2008a), in most clinical trials of microbicides, male involvement was the desired norm among female participants. Building on the experience observed in clinical trials and in female condom programs, focusing on sexual pleasure may increase future use. Microbicides for anal use are also under development.

The first generation of microbicides is expected to be less than 100 percent effective and will ideally need to be used with a condom. However, even if used alone, a partially effective microbicide could have a significant impact on HIV incidence (assuming risk taking does not increase with the use of this method). "A deeper understanding of the female genital tract and mucosal immunity is key to guiding the development of strategic and targeted products most suitable for combating HIV infection in women" (Abdool Karim et al., 2010a: S123). The impact of vaginal practices motivated by views of sexuality common in many parts of the world, such as washing intravaginally, will need to be assessed as microbicides are developed (van der Straten et al., 2010). Currently there are more than fifty candidate microbicides in preclinical development and eleven products are being tested in 21 ongoing trials. "...Microbicides provide real potential to influence the course of the HIV epidemic and are likely to be available and accessible sooner than HIV vaccines and will fill an important gap for women-initiated prevention methods" (Abdool Karim et al., 2010a: S126).

But while not ready for roll out yet, a landmark study demonstrating proof of concept that a microbicide could reduce HIV acquisition was released in July 2010. A double-blind, randomized, controlled trial (CAPRISA 004) in South Africa compared tenofovir gel (445 HIV-negative women) and a placebo gel (444 women) and showed that in women who followed the instructions closely – i.e. insert the gel 12 hours before sex and 12 hours following sex, had a 54% reduced risk of acquiring HIV among those who were highly adherent. Among women who were less adherent, the reduced risk of acquiring HIV was between 28% and 38% (Abdool Karim et al., 2011c). The results of CAPRISA 044 were statistically significant with no serious side effects (Cohen, 2010a).

If a tenofovir gel with the effectiveness of CAPRISA 004 were used by women in 80% or more of sexual encounters, it could avert 2.33 million new infections and save 1.3 million lives. If used in 25% of sexual encounters it could avert approximately 500,000 new infections and save approximately 300,000 million lives over the next twenty years, which would be highly cost-effective (Williams et al., 2011b). However, once a microbicide is developed, "neither the elegance of the science nor the strength of the effect will predict the ease of implementation" (Stanton cited in Stanton and Ferris, 2011). Questions remain concerning access, cost, which populations, clinical monitoring,

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resistance and resources. Antiretrovirals are not over the counter products and will require frequent contact with health systems for HIV testing and monitoring for side effects (Stanton and Ferris, 2011). Further research to develop an effective microbicide is needed to provide women with additional prevention options.

Vaccines, microbicides, PrEP and other female-controlled technologies are needed for primary prevention for women. Once these prevention modalities are rolled out, they have the potential to greatly reduce the risk of acquiring and transmitting HIV to reduce the vulnerability of women and could have a profound impact on the pandemic (Stanton and Ferris, 2011). But further progress in these areas is urgently needed. "For the foreseeable future...[these] strategies [are] unlikely to serve as a stand-alone prevention strategy. We therefore need ongoing research to identify the most effective combination of interventions for each population and setting" (Burns et al., 2010: PREP, para 7) Scientists do not expect the first generation of these biomedical prevention modalities to be 100% effective, so programming for "combination prevention" where all effective prevention methods are used and tailored to the epidemiological and cultural context is critically important. Women will need access to both contraceptive and non-contraceptive microbicides, because some women will want to prevent HIV, STIs, and pregnancy, while other women will want to conceive without the risk of disease transmission. "No single, stand-alone HIV prevention intervention offers a 'magic bullet'...Combining several partially protective strategies might have additive or synergistic effects in reducing HIV incidence on a population level...there is a growing recognition that combination HIV prevention strategies might optimize HIV prevention impact potentially enough to reduce transmission below the reproductive rate necessary to sustain HIV epidemics around the globe" (Kurth et al., 2011: 62).

"...There is an ethical responsibility to educate women about HIV infection and offer accurate prevention and risk reduction even in the absence of clear data on effectiveness. Yet how to incorporate behavioral change programs into HIV prevention packages is unclear" (Mc Coy et al., 2010). NIH and PEPFAR have launched a research initiative to fund combination HIV prevention studies, scheduled to start in December 2012 and 50 studies are in development (Cohen et al., 2012). The US National Institutes of Health (NIH) has recently funded research on gender specific combination HIV prevention in high burden settings, with results anticipated in 2015. For updates on biomedical HIV prevention research, please refer to: www.avac.org.

Also underway as prevention approaches is are the launch of an ARV-containing vaginal ring (<a href="http://www.ipmglobal.org/the-ring-study">http://www.ipmglobal.org/the-ring-study</a>), and a long-acting injectable ARV.

## What Works in Prevention for Women and Girls

A number of prevention strategies already work to help women prevent new HIV infections in women. These include male and female condom use, partner reduction, delay of marriage, completing secondary education, and seeking treatment for some sexually transmitted infections. In addition, voluntary medical male circumcision works Gay, J., Croce-Galis, M., Hardee, K. 2012. What Works for Women and Girls: Evidence for HIV/AIDS Interventions. 2nd edition. Washington DC: Futures Group, Health Policy Project. www.whatworksforwomen.org

for men and will, in the long run, also protect women. Additionally, increasing access to ART for all PLHIV will greatly reduce girls' women's risk of acquiring HIV infection by reducing the transmissibility of HIV by male sexual partners. Each of these areas has substantial evidence to justify their use in public health programming. Little evidence exists for how people can be encouraged to reduce the numbers of concurrent sexual partners, both as adults and adolescents. Each of these topics is discussed in more depth in the following sections. Preventions efforts must be informed by "what works to support women and girls," particularly to strengthen the enabling environment by transforming gender and legal norms; addressing violence against women, legal capacity, inheritance and property rights; increasing opportunities for employment and income, reducing stigma and discrimination, and promoting women's leadership. [See Strengthening the Enabling Environment | Women have multiple types of sexual partnerships: some women have only one sexual partner but are still at high risk for HIV acquisition from their sexual partner; some women have multiple sexual partnerships to survive economically [See Prevention for Key Affected Populations]; some women are young and are engaged in cross-generational sex, placing them at high risk [See Prevention for Young People and Care and Support: Orphans and Vulnerable Children]. HIV prevention efforts will need to be tailored to a wide spectrum of risks for women. Women, themselves, have been leaders in HIV prevention efforts and creating awareness of the epidemic both at grassroots community levels as well as at the highest levels of government in fighting for prevention efforts to meet their varied needs. These efforts must be encouraged and promoted. "... A growing number of interventions have shown promise in partially protecting against HIV transmission and acquisition, including knowledge of HIV serostatus, behavioral risk reduction, condoms, male circumcision, needle exchange, treatment of sexually transmitted infections and use of systemic and topical antiretroviral medication by both HIV-infected and uninfected persons. Designing the optimal package of interventions that matches the epidemiological profile of the target population, delivering that package at the population level, and evaluating safety, acceptability, coverage and effectiveness all involve methodological challenges," however (Kurth et al., 2011: 62).

The prevention strategies in this section are applicable for all women; however certain groups of women and girls have particular prevention needs. Therefore, while this section presents what works for generally for all women, other sections, particularly *Prevention for Key Affected Populations* and *Prevention for Young People* provide additional considerations and strategies for groups such as sex workers, female drug users, women and girls in complex emergencies, young people, etc. The three sections should be viewed together as a whole to identify what works in prevention for women and girls.

For additional information, summaries for all WHO HIV/AIDS priority intervention recommendations (WHO, 2011h) are available at: <a href="http://www.who.int/hiv/pub/guidelines/9789241500234/en/index.html">http://www.who.int/hiv/pub/guidelines/9789241500234/en/index.html</a>

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- A. Male and Female Condom Use
- B. Partner Reduction
- C. Voluntary Medical Male Circumcision
- D. Treating Sexually Transmitted Infections
- E. Treatment as Prevention

## What Works in Prevention for Women

### 3A. Prevention for Women: Male and Female Condom Use

The role of condom use in prevention of sexual transmission of HIV is clear. According to the WHO and the U.S. National Institutes of Health, male condoms that are intact are essentially impermeable to even the smallest sexually transmitted virus (UNAIDS, 2004). The effectiveness of male condoms has been shown to be between 80–95 percent, depending on how correctly they are used (Weller and Davis-Beaty, 2007; Holmes, Levine and Weaver, 2004; Hearst and Chen, 2004). Despite the fact that condoms are an old technology, "condom

"Why is the government genderbiased in as far as it issues only male condoms? Why are women discriminated against by having no condoms to use, leaving women no choice if their man refuses to use male condoms?"

— Fifteen year old Kenyan girl (cited in Njoroge et al., 2010: 146)

promotion remains a critical component of all prevention programmes" (Katsidizra and Hakim, 2011: 1122).

While the efficacy of neither the male nor the female condom in preventing HIV transmission has yet to be studied (IOM, 2001), mathematical modeling indicates that consistent use of female condoms, even at lower rates of efficacy, can play an important role in HIV prevention, especially for women whose partners will not use male condoms (Musaba et al., 1998). The efficacy of the female condom in preventing HIV transmission may never be fully determined. "While all evidence points to the effectiveness of female condoms to prevent HIV transmission and acquisition, it would be ethically impossible to test female condoms for HIV prevention: one cannot conduct a trial and give participants only female condoms and female and male condoms cannot be combined during the same sexual act. There is no possibility of doing a true gold standard randomized controlled clinical trials for female condoms" (Gabelnick, 2007, cited in CHANGE, 2008). Still, with laboratory and modeling studies indicating that the female

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condom is likely as effective as the male condom, the female condom is a critical component to HIV prevention for women.

Consistent Condom Use is Effective in Reducing HIV Transmission

Consistency is key. Women's lifetime risk of infection decreases with the consistent use of condoms. A microsimulation in Malawi found that if men always use male condoms with women who are not their wives, women's lifetime risk falls to 9 percent and that if both men and women

"The condom is not pleasurable, but one uses it for the sake of one's life."

—Woman, South Africa (Susser, 2009:123)

always use condoms with partners other than their spouses, women's lifetime risk of infection falls to 8 percent (Bracher et al., 2004). Findings from Rakai, Uganda, showed that among 350 women who reported consistent male condom use, none became HIV-positive, but annual HIV incidence was 4.6 percent among women who reported inconsistent condom use (Kiddugavu et al., 2003). Conversely, many studies have shown that inconsistent condom users are at higher risk of HIV transmission than those who never use condoms. This may be because their behavior is riskier in other ways. Mathematical models suggest that a small number of people who use male condoms consistently can have a greater impact on reducing HIV transmission than a larger number who use them inconsistently (Hearst and Chen, 2004). An analysis of DHS data from 2005 to 2006 in Zimbabwe found that among 8709 women, knowledge that consistent condom use can prevent HIV infection was associated with HIV testing uptake (Sambisa et al., 2010). Interventions promoting consistent condom use are therefore paramount in reducing the incidence of HIV.

Variations in condom use across regions, countries and populations indicate that condom promotion should address barriers (socio-cultural, legal and policy, economic and financial and structural barriers) faced by different groups of women such as youth, married women, discordant couples, sex workers, and PWID, among others (Drezin, Torres and Daly, 2007).

### Female Condoms Are The Only Female-Initiated HIV Prevention Method

While attention is drawn to work on AIDS vaccines and microbicides, the female condom is the first HIV prevention technology for sexual transmission developed since the beginning of the AIDS epidemic (Brown et al., 2007). In fact, "twenty years into the HIV epidemic, female condoms are the only currently available female initiated method of HIV...prevention (Napierala et al., 2008: 121). The female condom is woefully underprogrammed in prevention programs. By 2009, 50 million female condoms per year were distributed, an increase from 11.8 million in 2004. But in 2009, 71 male condoms were purchased for every female condom (UNFPA, 2011). "Nearly 25 years after its invention, the female condom is still not generally accessible" (Peters et al., 2010: 120). "Despite comparable efficacy rates between male and female condoms, and high acceptability levels, limited access to female condoms and substantially higher costs have limited Gay, J., Croce-Galis, M., Hardee, K. 2012. What Works for Women and Girls: Evidence for HIV/AIDS Interventions. 2nd edition. Washington DC: Futures Group, Health Policy Project. www.whatworksforwomen.org

uptake and use of female condoms and thus an opportunity to reduce HIV infection in women through a women-initiated method" (Abdool Karim et al., 2010a: S125).

An analysis of five randomized controlled trials on effectiveness of the female condom found that the female condom increased the number of protected sex acts (Vijayakumar et al., 2006). While more costly than male condoms, "female condoms are safe to reuse repeatedly if proper care procedures are followed" (Marrazzo and Cates, 2011: S68).

"If you are not equipped, I have mine [female condom]."

—Ugandan woman (Green et al., 2001: 596)

Increasing Consistent Condom Use in Regular Partnerships is Important for Prevention Promoting the use of condoms for high-risk sex is an effective approach to reducing HIV transmission, and studies indicate that interventions can achieve high rates of condom use in casual and commercial sex (Bollinger et al., 2004). However, promoting condom use for high-risk sex has contributed to the association of condom use with illicit sex (Feldman and Masophere, 2003; Webber et al., 2010a; Kendall and Pelcastre, 2010), making it more difficult for women to negotiate condom use with regular sexual partners. Condom use among married couples is universally low, and normalizing condom use for all sex acts, including within marriage, is a challenge (Ali and Cleland, 2005; Hearst and Chen, 2004). In some countries, such as Malawi, remarriage following divorce is common and exposes adults to sequential multiple partners and risk of HIV acquisition (Kaponda et al., 2011).

