### GLOBAL HIV PREVENTION WORKING GROUP AUGUST 2008

# BEHAVIOR CHANGE AND HIV PREVENTION:

(Re)Considerations for the 21st Century

### ABOUT THE GLOBAL HIV PREVENTION WORKING GROUP

The Global HIV Prevention Working Group is a panel of over 50 leading public health experts, clinicians, biomedical and behavioral researchers, advocates, and people affected by HIV/AIDS, convened by the Bill & Melinda Gates Foundation and the Henry J. Kaiser Family Foundation. The Working Group seeks to inform global policy-making, program planning, and donor decisions on HIV prevention, and to advocate for a comprehensive response to HIV/AIDS that integrates prevention, treatment, and care. More information and Working Group publications are available at www.GlobalHIVPrevention.org.

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# **EXECUTIVE SUMMARY**

Recent results from clinical trials of potential new HIV prevention interventions underscore what we have known for decades: Wider delivery of effective behavior change strategies is central to reversing the global HIV epidemic. The availability of new biomedical HIV prevention modalities, such as vaccines and microbicides, is still many years away. Even when these tools finally emerge, human behavior will remain critical, as new prevention strategies are unlikely to be 100 percent effective in preventing transmission. With 2.5 million new HIV infections in 2007, there is an obvious and urgent need to pursue the effective strategies we have to promote safer behaviors.

Human behavior is complex; widespread behavior changes are challenging to achieve; and there are important gaps in our knowledge about the effectiveness of HIV prevention. Yet the research to date clearly documents the impact of numerous behavioral interventions in reducing HIV infection. We also know that in all cases in which national HIV epidemics have reversed, broad-based behavior changes were central to success.

To be more effective in the 21st century, the HIV prevention effort must confront several challenges of perception: misplaced pessimism about the effectiveness of behavioral HIV prevention strategies; unfortunate confusion between the difficulty in changing human behavior and the inability to do so; and misperception that because it is inherently difficult to measure prevention success—a "nonevent"—prevention efforts have no impact.

This report from the Global HIV Prevention Working Group (PWG) focuses specifically on behavioral HIV prevention. The report surveys what we know about the effectiveness of behavior change strategies, what we still need to learn, and what we need to do to advance such efforts in coming years. Based on a comprehensive review of hundreds of studies of behavior change for HIV prevention, we find that the evidence base for behavioral HIV prevention is robust, with multiple studies documenting the effectiveness of interventions in numerous settings, among diverse populations, and throughout the course of the epidemic. Our review also indicates that the evidence base is not yet complete, and that important gaps and limitations remain in our knowledge about what works. Maximizing the effectiveness of prevention efforts requires that these limitations be acknowledged and addressed.

### WHAT WE KNOW

A comprehensive review of the evidence documents both the efficacy (the impact seen in a clinical trial setting) and the effectiveness (the impact seen in realworld settings) of behavioral HIV prevention efforts. Encompassing both randomized controlled trials and observational analyses, our review identified common elements of success:

• RANDOMIZED CONTROLLED TRIALS:

Hundreds of randomized controlled trials<sup>1</sup> have demonstrated that individual, small group, and community-level interventions can generate safer behaviors. For example, a recent review of 18 meta-analyses of sexual risk reduction interventions found significant increases in condom use and reductions in unprotected sex (Noar 2008). On the basis of peer-reviewed publications through 2004, the U.S. Centers for Disease Control identified 42 prevention interventions that were demonstrated by welldesigned studies to be efficacious (Lyles 2007; CDC 2001). Studies in low- and middle-income countries among young people (WHO 2006), sex workers (Foss 2007), and other populations have demonstrated that prevention programs have the ability to change sexual and drug-use behaviors in resource-limited settings to prevent HIV transmission.

- OBSERVATIONAL RESEARCH: Successes have been well-studied and documented through observational research in Uganda, Thailand, Australia, Brazil, and numerous other places. The early achievements of Uganda and Thailand in implementing effective prevention programs have been well-documented (UNAIDS 2001), as has Australia's striking success in sharply lowering HIV incidence as a result of significant behavior changes among men who have sex with men (National Centre in HIV Epidemiology and Clinical Research 2007; Bowtell 2005). As a result of strong national support for multiple complementary HIV prevention strategies, Brazil's epidemic in the early part of this decade was half the size of projections based on infection trends in the late 1980s and early 1990s (Ministry of Health 2003). Analysis across multiple studies indicates that national implementation of evidence-based combination HIV prevention efforts in the 1990s was associated with a 50 to 90 percent decline in HIV incidence and prevalence in key populations (Auerbach 2006).
- COMMON ELEMENTS OF SUCCESS: According to the available evidence from these and other studies, effective strategies pursue a combination of behavior change approaches that are delivered

with sufficient coverage, intensity, and duration, and that are tailored to address the main drivers of HIV transmission in national epidemics. Effective HIV prevention addresses the specific needs and circumstances of the target population and aims to affect multiple determinants of human behavior, including individual knowledge and motivations, interpersonal relationships, and societal norms. Community engagement and strong political support have been key ingredients of successful national efforts to change behavior to prevent HIV infection.

## WHAT WE NEED TO LEARN

Although much evidence exists to demonstrate that it is possible to change human behavior to reduce the risk of HIV transmission, there are important gaps and limitations in what is known. There is also an inherent challenge in measuring the impact of any health effort that includes HIV prevention: measuring and determining causality for an event that did not occur (for example, an HIV infection averted) is intrinsically more complicated than evaluating an event or phenomenon that did happen. Some of the key limitations in what we know and areas in need of additional research follow:

• MOVING FROM EFFICACY TO EFFECTIVENESS:

- For both biomedical and behavioral interventions, it is often difficult to translate the impact seen in clinical trials (efficacy) into comparable results in the real world (effectiveness). Most clinical trials of behavioral HIV prevention programs have occurred in high-income countries, using intensive, professional program models that may not apply in more resource-limited settings or in different cultures. Few trials of behavior interventions have used such biological end points as incidence of HIV or sexually transmitted infections (STI), which potentially reduces confidence that behavior changes documented in clinical trials will have a public health impact in the real world.
- GENERALIZABILITY: Even where there is evidence of effectiveness in real-world settings, key questions remain about the transferability of these successes to other communities, subgroups, and types of epidemics (for example, high-prevalence, concentrated, etc.).

<sup>1</sup> The National Institutes of Health defines a randomized controlled trial as "a prospective experiment in which investigators randomly assign an eligible sample of patients to one or more treatment groups and a control group and follow patients' outcomes" (National Library of Medicine 2007).

 SUSTAINING BEHAVIOR CHANGE OVER THE LONG TERM: Few clinical trials for behavior interventions have followed participants for more than 12 months. Yet emerging evidence suggests that favorable behavior changes seen in individuals during the first year following exposure to a prevention intervention can fade over time (Coates In press). At the population level, positive behavior changes often fail to endure because these changes require a level of diligence-for example, consistent condom usethat is often difficult to maintain over the course of people's everyday lives and within their social contexts. In Uganda, Thailand, and many highincome countries, early prevention successes have been followed years later by marked increases in risk behavior, which underscores the difficulty of sustaining prevention gains. It can be particularly difficult to preserve prevention achievements in the face of changes in the underlying social or physical environment that make HIV seem less threatening.

#### • ASSUMPTIONS ABOUT INDIVIDUAL AGENCY:

Existing models of behavior interventions are often based on various cognitive behavioral theories that assume that individuals will take steps to avoid risks if they are fully informed and sufficiently motivated—that is, that they can exercise personal "agency" in the context of HIVassociated risk. Yet individual behavior is often heavily influenced by broader socioeconomic, cultural, and environmental factors. More validated program models are needed that affect social norms and institutions, although to date social and ethnographic research studies have not been sufficiently used to inform behavioral interventions.

 ONE-DIMENSIONAL EVALUATIONS: Few prevention trials have studied combinations of interventions, opting instead to evaluate the behavioral and epidemiological impact of discrete components of comprehensive HIV prevention strategies (for example, individual behavioral interventions, voluntary HIV testing and counseling, or condom promotion). This approach runs counter to actual prevention practice and the way people live their lives and make decisions, rendering it difficult to gauge the likelihood of success in the field when these individual approaches are combined with other prevention components. Often, national programs and donor initiatives have opted to support certain elements of a comprehensive prevention strategy while ignoring others, diminishing their impact on behaviors and HIV incidence (see Corno and de Walque 2007; Fiellin 2007).

### WHAT WE NEED TO DO-RECOMMENDATIONS

Significantly increasing the long-term effectiveness of HIV behavior change will require countries, donors, researchers, civil society, and other stakeholders to work together to expand the evidence base for HIV prevention—to address the limitations and gaps that still exist, while also putting available evidence to use in the most strategic manner possible. On the basis of the best available evidence, the Prevention Working Group recommends the following:

#### FOR NATIONAL AUTHORITIES AND

**GOVERNMENTS:** National political and public health leaders should develop and implement national AIDS strategies and operational plans that are tailored to the particular dynamics of national epidemics, integrate prevention and treatment services, and bring prevention interventions to a scale sufficient to have measurable impact. Countries scaling up medical male circumcision—and other new interventions that prove effective—should combine these efforts with complementary behavior interventions to avoid the increases in risk behavior that can occur when new strategies or tools are introduced.

