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OTA BACKGROUND PAPER

THE EFFECTIVENESS OF AIDS PREVENTION EFFORTS

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PROJECT STAFF

Michael Gluck
Eric Rosenthal
Project Directors

Hellen Gelband
Senior Associate

Romulo Colindres
Research Assistant

Laura Esslinger
Research Assistant

Clyde J. Behney
Assistant Director, OTA

Sean R. Tunis
Health Program Director

ADMINISTRATIVE STAFF

Louise Staley
Office Administrator

Carolyn Swann
PC Specialist

Monica Finch
Word Processing Specialist

Charlotte Y. Brown
Word Processing Specialist

CONTRACTORS

Thomas J. Coates, Ph.D.
Center for AIDS Prevention Studies
University of California at San Francisco

Donald C. Des Jarlais, Ph.D.
Chemical Dependency Institute
Beth Israel Medical Center
New York, NY

Anke Ehrhardt, Ph.D.
HIV Center
Columbia University
New York, NY

Douglas Kirby, Ph.D.
ETR Associates
Santa Cruz, CA

Barbara VanOss Marin, Ph.D.
Center for AIDS Prevention Studies
University of California at San Francisco

Steve Rabin, J.D.
Porter/Novelli
Washington, DC

Jane E. Sisk, Ph.D.
Columbia University
School of Public Health
New York, NY

Marc A. Zimmerman, Ph.D.
University of Michigan
School of Public Health
Ann Arbor, MI

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THE EFFECTIVENESS OF AIDS PREVENTION EFFORTS

OTA first addressed the question, *How Effective Is AIDS Education?* (91) in 1988. At that time, we concluded that "knowledge about the effectiveness of particular programs and of specific elements of programs has been slow to accumulate." The Sub-committee on Health and the Environment of the House of Representatives Committee on Commerce asked OTA to take a fresh look at the question, and this background paper is the result. In 1995, there still is a need for additional research and for development and use of more carefully-refined research methods, but we know now that certain interventions can successfully reduce the risk behaviors¹ associated with Human Immunodeficiency Virus (HIV) transmission in certain groups at high risk of AIDS. The details of what is known and still unknown are reviewed in this background paper.

Most of the information comes from a series of commissioned papers written by experts on the following topics:

¹ "Risk" and "risk behavior" are used in this paper to mean behavior that may lead to the transmission of HIV.

- ◆ *HIV/AIDS Prevention for Injecting Drug Users*
- ◆ *Does HIV Prevention Work for Men Who Have Sex with Men?*
- ◆ *AIDS Prevention Among African-Americans and Latinos in the United States*
- ◆ *A Review of Educational Programs Designed To Reduce Risk-Taking Behaviors Among School-Aged Youth in the United States*
- ◆ *A Review of HIV Interventions for At-Risk Women*
- ◆ *Applications of Social Marketing Principles to AIDS Education*
- ◆ *Economic Evaluation of HIV/AIDS Education and Primary Prevention*
- ◆ *HIV / AIDS Education: National Surveys, Counseling and Testing Programs and the Role of Physicians*

KEY FINDINGS

- ◆ Much has been learned since 1988 about which interventions are effective in changing risk behaviors related to HIV infection and AIDS among certain key subpopulations. Adult gay and bisexual men who do not belong to ethnic minority groups

have been the most intense focus of AIDS prevention, and most is known about which interventions work in this population.

- ◆ There still are major gaps in what is known about interventions for certain high-risk populations. African Americans and Latinos account for a disproportionately large share of people with AIDS, yet relatively little research has been directed toward prevention in these population groups.
- ◆ Younger gay and bisexual men of all ethnic groups still need to be reached, and continued efforts are required for the entire population of gay and bisexual men, to make sure that those who have changed their behavior do not lapse back into early, risky behaviors. Intravenous drug use is also a very important risk factor for HIV transmission among gay and bisexual men.
- ◆ Interventions developed through in-depth preliminary work with the target population, that consist of small-group programs that are interactive and include skills development, have been among the most successful at reducing risky sexual and drug-related behaviors.
- ◆ The availability of sterile needles does not increase the incidence of illicit drug use and they can play an important role in reducing the transmission of HIV among injection drug users. Other approaches--including the increased availability of drug treatment and changes in methadone prescribing policies--while not the focus of much research, also are potential tools for reducing HIV transmission in this population.
- ◆ Sex education and AIDS education directed at school-aged youth do not increase sexual activity. Some specific sex and AIDS education programs have been shown to reduce unprotected sexual activity, either by delaying the onset of intercourse, reducing the number of sexual partners, or increasing the use of condoms.
- ◆ Voluntary HIV "testing and counseling"--the combination of HIV blood tests and the information provided before and after testing--are of variable impact, possibly because they are done differently in different places, in some cases more effectively than others. Done correctly, they have an important role in serving as a bridge to appropriate AIDS preventive, medical, and social referrals, and in some cases, altering behavior.
- ◆ Mandatory testing of certain low-prevalence populations (e.g., marriage license applicants) is an expensive way of detecting HIV positive individuals, and there is no evidence that interventions to change behavior would be effective with mandatory testing.
- ◆ Maintaining safe sex and needle use behavior over the long term once a change is made--perhaps over the course of one's lifetime--is likely to be important for individuals at risk of

HIV, but little is known about the interventions needed to maintain these changes.

- ◆ The value of the research on AIDS prevention that has been conducted has been diminished by poor study design. Flaws include poor basic design, small study groups, short evaluation periods, and lack of control or comparison groups. (These same flaws are common to a surprisingly high percentage of research in all areas of medicine, and are not necessarily more problematic in the AIDS area than in others.)
- ◆ There is a gap between what is known about effective interventions and what is actually delivered as prevention. Community-based organizations, which deliver a significant amount of prevention, often are not able to or simply do not take advantage of current knowledge about program effectiveness.
- ◆ "Social marketing"--the application of commercial marketing strategies to societal issues--offers a possible method of inducing behavior change and maintaining non-risk behavior. Although social marketing has not been widely applied to AIDS prevention in the United States, it has demonstrated impact on other health problems in this country and on HIV transmission in some other countries. Although potentially very effective, social marketing programs can also be very expensive.
- ◆ Programs of voluntary, testing, counseling, referral, and partner

notification, as exemplified by sites funded by CDC, appear to be cost-saving in the long run, i.e., the costs of the programs are exceeded by the long-term savings (discounted) in AIDS treatment costs averted. This is true if only about 7 percent of infected people notified change their behavior to avoid further HIV transmission. Needle exchange and bleach distribution programs for injecting drug users also appear to be cost-saving.

- ◆ AIDS prevention resources could be used much more effectively, even with current technology. In some instances, social and cultural influences have impeded their use. Specifically, there has been reluctance to encourage condom use, and there are societal and legal barriers to making sterile needles available to injection drug users.