Despite substantial risk within many primary relationships, condom use is low (Morrison et al., 2009: 265). Or as a sex worker in Ghana put it: "Even a married woman would be taking a risk in Ghana if she asked her husband to wear a condom. In my line of work, I can ask a man to wear a condom" (cited in Raingruber et al., 2010: 517). [See also Strengthening the Enabling Environment: Addressing Violence Against Women] But national norms can change with regard to condom use: in Cuba, the percent of those who used a condom in a relationship lasting less than a year increased from 61.8 in 2001 to 78.1% in 2009; those who used a condom in the last sexual relation with a stable partner increased from 30.6% in 2001 to 41.95 in 2009 (Gorry, 2011). "Being married virtually always means being sexually active" (Clark et al., 2009: 398).

Consistent condom use remains largely uncommon among married couples and regular partners. A review of published literature on patterns of incident infection, risk factors for HIV infections, and rates of condom use used in regular partnerships found that a large proportion of incident HIV infection in some settings is in regular partnerships (Dunkle et al., 2009). For example, several epidemiological studies find marriage to be the main risk factor for infections in women. An analysis of 23 Demographic and Health Surveys (DHS) from low- and middle-income countries conducted between 1994 and 2000 found

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that in eight of the 23 countries, fewer than five percent of women aged 15 to 49 used condoms to prevent STIs (Snelling et al., 2006; de Walque and Kline, 2011). Married women particularly find it difficult to discuss condom use with their husbands as doing so touches on sensitive issues including fidelity and trust (Smith, 2007; Maharaj and Cleland, 2004; Nyblade et al., 2003; and Chimbiri, 2007). Even when women can insist on condom use they may not want to negotiate condom use "...because condoms seem antithetical to trust, love, closeness and fidelity" (Higgins et al., 2010: 436). Women, as well as men, may be reluctant to press for condom use if they perceive condoms as interfering with physical pleasure. Men may be reluctant to press for condom use lest they signify lack of trust, closeness and fidelity (Higgins et al., 2010). Perceptions must be challenged, however; a study found that youth in Swaziland, Namibia, Kenya, Nigeria, Burkina Faso and Senegal believed that women initiate condom negotiation and men resist their use (Winskell et al., 2011b).

Condom use can be increased among all groups, including youth, discordant couples and sex workers. Promoting condoms to prevent STIs that may result in infertility may be a promising way to make condom use more socially acceptable within longterm or married relationships (Delvaux and Nöstlinger, 2007). In addition, promoting condoms for pregnancy prevention as well as for HIV prevention can increase condom "For women who do not currently use desire pregnancy, the dual method approach - combining condoms for HIV/sexually transmitted disease (STD) prevention with longer-acting, more effective contraceptives for added protection against pregnancy -

"...It is always men who dictate when and how to use the condom. We cannot really decide on our own."

—HIV-positive woman, Uganda (Kyomuhendo and Kiwanuka, 2007:6)

"'As a woman, I have the right to negotiate for safer sex with the use of female condom in order to protect mvself...'"

—Joy, volunteer with Society for Women and AIDS Cameroon, cited in Whipkey, 2011: 41).

simultaneously prevents both heterosexual and perinatal HIV transmission" (Mark et al., 2007:1201). However, increasing condom use among women ultimately requires the cooperation of men (Foss et al., 2007), who need to be persuaded to use male condoms or to support women's use of female condoms.

Condom Distribution and Programming is Critical to HIV Prevention

Limited access to condoms and inadequate supplies of condoms are also a challenge to prevention of sexual transmission of HIV (Haddock et al., 2008). In 2004, the Global HIV Prevention Working Group noted that only 42 percent of people who wanted to use a condom during sex could obtain one. Of the estimated 18 billion condoms needed in 2006, donors provided just 2.3 billion (UNFPA, 2008 cited in Haddock et al., 2008).

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Evidence from South Africa demonstrates that condoms distributed to the public are in fact used in sex and not wasted (Myer et al., 2001). Public sector male condom distribution rose from six million in 1994 to 198 million in 1999 as part of the government's condom promotion efforts for HIV/AIDS prevention. The government is the largest distributor of condoms in South Africa, with social marketing programs and commercial retailers together distributing an additional 10 to 20 million male condoms in 1997. A prospective study was undertaken during 1998-1999 at 12 representative public health facilities where a total of 384 participants and the 5,528 condoms they received were followed successfully. After five weeks, 43.7% of the condoms had been used or broken in sex, 21.8% had been given away, 8.5% had been lost or discarded, and 26% were still available for use. Those who had actively procured condoms (rather than passively receiving them) had increased rates of use. After five weeks, less than 10% had been wasted (Myer et al., 2001). Continuous monitoring for condom availability and ensuring that condoms are displayed can dramatically increase condom sales (Piot et al., 2010). Condom access requires national and district level planning and coordination, with systems to track demand and supply.

Expanding access to female condoms allows women greater control over protecting themselves and could even be preferred by some men as well. "Men may prefer using the female condom if it gives them more pleasure than does use of the male condom and some men may prefer not being responsible for HIV protection" (Agha, 2001: 55). Qualitative studies with female sex workers in Kenya, India, Uganda, South Africa and Zimbabwe found that they covertly used female condoms to compensate for their inability to enforce male condom use (Okal et al., 2011; Ghose et al., 2011; Scorgie et al., 2011). Programs must pay more attention to increasing access to the female condom, along with education about proper use. "As a currently available device that women might use to protect themselves against HIV, the female condom stands alone" (Barbosa et al., 2007: 261).

Condom use is a critical component to HIV prevention (Cohen, 2002 cited in Feldblum et al., 2003) and remains the best method of protection for sexually active women. Interventions that increase condom availability and use are urgently needed to prevent HIV among women and girls. Additional condom promotion interventions are needed to address barriers (socio-cultural, legal and policy, economic and financial, and structural) faced by different groups of women such as youth, married women, discordant couples, sex workers, and women who use drugs, among others.

### 3A. What Works—Prevention for Women: Male and Female Condom Use

- 1. Consistent use of male condoms can reduce the chance of HIV acquisition by more than 95%.
- 2. Male and female condoms when used consistently and correctly, are comparable in

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effectiveness.

- 3. Expanding distribution of female condoms may increase female condom use, thus increasing the number of protected sex acts and preventing HIV acquisition and transmission.
- 4. Increasing couple communication about HIV risk can increase preventive behaviors, including condom use.
- 5. Promoting the dual use of condoms as a contraceptive as well as for HIV prevention may make use more acceptable and easier to negotiate.
- 6. Peer education for women may increase condom use.
- 7. Promoting condoms, either in individual or group sessions, along with skills training, provision of condoms, and motivational education can increase condom use.

### Promising Strategies:

- 8. Providing women with condom negotiation skills may improve condom use.
- 9. Promoting acceptability of condom use by both women and men as the norm in sexual intercourse may decrease national HIV prevalence.
- 10. Increasing accessibility and availability of condoms can increase condom use.
- 11. Promoting pleasure in male and female condom use can increase the practice of safer sex.

### 3A. Evidence

- 1. Consistent use of male condoms can reduce the chance of HIV acquisition by more than 95% (IOM, NAS, 2001).
  - "Male latex condoms, when used consistently and correctly, are highly effective in preventing sexual transmission of HIV" (Cochrane Collaborative Review Group on HIV Infection and AIDS, 2004: 4). Conclusions were based on systematic reviews and meta-analysis of high methodological quality, which met pre-determined criteria of methodological rigor. Cochrane reviews are the "gold standard" of study synthesis. 60 reviews met the criteria (Cochrane Collaborative Review Group on HIV Infection and AIDS, 2004). (Gray I) (condoms)
  - Information on condom usage and HIV serology was obtained from 25 published studies of serodiscordant heterosexual couples in the **United States, Europe, Haiti, Brazil, Thailand, Zaire, Rwanda, and Zambia**. Condom efficacy was calculated from the HIV transmission rates for always-users and never-users. For always-users, 12 cohort samples yielded a consistent HIV incidence of .9 per 100 person years. For 11 cohort samples of never-users, incidence was estimated at 6.8 per 100 person years for male-to-female transmission and 5.9 per 100 female-to-male transmissions. The condom's effectiveness at preventing HIV transmission is estimated to be 87% with consistent use, but it may be as low as 60% or as high as 96%. Condom efficacy for HIV reduction is similar to, although perhaps lower than that for pregnancy, which is 97%. However, the condom may be less efficacious in preventing

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HIV transmission than in preventing pregnancy for a number of reasons. Pregnancy results only from vaginal sex, but HIV can be transmitted through vaginal, oral, and anal routes. In addition, conception can only take place during a few days of a woman's menstrual cycle, while HIV may be transmitted at any time. (Davis and Weller, 1999). (Gray I) (condoms)

- A study done in Eastern and Southern Africa showed that HIV transmission per coital act among serodiscordant couples is similar between sexes while condom use reduced HIV transmission. A total of 3,297 serodiscordant couples were included in the prospective study. The HIV-1 positive partner was also infected with HSV-2. After the initial examination uninfected partners had a quarterly visit consisting of a genital examination and an HIV test. The clients received prevention measures and risk-reduction counseling, quarterly syndromic STI treatment and free condoms. Plasma viral level of the infected partner was measured at enrollment, 3, 6, 12 months and at study exit (at 24 months). HIV-positive clients were interviewed every month on the number of coital acts with or without condoms. Secondary source information was sought from their non-infected partners to confirm the number of coital acts and condom use. HIV transmission was confirmed by Western blot if a rapid test was positive. Timing of infection was determined by PCR before seroconversion. The time of HIV infection was defined as the earlier positive PCR. Each confirmed transmission between the study partners was classified as "linked." It was "unlinked" if HIV was acquired from another person other than the study partner confirmed with sequencing of plasma samples between the source and infected partner. Analysis was done only for linked transmissions. Sixty-seven percent of the HIV infected partners were women. Thirty-four percent of the HIV infected and 55% of the HIV-uninfected males were circumcised. Eighty-six linked HIV transmissions occurred in the study period. Condom use reduced infectivity by 78% and was similar in both sexes. In cases of unprotected sex the risk of male-to-female transmission was 1.95 times greater than female-to-male transmission. However, the increased male-to-female transmission was largely explained by higher viral loads in male partners. The study found that HIV transmission risk per sexual act among serodiscordant couples is similar between sexes. For each 10-fold increase in plasma viral RNA, increased transmission of HIV by 2.9 fold was observed (Hughes et al., 2012). (Gray IIIb) (condoms, Eastern and Southern Africa)
- Low HIV prevalence in **Brazil** coincides with aggressive government efforts to promote and distribute condoms, resulting in high levels of reported use of condom in first sexual encounter among the general population. Condom use increased from 4% to 55% between 1986 and 2003, according to Ministry of Health statistics (Gauri et al., 2007). HIV prevalence has remained low in Brazil at 0.6% of the population between 2001 and 2007 (UNAIDS, 2008). (Gray V) (condom use, Brazil)

## 2. Male and female condoms when used consistently and correctly, are comparable in effectiveness.

- Laboratory studies have shown that the female condom is impermeable to various STI organisms, including HIV (PATH and UNFPA, 2006; Drew et al., 1990 cited in Hoke et al., 2007). (Gray II) (female condoms)
- Male and female condoms, when used consistently and correctly, are comparable in effectiveness (Feldblum et al., 2001; Fontanet et al., 1998; French et al., 2003 cited in Dias et al., 2006). (Gray II) (female condoms)
- Correct use of the female condom has been estimated to reduce the per-act probability of HIV transmission by 97% (Trussell et al., 1994 cited in Fernandez et al., 2006). (Gray II) *(female condoms)*

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- "Studies of female condoms show that their...ability to prevent disease transmission are similar to those of male condoms" (Nelson, 2007 in *Lancet*). (Gray V) (female condoms)
- 3. Expanding distribution of female condoms may increase female condom use, thus increasing the number of protected sex acts and preventing HIV acquisition and transmission.
  - A study in Brazil on the introduction of the female condom also showed that making the female condom available increased the number of protected sex acts (Barbosa et al., 2007). A 1998 to 1999 preparatory study at 20 sites in six cities in Brazil preceded a national effort to introduce the female condom into public health services. The State and Municipal Health Departments in each city signed an agreement to ensure female condom availability at the end of the study. The twenty sites represented a range of different HIV epidemics within Brazil. Professional teams generated educational and training materials to use in the clinics, with availability publicized in the media. The health workers received a standardized 48-hour training program three times at each clinic. Following an educational session, 2,832 women volunteered to use the female condom and report their experiences. Of those seen fifteen days later, 1,782 had used the female condom at least once. Among those seen at the 90-day follow-up, 1,453 women had used female condoms at least once, with 1,296 stating that they liked the female condom and wanted to continue to use it, an acceptability rate of 54% (1,296 out of the original 2,342). Among these 1,296 women, barrier use at last intercourse, either with a male or female condom, increased from 33% at baseline to 70%. "The advent of the female condom substantially raised the proportion of sexual intercourse acts that were protected... The reasons are...not well understood, but may be due to the dialogue between partners stimulated by introduction of the female condom...or couples may prefer to alternate the method of protection ... Access to an alternative to the male condom makes it possible to increase women's capacity to negotiate their protection from HIV and other STIs" (Barbosa et al., 2007: 265). (Gray IIIb) (female condoms, Brazil)
  - A study with sex workers in Kenya found that adding female condoms to a male condom promotion and distribution peer education program for 151 sex workers over the course of a year led to small but significant increases in consistent condom use with all sexual partners (a declining mean number of unprotected coital acts with all partners from 1.7 before female condom introduction to 1.4 after), verified by a biological marker. Sex workers also stated that they could secretly use the female condom (Thomsen et al., 2006). (Gray IIIb) (female condoms, sexual partners, Kenya)
  - A cost-effectiveness analysis assessed HIV infections averted annually and incremental cost per HIV infection averted for country-wide distribution of the nitrile female condom (FC2) among sexually active individuals, 15-49 years, with access to publicly distributed condoms in **Brazil and South Africa**. In Brazil, expansion of FC2 distribution to 10% of current male condom use would avert an estimated 604 HIV infections at 20,683 US dollars per infection averted. In South Africa, 9,577 infections could be averted, at 985 US dollars per infection averted. The estimated cost of treating one HIV-infected individual is 21,970 US dollars in Brazil and 1,503 US dollars in South Africa, indicating potential cost savings. The incremental cost of expanded distribution would be reduced to 8,930 US dollars per infection averted in Brazil and 374 US dollars in South Africa by acquiring FC2s through a global purchasing mechanism and increasing distribution threefold. Sensitivity analyses show model estimates to be most sensitive to the estimated prevalence of sexually transmitted infections, total sexual activity, and fraction of FC2s properly used. Expanded distribution of FC2 in Brazil and South Africa could avert substantial numbers of HIV infections at little or no net