- FOR INTERNATIONAL DONORS: Donors should commit to rapidly fund national HIV prevention programs that are tailored to national epidemics. Additionally, they should make available by 2010 at least U.S. \$11.9 billion annually to support scale-up of evidence-based HIV prevention programs as part of a comprehensive response to HIV. Donors should ensure robust financing for community-driven responses that build local civilsociety capacity and leadership (UNAIDS 2007).
- FOR TECHNICAL AGENCIES: Multilateral and other technical agencies should develop a mechanism to assess the soundness of national HIV prevention strategies, identifying instances where national plans conflict with available evidence about the dynamics of HIV incidence, or where selected prevention strategies are not based on evidence of what is effective with particular populations. Technical agencies should increase their assistance to countries in integrating social-research findings into national strategic planning. Improving national HIVinformation systems and their use in national planning should remain a priority for technical support.
- FOR HIV SERVICE PROVIDERS: Sponsors of HIV prevention programs should forge strong working partnerships with affected communities to ensure that programs are optimally tailored to

local circumstances and needs and are ethically conducted. Providers of HIV prevention services should integrate their efforts with other service systems, such as those for tuberculosis and sexual and reproductive health. Drug treatment programs should be adequately resourced to provide for the routine provision of HIV prevention services to their clients.

• FOR CIVIL SOCIETY: AIDS activists and other civil-society groups should strongly advocate for the simultaneous scaling up of HIV prevention and treatment. Civil-society groups should participate in the development of national HIV prevention targets, monitor national progress toward their achievement, and push for strategies that deliver evidence-based interventions to those populations most at risk of HIV infection.

• FOR HIV PREVENTION RESEARCHERS: Greater priority should be placed on social research to inform the design and delivery of prevention interventions, the adaptation of model programs to particular populations or settings, and the targeting and delivery of prevention services. Researchers and their funding agencies should increase their focus on basic research about the social drivers of HIV transmission, and the development and evaluation of community-level interventions, structural interventions, and prevention approaches for populations most at risk of HIV exposure. Additional research is required to assess the effectiveness of HIV prevention programs in the field and to develop and evaluate prevention models that prevent risk compensation in response to treatment or the introduction and uptake of new prevention technologies. Prevention trials should increase their use of biological endpoints, where possible and appropriate, and the length of time over which study participants are followed.

### CONCLUSION

Although much work remains to expand the evidence base for HIV prevention, this Prevention Working Group review argues for the urgency of scaling up programs to change behavior to prevent HIV infection. The evidence on behavior change HIV prevention cannot be overstated, but it also must not be overlooked. The central problem in HIV prevention is not lack of evidence but failure to bring to scale programming that addresses the major drivers of HIV infection in specific national settings. In the 21st century, pessimism about the real challenges ahead, or concern that we do not yet have all the answers, should not stop us from preventing the next HIV infection.

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# BEHAVIOR CHANGE AND HIV PREVENTION:

(Re)Considerations for the 21st Century

As HIV infection is invariably the result of human behavior, change in behavior has long been understood as essential to curbing the spread of infection. In all cases where national epidemics have been reversed, broad-based behavior changes were central to success.

Yet numerous questions and controversies have beset efforts to promote behavior change. Because of sensitivities associated with human sexuality and drug use, many political and opinion leaders have shied away from open, frank discussion of how to change behaviors to prevent transmission. Widespread hostility toward the populations at greatest risk for infection has further undermined support for HIV prevention, and efforts to change behavior have frequently become ensnared in bitter ideological disputes.

While the epidemic has expanded over the past quarter-century, some have questioned whether it is possible to accomplish marked and sustained changes in behavior sufficient to alter the epidemic's trajectory. The suggestion has been made that factors unrelated to prevention programming may account for the favorable behavior shifts seen in some countries. Moreover, recent years have witnessed an increase in risk behaviors in some settings where HIV prevention successes were first documented, calling into question the sustainability of favorable behavior shifts and highlighting the need for better understanding of how human behaviors might change in response to an ever-evolving epidemic.

In addition, HIV is no longer a new threat. There are doubts in some quarters about whether strategies or program models that may once have worked remain relevant in settings that have undergone important social and economic changes. Whether HIV prevention can remain effective as rates of HIV-related illness and death fall is a topic of debate in the HIV field. In addition, some commentators have argued that core HIV prevention strategies, such as condom promotion and treatment of sexually transmitted infections, are unlikely to significantly lower transmission rates in high-prevalence settings (see Potts 2008).

At the beginning of this decade, the global community embraced a set of ambitious development goals for the new millennium. Among these was the commitment to halt and begin to reverse the global HIV epidemic by 2015. Because behavior change remains the world's primary tool for achieving this goal, clarity is urgently required regarding the optimal means of producing needed behavior changes. In particular, clearer understanding is needed regarding the best strategies to reduce the number of new

HIV infections in hyperendemic settings, where modest favorable changes in individual risk behavior are likely to have only limited effect due to such structural factors as partnership concurrency and gender inequity that magnify transmission risks associated with low levels of risk behavior.

This latest report by the Global HIV Prevention Working Group (PWG) focuses specifically on behavior change, surveying the evidence for behavioral HIV prevention to identify what is known and not known about generating and sustaining behavior change. The report describes the elements of successful behavioral initiatives, the limitations of current approaches, key outstanding questions, and research needed to strengthen the evidence base for behavior change. It ends with suggested next steps for moving forward with a clear and more focused strategy for using behavior change in HIV prevention efforts.

Assessing the effectiveness of HIV prevention is intrinsically challenging. Understanding why something did not happen is typically more complicated than understanding an event or phenomenon that can be observed, studied, and measured. The totality of evidence, however, indicates that available HIV prevention strategies have the potential to significantly reduce the rate of new HIV infections—in all regions, among diverse populations, and at different stages of national epidemics.

Indeed, available strategies have the capacity to achieve in the field of HIV prevention what antiretrovirals have accomplished in the clinical setting, as the parallels between HIV prevention and treatment are striking. Like antiretroviral therapy, HIV prevention is lifelong, and its impact must be continually monitored and the prescribed regimens revised as circumstances and needs change. Just as a single pill cannot eradicate HIV, one-shot prevention efforts will not achieve the magnitude or sustainability of behavior change required to alter the epidemic's course.

Like treatment, effective HIV prevention requires a combination of strategies. Evidence-based approaches to prevent infection include programs targeting individual behavior; broad-based efforts to alter social norms and address the underlying drivers of the epidemic; and effective use of biomedical or technological tools, such as treatment of sexually transmitted infections (STIs), medical male circumcision, substitution therapy for chemical dependence, and programs that provide access to clean injecting equipment.

### BEHAVIOR CHANGE FOR HIV PREVENTION

Behavioral HIV prevention programs can target individuals, families, communities, entire societies, or (ideally) a combination of all these. Welldesigned programs seek to achieve results on multiple levels. They promote accurate individual knowledge and perception of risk and increase individual motivation to avoid risky behavior. Prevention programs also build individual skills needed to use prevention commodities properly and, to the extent feasible, to avoid or effectively negotiate risky situations. Within households, HIV prevention programs aim to decrease the stigma associated with both HIV and sexuality, to promote open discussion about sexuality and drug use, and to influence gender roles and norms. At a community level, effective programs seek to increase the value associated with safer behaviors, to support community members to reduce their risk, to build social solidarity and reciprocity, and to reinforce new norms.

Behavioral HIV prevention programs may also seek to achieve results at a broader social or structural level. Such approaches might include direct interventions that introduce prevention tools into particular environments (for example, mandating condom use in brothels), influence the physical environment (improving street lighting to reduce the likelihood of rape), expand clinical services (ensuring access to drug substitution therapy for chemical dependence), or create more supportive legal and policy norms (legalizing samesex relations). Social or structural interventions might also be indirect, by supporting broader efforts to improve the overall protection and promotion of human rights, to reduce income inequality, and to address gender inequities.

Individuals and groups might change behaviors in any number of ways—including some that may be detrimental to the cause of HIV prevention. When this report refers to behavior change, it intends to encompass only the range of behavior changes that reduce the risk of HIV transmission or otherwise promote the development of social, physical, and legal environments that are conducive to risk reduction. Like treatment, HIV prevention works best when it addresses individual needs and circumstances. In the case of treatment, different patients have different therapeutic needs and respond differently to therapy. Children and adults living with HIV require different doses of antiretroviral medications, and patients' response to a particular regimen will depend in part on whether they have been exposed to any of the prescribed medications, and whether clinicians take care to avoid certain regimens for patients who have specific comorbidities. Likewise, effective HIV prevention acknowledges the complexities and needs of specific individuals and communities, eschewing cookie-cutter approaches that ignore the diversity of needs in the real world.