BACKGROUND

HIV disease and AIDS are progressive conditions. They begin with infection with HIV and conversion from HIV seronegative to HIV seropositive. HIV may remain in the body for up to ten years or more without causing any apparent symptoms, and an individual may be HIV seropositive for many years without being diagnosed as having HIV disease or AIDS. During this period they are infectious. A person who has not been tested for the presence of HIV antibodies or antigens is unlikely to be aware of the infection. All the while though, HIV attacks certain cells of the immune system and causes the system to

erode. Eventually, the body falls prey to "opportunistic" infections (e.g., bacterial and viral infections of the respiratory and digestive tract) that are able to take hold due to the body's weakened immune defenses. A formal diagnosis of AIDS is not made until at least one of a certain group of infections occurs or until the immune system reaches a certain, critical level of deterioration. In most cases these infections—not HIV directly—incapacitate patients and cause illness and death.

HIV is transmitted in relatively clearly defined and understood ways, all of which involve the transfer of blood, semen or certain other body fluids from one individual to another (including transmission from infected woman to fetus). Transmission occurs in the course of certain behaviors, generally sexual or those associated with injecting drug use. HIV also may be transmitted from a seropositive pregnant woman to her fetus during pregnancy or birth and, in rare cases, to health care workers through needlesticks and other injuries.²

Rapid progress was made in identifying HIV as the causative agent of AIDS, in developing a test for antibodies to it, and in finding prophylaxis and treatment regimens for some of the opportunistic diseases associated with AIDS, but there is no short-term prospect for a preventive vaccine or any kind of cure. Currently available antiviral treatments are of temporary value at best. Consequently, the only

viable method for stopping the spread of AIDS is prevention, which depends almost entirely on individual behavior change (95).

Like other areas of medicine and health, public and private funding for HIV/AIDS has supported biomedical research and development more heavily than behavioral and social science research. It is noteworthy that the first preventive intervention shown through rigorous evaluation to be efficacious was a device-based technology: the HIV-antibody test for blood. Moreover, development of the blood test responded to a pervasive fear that people receiving blood products could become infected independently of their behavior. Developers of the antibody test could thus count on a large, secure market among mainstream health organizations, such as hospitals and blood banks.

By contrast, behavioral and social science research has received less emphasis and less funding, even though behavior change could prevent almost all further HIV transmission. This situation at least partly reflects the conflicting views within funding organizations and society about the behaviors associated with HIV transmission, namely sex, reproduction, and drug abuse. It has also characterized work on other sexually-transmitted diseases and drug abuse generally. Only in recent years has more rigorous research using experimental designs become common in behavioral and social science research, a development notable from the 1988 OTA report to the current background papers. Many of the

² Through the end of 1994, there were 42 documented cases of occupational transmission of HIV to health care workers and 91 possible cases (104).

economic evaluations of the early 1990s in fact grew out of such research funded by the Centers for Disease Control and Prevention (45,51,52).

The Federal Government has appropriated funds primarily through the Centers for Disease Control and Prevention (CDC) for AIDS prevention and education. Beginning in 1985, the Federal Government appropriated \$33 million for AIDS prevention and education. The appropriated funds have grown to \$589 million, the estimated expenditure for Fiscal Year 1995.

Even where AIDS prevention programs have been developed and tried, judging how effective they are remains a difficult task. It is challenging--particularly so when interventions are multifaceted and community-wide--to design studies that allow cause-and-effect to be inferred. Debate is ongoing about what types of studies and other types of evidence are sufficiently rigorous that they can be relied on to provide evidence of effectiveness, and some progress has been made in developing methods to evaluate the effectiveness and cost-effectiveness of particular interventions.

Interventions have been studied more in some communities and populations than in others, and not necessarily in relation to their importance to the current spread of HIV. Much more is known, for example, about how to prevent HIV transmission among white, gay and bisexual men over 30 than among sexually active young people or heterosexual African American or Hispanic men or women. And among injecting drug users, efforts have been directed mainly at changing their drug-taking

behavior, but not their sexual behavior, through which they can infect others. Because this paper is largely a review of literature, it reflects the balance of what has been done, which is not always the right balance for new efforts. It is particularly important to recognize that women and people of color are glaringly absent from much of the work on interventions. It is these groups among whom transmission is increasing the fastest, and they deserve higher priority in research and intervention programs than they have had up to now.

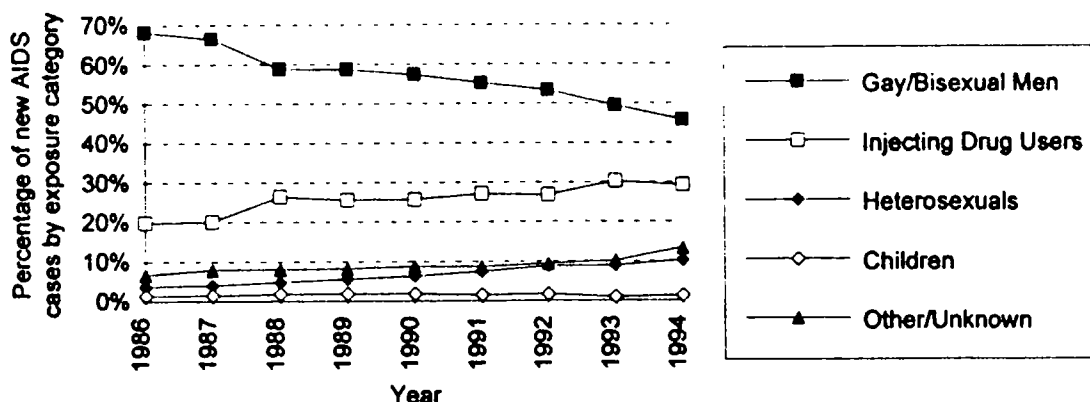
TRENDS IN NUMBERS OF AIDS CASES

The first cases of AIDS in the United States were reported in 1981. By the end of 1994, 442,000 Americans had been diagnosed with AIDS and 271,000 had died from symptoms related to the disease. The number of AIDS cases in the United States increased by about 3 percent from 1992 to 1993 and another 3 percent from 1993 to 1994.³ Women, African Americans, Hispanics, and people in the South and Northeast accounted for higher proportions of cases in 1994 than in 1993. The largest decline in the proportion of reported cases was among gay and bisexual men (figure 1).⁴

³ Because the AIDS surveillance case definition was expanded in 1993, AIDS incidence trends from 1993 to 1994 are evaluated using the estimated incidence of AIDS-defining opportunistic illnesses (103) in order to make accurate comparisons over time.

⁴ The term "gay and bisexual men" is used here to refer to all men who have sexual relationships with other men regardless of their identification or sexual orientation.

Figure 1: Trends in New AIDS Cases by Category



SOURCE: OTA, 1995.

AIDS strikes the relatively young. In 1993, it became the largest killer of Americans aged 25-44. This group accounts for about three-quarters of the cases. It also is the leading cause of death in that age group in 79 out of the 169 American cities with populations larger than 100,000 (1). In 1992, AIDS was responsible for the fourth greatest number of years of potential life lost for people under 65 years of age.⁵ AIDS was the only major cause of years of potential life lost to show a significant increase--11 percent--from the previous year (102). An estimated one million Americans are infected with the human immuno-deficiency virus (HIV), the virus that causes AIDS. HIV is one of the most virulent human viruses known, with death rates exceeding 75 percent of those infected, and the ability to infect large numbers of people.