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cost to donor or government agencies. FC2 may be a useful and cost-effective supplement to the male condom for preventing HIV (Dowdy et al., 2006). (Gray IIIb) (female condoms, Brazil, South Africa)

- A 2007 study of 818 female sex workers in **Madagascar** for 18 months found that short and medium term promotion of both male and female condoms increased the total number of protected sex acts and reduced STI prevalence. "This trial provides moderate but promising evidence of public health benefits gained from adding the female condom to male condom distribution" (Hoke et al., 2007: 465). Provision of female condoms allows women to "substantially reduce risk of STI acquisition" (Hoke et al., 2007: 465), as STI rates were significantly lower in periods of both male and female condom availability. Participants were tested for three different STIs (chlamydia, gonorrhea and trichomoniasis) every six months. Peer educators trained by the study promoted condoms and counseled participants on risk reduction. Sex workers were counseled to use female condoms only when the male condom could not be used. Both male and female condoms were available for the same price. Following six months of male condom distribution, participants used protection in 78% of sex acts; with the addition of the female condom, protected sex acts increased to 83% at twelve months and 88% at 18 months. STI prevalence declined from a baseline of 52% to 50% with male condoms only at 6 months. With the female condom added, STI prevalence dropped to 41% at month 12 and 40% at month 18 (Hoke et al., 2007). (Gray IIIb) (female condoms, sex workers, STIs, Madagascar)
- A study in **China** found that including female condom outreach, distribution and promotion as well as male condoms resulted in over one-fifth of 301 sex workers had tried the female condoms one year later and 10% had used the female condom more than once. Introduction of the female condom led to an increase of 15% of women reporting 100% condom use with all partners (clients and boyfriends) and the proportion of those reporting no protected sex in the last thirty days decreased by 13%. Educational sessions with a demonstration of female condom insertion using a plastic vagina model were conducted, with 234 educational sessions held during one year. Women who used female condoms were more likely to be exposed to the intervention. Prior to this study, no female condoms had not been available in any of the study sites (Liao et al., 2011a and b). (Gray IIIb) (female condoms, sex workers, China)
- A two month prospective study from 2000 to 2001 of male and female condom use among sexually active women in **Zimbabwe** found that reported use of female condoms increased from 1% to over 70% two months later. Women were given a thirty-minute one-on-one counseling program about HIV and safer sex conducted by a trained counselor, with practice on how to insert the female condom and condom negotiation skills and were give a one month supply of no cost male and female condoms. Women reported more than 28% of sex acts were protected by female condoms. Women reported using female condoms for both HIV prevention and for pregnancy prevention. Over 8% used only the female condom to protect all sex acts, with 67% using the female condom for at least a portion of sex acts. However, most of the women in the study used hormonal contraception so that exclusive female condom use was lower (Napierala et al., 2008). (Gray IIIb) (female condoms, counseling, Zimbabwe)

## 4. Increasing couple communication about HIV risk can increase preventive behaviors, including condom use.

A qualitative and quantitative study in three districts in rural Malawi that analyzed data collected in 1998, 1999, and 2001 found that both informal and formal sources of information on HIV/AIDS were important factors influencing AIDS-related communication between spouses. 1,541 ever been married women ages 15-49 and 1,065 husbands were surveyed in Gay, J., Croce-Galis, M., Hardee, K. 2012. What Works for Women and Girls: Evidence for HIV/AIDS Interventions.

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1998, a randomly chosen sub-sample of the original cohort was interviewed in 1999, and a follow-up interview was conducted in 2001 among 80 men and 76 women. Study findings indicated that couples where both the husband and wife had accessed accurate information about AIDS from sources such as health clinics and social networks were significantly more likely to have discussed risk of HIV infection with their spouses. Greater levels of exposure and involvement with social programs were significantly associated with the likelihood of having discussed HIV with partners. The size of the woman's social network was a significantly determinant in whether or not HIV discussions among couples took place. Discussion between spouses about HIV was more likely to have occurred when both spouses had reported being concerned about infection. Women most often initiated discussion, in response to concern over infidelity. It is important to note that both women and men reported believing that their fates were directly joined with those of their spouses: if one became HIVpositive than the other would as well. Discussions related to HIV were usually initiated with HIV/AIDS-related information discussed over the radio or in a health clinic. When asked, however, if an individual could be satisfied with only one sexual partner, 40% of men and 33% of women did not think it was possible. Lastly, while the importance of fidelity in marriage was discussed between couples, condoms were never presented as an option for HIV prevention within marriage. In the one instance where a wife did report discussing condoms with her husbands, she claimed to have advised him to use condoms with his "other partners" (Zulu and Chepngeno, 2003). (Gray IIIb) (communication, sexual partners, marriage, Malawi)

- A nationally representative survey of young women in **South Africa** found that those who discussed condom use with their partners were more likely to use condoms for dual protection, and to use them consistently (MacPhail et al., 2007). (Gray IV) (condoms, South Africa)
- A qualitative study conducted among 39 married couples in **Uganda** who reported 100 percent condom use in the last three months suggests that stable couples should not be ignored in condom promotion campaigns particularly those that promote the dual protection nature of condoms. The study found that wives promoted condom use among 22 of the 39 couples, in six cases use was initiated by the husband and among the remaining couples there was disagreement as to which partner initiated discussions. Women were able to convince their partners to agree to consistent condom use by being insistent and persuasive, refusing sex, or proposing condom use for family planning or to safeguard their children from becoming orphans. Men reported agreeing to condom use to please their wives, to protect their wives and children, to protect themselves, and to be able to maintain other partnerships (Williamson et al., 2006). (Gray IV) (condoms, sexual partners, marriage, Uganda)
- A study in three countries assessed the feasibility of a group-based couples intervention to increase condom use in HIV-serodiscordant couples in **India**, **Thailand and Uganda**. The intervention focused on communication, problem solving, and negotiation skills. Forty-three couples enrolled in the intervention (15 in India, 14 in Thailand, and 14 in Uganda) and 40 couples completed all study activities. Participants were interviewed at baseline and at one-and three-months post- intervention. The intervention consisted of two same sex sessions and two couples sessions with 'homework' to practice skills between sessions. The same intervention modules were used at each site, tailored for local appropriateness. Participants at each site were enthusiastic about the intervention, citing information about HIV serodiscordancy and the opportunity to meet couples 'like us' as important features. Participants reported increased comfort discussing sex and condoms with their partner, although some participants remain concerned about situations when condoms might not be used (e.g. when drunk). At baseline, the majority of Thai and Ugandan participants and one-

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third of Indian participants reported having 'ever' used a condom with their regular partner. The percent of sexual contacts with condom use reportedly reached 100% at all sites by the first follow up visit. Although social acceptability bias cannot be ruled out, researchers note that participants also reported that a primary benefit of the intervention was condom information, including demonstrations of correct condom use, and increased confidence in their ability to discuss and use condoms with their partner (McGrath et al., 2007). (Gray V) (condoms, communication, India, Thailand, Uganda)

# 5. Promoting the dual use of condoms as a contraceptive as well as for HIV prevention may make use more acceptable and easier to negotiate.

- A three-armed randomized controlled trial at a VCT clinic in Lusaka, **Zambia** with 251 couples found a three-fold higher contraceptive initiation rate where family planning education and offer of contraceptives where available on site rather than by referral to an outside clinic. All couples receive a presentation on family planning methods and the advantages of dual method use, along with a free, unlimited supply of condoms. HIV discordant and concordant couples are advised to use condoms with every act of intercourse, with this information given during initial post-test counseling and repeated at each subsequent visit. Trained nurses help couples overcome barriers to condom use. The control group was referred to the Lusaka Planned Parenthood Association of Zambia for family planning methods, with all fees paid by the research project. Women in the intervention group who desired Norplant or surgical sterilization were referred to University Teaching Hospital, with transport and service fees paid. Self reported condom use was assessed. Approximately half of the couples eventually wanted to have children. Self reported condom use remained consistent at between 58 to 63% (Mark et al., 2007). (Gray II) (HIV testing, family planning, contraception, condoms, Zambia)
- A study of 372 sex workers in **Ethiopia**, of whom 73% were HIV-positive, found more consistent and correct condom use when used primarily for pregnancy prevention rather than for STI prevention. Sex workers who were using condoms for contraception were compared with others, more likely to use condoms consistently (65% compared to 24% and less likely to be HIV-positive (55% compared to 86% (Aklilu et al., 2001). (Gray IIIa) (condoms, pregnancy, STIs, Ethiopia)

### 6. Peer education for women can increase condom use.

- A randomized study in 2007 and 2008 with 737 married women (353 in the peer education HIV intervention group; 384 in the control group) in rural North Anhui, **China** found that peer education programs for married women increased condom use. The percentage of married women who used condoms in the past three months rose from 4.5% to 21.5% in the intervention group, with no significant increase in the control group (Hong et al., 2009). (Gray IIIa) (condoms, marriage, peer education, China)
- A study in Malawi with 2,242 rural adults using a quasi-experimental design to evaluate a six-session peer group intervention resulted in increased condom use. More intervention district adults reported ever using condoms in the past two months, 12.7% compared to 7.4% in the non-intervention communities. Surveys were conducted at six months and 18 months following the completed intervention. Having ever used condoms in the past two months among sexually active adults was higher in the intervention district than the control group at both six months and 18 months. The six two-hour sessions discussed sexuality; HIV;

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condoms; partner negotiation and guided discussion about social norms. Each peer group had two co-facilitators and between ten and twelve community members. Groups were either all male or female. Following the 18-month intervention, health workers were offered the intervention and encouraged to bring the intervention to rural communities with additional two week training. The project worked closely with village headmen and headwomen. (Kaponda et al., 2011). (Gray IIIa) (condom use, sexual behavior, peer education Malawi)

- 7. Promoting condoms, either in individual or group sessions, along with skills training, provision of condoms, and motivational education can increase condom use.
  - A meta-analysis of 42 studies with 67 separate interventions from **North America**, **Asia**, **Africa**, **Europe and South America** found that providing HIV education, with face-to-face delivery both with individuals and groups, which addressed motivation, attitudes, skills training and/or putting condoms on models, as well as providing condoms, found that those exposed to the intervention significantly increased condom use and reduced HIV incidence, with duration up to four years. Group interventions met for a median of four sessions of 120 minutes each with a median of two facilitators and ten participants per session. Individuals met for a median of one session for 39 minutes each with one facilitator. Studies used a randomized controlled trial or a quasi-experimental design. The meta-analysis covered studies from 1991-2010. However, simply providing condoms was insufficient to increase condom use (Scott-Sheldon et al., 2011b). (Gray I) (condoms, condom use, education, North America, Asia, Africa, Europe, South America)

### **Promising Strategies:**

- 8. Providing women with condom negotiation skills may improve condom use.
  - A randomized trial in **South Africa** with 583 women found that training in condom negotiation skills significantly increased condom use at three and six months follow-up for women who did not know their serostatus and women who had tested HIV-positive. The training consisted of two private one-on-one, hour-long sessions including role-playing within a two week period. Those who did not receive the intervention received information on HIV, HIV testing and a condom demonstration. Of the 584 women, 384 were sex workers and 199 were not sex workers (Wechsberg et al., 2010). (Gray IIIb) (condom use, training, South Africa)
  - A 2000-2001 study of 394 married women in Harare, **Zimbabwe** found that condom use increased from 1% prior to the intervention to almost 50% after a half-hour one-on-one HIV education program by trained counselors that emphasized negotiation skills; practice using male and female condoms; and education about HIV transmission, and safer sex. VCT was offered. The intervention provided a booster session after one month and results were collected after two months. Of the women (aged 17-47, mean age of 28), 60% suspected their husbands of having other sexual partners. Initial condom usage was low: only one woman reported using condoms consistently and only 40 (10%) reported using condoms at last sex. After two months, consistent condom usage had increased to 48.5% while 87% of women had used condoms during their last sexual encounter. Overall, feelings of self-efficacy increased: the proportion of women who felt that they had control over condom usage increased from 47% to 72%, and the proportion who felt that they could refuse sex without a condom

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increased from 23% to 57% (Callegari et al., 2008). (Gray IIIb) (condom use, marriage, education, Zimbabwe)

## 9. Promoting acceptability of condom use by both women and men as the norm in sexual intercourse may decrease national HIV prevalence.