Comparable to treatment, HIV prevention will have an effect only if it reaches those who need it. Just as concerted global efforts have led to dramatic increases in access to antiretrovirals, similar efforts are required to bring evidence-informed HIV prevention approaches to scale. And as robust research efforts point the way toward newer classes of antiretrovirals, substantially stronger research is needed to address the gaps and limitations in existing prevention strategies.

To be more effective in the 21st century, the HIV prevention effort must confront several challenges of perception: a misplaced pessimism about the effectiveness of behavioral HIV prevention strategies; the unfortunate confusion between the difficulty in changing human behavior and the inability to do so; and the misperception that just because it is inherently difficult to measure prevention success—a "nonevent"—prevention efforts have no impact.

## THE CONTINUING URGENCY OF HIV PREVENTION

In December 2007, UNAIDS and the World Health Organization (WHO) released updated estimates of prevalent and incident HIV infections worldwide. In 2007, an estimated 33.2 million people were living with HIV, approximately 2.5 million people became infected, and 2.1 million people died (UNAIDS and WHO 2007). These estimates represent notable downward revisions of estimated global HIV prevalence and incidence. Based on the best available evidence, it now appears that the global epidemic stabilized in the late 1990s and that the annual number of new infections may have since modestly declined.

Yet the dimensions and pace of the epidemic remain staggering. The news is especially dire in southern Africa, where little progress in curbing the rate of new infections has occurred outside Zimbabwe. HIV infections continue to increase in a number of countries, including China, Indonesia, Mozambique, Russia, Ukraine, Vietnam, and several high-income countries.

The most recent evidence regarding the state of the global HIV epidemic leads to several conclusions:

- HIV PREVENTION REMAINS ONE OF THE WORLD'S MOST IMPORTANT PRIORITIES. While substantial media attention focused on the lowering of global estimates of HIV prevalence as a result of improved epidemiological methods, the levels of infection and the human toll from the epidemic remain unacceptably large. A virus that was unknown 30 years ago is the fourth leading cause of death globally (WHO 2003).
- THE HIV EPIDEMIC CONTINUES TO EXPAND, AND TREATMENT ALONE WILL NOT REVERSE

IT. Because the number of new infections exceeded the number of AIDS deaths, the epidemic further expanded in 2007. The number of new infections was 2.5 times greater than the increase in the number of HIV-infected individuals on antiretroviral therapy, underscoring the urgent need for more effective HIV prevention to preserve the future viability of treatment initiatives (U.N. Secretary-General 2008).

- IN SUB-SAHARAN AFRICA, WHERE THE HIV BURDEN IS HEAVIEST, PROGRAMS FOCUSING ON INDIVIDUAL RISK BEHAVIOR ARE UNLIKELY ON THEIR OWN TO ACHIEVE THE LEVEL OF SUCCESS NEEDED TO REVERSE THE EPIDEMIC. More than two out of three infections worldwide are in sub-Saharan Africa (UNAIDS and WHO 2007). Although individual behavior change programs and initiatives that target groups at highest risk retain an important place in the region's HIV prevention continuum, meaningful reductions in HIV prevention levels will require major population-wide changes in social norms with regard to sexual and relationship norms and gender equity (see U.N. Secretary-General 2008).
- IN MOST COUNTRIES OUTSIDE SUB-SAHARAN AFRICA, PREVENTION EFFORTS SHOULD FOCUS ON POPULATIONS AT HIGHEST RISK OF INFECTION. Low national HIV prevalence frequently masks extremely high infection rates in key populations. In Latin America, for example, where HIV prevalence is below 1 percent, an estimated one-third of men who have sex with men (MSM) are HIV-infected (Baral 2007). Similarly high infection

rates are reported for sex workers, injection drug users (IDUs), prisoners, mobile populations, and other vulnerable groups. Although HIV is unlikely to become generalized in most countries with low overall HIV prevalence, the rapid spread of HIV in Russia, Ukraine, Indonesia, and other countries is of grave concern. Preventing new infections in the most heavily affected populations represents a pressing public health and humanitarian imperative.

### • BEHAVIOR CHANGE REMAINS THE DRIVING FORCE FOR NATIONAL SUCCESS AGAINST HIV.

Clinical trial results in 2007 suggest that the timeline for major technological breakthroughs in the HIV prevention field is likely to be long. Trials of the most promising HIV vaccine candidate were terminated in September 2007 due to lack of efficacy, and similarly disappointing results have recently been reported for early-generation microbicides (Nelson 2007), female diaphragms (Padian 2007), and community-wide treatment for herpes simplex virus 2 (Watson-Jones 2008). Behavior change remains the primary tool for reversing national epidemics, as illustrated by recent experience in Zimbabwe, where population-wide changes in sexual behavior have resulted in marked declines in HIV prevalence and incidence (UNAIDS 2005a).

The countries most heavily affected by the epidemic have waited many years for signs of a decline in the number of new HIV infections, and emerging evidence of a modest fall in incidence over the last decade should be greeted with relief and optimism. Declining incidence, however, must not lull decision-makers or individuals at risk into believing that the epidemic is nearing extinction. While some epidemics expand, peak, and then decline into oblivion, this is not always the case, especially for sexually transmitted epidemics. The HIV epidemic has repeatedly upset authoritative projections, and additional surprises are likely. Disturbing increases in risk behaviors in Uganda and many high-income countries underscore the risk in relaxing prevention efforts following early signs of success.

# THE EVIDENCE BASE FOR BEHAVIOR CHANGE FOR HIV PREVENTION

The scientific literature and documented national experience clearly demonstrate the effectiveness of HIV prevention in changing sexual and drug-using behaviors (see Prevention Working Group 2007). Notwithstanding the strong evidence base for HIV prevention, policy makers and affected communities still express a need for such information and/or misunderstand what is known.

### EFFECTIVE HIV PREVENTION IN HYPERENDEMIC SETTINGS

In countries with low HIV prevalence, most people are at low risk of contracting HIV even when engaging in unprotected sex. In such settings, the basic approach to HIV prevention is clear: concentrated HIV prevention for groups at elevated risk of infection, attention to potential epidemiological "bridges" between the general population and populations most at risk, and education, awareness, and anti-stigma measures for the population as a whole.

In hyperendemic settings,<sup>2</sup> where high levels of HIV are present throughout the general population, even low levels of risk behavior often carry substantial risk of infection. In sub-Saharan Africa, at least 15 percent of the adult population in seven countries is infected. In such settings, the risk that one's spouse will be HIV-infected, or that young people will encounter the virus the first time they have sex, can be considerable. Where the risk of infection is omnipresent, the discrete aims of HIV prevention in low-prevalence settings are not sufficient.

In hyperendemic countries, nothing short of countrywide mobilizations will sufficiently address the epidemic's threat. Where HIV is generalized, every workplace, school, and community setting must be used for intensive HIV prevention activities. HIV must become a natural and central topic of discussion, and new societal norms must be forged regarding gender relations and sexual behavior.

This section of the report summarizes the most recent available evidence on effective strategies for changing behaviors in order to prevent HIV, examining evidence on behavioral interventions derived from both clinical randomized controlled trials (RCTs) and observational epidemiology.

<sup>&</sup>lt;sup>2</sup> Technically, HIV does not fit the usual epidemiological definition of a "hyperendemic disease," in that it does not affect all age groups equally, even in the most heavily affected areas. The term, however, is convenient as a way to denote a country where HIV is widely prevalent throughout the general population. UNAIDS considers countries to be hyperendemic if their adult HIV prevalence exceeds 15 percent.

### PRIORITIZING BEHAVIOR CHANGE AS NEW PREVENTION TOOLS ARE INTRODUCED

The distinction commonly made between behavioral and biomedical tools for HIV prevention is a false one. Not only do behavior change programs depend on the existence of essential technologies—such as condoms, clean injecting equipment, and HIV testing kits—but biomedical tools will have limited impact in reducing new infections in the absence of supporting behaviors. The emergence of new biological tools to reduce the risk of HIV transmission offers potential opportunities to improve understanding of human behavior with respect to health-seeking and adoption of new health technologies.

Medical male circumcision is an example of the synergistic relationship between behavior change and biomedical prevention. Recent studies in Africa indicate that the surgical procedure can help reduce the risk of female-to-male HIV transmission by as much as 60 percent (Bailey 2007; Gray 2007; Auvert 2005). As a result of these findings, medical male circumcision is now regarded as a core evidence-based HIV prevention strategy, with particular potency in the countries most heavily affected by the epidemic. The effectiveness of adult medical male circumcision depends, however, on appropriate behavioral responses to this potentially powerful new intervention. At-risk men must be persuaded to undergo the procedure, health-care providers and traditional practitioners must be convinced and properly trained to ensure the safety of the procedure, and men should avoid engaging in sexual intercourse before circumcision wounds are completely healed, before which the risk of HIV transmission may actually be accentuated.