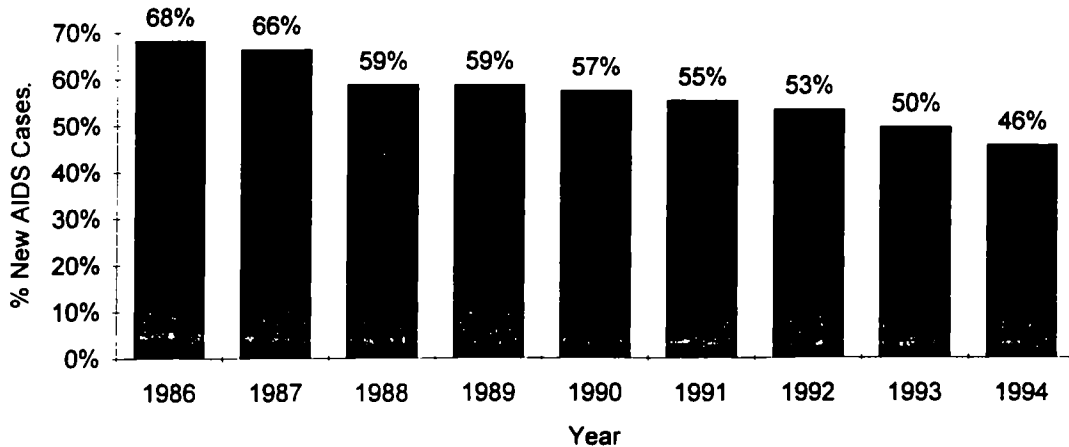
⁵ Years of potential life lost is a public health measure that reflects the impact of deaths occurring in years preceding a conventional cut-off of age, in this case 65 years old. It is a measure that takes into account number of deaths and age of decedents.

Gay and Bisexual Men

At the end of 1994, AIDS cases among gay and bisexual men, the largest group of people with AIDS, constituted 228,954 or 53 percent of the cumulative case load (figure 2). An additional 28,521, or 7 percent, of the cases are in gay and bisexual men who also inject illicit drugs (104). Gay and bisexual men represent a decreasing percentage of newly-diagnosed cases of AIDS, both because their rate of increase has slowed in recent years⁶ (1989 through 1994) and because the epidemic is growing more rapidly in other segments of the population (105). Gay and bisexual men have reduced their sexual risk behavior, including reductions in multiple sexual partners and reductions in incidence of unprotected sex, since the start of the AIDS epidemic. But gay and bisexual men continue to constitute the largest

⁶ Because the AIDS surveillance case definition was expanded in 1993, AIDS incidence trends in the study being discussed are evaluated using the estimated incidence of AIDS-defining opportunistic illnesses (103) in order to make accurate comparisons over time.

Figure 2: Percentage of New AIDS Cases Represented by Gay and Bisexual Men



SOURCE: OTA, 1995.

portion of people with newly-diagnosed AIDS, so success in controlling the AIDS epidemic depends on preventing new cases among this group.

The AIDS epidemic among gay and bisexual men, like the AIDS epidemic more generally, is a composite of epidemics among different groups, with different times of onset and patterns of spread. The rate of new cases among certain subcategories of gay and bisexual men, especially white gay and bisexual men, originally hardest hit by AIDS, is slowing (table 1). However, rates of growth are increasing among other groups less affected early in the epidemic (105). Rates of AIDS among

African American gay and bisexual men were highest in 1994 and showed the greatest increase since 1989. The rates of increase among other ethnic minority (Hispanic, Asian/Pacific Islander, and American Indian/Alaskan Native) gay and bisexual men also exceeded that for whites. In New York, Los Angeles, and San Francisco, where 27 percent of the AIDS cases among gay and bisexual men have occurred, the rate for white men decreased (20 percent, 16 percent, 3 percent, respectively) and for African American men, it increased (49 percent, 48 percent, 53 percent, respectively).

AIDS continues to spread beyond major metropolitan areas. The number

Table 1. Increases in the rate of newly-diagnosed cases of AIDS among gay and bisexual men from 1989 to 1994 and the rate of AIDS among gay and bisexual men per 100,000 men in mid 1994 are shown by race and ethnic group.

Race/Ethnicity	Increase from 1989 - 94	Rate in Mid 1994 (per 100,000)
African American	79 percent	37.3
Hispanic	61 percent	22.6
Native American/Alaskan	77 percent	6.9
Asian/Pacific Islander	55 percent	6.2
White	14 percent	12.2

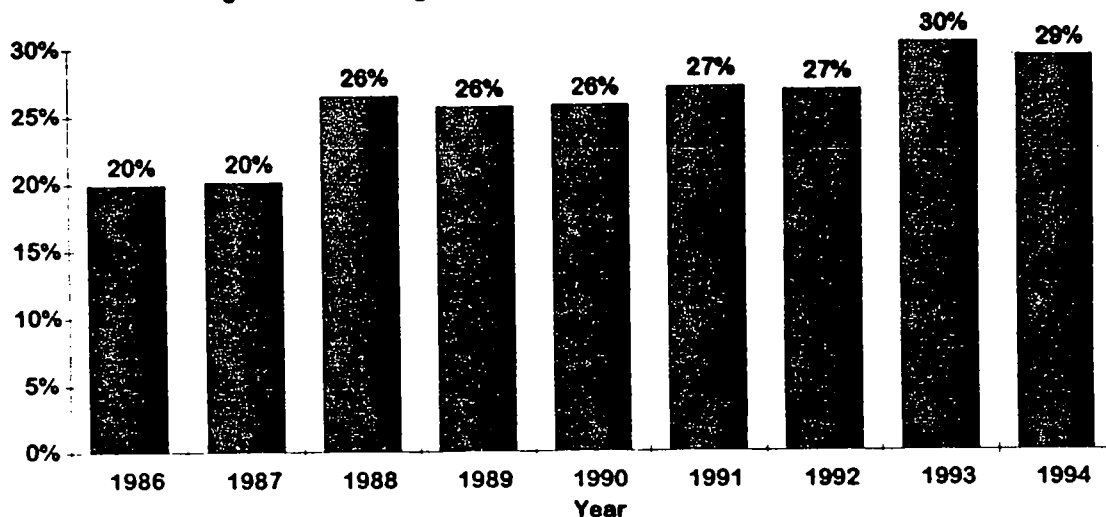
Table 2. Increases in the rate of newly-diagnosed cases of AIDS among gay and bisexual men from 1989 to 1994 and the rate of AIDS among gay and bisexual men per 100,000 men in mid 1994 are shown by size of area.

Size of Area (population)	Increase from 1989 - 94	Rate in Mid 1994 (per 100,000)
<50,000	69 percent	4.4
50,000 - 1 million	55 percent	10.2
>2.5 million	19 percent	24.8

of cases continues to be greatest in the West and Northeast and in urban areas, but the highest rate of growth is occurring in the South and Midwest, and in less populated areas (table 2). From 1989 to 1994, the number of AIDS cases

diagnosed among gay and bisexual men increased most in the Midwest (51 percent) and in the South (49 percent) and least in the West (21 percent) and the Northeast (13 percent) (105).

Figure 3: Percentage of New AIDS Cases Represented by Injecting Drug Users



SOURCE: OTA, 1995.