- In association with to a national multi-year campaign, HIV prevalence in **Uganda** fell from 15% in 1991 to 5% in 2001. Among those who had had sex in the past four weeks, the proportion of women using condoms increased from 0% in 1989 to 8% in 1995; among men, it increased from 1% to 11%. Among unmarried women, the proportion using the condom increased from 1% to 14% and among unmarried men, it rose from 2% to 22%. From 1995-2000, condom use increased from 5% to 25% among women aged 15-17 and from 3% to 12% for women ages 18-19. Among sexually active men from 15 to 17, condom use rose from 16% in 1995 to 55% in 2000, and among those aged 18 and 19, it increased from 20% to 33%. Among unmarried sexually active women, condom use increased from almost nothing to 37% by 2000. Condom use rose significantly among unmarried sexually active men from 29% in 1995 to 57% in 2000 (Singh et al., 2003a). (Gray IIIb) (condoms, Uganda)
- A qualitative study conducted from 2001 to 2003 in rural and urban Ethiopia, Tanzania, and Zambia with structured text analysis of more than 650 interviews and 80 focus group discussions and quantitative analysis of 400 survey respondents found that preventive methods such as condom use are hampered when condom use was considered an indication of "HIV infection or immoral behaviors and are thus stigmatized" (Nyblade et al., 2003: 2). In all three countries most respondents think that women are to be blamed for acquiring HIV, particularly if this behavior is associated with "immoral sexual behavior. "Gender-based power relationships also play a more direct role in the blame women face," (p. 26) as women's transgressions tend to be more severely regarded than men's (Nyblade et al., 2003) (Gray IIIb) (condoms, stigma, Ethiopia, Tanzania, Zambia)
- A survey of 209 women affected by HIV/AIDS and in-depth interviews with 59 women in **Zimbabwe** found that women perceived condoms for use only with sex workers. "...My husband and I never used condoms. We thought they were only for prostitutes" (Feldman and Masophere, 2003: 165). (Gray IIIb) (condoms, marriage, sexual partners, Uganda)
- A study of trends from Demographic and Health Surveys in 1993 and 2001 in **18 countries in Sub-Saharan Africa** shows condom promotion has increased condom use among for single women: from 5% in 1993 to 19% in 2001. Preventing pregnancy is a major motive for single women, suggesting that marketing campaigns positioning condoms for pregnancy, rather than disease, prevention may be more successful. Condoms are also beginning to permeate into marriage in East and Southern Africa ("occasional use" reported in 10-21% of both husbands and wives in three national settings—Kenya, South Africa and Uganda), suggesting that promoting condom use within marriage can save lives by preventing HIV transmission within serodiscordant married couples (Cleland et al., 2006a). (Gray V) (condoms, pregnancy, Kenya, South Africa, Uganda, Sub-Saharan Africa)

### 10. Increasing accessibility and availability of condoms can increase condom use.

 A systematic review of 21 studies from Tanzania, Cameroon, Ghana, China, Indonesia, Thailand, the Caribbean, Mexico and Central America published from 1998 to 2007 found that increasing condom availability and accessibility increased condom use behaviors.

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Condom availability and accessibility was increased through mass media campaigns and community mobilization, expanding publicly funded condom distribution via mobile vans, etc., and making condoms available in prisons. Studies were included if they reported a HIV behavioral intervention with data collected on at least one behavioral outcome or biological outcome with sufficient data (Charania et al., 2011). (Gray IIIa) (condoms, condom use, Tanzania, Cameroon, Ghana, China, Indonesia, Thailand, Carribbean, Mexico, Central America)

• A study that surveyed 630 people in **Kenya** found that condoms were 8.1 times more likely to be used by those who did not experience supply-side or demand side barriers. Supply side barriers were measured by self-reported time to the nearest health facility to obtain no cost condoms and ability to pay for commercial condoms. Demand-side barriers were measured based on self-reported attitudes towards condoms, partner attitudes towards condoms and have never been given or shown how to use a condom. The study found that 19% of potential condom outlets were out of stock. Among individuals with no supply side barriers, condom use was three times greater; among individuals with no demand side barriers were 3.8 times more likely to use condoms. Women experienced the highest rates of supply side barriers (Papo et al., 2011). (Gray IIIb) (condoms, condom use, Kenya)

## 11. Promoting pleasure in male and female condom use can increase the practice of safer sex.

- A literature review found that integrating elements of pleasure and the erotic into HIV prevention interventions could increase safer sexual practices and empower women to negotiate safer sex. A meta-analysis (Scott-Sheldon and Johnson, 2006 cited in Knerr et al., 2009) found 21 studies measuring effectiveness of sexual risk reduction interventions that integrated a safer sex eroticization component and found that where eroticization was incorporated, participants showed significant risk reduction behavior in condom use; communication with sexual partners and a decrease in the number of sexual partners. The meta-analysis included studies with randomized control trials or those that had a quasi-experimental design. Of the 21 studies, one took place in **Brazil**, with the rest in **North America** and **New Zealand**. Erotic was defined as tending to arouse sexual desire or excitement. Literature from PubMed, Medline and IAC conferences was used from 2001 to 2007 for the review (Knerr et al., 2009). (Gray IV) (sex behavior, Brazil, North America, New Zealand)
- Public health outcomes may benefit from adopting more positive views of safer sex. Citing grey literature and personal accounts of programs in Cambodia, Namibia, South Africa, Senegal, Zimbabwe, Sri Lanka, Mongolia, India and the UK, the Pleasure Project contends that focusing on sexual pleasure—particularly eroticizing male and female condoms to increase use—can play a key role in the prevention of STIs/HIV (Philpott et al., 2006). (Gray V) (female condoms, sex behavior)

### 3A. Gaps in Programming—Male and Female Condom Use

1. Condom promotion and HIV testing aimed at serodiscordant couples, particularly those in long-term, stable relationships are needed.

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- 2. Interventions are needed to increase condom access by women.
- 3. Tailored interventions are urgently needed to provide greater availability and access to female condoms, along with education and training regarding their use as an alternative to male condoms.
- 4. Providers and HIV testing counselors need training on female condoms to promote use.
- 5. Women, especially married women, need ongoing education about the role of condoms in preventing HIV acquisition and transmission, along with condom negotiation skills.
- 1. Condom promotion and HIV testing aimed at serodiscordant couples, particularly those in long-term, stable relationships are needed. Studies found that counselors and serodiscordant couples did not understand that the HIV-negative partner could acquire HIV, even after many years and HIV-positive women reported that their husbands refused to use condoms. Fear of partner reaction was a barrier to HIV testing.
  - Gap noted, for example, in **Rwanda and Zambia** (Kelley et al., 2011); **five African countries** (Desgrées-du-Loû and Orne-Gliemann, 2008); **Uganda** (Bunnell et al., 2005); **Thailand** (Yoddumnern-Attig et al., 2004).
- **2. Interventions are needed to increase condom access by women.** Studies found inadequate supplies of condoms to have protected sex.
  - Gap noted, for example, in **Kenya**, **Uganda and Zimbabwe** (Scorgie et al., 2011).
- 3. Tailored interventions are urgently needed to provide greater availability and access to female condoms, along with education and training regarding their use as an additional option to male condoms. Studies found that women, including female sex workers, felt that they could avoid conflict and enhance their safe sex bargaining power by using a female condom when their sexual partner refused to use a male condom.
  - Gap noted, for example, in **Mozambique** (Hayford and Agadjanian, 2010); **South Africa** (Scorgie et al., 2011; Mqhayi et al., 2003 cited in Mantell et al., 2005); **Kenya** (Brady et al., 2009); **Brazil** (Dias et al., 2006); **Uganda** (Wanyenze et al., 2011a; Green et al., 2001); generally (Hoffman et al., 2004; Green et al., 2001; Okunlola et al., 2006; Mathews and Harrison, 2006).
- 4. Providers and HIV testing counselors need training on female condoms to promote use. Studies found that providers and counselors need training in order to be able to promote female condom use.
  - Gap noted, for example, in **Kenya**, (Mung'ala et al., 2006); **South Africa, the US, and Nigeria** (Mantell et al., 2001).
- 5. Women, especially married women, ongoing education about the role of condoms in preventing HIV acquisition and transmission, along with condom negotiation skills.

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A study found that women did not believe that condoms reduce the risk of HIV transmission. Another study found that married women of alcoholic men are aware of risks of contracting HIV from their husbands but reported difficulty in negotiating condom use as well as violence.

• Gap noted, for example, in **India** (Varma et al., 2010); **Botswana** (Dintwa et al., 2010), **South Africa** (Bogart et al., 2011); **Guinea** (Kis, 2010) and **Kenya** (Papo et al., 2011).

## 3B. Prevention for Women: Partner Reduction

Multiple sexual partnerships have long been a concern in HIV prevention programming, which has focused on partner reduction. Multiple partnerships bring increased risk of HIV acquisition: A meta-analysis of 68 epidemiological studies from 1986 to 2006 with 17,000 HIV-positive people and 73,000 HIV-negative people found that women who reported three or more sex partners had three times as much likelihood of HIV acquisition versus women with up to two partners (Chen et al., 2007 cited in Vergidis et al., 2009). An analysis of DHS data in Zimbabwe found that 64% of men reported more than three lifetime sexual partners compared to 13% of women (Sambisa et al., 2010).

When designing prevention interventions it is important to understand women's various partnership patterns. A woman may be married with only one sexual partner. Or she may be married with multiple sexual partners. A young woman might be sexually active with uninfected boys her own age. Or she may be in a much riskier cross-generational sexual relationship, with an older male partner upon whom she relies for school fees. [See Prevention for Young People] A woman may also have multiple partners to enable her to survive financially. Women may work as sex workers, an occupation that requires multiple sexual partners. [See Prevention for Key Affected Populations] Men may also have multiple partnerships, which may place women at risk for HIV acquisition. Concurrent, or overlapping, sexual partners presents additional risks for HIV acquisition.

### Concurrency is an Important Aspect of Multiple Partnerships

More recently, the concept of concurrent sexual partnership has dominated discussions of multiple partnerships. UNAIDS defines concurrency as "overlapping sexual partnerships in which sexual intercourse with one partner occurs between two acts of intercourse with another partner" (UNAIDS, 2010d). While this definition helps distinguish between multiple partnerships that are serial and those that occur at the same time, "this limited definition is unlikely to capture the rich and variable characteristics of sexual partnerships [and] detailed understanding of the sexual behaviors in a given context [that] is necessary for the optimal design of prevention interventions" (Powers et al., 2011a: 665). A recent study analyzing data from Thailand and Uganda found that prevalence of concurrent partnerships is aligned with HIV prevalence (Morris et al., 2010). However, a more recent study found that increases in lifetime numbers of partners for men, not concurrency, raised the individual risk of seroconversion in women from the same area

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(Tanser et al., 2011 cited in Padian and Manian, 2011). In addition, other studies found that regions with large numbers of partners and low concurrency were associated with high incidence of infection of women (Tanser et al., 2011 cited in Padian and Manian, 2011).

New methodologies are being developed to measure changes in concurrency and HIV incidence (Maher et al., 2011). However, countries will need to improve their surveillance in order to obtain information on concurrency. For example, prior to 2007 in Jamaica, surveillance forms collected information on the number of lifetime partners rather than partners during a 12-month period (Duncan et al., 2010b).

Concurrent Partnerships During the Acute Infection Stage Can Pose a Higher Risk for HIV Acquisition for the Seronegative Partner

Viral load and infectivity are higher in the early, acute stage of infection, so recently infected individuals with concurrent partners are more likely to transmit HIV to others than recently infected individuals that have one or no partners (Pilcher et al., 2004; Morris and Kretzchmar, 1997 cited in Carter et al., 2007). Acute infection can result in an estimated 26-fold increased risk of transmission during the first three months following HIV acquisition (Hollingsworth et al., 2008). However, detection of acute infection requires specific testing for p24 antigen and is not available in many resource-limited settings (Cohen and Gay, 2010). [See also HIV Testing and Counseling and Treatment] "Concurrent partnerships increase the overall probability that uninfected partners will have sexual intercourse and be exposed to a partner during acute infection" (Mah and Halperin 2010: 14). Other modeling has also found that acute infection amplifies the importance of concurrent partnerships and suggests "intervention programs that are effective in reducing concurrency may play a crucial role in stemming the incidence of new HIV infections" (Eaton et al., 2011: 691). Others have also noted the importance of acute HIV infection and concurrency to explain high rates of HIV (Goodreau, 2011).

Multiple Partnerships Are Common and Place both Women and Men At Risk of HIV Acquisition

While both men and women may have multiple sexual partners, in some environments "men's extramarital sexual activities are not only socially condoned but are a defining element of masculine identity...." (Stephenson, 2010: 179; also see Hirsch, et al. 2009). [See Strengthening the Enabling Environment: Transforming Gender Norms] However, studies have found a very strong relationship between people having had more than one sexual partner and living with HIV but found no association between concurrence in men and HIV incidence in women (Tanser et al., 2010 cited in WHO et al., 2011b) or between concurrency and HIV prevalence in men (Maher et al., 2011 cited in WHO et al., 2011b). A recent analysis of DHS data in 14 sub-Saharan countries found that women (47%) were as likely to be the HIV-positive partner in a serodiscordant couple as men (Eyawo et al., 2010). The number of those having multiple partnerships has been decreasing: analysis shows that the percentage of young men with multiple partners in the 12 months before

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the most recent survey decreased significantly in 11 countries, including four countries with national adult HIV prevalence exceeding 10% in 2009. Among women, most recent surveys showed a decrease in multiple partners in six countries (WHO et al., 2011b). However, in Rwanda and Zimbabwe, the number of young women with multiple partners has increased (WHO et al., 2011b).