# What Is the Best Way to Measure the Effectiveness of HIV Prevention?

Assessing the effectiveness of HIV prevention programs is inherently difficult. As a threshold matter, determining what caused an event to never occur is intrinsically more complicated than discerning the cause of something that can be readily observed. In some countries where HIV prevalence has remained low, it is likely that HIV prevention played a role in promoting safer behaviors. With the exception of Senegal, however, where early adoption of strong prevention measures and a high rate of medical male circumcision appear to have averted a potentially serious epidemic (see UNAIDS 2001), efforts to ascribe continued low HIV incidence solely to prevention programming are not substantiated. For drugs, vaccines, and medical devices, the RCT is universally regarded as the gold standard for evaluating efficacy in a new product. Indeed, national regulatory authorities require clear evidence of a product's safety and efficacy in RCTs before it can be approved for marketing.

RCTs have similarly demonstrated the efficacy of a wide range of individual and small group interventions in reducing risky sexual and drug-using behaviors (Lyles 2007; CDC 2001a). As explained below, however (see page 17), demonstration of efficacy under the controlled conditions of a clinical trial does not ensure that the same intervention will be effective in the real world, especially with respect to behavioral interventions that may be highly sensitive to social environment and to differences in the target population.

Moreover, while RCTs will continue to have a role in HIV prevention research, especially with regard to the development of new prevention technologies, it is unclear whether such trials best gauge the effectiveness of behavioral interventions. RCTs are primarily a vehicle for evaluating biomedical interventions, rather than strategies to change human behavior. Altering the norms and behaviors of social groups can sometimes take considerable time, and such shifts may be difficult to capture by time-limited studies. In addition, quantifying the social effects that may ultimately contribute to broadbased behavior changes may be difficult, and sometimes even impossible.

To discern strategies that are effective, observational data on national responses and epidemiological or behavioral impact often provide the best information (see Hallett 2007). Observational data are intrinsically more difficult to interpret than RCTs and cannot tie behavioral or epidemiological trends to particular actions. However, carefully studying national responses and contemporaneous behaviors helps clarify the array of factors that appear to contribute to population-wide shifts in behaviors.

### Randomized Clinical Trials: Changing Individual Behavior<sup>3</sup>

Researchers have conducted clinical trials on a wide range of individual and small group interventions targeted to particular populations. Most such studies have been conducted in high-income countries and have involved interventions grounded in one or more cognitive behavioral theories.

A review of sexual risk reduction interventions found that all meta-analyses that examined condom use detected a significant increase in usage, and most studies also found a reduction in the incidence of unprotected sex. Among meta-analyses<sup>4</sup> that studied the impact of interventions on the number of sex partners, fewer than half found a significant reduction. Most studies that tracked incidence of STIs detected a significant reduction following the behavioral intervention, although one-third found no significant effect (Noar 2008).

On the basis of peer-reviewed publications through 2004, the U.S. Centers for Disease Control (CDC) identified 42 prevention models demonstrated to be efficacious in welldesigned studies (Lyles 2007; CDC 2001a). In each of the studies accepted by the CDC, trial participants exposed to the prevention model exhibited significant reductions in HIV risk behaviors in comparison with unexposed participants. Nineteen of the 42 "best practice" models identified by the CDC target heterosexual adults, 11 focus on young people, 10 aim to reduce risk behaviors of IDUs, and eight target MSM. Four of the most recent behavioral prevention models are specifically designed to reduce risky behaviors among people living with HIV.

Meta-analyses have similarly found evidence of efficacy for behavioral models targeting populations at highest risk:

- YOUNG PEOPLE: Among 22 studies of school-based prevention education programs in low- and middleincome countries, 16 were determined by WHO and others to significantly delay sex, reduce frequency of sex, reduce number of partners, increase use of condoms or contraceptives, and decrease frequency of unprotected sex (WHO 2006).
- MEN WHO HAVE SEX WITH MEN: A meta-analytic review of well-designed studies of behavioral models targeting MSM in high-income countries found that

### HIV PREVENTION EFFECTIVENESS: THE EVIDENCE FROM CLINICAL TRIALS OF NEW PREVENTION TECHNOLOGIES

In prevention trials, participants receive extensive state-of-the-art HIV prevention services, including HIV education, client-centered counseling, HIV testing, screening and treatment of sexually transmitted infections, and essential HIV prevention commodities, such as male and female condoms. Prevention messages are periodically reinforced, and receipt of standard prevention services is assured as long as the trial continues.

Researchers have long noted the remarkable effectiveness of HIV prevention in clinical trial settings. Indeed, due to the impact of HIV prevention services in lowering HIV incidence, it is widely agreed that future prevention trials may need to be much larger than in the past in order to have sufficient statistical power.

This was recently quantified by investigators in the previously referenced MIRA trial, which found that the combination of a female diaphragm and lubricant provided no additive prevention benefit beyond condoms (Padian 2007). Interviews with trial participants conducted 14 months following participation documented the impact of ongoing receipt of HIV prevention services. While 82 to 84 percent of sex acts involving MIRA trial participants involved use of a condom during the study, only 57 percent of such acts were protected 14 months after trial participation. Whereas 64 to 67 percent of study participants reported consistent condom use during the trial, barely one-third (35 percent) regularly used a condom 14 months after the trial (Padian 2008).

Experience in clinical trials demonstrates that the regular delivery of evidence-based HIV prevention services is highly effective in changing individual behavior. While it may not be feasible to replicate the intensity of prevention services in most non-trial settings, the record in the prevention research field indicates that greater investment in evidence-based prevention services would yield favorable behavioral results.

<sup>&</sup>lt;sup>3</sup> The National Institutes of Health defines a randomized controlled trial as "a prospective experiment in which investigators randomly assign an eligible sample of patients to one or more treatment groups and a control group and follow patients' outcomes" (National Library of Medicine 2007).

<sup>&</sup>lt;sup>4</sup> Meta-analyses analyze multiple studies to assess key findings across a large body of data and to discern the weight of scientific evidence on a particular question.

### HIV PREVENTION IN THE ERA OF EXPANDED TREATMENT ACCESS

Although each episode of HIV transmission requires the participation of an individual living with HIV, prevention efforts have historically focused on individuals who are HIV uninfected or unaware of their HIV serostatus. This represents a significant gap in prevention efforts, because people living with HIV have a potentially critical role to play in reducing the risk of HIV transmission.

Including people living with HIV in prevention efforts offers a potentially important avenue to further bolster the effectiveness of HIV prevention. In high-income countries, where combination antiretroviral therapy has been widely available for more than a decade, notable efforts have been made to develop and implement prevention programs specifically tailored for people living with HIV. According to early studies, such "positive prevention" programs show promise in promoting safer behaviors among HIV-infected people (Crepaz 2006).

As HIV testing initiatives expand, especially in developing countries where HIV treatment access is on the rise, knowledge of HIV serostatus will become more widespread, potentially permitting better serostatus targeting of prevention messages and programs. HIV clinical settings offer an especially important venue for the delivery of HIV prevention services for people living with HIV (Prevention Working Group 2004).

MSM-targeted prevention programs reduced the odds of reported unprotected anal intercourse by 27 to 43 percent. Group-level interventions increased the chances of condom use by 81 percent among MSM studied (Herbst 2007).

• SEX WORKERS: A meta-analysis of 62 well-designed evaluation studies (44 from sub-Saharan Africa and 18 from Asia) found that behavioral models targeting sex workers significantly increased condom use with clients, although these programs had only limited impact on condom use with casual partners. The prevention models had no significant effect on condom use in marital or steady relationships, except in the case of couples in which one partner had been diagnosed as HIV positive (Foss 2007). • INJECTION DRUG USERS: In a meta-analysis of data on IDUs in New York City, researchers determined that nonparticipants in harm-reduction programs were 3.5 times more likely to become HIV-infected than participants (DesJarlais 1996). Multiple studies conducted in resource-limited settings have confirmed the public health benefits of harm reduction programs (Institute of Medicine 2006; Wodak and Conney 2006). Numerous behavioral models have demonstrated efficacy in reducing HIV risk behaviors among IDUs (Lyles 2007; CDC 2001a), although such programs have had greater success in influencing drug-using behaviors than in altering sexual risk behaviors of IDUs (see Lindenburg 2006). An analysis of study results on 33 different behavioral models targeting IDUs found that individuals exposed to such interventions were 12.6 percent more likely to reduce risk behaviors (Semann 2002). Receipt of drug substitution therapy or other drug treatment also reduces drug-using behavior and lowers the risk of HIV transmission (Zaric 2000).

### Observational Epidemiology: Evidence of National Success

Countries in diverse regions and of different income levels have markedly lowered the rate of new HIV infections. In all such cases, favorable epidemiological trends were the result of major shifts in human behavior.