Injecting Drug Users

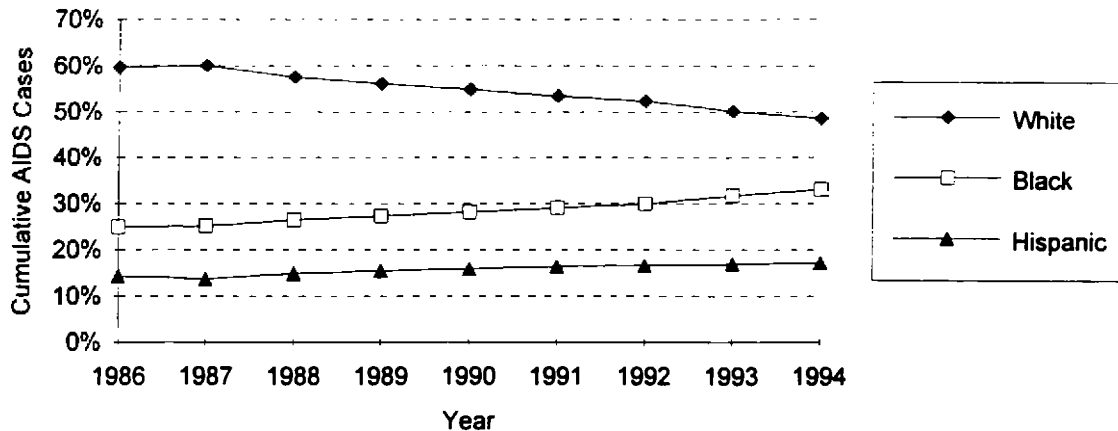
As many as 138,000 (32 percent) of the diagnosed AIDS cases reported through the end of 1994 are the result of injecting drug use⁷ (figure 3) (104). Estimates of new HIV infections in the United States suggest that injecting drug use is associated with a plurality of new

infections (43), which has implications for the future course of AIDS cases.

Ethnic and Racial Minorities

Ethnic and racial minorities represent a disproportionate and increasing share of AIDS cases in the United States (figure 4). Fifty-one percent of all cases have been among people of racial minorities, which comprise only 23 percent of the population. One-third of all cases are African Americans, 17

⁷ These figures include the categories "injecting drug use" (109,393 cases) and "men who have sex with men and inject drugs" (28,521 cases), as used in the HIV/AIDS Surveillance Report.

Figure 4: Trends in Cumulative AIDS Cases by Race

SOURCE: OTA, 1995.

are Latinos, 0.7 percent are Asian/Pacific Islanders, and 0.2 percent are Native Americans, compared to 11 percent, 8 percent, 3 percent, and 0.8 percent, respectively, in the population as a whole (104). Data from HIVseroprevalence studies suggest that the proportion of racial minorities diagnosed with AIDS will continue to grow in the coming years (38,75,93).

Ethnic minority groups are often viewed as homogeneous clans but, in fact, there is enormous variety in the demographic characteristics, immigration history, and cultural values of ethnic subgroups. HIV infection also is not spread evenly within these groups. For instance, there is a high concentration of HIV among Latinos in the Northeast United States, who have come mainly from Puerto Rico and the Dominican Republic. Much lower incidence and prevalence rates are reported for Latinos from the West and Southwest, who have come mainly from Mexico and Central and South America.

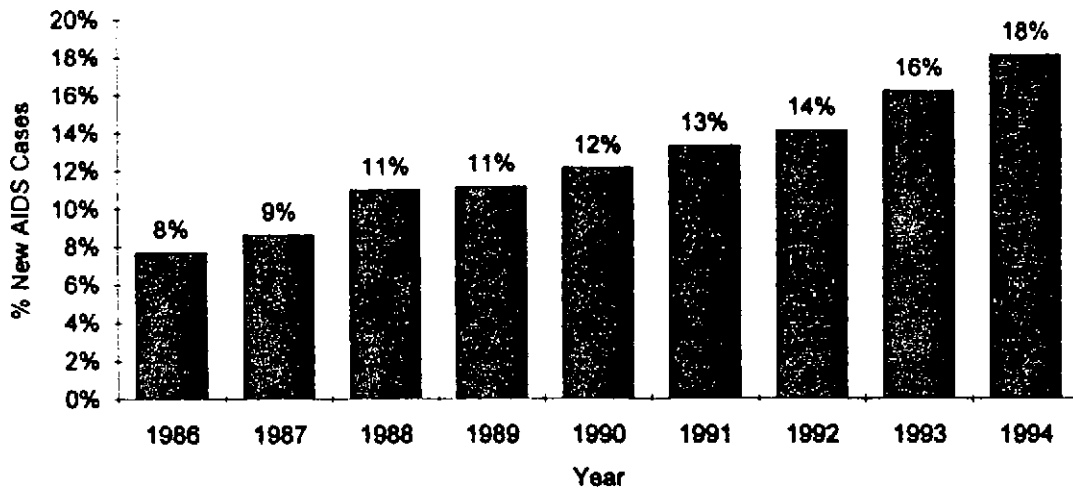
Women

The proportion of AIDS cases among women tripled from 1985 to 1994, rising to 18 percent of all new adult and adolescent cases (figure 5). Thirty-eight percent of the 14,000 cases among women diagnosed in 1994 were contracted from heterosexual sexual partners and 41 percent from injecting drugs (106). Seventy-seven percent of the 1994 cases were among African American and Hispanic women.

Youth and Children

Many young people are at risk for HIV transmission through their sexual practices. Through the end of 1994, 68,000 males and 14,000 females age 20 to 29 were diagnosed with AIDS (104). Because the period between HIV infection and onset of AIDS may be up to ten years, it is likely that many of these people, who represent almost one-fifth of AIDS cases, were infected with HIV as teenagers. Most of these cases were among gay and bisexual males,

Figure 5: Percentage of New AIDS Cases Represented by Women



SOURCE: OTA, 1995.

male and female injecting drug users, and heterosexual female sexual partners of injecting drug users.

There were 6,000 pediatric AIDS cases in the United States as of the end of 1994,⁸ representing just under 1.5 percent of the cumulative cases. The rate of pediatric AIDS cases has remained fairly constant at between 1 percent and 2 percent of the total new cases of AIDS each year.

APPROACHES TO AIDS PREVENTION—CHANGING BEHAVIOR

More than 40,000 cases of new HIV infection occur each year in the United States, despite a clear understanding of how the virus is transmitted. Although a

small number of infections arise from accidental transmission (i.e., blood transfusions, organ transplants, and needlestick injuries), nearly all infections are potentially preventable if behavior could be changed. This does not mean, however, that prevention depends entirely on persuading people to change their behaviors. It also involves access to the necessary information and technologies, and structural changes that make it easy for people to practice preventive behaviors.

With respect to Americans who are sexually active outside of a mutually monogamous relationship with an uninfected individual, behavior change means abstaining from certain sexual practices, using condoms, or both.⁹ For

⁸ The CDC defines pediatric AIDS as AIDS occurring in children less than 13 years old.