### Married Women Are Still At Risk for HIV Acquisition

Marriage is often portrayed to women and girls as a haven from the risk of HIV infection. In fact, the risk of HIV transmission between sexual partners is nonexistent when both partners are uninfected at the time of marriage and subsequently engage in sexual activity exclusively with each other. However, these conditions are often not met. In some countries, married women are at high risk of acquiring HIV (UNAIDS, 2006: 22; Hirsch et al., 2007; Hageman et al., 2009; Ugonnet et al., 2002 cited in Matovu et al., 2007), particularly in generalized epidemics. An estimated 55% to 92% of new heterosexually acquired HIV infections among sexually active adults in urban Zambia and Rwanda occur within serodiscordant martial/cohabitating relationships (Dunkle et al., 2008). In some countries, HIV prevention messaging has focused on "love faithfully" and "zero grazing" which may have inadvertently increased risk for married women who were seronegative with HIV-positive husbands (Grabbe and Bunnell, 2010). Unless attention is given to gender norms, married women may not understand that they are at risk of HIV acqustion. A study of 50 low-income Chilean women found that "women who are vulnerable to HIV do not perceive themselves at risk. They believe that HIV is something that happens to homosexually active men or to [sex workers], not something that happens to women in a stable relationship" (Cianelli et al., 2008: 298). Couples interventions to reduce transmission in serodiscordant relationships could have a large impact on the epidemic (Dunkle et al., 2008). However, transmission may result from partners outside marriage (Spino et al., 2010). A study using a national survey in China found that men who paid for sex were ten times more likely to have a STI, yet less than 4% used a condom consistently with their spouse (Huang et al., 2011).

Additional risks may be posed by polygyny (i.e. legal or customary marriage with multiple wives), which may place women at risk of HIV acquisition with low rates of condom use and unequal power relations (Bove and Valeggia, 2009). A study of 1,137 women in a village in Kenya found that women in polygamous marriages were more likely to be HIV-positive than those in monogamous marriages (Negin et al., 2009). Polygynous women in focus group discussions in Nigeria agreed that any kind of sexual negotiation within marriage was difficult (Saddiq et al., 2010). Other studies, however, have not found an elevated risk among polygynous marriages in Western Africa (Reniers et al., 2010; Reniers and Watkins, 2010). Yet, a study based on the 2005 to 2006 Zimbabwe Demographic and Health Survey with 4,023 married women found that currently married women who were in polygynous marriages were at higher risk of spousal violence. Currently married women who experienced physical violence only, or both physical and sexual violence, were significantly more likely to be HIV-positive than

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those who had not experienced any physical or sexual violence (Nyamayemombe et al., 2010).

It is critical that partners know their serostatus and practice safe sex. Both married and unmarried women need basic knowledge of HIV and how to prevent transmission. However, married women are often not reached by prevention messages because married women "were not considered part of the so-called risk groups. Prevention efforts have been focused on

"Two kinds of women run the greatest risk: the one who stays home and trusts her husband and the one who turns tricks."

—Brazilian woman (cited in Hebling and Guimaraes, 2004: 1213)

pregnant women, sex workers, and people who inject drugs. Therefore, the majority of women received a message of false security that women who are married and monogamous have no risk for acquiring HIV" (Ross Quiroga, 2006:1-2). Despite the fact that HIV transmission occurs within stable partnerships or marriage, a review of the literature on couples' HIV prevention found that "couples-focused approaches to HIV prevention are still in an early phase of development" (Burton et al., 2010: para 8). Many couple-focused approaches are ready to be scaled up. [See Prevention for Women: Male and Female Condom Use, HIV Testing and Counseling, and Safe Motherhood and Prevention of Vertical Transmission]

Married adolescent girls are particularly vulnerable and are often more at risk of HIV infection than unmarried sexually active girls. For example, a study analyzing Kenyan and Zambian data from 1997 and 1998 found that married adolescent girls living in urban areas had higher incidence of HIV than unmarried sexually active girls in the same age group. "Although married girls are less likely than single girls to have multiple partners, this protective behavior may be outweighed by their greater exposure via unprotected sex with partners who have higher rates of infection" (Clark, 2004: 149). Young women who engage in transactional sex have an incentive to change partners and to end relationships to find more lucrative male partners (Wamoyi et al., 2010). Women may also oppose condom use to keep partners in a competitive world of multiple concurrencies. For some women, concurrent sexual partners may be culturally acceptable as long as they are conducted covertly (Jewkes and Morrell, 2010).

### Reducing Concurrent Partnerships Can Reduce HIV Transmission

"There are...few demonstrated replicable approaches to reducing multiple sexual partnerships on a large scale" (Potts et al., 2008: 750). There is currently programmatic focus on partner reduction, yet this review (Ross, 2010) identified few evaluations of interventions of partner reduction, particularly among adult men. Interventions targeting concurrency "are still largely in their infancy and their introduction should be linked to careful evaluation" (Ross, 2010: S12). A 2011 review found that "most interventions to raise awareness of the risks of concurrency are less than two years old: few evaluations

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and no randomized controlled trials of these programmes have been conducted" (Epstein and Morris, 2011: para 1). Some agree that more specific knowledge concerning the role of concurrency is needed (Shelton, 2009), but have found that the evidence that concurrency is a key issue for HIV acquisition and transmission is compelling (Mah and Shelton, 2011). Others have also argued for more research on this topic (Lurie and Rosenthal, 2010) and still others have critiqued modeling of concurrency as a key driver of the epidemic or have conducted surveys, for example in Uganda, that did not find that concurrency was correlated with increased risk of HIV acquisition (Sawers and Stillwagon, 2010; Sawers et al., 2011; Maher et al., 2011).

But a rigorous study with participants in Malawi who had physical exams, HIV tests and responded to questionnaires with detailed questions about sexual partners during the prior two months found that among those reporting multiple recent partners, both long-term concurrency and narrowly spaced consecutive partnerships could present substantial risk for efficient transmission of HIV (Powers et al., 2011a). Others have found vast variation from 1% in Ethiopia to 28% of men reporting two or more sex partners in the 12 months prior to being interviewed, with no correlation between the prevalence of multiple partnerships and the severity of the HIV pandemic (Bingenheimer, 2010). Still others have found that it is multiple partnerships by men, rather than concurrent partnerships, that increase the risk of HIV acquisition for women, at least in one area of South Africa (Tanser et al., 2011). Ultimately, "the needs of the married and cohabitating population have been neglected... despite the fact that more than half of HIV infections in the severe epidemics of Southern and East Africa are occurring in this group" (Delvaux and Nöstlinger, 2007: 56).

Interventions to reduce concurrent partnerships that are gender transformative are urgently needed. "Although there is no disagreement that multiple concurrent partnerships contribute to risk for HIV transmission, and thus should be subject to HIV prevention programming responses," the fact that concurrent partnerships are the norm in many places "makes such partnerships difficult to address directly" (Padian et al., 2011: 274). Multiple partnerships is closely tied to gender norms of masculinity, where men are required to have multiple sexual partnerships simultaneously, be unfaithful to their regular sexual partner and buy sex as proof of their masculinity (Peacock et al., 2008). Many women are unaware that their husbands or sexual partners may have other sexual partners. Surveys in Africa have found that women are less likely to have concurrent partners than men (Sawers and Stillwaggon, 2010).

However, "if education focuses merely on abstinence and fidelity as methods of prevention, those who become infected and those already living with HIV may feel that their needs are being overlooked" (Ansari and Gasestel, 2010: 634). Programs need to work with communities to address gender norms that put women at risk through expectations of fidelity, while failing to address gender norms that are expect multiple partnerships among men as a sign of masculinity. [See Prevention for Young People and

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Strengthening the Enabling Environment: Transforming Gender Norms] Increasing couple communication is a promising strategy to begin addressing these risks and raise awareness that married women are indeed at risk for acquiring HIV. A few areas regarding partner reduction still have major gaps that need to be filled, including interventions that address the risks of polygamous marriage (Sandøy et al., 2008), and the role of homophobia in leading men who have sex with men to feel they must hide their sexuality through concurrent partnerships with women.

### 3B. What Works—Prevention for Women: Partner Reduction

## Promising Strategies:

1. Programs that persuade men to reduce their number of sexual partners could greatly reduce the risk of HIV acquisition for their female partners.

#### 3B. Evidence

#### **Promising Strategies:**

- 1. Programs that persuade men to reduce their number of sexual partners could greatly reduce the risk of HIV acquisition for their female partners. [See also Strengthening the Enabling Environment: Transforming Gender Norms]
  - Reduction in concurrent sexual partnerships may have contributed to the recently observed decline in HIV prevalence in **Zambia**. While the proportion of women engaging in concurrent partnerships was less than 2%, there was a significant decline in concurrent partnerships for young urban men and older rural men. Men were 7 times more likely than women to report several ongoing relationships in both 1998 and 2003 in the young age group and 6 to 17 times more likely in the age group 25 to 49. Polygamy was common among older rural men (12%). The percent of rural men aged 15 to 24 who reported concurrent sexual partners declined from 58% in 1998 to 3.5% in 2003; among urban male youth aged 15 to 24 from 7.1% in 1998 to 1.9% in 2003 and among rural men aged 25 to 49 from 17.8% in 1998 to 11.9% in 2003. In addition, reported condom use increased during the most recent sexual intercourse both with the spouse and with the latest non-cohabitating partner increased from 1998 to 2003. An important predictor of concurrency was early sexual debut and early entry into marriage, as well as absence from home. (Sandøy et al., 2008). (Gray IIIb) (sexual partners, condom use, Zambia)
  - A study from 2003 to 2007 of women and men presenting for VCT at a community-based AIDS service organization in Moshi, **Tanzania** found that the number of partners was strongly associated with rates of HIV seropositivity for both men and women. However, even women reporting lifetime monogamy had a high risk for HIV infection. Of 6,549 clients, 3,067 were female, with 25% of the women and 10% of the men HIV-positive. Among 1,244 monogamous females, 34% were HIV-positive. Among 423 monogamous males, 4% were HIV-positive. A monogamous female with a partner who had other partners (as is the case for polygamy) or who did not know if the partner had other partners was 36% more likely to be

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HIV-positive than an otherwise identical female who reported no partners with other partners. The risk increased up to 45% for women with five or more partners and 15% for men with five or more partners. In a multivariate analysis, HIV seropositivity among monogamous women was associated with reporting a partner with other partners; among monogamous men, with age. Women having more than one lifetime sexual partner reported fewer total partners, with a median of three, as compared to a median of four among men (Landman et al., 2008). (Gray IIIb) (counseling, HIV testing, sexual partners, Tanzania)

Sixteen focus group discussions with 200 women and men, aged 32-55 held in 2007 in Zimbabwe to discuss underlying factors and programs in 1992, 1999 and 2006-2007 mirrored epidemiologic survey findings from 2000 to 2005: social norms changed to reduce acceptability of casual sex and payment for sex. In addition, between 2006 and 2009, 24 indepth interviews were held with key AIDS experts in Zimbabwe, along with a review of 120 publications. As one man in a focus group discussion said, "These days when a man is said to have two or more wives, he is seen as uncivilized" (Muchini et al., 2011: 491). Participants mentioned messages concerning fidelity and increased availability of condoms. Growing poverty also reduced men's ability to afford multiple partners (Muchini et al., 2011). Evidence from surveys, qualitative research and expert opinion indicates that the drop in national HIV prevalence in Zimbabwe is due in part to a reduction in multiple and concurrent partnerships and to changes in norms regarding such partnerships. HIV prevalence has declined in Zimbabwe by around 50 percent and data from national surveys indicate an approximate 30 percent reduction in the proportion of men reporting extramarital partners between 1999 and 2005/06. A national stakeholders meeting concluded that the reduction in multiple partnerships was "the most likely proximate cause of the most recent decline in HIV risk" (Halperin et al, 2011: 2). HIV programs have incorporated these new norms into messages by more assertively warning against multiple and concurrent partners and fidelity, in addition to other programming (Halperin, 2011: 6). (Gray IV) (sex behavior, sexual partners, Zimbabwe)

## 3B. Gaps in Programming—Partner Reduction

- 1. Evaluated interventions are urgently needed to reduce multiple and concurrent partnerships particularly for both men and women where perceived HIV risk is low and the woman is subjected to gender norms of faithfulness while the man is subjected to gender norms of having multiple sexual partners.
- 2. Interventions are needed to reduce homophobia, which may lead MSM to have partnerships with women.
- 3. Innovation and research is needed on what works to reduce alcohol consumption and associated risks.
  - 1. Evaluated interventions are urgently needed to reduce multiple and concurrent partnerships particularly for both men and women where perceived HIV risk is low and the woman is subjected to gender norms of faithfulness while the man is subjected to gender norms of having multiple sexual partners. [See also Strengthening the Enabling Environment: Transforming Gender Norms] Studies found that married women were at risk of HIV acquisition, but were either unaware

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of the risk or did not believe they were at risk. Studies found that extra-relational sex on the part of the husband was common. Other studies found that a significant portion of women have had high rates of multiple partners. Other studies found that serial monogamous relationships led to a high risk of HIV acquisition.