- AUSTRALIA: Much sooner than the United States and some other high-income countries, Australia mounted a visible, well-supported national AIDS response beginning in the early 1980s. Early initiatives included broad public-awareness campaigns, focused behavioral interventions for gay men, public-sector support for needle and syringe exchange, and voluntary HIV counseling and testing (Bowtell 2005). Dramatic declines in unprotected anal intercourse and the sharing of needles for drug use were recorded (National Centre in HIV Epidemiology and Clinical Research 1995). As a result of Australia's early, comprehensive response, focused largely on behavior change, annual HIV incidence peaked in 1985 and declined through the end of the 1990s. Between 1990 and 2000, the annual number of new HIV diagnoses fell by half (National Centre in HIV Epidemiology and Clinical Research 2007).
- BRAZIL: Like Australia, Brazil encouraged open discussion of HIV, supporting frank public-awareness campaigns, condom promotion, focused behavioral interventions, syringe and needle exchange, schoolbased HIV education, prevention services in prisons, and voluntary HIV counseling and testing. Especially noteworthy is Brazil's success in reversing a serious epidemic among IDUs. Condom use increased by almost 50 percent among sexually active adults between 1998 and 2005, and focused behavior change

# BEHAVIORAL INTERVENTIONS TO ENHANCE THE SUCCESS OF PROGRAMS TO PREVENT MOTHER-TO-CHILD HIV TRANSMISSION

Implementation of a package of prevention services—including routine voluntary HIV testing and counseling, timely antiretroviral prophylaxis, and breast-feeding alternatives—has sharply lowered the rate of mother-to-child HIV transmission in highincome countries. In 2006, only 13 children were diagnosed with HIV in New York City (New York City Department of Health and Mental Hygiene 2007), while in the same year only 191 children contracted HIV infection in all of western Europe (EuroHIV 2007).

Considerable progress has also been achieved in the past two years in expanding access to prevention services in antenatal settings in low- and middleincome countries. Globally, the percentage of HIVinfected pregnant women who received antiretroviral prophylaxis rose from 14 percent in 2005 to 34 percent in 2007. In a number of countries—including the Bahamas, Botswana, and Thailand—coverage now exceeds 80 percent. In Botswana, the provision of evidence-based prevention services in antenatal settings has lowered the transmission rate for newborns born to HIV-infected mothers from 30 to 40 percent to under 4 percent (U.N. Secretary-General 2008).

While remarkable, these gains are not uniformly evident. Global coverage, for example, is well shy of

prevention programs also maintained HIV prevalence at low levels among sex workers (Okie 2006). Although the World Bank had predicted in 1990 that 1.2 million Brazilians would be infected by 2000, fewer than 600,000 were living with HIV in 2002 (Ministry of Health 2003).

• THAILAND: In response to an increase in infections in the late 1980s, Thailand initiated an innovative national program that has served as a model for other countries. The country's 100 percent condomusage program promoted condom use in brothels, and national leaders encouraged discussion of the HIV threat and the fair treatment of those who were infected (UNAIDS 2001). As a result of the country's energetic support for HIV prevention, condom rates increased, while the percentage of men visiting brothels declined. Annual HIV incidence declined from 143,000 in 1991 to 19,000 in 2003, helping reverse what was once one of the world's fastest-growing epidemics. Had Thailand not brought comprehensive HIV prevention to scale, it would now have 7.7 million HIV infections, rather than the estimated 580,000

the 80 percent target to which U.N. member states agreed in the 2001 Declaration of Commitment on HIV/AIDS, which was unanimously endorsed at the first-ever U.N. General Assembly Special Session on HIV/AIDS.

Although prevention of mother-to-child transmission relies in large part on a biomedical intervention (antiretroviral prophylaxis), human behavior is essential to prevention success. Prevention efforts depend on health-care workers to routinely offer testing to their patients in antenatal settings and on pregnant women to accept HIV testing, adhere to prophylactic regimens (both for themselves and for their newborn), adopt recommended procedures for infant feeding (typically exclusive breastfeeding for a short period), and return their infants for follow-up testing and monitoring.

Primary HIV prevention for women is also central to the long-term success and sustainability of prevention of mother-to-child transmission. The Elizabeth Glaser Pediatric AIDS Foundation, which provides services to prevent mother-to-child transmission at 2,800 sites worldwide, reports that HIV prevalence among pregnant women has steadily declined in most of the 13 African countries studied (Amouzou 2007).

residents currently living with HIV (Ravenga 2006; UNAIDS 2006).

• UGANDA: In what is perhaps the world's bestdocumented national prevention success, Uganda moved in the mid-1980s to address the rapid spread of HIV, implementing public-awareness campaigns that encouraged young people to delay initiation of sex and urged sexually active adults to reduce the number of sex partners. In the 1990s, the country supplemented these early measures with condom promotion and investment in voluntary counseling and testing. From the earliest years, community-generated programs played a major role in the country's AIDS response. The results of these efforts were remarkable. The percentage of young people who were sexually active fell by more than half between 1989 and 1995, and Ugandans were significantly less likely to have multiple sex partners than people living in neighboring countries (UNAIDS 2001). Increases in condom use in the 1990s helped preserve and accelerate early prevention gains (USAID 2002). By the late 1990s,

infection levels in capital city Kampala had fallen by two-thirds, and national HIV prevalence had been cut in half (UNAIDS 2002). $^5$ 

These countries are not alone in the progress they have achieved in reducing new HIV infections through broadbased behavior change. Cambodia, Zimbabwe, and others have seen similar declines in HIV prevalence following significant shifts in sexual behaviors. In the case of Senegal, early investment in awareness-raising, condom promotion, intensive prevention services for populations at greatest risk, and engagement of community leaders and faith-based organizations, combined with high rates of medical male circumcision, succeeded in keeping national HIV prevalence below 1 percent, when neighboring countries experienced significant increases in infections (UNAIDS 2001).

Unlike controlled efficacy trials, observational epidemiology cannot definitively establish a causal link between HIV prevention and declines in new HIV infections. Yet together, these examples suggest that countries in a wide variety of settings have contributed to changes in HIV risk behaviors and, in doing so, have saved countless lives by averting HIV transmission. Based on the totality of epidemiological evidence, it appears that national implementation of evidence-informed combination HIV prevention efforts in the 1990s was associated with a 50 to 90 percent decline in HIV incidence and prevalence in key populations (Auerbach 2006).

### What Available Data Say: Common Attributes of Successful Behavioral Prevention Programs

The record on effective HIV prevention, as derived primarily from national experience but also supported by RCTs on discrete interventions, reveals that successful programs share certain basic characteristics:

• **COMBINATION PREVENTION:** Effective HIV prevention involves the simultaneous use of diverse

prevention strategies—programs that help individuals prevent transmission, broader-based initiatives that alter the norms and behaviors of social groups, and increased access to tools that reduce the biological likelihood of transmission (for example, STI treatment and medical male circumcision).<sup>6</sup>

- ENSURING PROPER SCALE: To achieve optimal public health impact, the appropriate combination of evidence-based HIV prevention strategies must achieve sufficient coverage, intensity, and duration to have optimal public health impact.
- AFFECTING KNOWLEDGE, ATTITUDES, PRACTICES, AND BEHAVIORS: Accurate knowledge about HIV, although critical, often does not lead on its own to sustained behavior change. Effective HIV prevention helps individuals perceive whether they might be at risk for HIV, increases the motivations and intentions to reduce risk, and builds the skills required to enable individuals to protect against transmission.
- CHANGING SOCIAL NORMS: Effective HIV prevention addresses the social dynamics that influence individual behavior. In places where changes in community norms have occurred to promote HIV prevention, diverse strategies appear to have played a role in the favorable results. These include social marketing; mass-media campaigns, use of celebrities, faith-based groups, and opinion leaders to promote new norms; and other interventions designed to operate at a community level.
- ENSURING ACCESS TO HIV PREVENTION TECHNOLOGIES AND COMMODITIES: Globally, prevention efforts have prioritized ready access to condoms, while focused prevention efforts for drug users have facilitated the provision of sterile injection equipment. In the case of condoms, extensive marketing efforts have promoted them and addressed potential impediments to use, such as the perception that sex is no longer enjoyable when condoms are used.
- SPECIFICITY TO CONTEXT: Efforts to change behavior will be successful only if they resonate with the intended audience and address the specific needs and values of the focus population. While it is possible to distill certain principles from diverse experience globally, and is sometimes feasible to adapt model programs in diverse settings, experience teaches

<sup>&</sup>lt;sup>5</sup> For a discussion of more recent, less favorable epidemiological and behavioral trends in Uganda, see p. 18.

<sup>&</sup>lt;sup>6</sup> Use of a combination of prevention strategies is common to most successful health promotion efforts, including those not focused on HIV prevention. For example, recent research has found that malaria prevention uptake is greater when free bed-net distribution is supported by social marketing (Fegan 2007). With respect to injury prevention, declines in incidence occurred following the implementation of a combination of measures, including public awareness campaigns, initiatives to change social norms, and policy initiatives to regulate or prohibit unsafe behaviors and to improve safety engineering of products or environments (see Wohlfeiler and Ellen 2007).

The history of antismoking campaigns in high-income countries is similarly illustrative. In the United States, for example, a broad array of strategies have been pursued to reduce tobacco intake: extensive public-awareness campaigns in the mass media, school-based antismoking programs, concerted efforts to alter social norms and attitudes regarding smoking, policy changes (for example, prohibiting or regulating smoking in public places, increasing cigarette taxes), technological innovations (for example, nicotine replacement therapies), and litigation to hold cigarette companies accountable for the medical expenses associated with smoking. These strategies have combined to reduce by more than half the percentage of adults who smoke tobacco products over the last 40 years (CDC 2007). While few would claim or expect that any element of this decades-long public health initiative was single-handedly responsible for the dramatic decline in smoking in the United States, this has often been the methodological approach taken to date with respect to measuring the impact of behavioral HIV prevention.

that prevention efforts need to be specific to the geographic and social context in which risk behavior occurs (UNAIDS 2005b).