⁹ Although refraining from intercourse with an infected individual remains the most effective way to prevent sexual transmission of HIV, the Centers for Disease Control and Prevention has found that consistent and correct use of latex

individuals who inject illicit drugs, behavior change means ceasing to inject drugs, using only sterile needles, or not sharing needles.¹⁰

To be judged as effective, an intervention must reduce or eliminate the transmission of HIV. No prevention measure for any disease is 100 percent effective--many nowhere close to that--but they are still considered valuable. Likewise, attempts to change behavior will never stop all HIV transmission. But if an intervention even delays transmission, there is a beneficial effect both for the individual and for the course of the epidemic. An individual who avoids risk behavior even temporarily may avoid becoming infected or avoid infecting someone else. Partial success also may have benefits in diminishing the number of sexually transmitted diseases, unwanted pregnancies, and abortions.

Most premature deaths in the United States spring from "choices" people make--though not necessarily informed or "free" choices--and from social conditions that promote health or disease. These choices may be about sexual behavior, illicit drug use, smoking, drinking, diet, exercise, seat belt use, or recreation. Like these activities, HIV transmission depends on individual behavior choices. Similarly, HIV prevention is part of a spectrum of disease-fighting efforts that depend on risk avoidance, long-term behavior

change, and the development of policies that promote health and prevent disease. In most cases, simply telling an individual that HIV is spread through certain sexual and drug-use behaviors is not sufficient to alter that person's behavior, just as simply providing information on risk factors for heart disease or cancer is not sufficient. To be most effective, prevention strategies should provide information, motivation, skills, modification of perceived norms, and social or peer reinforcement. Just as important, long-term prevention requires long-term prevention efforts, so that positive behavior changes are sustained once they begin.

At least some attempts to change behavior to improve individual and public health historically have been beneficial, even though they have achieved only partial success. Campaigns to reduce smoking, the most important single cause of death in the United States, were initiated over three decades ago, but still about a quarter of Americans smoke. Attempts to increase exercise and improve dietary habits have found far less than full acceptance. The American Cancer Society and the National Cancer Institute recommend breast cancer screening through both mammography and clinical breast examinations for asymptomatic women aged 50 years or older. In a 1992 study, the CDC found that while 64 percent of women in the previous year had at least one of the exams, only 40 percent of women complied with the recommendation to have both (108).

Evidence shows that behavior change is difficult for most people and sustained behavior change even more so. Public

condoms is highly efficacious for preventing HIV transmission (107).

¹⁰ For the purposes of this paper, "needle sharing" and "needle exchange" includes sharing or exchange of syringes and other drug injection equipment.

health messages must compete with natural human desires, many of which are pleasurable (e.g., sexual relations) as well as with frequently appealing counter messages from entertainment media (e.g., to engage in sexual activity) or from peers (again, to engage in sexual activity or to use illicit drugs). These counter messages provide a constant challenge to AIDS prevention.

Judging Effectiveness

The biggest barrier to knowing which interventions are most effective at preventing the spread of HIV is that, considering the size of the problem and the amount of effort that has gone into solving it, too few interventions have been evaluated formally. And of those that have, many of the evaluations have not been rigorous enough to provide highly reliable information.

Some interventions have been studied in some locations and populations, but not others. More studies of gay men (mostly white) have been carried out than of any of the other important target groups, including women; younger, and non-white gay and bisexual men; adolescents and young adults generally; people with other sexually transmitted diseases; military personnel; prostitutes, and incarcerated populations. In addition, evaluation has, of necessity, focused on relatively short-term changes, in an area where the need is for changes that persist over a lifetime.

Many individuals--especially those in communities targeted for special prevention efforts--are subject to many influences on their behavior. If someone is taking part in a formal study of an

intervention's effectiveness, they will almost always be exposed to information (e.g., news reports) or events (e.g., a friend or relative sick with or dying from AIDS) external to the study. The only reliable way to determine what effects the planned intervention had, versus the effects of other influences, is to compare the behavior of people who got the intervention with that of a "control" group which, other than the study intervention, had similar inputs. The intervention and control groups should, ideally, be allocated by a method that gives an equal chance of getting into one group or the other, regardless of the individual's (or group's) characteristics, and this requires some form of randomization. The "unit of randomization" may be the individual, the community, the school, or some other unit. It is often difficult and expensive (and in some cases, not feasible) to apply randomized controlled conditions to real world intervention projects, but in fact, it is possible and the method should not be abandoned as facilely as it often is. This is not to say that other types of studies can't produce useful information, but the results of other types of studies will never be as reliable as the results of randomized studies. Even the strongly-held opinions of professionals about what does and doesn't work in AIDS prevention are not, by themselves, reliable guides for further programs.

The methodological challenges in studying and validating interventions to change behavior are even greater than for many other medical interventions (e.g., pharmaceuticals, surgical procedures). Trying to generalize the results of individual studies to the broader population is also more difficult.

Interventions to change individual behaviors can usually be considered "complex interventions," with the following features: First, the intervention itself can be highly variable, depending on who actually conducts it. For example, the counseling portion of a testing program may vary substantially according to the style and knowledge of the provider. Much of this variability may not be easily characterized or even detected. Second, contextual factors may be important variables in the effectiveness of the intervention. For example, an educational program delivered to teenagers in a schoolroom may have a different impact than the same program offered in a community center. Third, complex interventions are characterized by a range of possible endpoints that could be used to determine effectiveness. The effects of an educational leaflet could be measured by how many are distributed, by surveys of how knowledge changes among the target population, by measuring changes in condom sales, or by tracking the prevalence of HIV.

In a practical sense, this means that an intervention found to be extremely effective in an individual study is not necessarily transferable directly to another population group or geographic area. It may be that the key factor in its success is the process by which the intervention was developed and implemented (e.g., with strong community input), rather than the actual content of the intervention. In reviewing the literature, therefore, it may not be possible to make a list of interventions that work, but it may be possible to list the characteristics of interventions and studies that have been successful.

GENERAL AND TARGETED EFFORTS

The overwhelming majority of new HIV infections continues to be concentrated in relatively few geographic areas ("communities") and demographic groups ("populations"), though some cases occur in every community and population. Controversy has surrounded the issue of whether to target funds intensively to the communities and populations with the largest number of new HIV infections or to stress universal risk to the entire U.S. population (19,86,96). The dilemma arises for two reasons: first, concerns about stigmatizing people in targeted groups, and second, because HIV can infect anyone who engages in certain sexual or drug-related behaviors with a person who is seropositive. It has the potential to spread more widely throughout society as it has, for example, in some African countries. In the United States, however, most people with AIDS are concentrated in small segments of the population¹¹ which are largely self-contained in terms of risk behavior. If HIV were spread exclusively within clearly defined communities, it might make sense to concentrate efforts only in these communities. However, risk behavior is not completely confined in this way and individuals outside these communities may become infected.

¹¹ For instance, at the end of 1994, 73.5 percent of the cumulative AIDS cases were in California, Florida, Georgia, Illinois, Maryland, New Jersey, Pennsylvania, New York, Texas and Puerto Rico. In addition, at least 88.3 percent of the adult and adolescent cases were among gay and bisexual men, injection drug users and their sexual partners.