- Gap noted, for example, in **Uganda** (Wawer et al., 2012; Kajubi et al., 2011); **India** (Solomon et al., 2010a); **China** (Li et al., 2011a; Yun et al., 2011); **South Africa** and **Zimbabwe** (Mavedzenge et al., 2011); **South Africa** (Mah, 2010); **Nigeria** (Adebayo et al., 2011; Oydiran et al., 2010); **Botswana** (Thomas and Lungu, 2010; Foster et al., 2010a); South Africa (Tanser et al., 2011); **Mozambique** (Noden et al., 2009); **Tanzania** (Exavery et al., 2011); **Ethiopia** (Molla et al., 2008); **India** (Chatterjee and Hosain, 2006). **Zimbabwe** (Callegari et al., 2008; Feldman and Masophere, 2003); **Mexico** (Hirsch et al., 2007; Pulerwitz et al., 2001); **Kenya and Zambia** (Glynn et al., 2001; Glynn et al., 2003); **Kenya** (Kaiser et al., 2011); **Zambia** (Clark, 2004) and **globally** (Green et al., 2009) and from HPTN 052 sites (Eshelman et al., 2011).
- 2. Interventions are needed to reduce homophobia, which may lead MSM to have partnerships with women. Studies found that homosexuality was heavily stigmatized and that gender norms pressured MSM to marry and have families.
  - Gap noted, for example, in **Nigeria** (Etiebel et al., 2012); **Malawi, Namibia and Botswana** (Beyrer et al., 2010b); **China** (Zhou, 2006): **India** (Guterrez et al., 2010; Hernandez et al., 2006); and **Nicaragua** (Beyrer et al., 2010 cited in WHO et al., 2011b).
- 3. Innovation and research is needed on what works to reduce alcohol consumption and associated risks. A study of community interventions to reduce alcohol use found reduced sexual risk behavior. Wives perceive alcohol as a stimulus for men's extramarital sex and violent behavior.
  - Gap noted, for example, in **India** (Schensul et al., 2010).

### 3C. Prevention for Women: Voluntary Medical Male Circumcision

Male circumcision has now been shown in three randomized clinical trials to reduce the risk of HIV acquisition for men by 50–60% (Auvert et al., 2005; Bailey et al., 2007; and Gray et al., 2007). Male circumcision at birth as part of postnatal care could result, upon sexual initiation and during his

"We need more information and workshops on medical male circumcision" – South African women (cited in Kehler, 2010, para 23)

lifetime, in a reduction in the risk of HIV acquisition. Voluntary medical male circumcision (VMMC) requires men to take action to prevent HIV acquisition and thus to protect their female partners. Counseling for both men and women concerning the addition of voluntary medical male circumcision to the HIV "prevention toolbox" is an important recent advance.

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The Evidence for Rolling Out Voluntary Medical Male Circumcision is Strong Male circumcision is a one-time procedure with lifelong protective benefits (Njeuhmeli, 2011) and thus potentially highly cost-effective (Galarraga et al., 2009; Njeuhmeli, 2011). Scaling up voluntary medical male circumcision is also cost saving, preventing future treatment costs (Hankins et al., 2011; Njeuhmeli, 2011) and it is imperative that scale-up is rapidly accelerated (WHO et al., 2011a; Wamai et al., 2011). Mathematical modeling found that voluntary medical male circumcision is cost saving for Botswana, Ethiopia, Lesotho, Malawi, Mozambique, Namibia, Kenya, Rwanda, South Africa, Swaziland, Tanzania, Uganda, Zimbabwe and Zambia. In order to achieve maximum impact, an estimated 20.3 million circumcisions among men 15 to 49 should be performed by 2015 (Njeuhmeli, 2011). If this were accomplished, an estimated 3.4 million new HIV infections would be averted in the next 15 years (Njeuhmeli, 2011). The number of voluntary medical male circumcisions needed to avert one HIV infection ranges from a low of four in Zimbabwe to a high of 44 in Rwanda (Njeuhmeli, 2011). Among the infections averted are those among women, because as more men are circumcised, women are less likely to encounter sexual partners who are living with HIV (Njeuhmeli, 2011). "Early on, most HIV infections averted occur among men, but the proportion among women would steadily increase over time until almost half of all HIV infections averted in the year 2025 are those that would have occurred among women" (Hankins et al., 2011: 3-4). Modeling from Tanzania found that in the absence of male circumcision, the annual number of new HIV infections is expected to rise from 84,000 in 2010 to 86,000 in 2025. However, with voluntary medical male circumcision, a significant decline of 64,000 additional HIV infections is expected (Ally et al., 2012).

"...Despite compelling scientific evidence, most countries in sub-Saharan Africa have been slow in developing national policies on circumcision or programmatically providing access to voluntary medical male circumcision. This provides another missed opportunity for reducing HIV risk in young women and implementing a highly efficacious HIV prevention intervention" (Abdool Karim et al., 2010a: 126). In 2010, 350,000 men were circumcised in eight priority countries, an increase from 100,000 in 2009 (UNAIDS, 2011a). But to achieve population level prevention benefit in Eastern and Southern Africa, more than 20 million additional men need to be circumcised in Botswana, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Swaziland, United Republic of Tanzania, Uganda, Zambia and Zimbabwe (UNAIDS, 2011b). Kenya has achieved more than 50% of their goal (Mwandi et al., 2011) and in Swaziland, 13.3% of the 80% target has been reached; but all the other countries have achieved less than 5% of the 80% target (Wamai et al., 2011). Kenya's greater achievement is likely due to demonstrated country ownership (Dickson et al., 2011) where officials reached out to tribal leaders and conducted voluntary medical male circumcision campaigns using tents rather than fixed facilities, similar to campaigns conducted to reduce the backed-up demand for female fistula surgery (Gay and Ramsey, 2009).

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There are some barriers to achieving higher levels of voluntary medical male circumcision. The setting of targets may make men hesitant. Just as women welcome contraceptives to reduce their own unintended pregnancies, rather than for the purposes of meeting global demographic targets, men will most likely welcome male circumcision as an intervention to prevent HIV acquisition rather than for the purposes of achieving a target. Another potential barrier to scaling up of voluntary medical male circumcision is that in some countries, the age of consent to be operated on for male circumcision is age 18 (Strode et al., 2010). But in many countries, boys are sexually active before the age of 18. Scientists are working to develop non-surgical methods for male circumcision (Barone et al., 2011 cited in Padian et al., 2011b). Voluntary medical male circumcision programs can, however, be a gateway to increase HIV testing and counseling for men: in 2010, more than 56% of those receiving male circumcision also received an HIV test (WHO et al., 2011b). In addition, voluntary medical male circumcision could be an opportunity to engage men in reproductive health, refer for treatment if HIV-positive, as well as training on gender norms to enhance risk reduction counseling. Further evaluated interventions and studies are awaited on this topic.

"To avoid stigmatizing HIV-1 infected men, WHO/UNAIDS guidelines recommend that circumcision be provided to healthy men who request the procedure, regardless of HIV-1 serostatus, including for those declining HIV-1 testing. Thus, HIV-1 infected men will undoubtedly undergo circumcision as roll-out programs are implemented" (Baeten et al., 2010: 738). A study in Uganda found that "circumcision of HIV-infected men did not reduce transmission of the virus to uninfected female partners. Furthermore, we cannot exclude the possibility of higher HIV transmission in couples who resumed intercourse before complete healing of the surgical wound...The findings suggest that strict adherence to sexual abstinence during wound healing and consistent condom use thereafter must be strongly promoted when men living with HIV receive circumcision" (Wawer et al., 2009: 235). In addition, this same study noted "an increase in HIV viral load in antiretroviral-naïve men after surgery, which could result in higher infectivity" (Wawer et al., 2009: 235).). "Understanding the potential short- and long-term effects of circumcision on HIV-1 infected men on risk of HIV-1 transmission to their sexual partners is a public health priority" (Baeten et al., 2010: 738). While male circumcision may have reduced efficacy such as early return to sex and disinhibition, "...none of these considerations (are)...a basis for rejecting male circumcision as part of HIV prevention strategies" (Wamai et al., 2011: Male Circumcision for HIV prevention: para 8). Two mathematical models, using DHS data on the HIV epidemics in Zimbabwe and Kenya, estimated that an increase in the risk of HIV acquisition and transmission during wound healing for male circumcision is unlikely to have a major impact on circumcision interventions. Estimates suggest that male circumcision confers a 46% reduction in the rate of male-to-female HIV transmission (Hallett et al. 2011). If this reduction begins two years after circumcision, the impact on infections averted by the intervention overall increases by 40%, doubling the number of infections averted among women. Modeling suggests that high degrees of increased risky behavior among circumcised men would not

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lead to increases in incidence overall under the intervention. If only uninfected men are circumcised in the intervention, the eventual reduction in incidence is increased by 30% overall and 66% for women, compared with 44% and 95% respectively, if HIV-infected men are circumcised too. Although male circumcision is an intervention applied to men, it brings substantial benefits to women as well (Hallett et al. 2011).

Questions Remain About the Short-Term Impact of Male Circumcision on Women How can male circumcision be effectively introduced so that it complements and does not detract from other HIV prevention strategies? Will male circumcision affect women's ability to negotiate condom use? Will male circumcision confer any protection during anal sex? (AVAC, 2007) Operations research will be useful to iteratively improve program delivery and impact, including rigorous monitoring and evaluation of expansion of male circumcision services "to ensure that there are no adverse consequences for female partners of men who become circumcised" (Weiss et al., 2010: S64). Surveys by women's groups on the ground in Kenya, Namibia, South Africa, Swaziland and Uganda have found cause for concern (AVAC et al., 2010). If a man refuses an HIV test, is circumcised and thinks he is protected, then "his partner is in a worse position than before" (Berer, 2008a: 172). "As sexual partners, women should not abandon negotiation of condom use with circumcised men, and this will be greatly facilitated if everyone understands that with circumcision alone, men are not fully protected and their partners are not directly protected from HIV infection" (Hankins, 2007: 65).

Yet male circumcision programs could be a platform to promote gender equity and all HIV risk reduction strategies as well as men and women's sexual and reproductive health with increased couple communication (Wamai et al., 2011). PEPFAR recommends that "where VMMC services are provided, they must be part of a comprehensive HIV prevention package along with provision of HTC, treatment for STIs, promotion of safer sex (including counseling of men and their sexual partners to prevent them developing a false sense of security) and provision of condoms (including how to use them correctly" (PEPFAR, 2011b: 20). While not addressing counseling needs for men or for women, WHO has released considerations for implementing models for optimizing the volume and efficiency of male circumcision services (WHO, 2010l). These questions will need to be addressed as male circumcision is rolled out. It is clear that male circumcision is an important component for HIV prevention strategies, but the extent to which it protects women is, while promising for the long term, unclear about women's risk in the short term. The protective effects of male circumcision "will eventually percolate to women and uncircumcised men if sufficient circumcision levels are achieved" (Hallett et al., 2008a; White et al., 2008 cited in Katsidzira and Hakim, 2011: 1124).

Given evidence that male circumcision could potentially put women at an *increased* risk for HIV under certain circumstances in the short term, how best to roll out programming through gender-equitable approaches that do not increase short term HIV risks for women remains to be evaluated (Zachariah et al., 2011). "The roll out of male circumcision

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presents [an ideal opportunity] to ...provide interventions to transform harmful gender attitudes and behavior as part of programming of the roll out of male circumcision... (Greig et al., 2008: S37-8). "Outside the clinical trial setting, the effect that the decreased perceived risk of HIV infection will have for circumcised men's willingness (and women's ability to negotiate) condoms requires close monitoring' (Gruskin and Ferguson, 2008a). Women will benefit in the long run from male circumcision, as fewer of their male sexual partners will be HIV-positive. Clear and consistent messages must emphasize that male circumcision is an additional prevention method for men, but that it does not replace measures such as delay in the onset of sexual relations, avoidance of penetrative sex, reduction in the number of sexual partners, and correct and consistent use of male or female condoms (Doyle et al., 2010b). Communicating partial protection remains challenging (Dickson et al., 2011).

Circumcision for male infants should be incorporated into WHO's Expanded Program on Immunization (Zachariah et al., 2011). Targeting newborns is not cost saving because circumcision will occur many years before men experience their highest HIV infection risk. However, after 20 years, the intervention directed at neonates is as cost effective as targeting adults (Galarraga et al., 2009). Circumcised male neonates, as they become sexually active, will be less likely to acquire HIV and subsequently, less likely to transmit HIV to their female partners. Neonatal male circumcision has several advantages over the procedure performed in other age groups. Complication rates have been observed to be low and neonatal male circumcision can be performed as a clean procedure (rather than sterile) in a newborn nursery or a post-natal outpatient clinic (Wiswell & Geschke 1989 cited in Plank et al. 2010). Neonatal male circumcision does not require an operating room, can be done with topical anesthetic and without sutures, and can be performed by midwives, in addition to physicians. Neonatal male circumcision can be performed at one-tenth of the cost of adult male circumcision (Manji 2000 cited in Plank et al. 2010).). A tool to calculate costs and impact of male circumcision (Decision Makers' Program Planning Tool – DMPPT), as well as additional information on male circumcision is available at: www.malecircumcision.org.

# 3C. What Works—Prevention for Women: Voluntary Medical Male Circumcision

1. Male circumcision reduces HIV acquisition for men and reduces the likelihood of transmission to HIV-negative women.

## Promising Strategies:

2. Counseling for both pregnant women and future fathers to circumcise male infants may reduce HIV acquisition and transmission when those male infants become sexually active young men.