In addition to these program characteristics of successful HIV prevention efforts, national experience has underscored the importance of certain environmental factors that contribute to the effectiveness of prevention programs:

- COMMUNITY LEADERSHIP: To produce strong and sustained behavior change, communities must own the response and help lead efforts to change behavior (Campbell 2003; see Barnett and Whiteside 2006; Bowtell 2005). In the countries where HIV prevention has been most successful, communities have been active participants in the development, implementation, and oversight of prevention efforts.
- POLITICAL LEADERSHIP: Few countries have substantially lowered HIV infection rates without strong, sustained, and high-level political leadership. Leadership from the highest political levels helps attract needed resources for prevention efforts and encourages the engagement of multiple ministries and sectors in the HIV response.
- ENCOURAGING OPEN DISCUSSION OF HIV: Where population-based behavior changes have driven longterm declines in HIV infection, the epidemic has been a topic of open discussion and debate (UNAIDS 2001). Bringing HIV into the light of day enables individuals to perceive their own risk and facilitates the development of new social norms.
- **RESPECTING HUMAN RIGHTS AND ALLEVIATING HIV STIGMA:** In countries with successful HIV prevention records, lawmakers have enacted strong legal protections against HIV-based discrimination (see Okie 2006; UNAIDS 2001). Respecting the human dignity of the target population is especially critical in reaching socially marginalized groups with effective HIV prevention services (Campbell 2003). Basing HIV prevention efforts in human rights encourages frank discussion of HIV, engagement in HIV prevention activities, and knowledge of HIV serostatus.

## LIMITATIONS TO EVIDENCE BASE AND IMPLEMENTATION OF BEHAVIORAL HIV PREVENTION

Although evidence demonstrates that it is possible to change human behavior to reduce the risk of HIV transmission, the evidence base on behavioral HIV prevention has important limitations. Policy makers and program implementers should take these limitations into account, especially when selecting strategies to implement in concert with specific behavioral strategies.

### Translating Efficacious Prevention Models Into Effective, Broad-Based Programs

The difficulty of ensuring that efficacious interventions are effective in the real world is not unique to behavioral strategies. Even for well-characterized biomedical interventions, it is sometimes difficult to replicate in the field the degree of success achieved in clinical trials.<sup>7</sup>

RCTs for behavioral program models typically fail to replicate the conditions under which such services will be delivered in the real world. For example, most RCTs recruit only from populations that are carefully defined, yet the universe of individuals at risk of HIV infection is extraordinarily diverse. Comparatively few behavioral models have been validated in RCTs for use in many of the populations at highest risk, including IDUs, MSM, and sex workers.<sup>8</sup> The poor correlation between behavioral RCTs and the real world reduces the confidence of program planners in basing prevention strategies on the scientific literature.

Moreover, many of the behavioral models validated in RCTs cannot feasibly be implemented in most settings. Among the CDC's "best practice" models, program protocols provide for as many as eight sessions, with time commitments for participants ranging up to 32 hours,

<sup>&</sup>lt;sup>7</sup> There are many reasons for the gap between the results of clinical trials and experience in the field for therapeutic interventions. Clinical trial participants often receive a level of care and support that is seldom achieved in busy real-world health-care settings, potentially affecting treatment adherence, side effect management, and patient motivation. Moreover, RCTs may fail to attract participation by a large number of individuals who experience problems that may interfere with protocol adherence, such as active substance addiction, acute mental illness, and homelessness.

<sup>&</sup>lt;sup>8</sup> Moreover, especially when the worldwide breadth of the epidemic is noted, it is apparent that key populations that appear unitary for epidemiological purposes are sociologically quite diverse. Interventions whose efficacy has been validated for MSM in Amsterdam or San Francisco, for example, may be wholly inapplicable in settings where same-gender sexual expression is more highly stigmatized and is the subject of severe criminal penalties. Similarly, interventions that aid opiate users to alter risky drug-using behaviors may be entirely ineffective for individuals who are dependent on stimulants. And brothel-based behavioral interventions for sex workers may be ineffective—and perhaps entirely unfeasible—for sex workers who do not work in brothels.

### DOCUMENTING AND BUILDING ON INDIGENOUS HIV PREVENTION SUCCESSES

In countries throughout the world, some of the most important prevention successes have been achieved by communities themselves, often working without external funding, institutional support, or strong partnerships with researchers. In the United States, for example, evidence indicates that radical behavior changes among MSM began occurring in the early 1980s, years before public funding was available for HIV prevention services in urban gay communities (see Vu 2002). While the Cambodian government has rightly been lauded for its leadership in implementing evidence-informed HIV prevention strategies, studies similarly suggest that behavior changes and declines in HIV incidence began prior to these actions by public health activities (Morineau 2006).

Community engagement is critical to creating broad-based demand for HIV prevention services. In every country in which HIV incidence has sharply declined, prevention efforts have been built on community mobilization and leadership (see Piot In press).

The indigenous community dynamics that promote leadership and innovation in HIV prevention are poorly understood. As a general rule, prevention researchers and public health authorities have directed only limited effort toward documenting and studying community-developed risk reduction strategies, opting instead to focus research resources on researcher-developed, theory-based behavioral interventions. This represents an important step in prevention research efforts.

inherently limiting the number of individuals at risk who are willing to seek and complete the intervention (see Lyles 2007; CDC 2001a). The cost per infection averted for such high-intensity prevention programs may render them unaffor urden countries

### Sustaining Behavior Change Over the Long Term

Few RCTs have followed recipients of behavioral HIV prevention models longer than 12 months, with many

studies reporting follow-up periods as short as three months (see Lyles 2007; CDC 2001a). Emerging evidence, however, suggests that favorable behavior changes seen in the first year following an intensive behavioral intervention might not be sustained.

For example, trials of 10-week individualized counseling for MSM initially found significant behavioral benefits, as well as reduced HIV incidence, as a result of the intervention. Yet after 3.25 years, recipients of the program did not differ significantly from the control group with respect to HIV incidence. Analysis determined that initially favorable behavior changes dissipated after 12 to 18 months, with the earlier beneficiaries of the program eventually reverting to riskier behaviors (Coates In press).

Population-level behavior changes also sometimes fade over time. In Uganda, the single most impressive success story in forging new social norms and behavior patterns for HIV prevention, recent surveys have detected an increase in sexual risk behavior (UNAIDS 2007). Among MSM in the United States, dramatic changes in sexual behavior and similarly sharp declines in HIV incidence occurred in the 1980s following the implementation and strengthening of community-based HIV prevention efforts (see CDC 2006), yet rates of both unprotected anal intercourse and new HIV infections have notably increased among American MSM (Task Force on Community Preventive Services 2007).

There are many reasons why initial HIV prevention success in a country or population might not be sustained. Prevention efforts may not be reinforced or adapted over time, and the targets of prevention programs may develop "prevention fatigue," making them less inclined to heed prevention messages and take appropriate precautions against the risk of transmission. Perhaps most important, individuals who are initially influenced by prevention programs are replaced over time by new population cohorts, who were not exposed to early prevention efforts and whose values, expectations, and social surroundings may be quite different.

In addition, changes may occur in the underlying physical or social environment that undermine the effectiveness of once-successful prevention strategies. For example, the emergence of highly effective treatments has made HIV seem less serious to some, leading to an increase in risk behaviors. According to studies in a variety of groups in high-income countries, optimism regarding prospects for the treatment of HIV is associated with greater sexual risk-taking (Grémy and Beltzer 2004; Tun 2003; Suarez 2001; Kelly 1998).

Moreover, the epidemic may evolve in ways that reduce the public health impact of previously successful prevention strategies. In Thailand, where the national epidemic was long concentrated among sex workers and their clients, nearly half of all new HIV infections are among heterosexuals with no history of intercourse with a sex worker.

### Limited Impact of Individual Behavior Change

Existing models of behavioral interventions are based on various cognitive behavioral theories that assume individuals will take steps to avoid risks if they are fully informed and sufficiently motivated.<sup>10</sup> While such approaches may work well for many people, they are unlikely to address the needs of the myriad populations at risk of infection. Because human sexuality and drug dependence are phenomena that are not always subject to cognitive control or mediation, cognitive approaches alone will not produce behavior change in many people.

Moreover, many individuals confront exceptionally elevated risk of infection not primarily as a result of their own risk behavior, but rather because of the behavioral characteristics of their partners or the particular structure and functioning of the social networks to which they belong. Influencing individual behavior in such cases will have only a limited impact on infection rates.