Effective AIDS prevention depends, therefore, on a combination of universal and targeted approaches. Universal education informs individuals who do not identify with a target population but may be at risk for infection. It also serves as reinforcement for targeted efforts. In order to reduce the spread of HIV, anyone, heterosexual or homosexual, who is potentially sexually active or who considers illicit drug use should understand his or her risk and how infection can be avoided. Universal AIDS prevention programs also can help reduce discrimination against people with HIV infection or AIDS. However, most new HIV infections could be prevented by intensive efforts aimed at the populations in which HIV is spreading, including gay and bisexual men, injecting drug users, and heterosexuals with high rates of sexually transmitted diseases (19). Intensive efforts in certain groups also could provide the continuing support individuals would need to maintain non-risk behavior over time.

Defining Groups

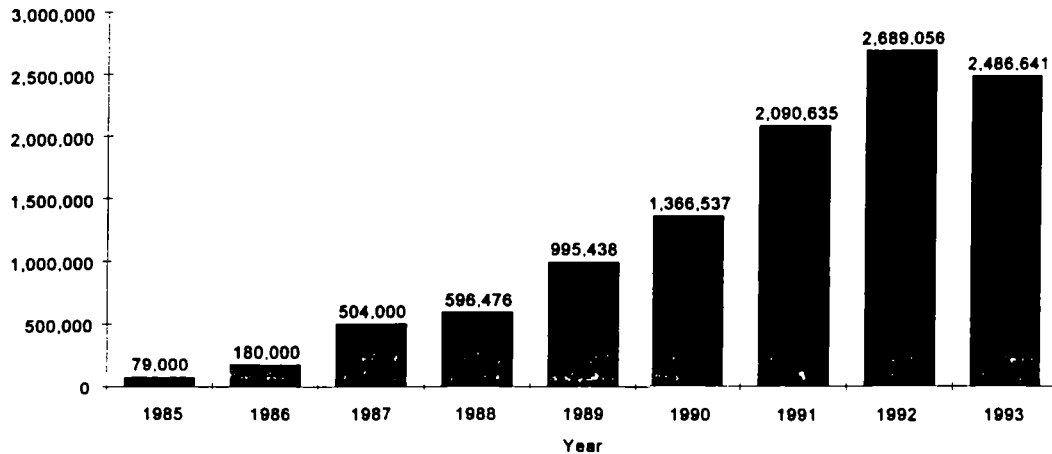
People often are defined for the purposes of AIDS education by the group or groups to which they belong--usually demographic or geographic. Many times, the groups are adopted conveniently from the epidemiological perspective, i.e., the groups for which data are reported. But in fact, the United States is a "complicated patchwork of behaviors, incomes, and ethnic backgrounds that confound simple cultural labeling" according to consumer marketers (85).

This suggests the need for a fresh look at how individuals are grouped for prevention efforts. Among African Americans, for example, there are varieties of consumption patterns and health indices depending, among other things, on location and aspects of heritage. In addition, many people fall into several groups. The commercial sector relies on statistical clusters based on geography, lifestyle, behavior, financial status, and attitudes more than on race alone. African Americans, Hispanics, Asians, and Native Americans should not automatically be lumped together as "minorities" if AIDS prevention efforts are to be most effective. Traditional consumer marketing also tends to segment the population along age lines rather than along the "risk group" lines suggested by epidemiological data. With half of the new infections occurring in individuals under 25, adolescents at risk may have more in common with each other than with individuals of similar race, ethnicity, or sexual orientation, but of different ages.

COUNSELING AND TESTING

The CDC spends substantial funds on its program of counseling, testing, referral, and partner notification (CTRPN), much of which has been mandated by Congress. The program began in 1985 with 79,000 people tested. By the end of 1993 11 million tests had been performed (figure 6). An additional 5 million tests had been performed in private physicians' offices and health maintenance organizations through 1990 (101).

Figure 6: HIV Tests in CDC Sites by Year



SOURCE: OTA, 1995.

The four main functions of counseling and testing, according to CDC are: (1) to provide a convenient opportunity for persons to learn their current HIV serostatus; (2) to help initiate behavior changes to avoid infection or, if already infected, to prevent transmission to others; (3) to refer individuals to additional medical and other services as needed; and (4) to provide prevention services and referrals to sex and needle-sharing partners of people with AIDS or HIV infection. (111). Counseling and testing also protect the blood supply and provide a method to notify sexual partners of seropositive individuals of potential risk (45).

In addition to the testing itself, each person is to receive counseling both at the time of providing a blood sample and upon receiving test results. The pre-test counseling is intended to assess the client's personal risk for HIV infection, discuss the elements of the test, and answer questions. The post-test counseling informs the client of his or her serostatus and discusses its

implications. If the result of the test is negative, the counselor should discuss the importance of adopting or continuing risk reduction behaviors. If a client tests positive, the counselor also provides emotional support and referrals for appropriate medical and other services. Many programs include a mechanism for notifying partners of infected individuals (36). Unfortunately, pre- and post-test counseling, as conducted currently, often are inadequate to assess the potential for risky behavior, and in many places, there are too few medical and prevention services available for referral.

Except for uniformed military personnel, Jobs Corps applicants, foreigners who attempt to immigrate to the United States, and some other selected groups (e.g., State Department employees, sex offenders, prostitutes, prisoners, blood donors), most HIV testing has been voluntary. One exception was an Illinois law requiring that couples be tested for HIV and receive their results before they could get a marriage license. In the six months

after the law took effect, only eight out of the 70,846 applicants tested seropositive. During the same time, applications for marriage licenses decreased by 22.5 percent, and licenses issued to Illinois residents in surrounding states increased. Research suggests the possibility that residents most likely to test seropositive were most likely to seek out-of-state licenses. Testing costs were paid by the applicants, not by the state, but the cost per case of HIV identified was estimated to be \$312,000, compared with \$2,000 per case identified through the state's voluntary counseling and testing program. The law was repealed and the Director of the Illinois Department of Public Health concluded that the experience "provides a strong argument against widespread mandatory or publicly supported HIV antibody testing of low-prevalence populations" (100).

There also is evidence that individuals, especially high-risk individuals, are more likely to come forward if they have the option of anonymous testing. In an Oregon study, anonymous HIV testing, as opposed to confidential testing, increased the number of people who came in to be tested and increased the proportion found to be seropositive (28).

Evaluation of Counseling and Testing

Counseling and testing programs have been difficult to evaluate because of the variety of study populations, research designs, methodologies, analyses, and results (42). In addition, testing is often performed without counseling (though CDC's guidelines require counseling with testing) (41). There is evidence that

counseling and testing can lead to reduced sexual and drug risk behavior associated with viral transmission (42,45). The effects vary, however, by serostatus, population, and the quality of the counseling and testing service.

The single area with clear data for behavior changes associated with reduced risk of HIV transmission following counseling and testing concerns both gay and heterosexual discordant couples (one partner infected with HIV and the other not). It is important to note, however, that this finding comes from programs in which the counseling extended beyond that typically received by most people who are tested. In several studies of discordant couples, there was a substantial increase in condom use over time. These results suggest that intensive counseling over a sustained period may be effective in reducing risk behavior for individuals at high risk for HIV infection (21,53,81,98,114). They may point to ways to improve counseling for other groups.