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### 3C. Evidence

- 1. Male circumcision reduces HIV acquisition for men and reduces the likelihood of transmission to HIV-negative women.
  - A Cochrane Review that reviewed Auvert et al., 2007; Bailey et al., 2007 and Gray et al., 2007 (below) found that based on these three randomized controlled trials in South Africa, Uganda and Kenya between 2002 and 2006, men had a relative risk reduction of acquiring HIV of 50% at twelve months and 54% at 24 months following circumcision. A meta-analysis of sexual behavior for Kenyan and Ugandan men found no significant differences between circumcised and uncircumcised men; however among South African men, there was a statistically significant increase in sexual contact for men who were circumcised at the 21-month visit. Medical male circumcision reduces the risk of HIV acquisition by heterosexual men by between 38% and 66%. "The background risk of HIV infection in the population should be considered in the decision to circumcise men" (Siegfried et al., 2009: 17). "Promotion of male circumcision at a country level must clearly present (male) circumcision as partly protective for the male partner and continue to advocate other prevention measures" (Siegfried et al., 2009: 20). (Gray I) (male circumcision, South Africa, Uganda, Kenya)
  - A randomized controlled study from 2002 to 2004 of 3,274 young, sexually active, heterosexual men in **South Africa** found that with 18 months of follow-up, 60% fewer men who had been circumcised acquired HIV as compared to men who had not been circumcised. There were 20 men who acquired HIV among those who had been circumcised, an incidence rate of 0.85 per 100 person years and 49 men who acquired HIV among men who had not been circumcised, an incidence rate of 2.1 per 100 person years. Male circumcision was offered to the control group at the end of trial. At each of four visits, each participant was invited to a counseling session of 15 to 20 minutes delivered by a certified counselor about HIV. Condoms were provided. STIs were screened and treatment. No deaths occurred due to circumcision. Circumcision was conducted by general practitioners and resulted in a limited and reasonable number of adverse events (Auvert et al., 2005). (Gray II) (male circumcision, condoms, South Africa)
  - A randomized controlled trial of 2,784 men aged 18 to 24 years in Kisumu, **Kenya**, with a follow up of 24 months found that 22 men who were circumcised acquired HIV compared to 47 men who had not been circumcised. The two-year HIV incidence was 2.1% in the circumcision group and 4.2% in the group of men who had not been circumcised. Circumcised men had a reduction in the risk of acquiring HIV of 53%. Adjusting for non-adherence to treatment and excluding four men who tested HIV-positive prior at enrollment in the study, the protective effect of circumcision was 60%. "Circumcision will be most effective if it is not perceived as a stand-alone procedure, but as one component of a full suite of HIV prevention and reproductive health services, including HIV testing and counseling, diagnosis and treatment of sexually transmitted infections, condom promotion, [and] behavioral change counseling and promotion...." (Bailey et al., 2007: 655). (Gray II) (male circumcision, Kenya)
  - A randomized trial in Rakai, **Uganda** with 4,996 uncircumcised HIV-negative men aged 15 to 49 years of age found that HIV incidence over 24 months was 0.66 cases per 100 person years among men who were circumcised and 1.33 cases per 100 person years among men who delayed circumcision for 24 months, with an estimated efficacy of 51%. (Gray et al., 2007). (Gray II) (male circumcision, Uganda)
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- A study done in Eastern and Southern Africa found that male circumcision reduced HIV transmission between serodiscordant couples. A total of 3,297 serodiscordant couples were included in the prospective study. The HIV-positive partner was also infected with HSV-2. After the initial examination, uninfected partners had a quarterly visit consisting of a genital examination and an HIV test. Patients received risk-reduction counseling, quarterly syndromic STI treatment and no cost condoms. Plasma viral level of the infected partner was measured at enrollment, 3, 6, 12 months and at 24 months. The HIV-positive clients were interviewed every month on the number of coital acts with or without condoms, confirmed by their HIV-negative partner. HIV-positive serostatus was confirmed by Western blot if a rapid test was positive. Timing of infection was determined by PCR prior to seroconversion. The time of HIV infection was defined as the earlier positive PCR. Each confirmed transmission between the study partners was classified as "linked". It was classified as "unlinked" if HIV was acquired from another sexual partner other than the study partner confirmed by genetic sequencing of plasma samples. Analysis was done only for linked transmissions. Sixty-seven percent of the HIV-positive partners were women. Thirty-four percent of the HIV-positive and 55% of the HIV-negative males were circumcised. Eighty-six linked transmissions occurred during the 24 months. Male circumcision decreased the risk of acquiring HIV by 47% by female HIV-negative sexual partners. For each 10-fold increase in plasma viral RNA, increased transmission by 2.9 fold was also observed (Hughes et al., 2012). (Gray IIIb) (male circumcision, Eastern and Southern Africa)
- A 2004 2008 prospective study in Kenya, Rwanda, South Africa, and Zambia found no increased risk, and potentially decreased risk, from male circumcision on male-to-female transmission of HIV-1 among 1,096 HIV-1 serodiscordant couples in which the HIV-1 seropositive partner was male. This effect was similar when restricted to the subset of HIV-1 transmission events confirmed by viral sequencing to have occurred within the partnership, after adjustment for male partner plasma HIV-1 concentrations, and when excluding followup time for male partners who initiated antiretroviral therapy. Physical examination at the time of study enrollment determined 374 (34%) male partners to be circumcised. During the median follow-up of 18 months, 64 female partners seroconverted to HIV-1, with 50 (78%) determined to be genetically linked within the partnership by viral sequencing analysis. The probability of HIV-1 acquisition was not statistically different for women whose partners became circumcised (21.7% at 24 months) compared with those whose partners remained uncircumcised (13.4%). Follow-up for HIV-1 seronegative female partners was also 18 months and a total of 1,685 person-years of follow-up were accrued. Prior to enrollment, all participants received an HIV-1 prevention package consisting of pre- and post-test counseling, risk reduction counseling (individual and couple), free condoms, and management of sexually transmitted infections (STIs) according to WHO guidelines (Baeten et al. 2010). (Gray IV) (male circumcision, Kenya, Rwanda, South Africa, Zambia)

### **Promising Strategies:**

2. Counseling for both pregnant women and future fathers to circumcise male infants may reduce HIV acquisition and transmission when those male infants become sexually active young men. [See Safe Motherhood and Prevention of Vertical Transmission: Testing and Counseling]

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# 3C. Gaps in Programming—Voluntary Medical Male Circumcision

- 1. Programs must continue to promote protective behavior such as condom use in addition to male circumcision.
- 2. Programs for male circumcision need to provide women, as well as men, with detailed factual knowledge of the benefits and risks of voluntary medical male circumcision.
- 1. Programs must continue to promote protective behavior such as condom use in addition to male circumcision. Studies found that male circumcision is only partially effective, making protective behavior such as partner reduction and condom use, in addition to circumcision, essential. Men who have been circumcised can still transmit HIV to women if they are HIV-positive. Until healing is complete following circumcision, men are more likely to transmit HIV. A post hoc analysis found the HIV-1 acquisition rate among partners of men who remained uncircumcised was 7.9% during the first 6 months after enrollment compared with 27.8% for partners of men who were circumcised and then resumed sexual activity prior to documented healing of the surgical wound, a substantially increased risk.
  - Gap noted, for example, in **Uganda** (Wawer et al., 2009); **sub-Saharan Africa** (Hallett et al., 2008a); **Kenya** (Agot et al., 2007); **South Africa** (Taljaard et al., 2008); **Uganda and Zimbabwe** (Matovu et al., 2007); **Kenya**, **Rwanda**, **South Africa**, and **Zambia** (Baeten et al., 2010).
- 2. Programs for male circumcision need to provide women, as well as men, with detailed factual knowledge of the benefits and risks of voluntary medical male circumcision. Surveys found that women lacked detailed factual knowledge of the benefits and risks of voluntary medical male circumcision and believed that if their male partner was circumcised (whether medically or traditionally) that condom use was unnecessary to protect them from acquiring HIV. Both women and men needed knowledge that abstinence is necessary during wound-healing. Women also need to know that female genital cutting does NOT protect against HIV acquisition or transmission. Women reported that circumcised men adopted risky sexual behaviors. Women feared that medical male circumcision would reduce their ability to negotiate for safer sex and would increase violence. A study of women who acquired HIV found that a large proportion of women reported not knowing whether their partner was circumcised.
  - Gap noted, for example, in **Kenya**, Namibia, **South Africa**, **Swaziland** and **Uganda** (AVAC et al, 2010); and **South Africa** and **Zimbabwe** (Mavedzenge et al., 2011b).

## 3D. Prevention for Women: Treating Sexually Transmitted Infections (STIs)

Worldwide, the burden of sexually transmitted infections in women is more than five times that in men (Sciarra, 2009). Multiple observational studies have found an

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association between STIs and HIV (Venkatesh et al., 2011; Cohen, and Eron, 2011; Mavedzenge et al., 2010b; Weber et al., 2010). A recent study found that the odds of acquiring HIV were 2.4 times higher in women with prior cervical HPV infection after adjustment for both behavioral and biologic risk factors (Averbach et al., 2010).

However, the evidence that treating STIs can reduce the spread of HIV to women has been generally disappointing (Padian, 2010; Celum et al., 2010). A Cochrane review from 2011 noted: "We failed to confirm the hypothesis that STI control is an effective HIV prevention strategy" (Ng et al., 2011b: 2). The only study to show an impact on HIV incidence from STI treatment has been the Mwanza trial in Tanzania. A combination of improved STI treatment services was shown to reduce HIV incidence in an environment characterized by an emerging HIV epidemic (low and slowly rising prevalence), where STI treatment services are poor, and where STIs are highly prevalent (Grosskurth et al., 1995). The other eight trials of STI treatment have shown no effect on HIV acquisition (Padian, 2010).

One hypothesis for why improved STI treatment services reduced HIV incidence in Mwanza but not elsewhere was that "...the Mwanza trial was implemented in an earlier phase HIV epidemic than was the case for the five [trials that showed no results]..... all of which were conducted in late-phase, generalized epidemics when genital herpes had largely replaced curable etiologies of genital ulcers, while rates of other curable STIs had fallen substantially in the general population" (Padian et al., 2010: 629). Treating STIs as a way to reduce HIV transmission begs the question: "is the juice worth the squeeze?" (Cohen and Eron, 2011: 410) that is, is treating STIs too far removed as a strategy for HIV prevention given that there are more direct prevention methods available? Given the recent study showing that antiretroviral therapy can reduce HIV transmission (Cohen et al., 2011b), it may not, indeed, be worth the squeeze. However, "notwithstanding, the inconsistent findings from these randomized controlled trials, the significant reproductive health challenge posed by the high burden of curable STIs needs to be addressed in any HIV prevention effort" (Abdool Karim et al., 2010a: S122). From a policy perspective, treatment of curable STIs is an essential part of primary health care. In addition, STI clinical services offer important entry points for provision of HIV prevention services (Hayes et al., 2010b).

Using STI services as a point of access to reach women at high risk of acquiring HIV is important both to offer HIV testing and counseling and as a gateway to HIV treatment and care (WHO et al., 2011b). These services "contribute to the achievement of universal access to HIV prevention by promoting condom use, behavioral change and the empowerment of vulnerable populations" (Chersich and Rees, 2008: S35). "Even if in the end it is found that STDs have only a limited impact on HIV transmission, we cannot afford to miss the potentially cost-effective chance of controlling HIV through their treatment. Additionally, STDs are important diseases, which by themselves cause major morbidity and reduced fertility, demanding control" (Rottingen et al., 2001: 594).

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Treatment of sexually transmitted infections is also critically important for women living with HIV. STIs in those who are HIV-positive may be associated with faster disease progression and may contribute to greater HIV transmission and thus is treating STIs is an important component of meeting the sexual and reproductive health needs of women living with HIV. [See Meeting the Sexual and Reproductive Health Needs of Women Living With HIV and Preventing, Detecting and Treating Critical Co-Infections]

# 3D. What Works—Prevention for Women: Treating Sexually Transmitted Infections

1. STI counseling, diagnosis and treatment represent an important access point for women at high risk of HIV, particularly in the earlier stages of the epidemic.

# Promising Strategies:

- 2. Screening for and treating STIs syndromically on a continuous, accessible basis improves overall health, and has been associated in one study with reducing the risks of HIV acquisition in a setting with high STI prevalence.
- 3. Providing HIV testing and counseling together with STI services can reach women at high risk for HIV.