Examples of this paradox of high risk in the context of lowrisk behavior are numerous. Although heterosexuals in Africa are no more sexually active than their counterparts in other regions and are no more likely to have multiple partners, the region has the world's most severe HIV epidemic, driven primarily by heterosexual intercourse (Wellings 2006). Similarly, while young African-American MSM are 4.5 times more likely to be infected than young white MSM (CDC 2001b), surveys indicate that they are less likely to have unprotected anal intercourse than their white counterparts (Crosby 2007; Millett 2006). To reduce new infections in such cases, HIV prevention must alter social norms or the functioning of social networks. In general, however, relatively few validated prevention strategies operate at a community level. Likewise, the evidence base for HIV prevention includes comparatively few policy (or structural) interventions that aim to reduce risk by altering the social, legal, or physical environments in which risk behavior may occur (Wohlfeiler and Ellen 2007; see Blankenship 2000).<sup>11</sup>

With respect to relationships or social networks with characteristics that increase collective risk, HIV prevention initiatives must persuade social groups to examine and alter long-established values, assumptions, and behavioral patterns. There is growing recognition, for example, of the role of concurrent partnerships in facilitating the rapid spread of HIV, especially in endemic settings (Epstein 2007; Halperin and Epstein 2007; Morris and Kretzschmar 1997). To disrupt the dynamics of transmission in many high-prevalence countries in Africa, programs are needed that alert individuals to the risks associated with concurrency and that forge new social norms that reduce the frequency of concurrent partnerships.

### Limited Impact of One-Dimensional Prevention Evaluations and Programs

All too often, both prevention research and prevention practice convey the belief that individual interventions or partial approaches have the capacity on their own to sharply reduce the number of new HIV infections. Truncated or partial approaches to HIV prevention inevitably fail to achieve optimal public health impact.

As an example of this mind-set, most prevention-efficacy trials to date have examined discrete programmatic models, such as individual or small group interventions, particular counseling protocols, or social-marketing campaigns for condoms. Few prevention trials have evaluated the impact of a combination of strategies designed to reduce unsafe behavior. This can lead to questionable programmatic decisions. For example, conflicting research findings on the impact of STI control

<sup>9 (</sup>UNAIDS 2004. data.unaids.org/Topics/Epidemiology/Slides12/bkk04slide004\_en.ppt).

<sup>&</sup>lt;sup>10</sup> These prevention models are based on one or more theories of individual behavior, including the health belief model (Rosenstock 1994), social-cognitive or social-learning theory (Bandura 1986), theory of reasoned action (Fishbein 1967), theory of planned behavior (Ajzen 1985), the AIDS risk reduction model (Catania 1990), the information-motivation-behavioral skills model (Fisher 1994), and the stages of change (Prochaska 1994).

<sup>&</sup>lt;sup>11</sup> In addition to failing to address the impact of broader social networks, an exclusively individualistic approach to HIV prevention may also overlook the intrinsically social nature of sexual HIV transmission. For example, serodiscordant partnerships may account for a considerable share of new infections in some countries (see Wawer 2005). By focusing behavioral interventions on individuals rather than couples, HIV prevention efforts may be missing strategic opportunities to prevent transmission.

## ADDRESSING THE EPIDEMIC'S UNDERLYING DRIVERS IN HYPERENDEMIC SETTINGS

Ultimately, addressing the paradox of elevated risk in the context of low-risk behavior will require concerted attention to the social factors that increase HIV risk and vulnerability (Barnett and Whiteside 2006; Parker 2000). This is especially critical in hyperendemic settings, where the generalized nature of the epidemic poses extreme risks to individuals who have low levels of risk behavior (Southern Africa Development Community 2006). Such social determinants of risk and vulnerability include gender inequities, institutionalized discrimination, and economic inequality (Piot 2007). Effective intervention to address such factors requires a combination of initiatives to change social norms (regarding intergenerational sex, gender violence, and the like), legal and policy reforms, and programmatic initiatives (such as recognition of women's property rights, universal education, antidiscrimination laws, and schemes regarding social insurance, cash transfer, and microcredit).

on HIV incidence (see Hitchcock and Fransen 1999) have led in some quarters to a de-prioritization of STI control as a key component of comprehensive HIV prevention. Similarly, ambiguous findings on the effect of HIV counseling and testing on HIV incidence have occasionally led to an academic discourse that suggests that HIV testing has little, if any, role in HIV prevention. The truth is that both STI treatment and HIV testing play a vital role in comprehensive HIV prevention, and each tends to be offered in the real world in conjunction with other services. Expecting either approach to achieve on its own the desired outcome for comprehensive HIV prevention may lead to an erroneous de-prioritization of important components of the prevention continuum.

Vigorous debates have sometimes divided policy makers and program implementers in recent years regarding the relative importance of the various components of the "ABC" model (Abstain from sex; Be faithful to your partner; Condom use if necessary). This discourse, too, reflects the belief that a single key to HIV prevention can be discerned (see Wellings 2006). In the words of one set of commentators, these debates over the ABC approach infantilize HIV prevention by reducing human sexuality to a game of alphabet soup (see Collins 2008). The reality is that no single HIV prevention model—even one as supposedly multifaceted as ABC—can meet the broad array of HIV prevention needs. While ABC might work for some, it is most certainly unworkable for others, such as adolescent girls in Africa, whose primary risk factor is often early marriage to an older, HIV-infected partner (Bearinger 2007).

The ABC debate reflects a counterproductive tendency of many policy makers to conceive of HIV prevention in paradigmatic terms. In reality, sexual and drugusing behaviors are inevitably complex, diverse, and individually specific, dooming prevention strategies founded on a single paradigm or theory of behavior change. Different people will have different needs and require different approaches, and these needs and requisite strategies may evolve over time. Efforts to reduce behavior change to a sound bite or simple formula are bound to fail.

### Poor Implementation of Evidence-Informed HIV Prevention

Even the best HIV prevention strategies will have little impact if they are not properly implemented. A major reason why only limited behavior change has been achieved for HIV prevention is that few people at risk have access to the most basic prevention strategies. The vast majority of HIV-infected people worldwide are unaware of their HIV status, and most young people lack basic knowledge about HIV (U.N. Secretary-General 2008).

The lack of zeal for HIV prevention is especially evident when compared with the inspiring and energetic support in recent years for HIV treatment scale-up. Even in countries that have dramatically scaled up HIV treatment, HIV prevention coverage often continues to lag, due in part to poor national leadership. Of the nearly 100 countries that have established national targets for universal access to HIV prevention, treatment, care, and support, twice as many countries have targets for antiretroviral treatment as for programs to achieve behavior change for HIV prevention (UNAIDS 2007).

In many cases, national programs and international donors have failed to heed the scientific evidence on behavior change, supporting approaches that have little or no evidence of effectiveness. For example, national leaders have often given limited priority to comprehensive HIV prevention for young people, opting instead for programs that promote abstinence as the sole means of avoiding infection (Corno and de Walque 2007). Yet studies in high-income countries indicate that youth-oriented prevention programs that exclusively promote abstinence do not reduce the risk of HIV infection (Underhill 2007).

The failure of many countries to embrace harmreduction programs for IDUs is similarly illustrative of a failure to abide by available evidence documenting the effectiveness of such programs in reducing HIV infections (see Institute of Medicine 2006). Among 12 countries studied in 2007 by a task force of the Center for Strategic and International Studies, six had no drug substitution therapy. In four of the countries where maintenance therapy was technically available, it reached less than 5 percent of those in need (Fiellin 2007).

Even when countries desire to base national AIDS responses on the best available evidence, they often lack basic information about the nature and trends of their own epidemics. In many countries, health surveillance systems are weak, and national strategies are frequently drafted without a clear understanding of the populations at greatest risk, key infection trends, and the social factors that are driving the spread of HIV. By understanding the rate, location, and demographic characteristics of the past 1,000 infections, national prevention planners would be better equipped to employ limited prevention resources most strategically. Improved epidemiological methods exist to permit a better, more timely understanding of key trends in national epidemics (Gouws 2006), but countries will require substantial additional capacity and targeted financial and technical assistance to implement these approaches.

## RECOMMENDATIONS FOR ACTION

To ensure implementation of the HIV prevention strategies proven to be effective—and to address the gaps and limitations in the HIV prevention tool kit—the Prevention Working Group recommends the following to key stakeholders.

### RECOMMENDATIONS FOR POLICY MAKERS FOR NATIONAL AUTHORITIES AND GOVERNMENTS

- SUSTAIN HIGH-LEVEL POLITICAL SUPPORT: Political leaders should energetically and visibly lead national HIV prevention efforts. High-level political support for HIV prevention should be sustained even after signs of success emerge.
- PRIORITIZE HIV PREVENTION IN NATIONAL STRATEGIES: National AIDS plans should provide for a comprehensive, simultaneous scaling up of both HIV prevention and treatment. National HIV prevention efforts should be comprehensive, supporting the full array of evidence-informed prevention strategies that suit their national epidemic, including but not limited to condom promotion, STI control, programs promoting voluntary knowledge of HIV serostatus, harm reduction programs, behavioral interventions for populations at highest risk of infection, and initiatives that address gender-based violence and other aspects of gender inequities that influence HIV risk and vulnerability. Especially in high-prevalence settings, prevention efforts should seek to persuade individuals to reduce the number of sexual partners and avoid concurrent partnerships.