EFFORTS DESIGNED FOR THE AMERICAN PEOPLE AS A WHOLE¹²

Education and prevention efforts aimed at the American people as a whole have several aims. In addition to the obvious aim of promoting safe practices, others are to reduce discrimination against infected people and to reduce anxiety among low-risk people by giving

¹² This section is based largely on a paper prepared under contract to OTA by Zimmerman, Pham, and Steinman (120).

them good information about how HIV is and is not transmitted. To a large extent these efforts are intended to reach sexually active heterosexual youth and adults for whom there are few targeted community-based programs. This group accounts for relatively few AIDS cases, but the percentage of heterosexual adolescents and adults among AIDS cases who do not belong to a defined high-risk category is growing. From 1988 to 1994, the percentage of newly-diagnosed AIDS cases in this group increased from 5 percent to 10 percent. AIDS is becoming a particular problem in some heterosexual subpopulations, particularly African-Americans and Hispanic-Americans (7,74).

Knowledge about HIV transmission has increased from 1987 to 1992, though there continue to be significant gaps (88). This increased knowledge may be explained by a combination of several influences, including media attention, high profile cases such as Magic Johnson and Ryan White, and school-based AIDS education. Americans are more likely to understand how AIDS can and cannot be transmitted. However, in 1992, 55 percent did not know whether latex condoms and natural-membrane condoms conferred the same protection against HIV/AIDS, and 60 percent did not know whether oil-based lubricants can cause latex condoms to break, two important factors in condom effectiveness.

Knowledge usually is necessary for behavior change, but there is no clear and consistent evidence that accurate AIDS knowledge alone necessarily changes behavior (4). Many sexually active heterosexual Americans may be at

modest risk for HIV transmission because they engage in sexual activity with more than one sexual partner, often without a condom (2,7,8,23).¹³ Despite the risk for transmitting HIV through heterosexual activity, few interventions have been evaluated to determine their impact on this behavior.

Mass Communication Campaigns

National surveys indicate that television is the most frequently cited source of information about AIDS. Thus, the mass media are well-positioned to play the dual role of influencing people who are not reached by other interventions and serving to reinforce non-risk behavior for those who are. The CDC developed America Responds to AIDS (ARTA), a national public service advertisement and public relations campaign designed to reach as many Americans as possible with information about HIV and how to prevent its spread. The campaign ran from 1987 to 1991, using electronic and print media, as well as public events. ARTA focused on providing information about AIDS rather than urging behavior change. It shied away from strong prevention messages, because the behavior changes needed to reduce the spread of HIV involve controversial topics such as sexual behavior and drug use. For instance, the public service announcements usually failed directly to address risk-reduction behaviors such as the use of condoms. In addition, there

¹³ Most Americans who engage exclusively in heterosexual sexual activity are at less risk for infection than most gay and bisexual men simply because the incidence of HIV is lower among heterosexuals than among gay and bisexual men.

are inherent limitations to public service announcements as opposed to paid commercials because television and radio station personnel determine if and when the commercials run. They are motivated primarily by the needs of the station, not by public health considerations. Further, to be most effective, mass media campaigns must be implemented for a sustained period of time and heard repeatedly, which is not likely with public service announcement campaigns. The media potentially offers an important source of AIDS prevention because of its reach, but the opportunity has not yet been used effectively.

AIDS Prevention by Physicians

Physicians are seen by the public as sources of reliable health care and prevention information (14,117) and physician counseling can lead to healthier behaviors (65). As yet, however, physicians have not played a major role in informing people about their risk of infection with HIV, or counseling them about how to avoid it. They represent a potential source of influence for the 60 percent of Americans who see a physician each year--though many of the people at highest risk may not see a physician.

The U.S. Surgeon General, the CDC, the Agency for Health Care Policy and Research, and many professional medical associations have encouraged physicians to assess their patients' risk behaviors and counsel them to prevent HIV transmission, but no clear guidelines about what steps to take with patients have been put forth. It appears that most physicians do not counsel about HIV or AIDS (6,35,110).

(Physicians often do a poor job with other prevention opportunities as well, e.g., influenza vaccines for older people, rubella screening for potentially pregnant women.)

Lack of information about and training in AIDS, discomfort in addressing sexual conduct, and incorrect assumptions about high risk behaviors may be holding back some physicians from counseling. Some research has shown that physicians are uncomfortable with AIDS, at least partially because most people with AIDS are gay or are members of other stigmatized groups (119). Other barriers to effective physician prevention efforts include rushed visits and limited or nonexistent reimbursement for counseling and testing. Finally some people cannot afford to visit doctors, choose not to see them regularly, or see them in settings not conducive to prevention counseling (69).

A nationwide program of AIDS Education and Training Centers (AETCs), set up through the Health Resources and Services Administration of the Public Health Service, began in 1987 to train physicians, nurses, and dentists. Most AETC activities are for training health care personnel to care for people with AIDS, but about 25 percent of the training activities are directed towards prevention (13), and there also are private sector continuing medical education programs on the topic. Few studies have evaluated the effects of training physicians or other health care workers, but some evidence suggests that training may improve risk assessment and prevention counseling for HIV (29,44). Any future efforts

should be subjected to rigorous evaluation.

PREVENTING AIDS AMONG GAY AND BISEXUAL MEN¹⁴

Carefully designed studies have demonstrated that interventions can be effective in lessening risk behavior among gay and bisexual men. The interventions studied included individual or small-group counseling, HIV counseling and associated testing, and community approaches. In these studies, reduction in risk behavior was defined as statistically significant increases in condom use or reductions in anal intercourse without a condom. The studies showed that positive behavior changes can be both short-term and relatively long-term (greater than one year). Evidence suggests that interventions can be effective with gay and bisexual men generally, including African Americans and adolescents. No studies of Latinos have been published, however.

Multiple session, small group counseling can result in both short-term and long-term increase in condom usage and less unprotected sexual activity (57,112), including with African American gay and bisexual men (83). No controlled studies have been conducted considering the effects of counseling on gay and bisexual adolescents, but in two uncontrolled studies, reductions in risk behavior were associated with counseling interventions.

Data suggest that HIV counseling and testing may play a role in HIV risk reduction for gay and bisexual men (42). Gay and bisexual men who have been tested tend to engage less often in sexual risk behavior. However, it is difficult to isolate the effects of HIV counseling and associated testing from other factors that may affect risk behavior, including the same personal factors that cause some people to be tested and others not to be.

Community-level interventions seek to modify the norms of entire groups of people in which there is a high level of HIV infection, so that there can be social and peer reinforcement for non-risk behavior. Several projects included pre- and post-intervention evaluations that suggest that community interventions may have an effect on reducing risk behavior (11,54,55). For example, the STOP AIDS Project in San Francisco conducts outreach and workshops for gay and bisexual men. An evaluation, conducted with the Center for AIDS Prevention Studies, revealed that of the last 505 pre- and post-test evaluations, 25.1 percent of the men reported unprotected intercourse prior to the workshop and 19.4 percent after, with greater differences observed for seropositive individuals (9). (None of these studies have randomized communities to have the intervention or not, or have had control communities, so it is not clear how much of the change can be attributed to the intervention.) In a study of small-town gay men who go to bars, training a small group of "trendsetters" in non-risk sexual behavior altered the norms of the group. "If risk reduction is an expected and accepted norm within one's peer and social network, individuals will be

¹⁴ This section is based largely on a paper prepared under contract to OTA by Coates et al. (10).

encouraged to adopt precautionary patterns (58)."