#### 3D. Evidence

- 1. STI counseling, diagnosis and treatment represent an important access point for women at high risk of HIV. [See also Safe Motherhood and Prevention of Vertical Transmission: Testing and Counseling]
  - A systematic review and meta-analysis of 1,064 reports between 1998 and 2000 found that genital ulcerative disease appears to have a greater impact than nonulcerative disease on the susceptibility to HIV. Men were more affected than women by the effects of STIs Untreated concurrent STIs in an HIV-positive individual increases the rate of progression towards AIDS. "A better and more quantitative understanding of the interactions between HIV infection and classic STDs is needed ...Sexual behavior is the common risk factor for contracting both HIV and STDs" (Rottingen et al., 2001: 592). (Gray I) (STIs, genital ulcers)
  - A 2004 to 2006 cross-sectional survey study of female sex workers in **India** found that of the 976 women who had symptoms of an STI, more than 78% sought medical treatment; behavior that was protective for both HIV and STIs. HIV infection was strongly associated with lifetime and active syphilis (Mishra et al., 2009). (Gray IIIb) (STIs, syphilis, India)
  - In a study where 109,500 samples were tested during a nine-month period from patients in STI clinics in the **US**, **Malawi and South Africa**, 1 to 2 percent had acute HIV infection, which greatly increases the risk for transmission of HIV (Cohen, 2006b). (Gray IIIb) (STIs, Malawi, South Africa, United States)
  - Ulcerative STIs, particularly chancroid, herpes simplex virus type 2 and syphilis are the most important STI cofactors for HIV transmission. Control of curative genital ulcers chancroid

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- and syphilis is highly feasible and correlates well with stabilization of HIV epidemics. Effective antibiotic treatment of gonorrheal or chlyamydial infection reduces HIV viral load to normal levels. "Evidence supporting the role of STIs as HIV cofactors is extensive and indisputable" (Steen et al., 2009: 862). (Gray V) (STIs, genital ulcers)
- The prevalence of genital shedding of herpes simplex virus (HSV)-2 and related risk factors was evaluated in a prospective population of 355 women attending the Maternity Joséphine Bongo, in Libreville, **Gabon**. Researchers found a high prevalence (66%) of HSV-2 seropositivity, with a high proportion, 14%, of women harboring HSV-2 DNA shedding in their genital secretions. HSV-2 genital shedding was positively associated with previous episodes of genital blisters, current genital ulcer, current genital blister, HIV seropositivity and HSV-2 seropositivity (Ozouaki et al., 2006). (Gray V) (herpes simplex, Gabon)

## **Promising Strategies:**

- 2. Screening for and treating STIs syndromically on a continuous, accessible basis improves overall health, and has been associated in one study with reducing the risks of HIV acquisition in a setting with high STI prevalence.
  - A randomized trial was conducted over two years in rural Tanzania. STI treatment was provided in the intervention communities to assess the impact on HIV transmission. Strong evidence indicates that the STI intervention program had a substantial effect on HIV incidence in this rural African population. Six communities received the intervention immediately following the baseline survey, while six comparison communities received the intervention after the follow-up survey two years later. HIV incidence was consistently lower in the intervention community than the comparison community in all six matched pairs. After two years of the intervention, there were 48 seroconversions (1.2%) in the intervention group and 82 (1.9%) in the comparison group. HIV incidence was approximately 42% lower in the intervention group. Prevalence and incidence of STIs was measured in a random cohort consisting of 1,000 adults in each community. STI services were based on syndromic algorithms recommended by WHO (WHO, 1991). The intervention program had five components: 1) Establishment of an STI reference clinic and laboratory to monitor the effectiveness of treatment algorithms; 2) Existing staff from health centers received one week of classroom training and two weeks of practical training at the STI clinic. Staff also were trained to provide patients with health education and to offer free condoms; 3) A special delivery system of drugs was established to supplement the national essential drugs program supplies; 4) Regular supervisory visits by a program officer were conducted to provide inservice training and to check drug supplies and patient records; 5) Periodic visits by health educators to villagers were conducted to provide information on STIs, inform villagers of available treatment, and encourage prompt attendance for treatment of symptomatic STIs. Men with a positive LED test and those reporting or found to have urethral discharge were asked to provide a urethral swab. Urethral swabs were tested for Neisseria gonorrhea by pram stain and for Chlamydia trachoatis by antigen capture immunoassay. HIV was tested by ELISA assay. Positive samples received a second ELISA assay, and in case of discrepant or indeterminate ELISA results, a western blot test. Serological tests for syphilis were conducted using RPR and TPHA. Evaluation of the impact of the intervention on the prevalence of STIs was based on the seroprevalence of active syphilis and on the prevalence of confirmed urethritis, N gonorrhea and C traehomanis infection in men. Surveys indicated that condom use did not increase nor did sexual behavior change during the course of the intervention (Grosskurth et al., 1995). (Gray IIIa) (STIs, health facilities, treatment, Tanzania)

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- A study done in Eastern and Southern Africa showed that HIV transmission per coital act among serodiscordant couples is similar between sexes while sexually transmitted illnesses increased the risk of transmission. A total of 3,297 serodiscordant couples were included in the prospective study. The HIV-positive partner was also infected with HSV-2. After the initial examination, HIV-negative sexual partners had a quarterly visit consisting of a genital examination and an HIV test. Clients received risk-reduction counseling, quarterly syndromic STI treatment and free condoms. Plasma viral level of the HIV-positive partner was measured at enrollment, 3, 6, 12 months and at 24 months. The HIV-positive clients were interviewed every month on the number of coital acts with or without condoms, confirmed by their HIVnegative sexual partners. HIV transmission was confirmed by Western blot if a rapid test was positive. Timing of infection was determined by PCR before seroconversion. The time of HIV infection was defined as the earlier positive PCR. Each confirmed transmission between the study partners was classified as "linked". Transmission was classified as "unlinked" if HIV was acquired from another person other than the study partner through genetic sequencing of plasma samples. Analysis was done only for linked transmissions. Sixty seven percent of the HIV-positive sexual partners were women. Thirty-four percent of the HIV-positive and 55% of the HIV-negative males were circumcised. Eighty-six linked transmissions occurred during the 24 months. In cases of unprotected sex the risk of male-to-female transmission was 1.95 times greater than female-to-male transmission. However, the increased male-to-female transmission was explained by higher viral loads in male partners and seropositivity for HSV-2 in the HIV-negative partners. The study found that the per-act risk of HIV transmission between the sexes in unprotected sex was equal. HIV-negative partners who tested positive for HSV-2 at enrollment were 2.14 times more likely to acquire HIV and those with genitourinary diseases were 2.65 times more likely to acquire HIV. The presence of trichomonal vaginalis at enrollment in the female HIV-negative sexual partner increased the risk of per-act transmission by a factor of 2.57. The presence of cervicitis or vaginitis (damaged lining of the female genitalia) was associated with a 3.63 fold increase in risk of per-act transmission. For each 10 fold increase in plasma viral RNA, increased transmission by 2.9 fold was observed (Hughes et al., 2012). (Gray IIIb) (STIs, health facilities, treatment, Eastern, Southern Africa)
- 3. Providing HIV testing and counseling together with STI services can reach women at high risk for HIV. [See HIV Testing and Counseling for Women]

## 3D. Gaps in Programming—Treating Sexually Transmitted Infections

- 1. Interventions are needed to screen and treat both male and female sexual partners for STIs.
- 2. While treatment of all STIs can improve everyone's health and well-being, further interventions are needed to treat ulcerative STIs, which have the most impact on HIV susceptibility and transmission.
- 1. Interventions are needed to screen and treat both male and female sexual partners for STIs. Studies found that efforts are needed to reach both men and women: if both partners were not treated, women can get recurrent infections.
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- Gap noted, for example, in **Uganda** (Kacwamu, 2008); **South Africa** (Fox et al., 2007).
- 2. While treatment of all STIs can improve everyone's health and well-being, further interventions are needed to screen and treat ulcerative STIs, which have the most impact on HIV susceptibility and transmission. Studies have found however, that, to date, regimens to suppress genital herpes and other STIs have not been effective in reducing HSV transmission.
  - Gap noted, for example, in **Uganda and Zimbabwe** (Van der Pol et al., 2008); **Tanzania** (Watson-Jones et al., 2008); **India** (Reynolds et al., 2006b); **generally** (Klausner, 2009).

# 3E. Prevention for Women: Treatment as Prevention

Antiretroviral medication has been successfully used in a number of ways: first and foremost to treat those with high viral load and diminishing CD4 counts; secondly to prevent vertical transmission of HIV from pregnant and breastfeeding women to their infants; third, as a prophylactic for those who have been exposed to HIV occupationally or through sexual assault (post-exposure prophylaxis, PEP); and finally as pre-exposure prophylaxis (PreP). ART can reduce HIV transmission both directly by reducing vireaemia and thereby HIV transmissibility and indirectly by reducing risk behavior among those diagnosed, counseled, and treated..." (IOM, 2011: 37). Recently, a landmark study, HPTN 052, has shown that early initiation of antiretroviral therapy (when CD4 counts were between 350 and 550 – before many would normally be eligible for treatment in most countries) for the seropositive partner in a discordant relationship resulted in a 96% relative risk reduction of HIV transmission to the seronegative sexual partner (Cohen et al., 2011b). While there are several contributing factors in this study [See Treatment: Staying Healthy and Reducing Transmission], the results of this study have led many to recommend the use of treatment as a prevention strategy. In 2011, following the results of this study, the US Institute of Medicine recommended "giving priority to prevention as a central tenet of a sustainable long-term response to the HIV/AIDS epidemic...applying evidence-based public health approaches...[and] increasing access to and coverage of synergistic combinations of known effective prevention technologies" (IOM, 2011: 8 and 9).

Critical questions around treatment as prevention include which populations living with HIV have access to treatment. Even if all serodiscordant couples had access to treatment as prevention, this would still not end the epidemic. In the study by Cohen et al. 30% of HIV-positive spouses also had an outside partner (Cohen et al., 2011b; Celum, 2011). But modeling has shown that for some countries, high rates of serodiscordant partnerships with treatment of the serodiscordant partner could lead to a fairly large reduction in incidence with a substantial number of infections prevented (El-Sadr et al., 2011). Thus the ethical and public health challenge is "how we choose to distribute a limited resource – antiretroviral drugs for treatment, for prevention or for both" (Cates, 2011: 225).

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When more people living with HIV are on treatment, incidence goes down. However, more methods are needed for detecting acute infection, as acute transmission has been shown to increase the risk of transmission (Powers et al., 2010 cited in Smith et al., 2011). No strategies, especially in resource-limited settings, have been developed to prevent transmission among those who are acutely infected and the use of antiretroviral therapy during acute infection, either for personal or public health benefit, is controversial (Cohen et al., 2012). In addition, those on treatment may reduce condom use (Hasse et al., 2010 cited in Smith et al., 2011), although results from different studies have been mixed. [See Treatment: Staying Healthy and Reducing Transmission] "...Challenges remain in defining the optimum strategy for using treatment as prevention, finding the most contagious people, and providing both personal and public health care" (Smith et al., 2011: 323).

While the biggest challenge is providing treatment to all who can benefit, another challenge for treatment as prevention is that some believe it may violate the rights of people living with HIV by rolling out treatment for a public health benefit for people living with HIV who have CD4 counts above 350 or even 500 who are asymptomatic rather than for the individual patients' benefit. In addition, concerns have been raised that treatment for prevention may lead to loss of follow-up, poor levels of adherence, and increase in the prevalence and transmission of drug-resistant strains of HIV (GNP+ and UNAIDS, 2011). If given treatment as prevention, the person with HIV must be fully informed and agree to the potential risks and benefits on her/his health (GNP+ and UNAIDS, 2011). Others have argued "treatment should first and foremost be used for therapeutic purposes," targeting those who are sickest, which would be "ethical, feasible and epidemiologically sound" (Wagner et al., 2010: 1). Other prominent scientists and treatment activists have agreed that treatment should be available to all in medical need (Ambrosioni et al., 2011). "Scientists and policymakers alike agree that infected people should receive the lifesaving drugs before the uninfected" (Cohen, 2011b: 1340). But treatment and prevention are synergistic and can work together to reduce the burden of the AIDS epidemic (AVAC, 2010). Or as Dr. Fauci, who heads U.S. National Institute of Allergy and Infectious Disease (NIAID) stated, "We should just forget about [the idea of the tension between treatment and prevention and just put it behind us, because treatment is prevention" (Fauci cited in Cohen et al., 2011c: 1628). Yet, "the logistical requirements for successful use of ART for prevention are considerable" (Smith et al., 2011: 315), while at the same time serving as a cornerstone of combination prevention of HIV (Smith at al., 2011). Numerous questions and challenges remain to enact treatment as prevention in resource-limited settings (Zachariah et al., 2010); however, inaction would also be inexcusable. Some of the challenges include missing acute infections, long-term adherence, the possibilities of drug resistance, and the concerns that condom use and other preventive measures would decrease (Shelton, 2011a). A continued focus on all prevention modalities, including treatment is warranted (Nguyen et al., 2011).

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Thus, although recent results "...support the use of antiretroviral treatment as a part of a public health strategy to reduce the spread of HIV-1 infection" (Cohen et al., 2011: 12), "the burden of adding antiretroviral-based prevention to already strained health systems remains to be determined" (Padian et al., 2011). Yet global consensus has been reached that treatment can serve to prevent HIV acquisition, especially at CD4 counts under 350; treatment for those at CD4 counts under 350 must be scaled up and health systems must work to increase adherence and reduce loss to follow up (see treatment section).

Experts agree that HIV prevention must be prioritized as a "mainstay of a sustainable response" (AIDS2031 Consortium, 2010: xiii). Without substantial targeted HIV prevention efforts, new HIV infections will continue to outpace treatment efforts – "even while recognizing some prevention effects from expanded treatment" (AIDS2031 Consortium, 2010: 24). For example, in Zambia, nearly twice as many incident infections would occur in 2031 under a treatment-only approach as would occur with a combination of robust prevention and treatment efforts" (AIDS2031 Consortium, 2010: 25). "Failure to reduce incidence rates will make the goal of universal access to treatment impossible".... (IOM, 2011: 60). Gender is key to testing and treatment. Globally, more women have been tested for HIV and more women have accessed antiretroviral therapy, with men facing numerous gender-related barriers to accessing testing and treatment, while women face gendered barriers to adherence. [See HIV Testing and Counseling and Treatment]

A fuller discussion of the role of treatment in reducing HIV transmission can be found in the treatment section.

## 3E. What Works—Prevention for Women: Treatment as Prevention

- 1. ARV therapy can reduce (but does not eliminate) the risk of HIV transmission and is an additional prevention strategy.
- 2. Providing antiretroviral treatment to people living with HIV can increase HIV prevention behaviors, including condom use.

## 3E. Evidence

- 1. ARV therapy can reduce (but does not eliminate) the risk of HIV transmission and is an additional prevention strategy. [See Treatment: Staying Healthy and Reducing Transmission]
- 2. Providing antiretroviral treatment to people living with HIV can increase HIV prevention behaviors, including condom use. [See Treatment: Staying Healthy and Reducing Transmission]

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# 3E. Gaps in Programming—Treatment as Prevention

- 1. Intensified efforts are needed to increase access to treatment, condom use and reduce multiple partnerships by people who know their HIV-positive status or who are on ARV treatment, including young people.
- 1. Intensified efforts are needed to increase access to treatment, condom use and reduce multiple partnerships by people who know their HIV-positive status or who are on ARV treatment, including young people. [See Treatment: Provision and Accesss and Treatment: Staying Healthy and Reducing Transmission]

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