### • ESTABLISH AND MONITOR NATIONAL TARGETS:

As part of their establishment of targets for universal access to HIV prevention, treatment, care, and support, national HIV authorities should establish and disseminate concrete goals for coverage, intensity, and impact of HIV prevention efforts. Working with international technical agencies, national HIV authorities should assess HIV prevention scale-up on an ongoing basis and identify factors that impede program expansion.

• GROUND THE AIDS RESPONSE IN HUMAN RIGHTS: All countries should have in place strong and well-enforced laws that prohibit discrimination on the basis of real or perceived HIV status or of membership in a population at elevated risk of HIV infection. • IMPROVE NATIONAL INFORMATION

SYSTEMS: Available data, derived from a thorough assessment of national and subnational epidemic dynamics, should help guide national decision-making on allocating prevention resources among different program components. To make an evidence-based approach to national strategic planning possible, countries, with assistance from technical agencies and donors, should build, strengthen, and maintain strong HIV monitoring and evaluation systems that enhance the timeliness, breadth, and relevance of epidemiological and behavioral HIV surveillance.

• STRENGTHEN HIV PREVENTION ALONGSIDE ROLLOUT OF MEDICAL MALE CIRCUMCISION: For countries that promote medical male circumcision as a component of comprehensive HIV prevention, community education and behavioral HIV prevention efforts should be strengthened to reinforce the need for continued precautions following circumcision procedures.

## RECOMMENDATIONS FOR POLICY MAKERS FOR INTERNATIONAL DONORS

- FUND COMPREHENSIVE HIV PREVENTION, INCLUDING BEHAVIOR CHANGE PROGRAMS: Donors should bring as comparable a zeal to HIV prevention funding as currently exists for treatment assistance. Donors should commit to provide full funding for essential behavior change and other HIV prevention programs by 2010.<sup>12</sup> For HIV prevention programs in general, donors should commit to covering two-thirds of funding requirements for 2010, or U.S. \$11.9 billion.
- **RESEARCH:** Bilateral donors should prioritize increased support for research to strengthen the evidence base for effective action. Donorsupported research should place substantially greater emphasis on operational and social science research. HIV prevention research forums

<sup>12</sup> UNAIDS has estimated funding targets for essential HIV interventions to achieve universal access to HIV prevention, treatment, care, and support (UNAIDS 2007). Funding targets relevant to behavior change for 2010 include, in U.S. funds, \$386 million for communication for social and behavioral change, \$135 million for community mobilization, \$1.35 billion for voluntary counseling and testing, \$145 million for programs targeting young people, \$1.54 billion for programs targeting MSM, \$3.18 billion for harmreduction programs for IDUs, \$835 million for workplace prevention programs, \$261 million for HIV interventions for prisoners, \$209 million for prevention programs focused on other vulnerable populations, \$900 million for condom provision (male and female), \$2 billion for STI management, and \$662 million for prevention of mother-to-child transmission. should expand well beyond behavioral scientists to include the broad array of social scientists who could contribute to HIV prevention efforts.

- EXPAND DONOR PRIORITIES: Donors should significantly increase funding for sexual- and reproductive-health services, capacity building for networks of people living with HIV, and microfinance programs and other initiatives to increase women's economic independence and reduce their vulnerability to HIV. Donor assistance should also place greater emphasis on building national analytic capacity regarding strategic information, program evaluation, and epidemiological and behavioral surveillance systems.
- ELIMINATE DONOR RESTRICTIONS: Donors should avoid programmatic restrictions that prevent national or local HIV prevention programs from using resources to support "best practices" in HIV prevention or to respond to documented prevention needs.

### RECOMMENDATIONS FOR HIV SERVICE PROVIDERS

- TAILOR PREVENTION PROGRAMS TO LOCAL CONTEXT: Development and implementation of prevention programs should be informed by ethnographic research that assesses key behaviors and contextual factors that influence individual behavior, characterizes relevant social networks, identifies relevant communal values, maps local resources, and identifies optimal delivery strategies. Prevention program implementers should forge a strong, meaningful, and ongoing partnership with the community served by prevention efforts.
- ADAPT PREVENTION STRATEGIES: Making use of relevant epidemiological, operational, and social science research, prevention providers should continually reassess the relevance and effectiveness of programs. Where indicated, prevention programs should be adapted to address changes in the social and physical environment of the target population.
- INTEGRATE SERVICES: HIV services should be closely integrated with key service systems, with particular attention to sexual- and reproductive-health settings, antenatal settings, and tuberculosis clinical settings. Health systems and providers should incorporate detection of active syphilis and the routine offer of HIV testing in antenatal care.
- HIV PREVENTION IN TREATMENT SETTINGS: All HIV treatment programs should provide patients with routine risk-reduction counseling,

access to condoms and other prevention tools, and other HIV prevention services in their clinical settings. Treatment programs should build partnerships with community-based HIV prevention providers to support clinic-based prevention efforts and facilitate patient referral to community-based prevention resources.

## RECOMMENDATIONS FOR HIV PREVENTION RESEARCHERS

- SOCIAL SCIENCE FOCUS: Social scientists should be actively engaged in research efforts to expand the evidence base for HIV prevention. Public-sector research agencies, academic researchers, and leading foundations should prioritize relevant social research in countries to improve understanding of factors that increase vulnerability, identify and characterize programs and specific policy actions to address such factors, and inform the development and adaptation of national HIV prevention strategies. Working partnerships should be formed between ethnographers and preventionprogram implementers to increase the capacity of providers to undertake the formative research required to tailor prevention strategies.
- EFFECTIVENESS: Substantially greater research focus is needed on studies to assess the effectiveness of HIV prevention in real-world settings. Studies of combinations of multiple prevention components should also be prioritized. While not appropriate for all intervention trials, biological end points (such as HIV or STI incidence) should be used in prevention trials.
- **RISK COMPENSATION:** Substantially greater research attention should focus on monitoring behavior changes in response to the introduction of treatments, medical male circumcision, and other developments; identifying contextual issues that may influence risk compensation; and evaluating interventions to minimize risk compensation.
- NEW INTERVENTION APPROACHES: Social researchers and behavioral scientists should collaborate in the development and testing of new prevention interventions that aim to influence the norms and behaviors of social networks and communities. Greater attention should be paid to the evaluation of structural interventions.
- **IMPROVE EPIDEMIOLOGICAL TOOLS:** Research is urgently needed to develop accessible, affordable technologies to permit rapid assessment of HIV seroincidence in resourcelimited settings.

### RECOMMENDATIONS FOR POLICY MAKERS AT TECHNICAL AGENCIES

 SUPPORT HIV PREVENTION PLANNING: A coordinated system of technical support is needed to assist countries in developing comprehensive national HIV plans that include well-targeted, evidence-based, and scaled-up prevention programming. Through coordinated technical mechanisms, such as the UNAIDS AIDS Strategy and Action Plan service (housed at the World Bank), regional AIDS technical support facilities, and the technical expertise of U.N. agencies, technical experts should provide independent feedback on national HIV prevention plans, as well as technical support for the development and review of these plans. This effort should assess three factors: the degree to which national programmatic actions are evidence based, the alignment of prevention allocations with available epidemiological data and documented national needs, and whether needed programmatic actions are supported by social or structural policy actions that address nationally relevant factors that increase vulnerability.

### • IMPROVE NATIONAL INFORMATION SYSTEMS:

WHO, UNAIDS, CDC, and other technical agencies should continue to enhance technical support to countries in building and strengthening national HIV-related data systems. Particular emphasis should be placed on improvements to behavioral surveillance and to the development and implementation of strategies to assess HIV seroincidence.

#### • TECHNICAL RESOURCES ON SOCIAL

**RESEARCH:** UNAIDS and WHO, in collaboration with social researchers, should develop global and regional clearinghouses for HIV-relevant social science research and increase assistance to countries in the interpretation of social science findings and use of research results in the design, adaptation, implementation, and evaluation of strategies to change HIV risk behaviors.

## RECOMMENDATIONS FOR MEMBERS OF CIVIL SOCIETY

• ADVOCATE FOR HIV PREVENTION: At national and global levels, HIV advocates should actively support a comprehensive response to the epidemic that simultaneously brings HIV prevention and treatment to scale. It is particularly important that HIV treatment activists advocate for the simultaneous scaling-up of HIV prevention strategies.

- MONITOR NATIONAL PROGRESS ON HIV PREVENTION: With support from donors and multilateral agencies, as well as national authorities, civil society networks should assist in monitoring national HIV prevention efforts and work to hold governments, donors, and other actors accountable for agreed targets.
- PARTICIPATE IN NATIONAL PREVENTION PLANNING AND MONITORING: Civil society should be integrally involved in national bodies that develop and/or monitor national efforts to bring HIV prevention to scale, including National AIDS Councils and Country Coordinating Mechanisms for the Global Fund. Countries should define civil society broadly to encompass community-based organizations, faith-based groups, business and labor, and people living with HIV.

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