Determining whether HIV infection prevention is working "on the ground" is difficult because of the small number of controlled studies and the lack of consistent, established surveillance systems to provide regular and reliable information about HIV transmission rates. Studies have found sharp declines in risk behavior among gay and bisexual men in San Francisco, New York, and other cities during the 1980s. Reported behavior changes early in the AIDS epidemic among gay and bisexual men were among the most profound in public health (11,27,71,72,73). There have been declines in seroconversion from HIV negative to positive (50), declines in potentially unsafe sexual relations (20,24), declines in other sexually transmitted diseases, and declines in the rate of new AIDS cases. For example, the San Francisco Department of Health projects the number of people in that city who will become infected with HIV between 1994 and 1997 at 1,000 per year (an estimated 650 among gay men), down from 8,000 in 1982. These changes appear to have continued into the 1990s (89) and cannot be explained simply by saturation of high-activity core groups (50). They almost certainly represent benefits gained through behavior change (but not necessarily from particular programs).

It must be underscored that while there is evidence of improvement for gay and bisexual men as a group, there continues to be high rates of new infections among some racial and ethnic groups and among younger gay and bisexual men. Young gay and bisexual

men are forging another wave of HIV infections. Existing intervention strategies do not appear to be successful in reaching these populations. In addition, there is some indication that gay and bisexual men who initially adopted low-risk behaviors may have failed to maintain these behaviors (11,27,56,94). These data collectively demonstrate a need to focus on and find more effective interventions for younger and non-white gay and bisexual men, while continuing to pursue prevention and maintenance strategies for all gay and bisexual men.

PREVENTING AIDS AMONG INJECTING DRUG USERS¹⁵

The exchange of blood through sharing of injecting drug equipment by two or more people is the second most common cause of HIV transmission after unprotected sexual intercourse between men. The major mechanism for the spread of HIV infection among injecting drug users is injection with traces of blood from contaminated needles or other paraphernalia previously used by an HIV infected individual. Providing previously used equipment to another injection drug user is often seen as an act of solidarity or as a service for which one may legitimately charge a small fee.

Transmission of HIV within the population of injecting drug users may be lessened by eliminating or reducing illicit drug injection, reducing needle sharing, or using sterile injection equipment. Without intervention, HIV

¹⁵ This section is based largely on a paper prepared under contract to OTA by Des Jarlais (16).

can spread rapidly among injecting drug users. In certain areas, the rate of infection has increased from 10 percent to 40 percent or more within just one or two years (17). In turn, HIV is often spread from infected injecting drug users to their sexual partners.

Successful drug detoxification and treatment are the best methods of AIDS prevention among injecting drug users but are not a completely satisfactory solution. Only 15 percent of active drug users are in treatment on any given day, and there are not enough treatment slots to meet the demand from drug users. In addition, many drug users do not want to enter treatment. Treatment programs can lead to substantial reductions in illicit drug use (47), but treatment does not guarantee ending risk behavior or preventing a return to drug use. Education at drug rehabilitation sites and "street outreach" to active drug users, including education, needle exchange, and instruction on needle sterilization were attempted in some places.

The National Institute of Drug Abuse (National AIDS Demonstration Research /AIDS Targeted Outreach Model) funded street outreach prevention efforts in 41 projects in 50 cities. These programs offered participants information about HIV and AIDS, personal risk assessment, and HIV counseling and testing. Results were somewhat mixed, but the interventions were followed by a decline in needle sharing and an increase in sterile needle use.

Needle Exchange

Needle exchange and bleach disinfectant efforts have proven

controversial, with some critics asserting they encourage illicit drug use or that they implicitly endorse the use of illicit drugs. In the United States, unlike in several European countries, no Federal funds may be used to support exchanges of needles or any distribution of sterile injection equipment to illicit drug users. In addition, many states prohibit the sale of such equipment without a prescription. By contrast, providing legal access to sterile injection equipment, either through expanded pharmacy sales, needle exchange or both is now a standard part of HIV prevention in many other industrialized countries.

Local needle exchange programs have been established in at least 102 U.S. sites through at least 37 programs. Programs provide a sterile needle in exchange for a used one. In addition, many of the programs make referrals to drug detoxification and treatment programs and distribute condoms, bleach, health pamphlets, and other AIDS prevention information. About half of the needle exchange programs are legal under the law of the state in which they operate. About one-quarter are not legal but receive support from a local elected body. The remainder operate outside of the law and without such support (52).

Several U.S. needle exchange programs have been evaluated. In every published study, including one conducted by the General Accounting Office (GAO) in 1993, no evidence was found that the programs result in any increase in illicit drug use. In fact, one program studied by GAO found a decrease in drug use in association with the implementation of a local effort (52). In addition, there is evidence that

outreach programs and needle exchange programs uncovered demand for drug detoxification and treatment and were a significant source of referrals to such treatment (3,49,79).

The National AIDS Demonstration Research/AIDS Targeted Outreach Model and other studies (18) have found that HIV infection rates are much lower in areas that permit over-the-counter sales of sterile injection equipment as opposed to areas that restrict them by requiring prescriptions for their purchase. In one study, incidence of HIV infection was lower by half in areas with legal over-the-counter sales of needles (30). Studies of injecting drug users participating in needle exchange programs in several U.S. cities also have found a low rate of HIV transmission among participants (39,78,80,82).

A study of hepatitis B and hepatitis C infection in Tacoma, WA provides good evidence for the effectiveness of needle exchange programs on reducing transmission of blood-borne viruses, particularly because the study used biological outcomes and a controlled experimental design. Failure to use the local needle exchange program was strongly associated with both hepatitis B and hepatitis C infection. Injecting drug users who did not use needle exchange were five times as likely to become infected with hepatitis B and seven times as likely to become infected with hepatitis C (18,40).

Taken together, these data and others provide evidence that access to sterile

injection needles has a beneficial effect on the drug-related behavior that puts individuals at risk for contracting HIV.

In addition to attempts to prevent the sharing and reuse of needles, there are interventions which involve teaching illicit drug users to clean their equipment with bleach which kills HIV. However, studies have raised questions about the effectiveness of this type of intervention, and it is not clear there is a relationship between self-reported use of bleach disinfectant "in the field" and protection from HIV infection.

Sexual Partners of Injecting Drug Users

HIV also is transmitted from infected injecting drug users to their sexual partners. By the end of 1994, heterosexual sexual activity between injecting drug users and individuals who do not inject drugs accounted for about 16,000 cases of AIDS (104). Injecting drug users have changed their sexual risk behavior more than heterosexuals in the United States generally (62), but studies have shown less success in persuading them to change their sexual risk behavior than their needle-sharing behavior (31). Thus, sexual relationships between injecting drug users and their partners continue to provide a route of HIV transmission into larger populations. Finding effective ways to persuade injecting drug users to avoid risk behavior during sexual activity is a critical challenge in slowing the spread of AIDS.

PREVENTING AIDS IN RACIAL AND ETHNIC MINORITY POPULATIONS¹⁶

Research focusing on AIDS prevention among minority populations has lagged behind research on other groups, despite the disproportionately high (and worsening) rate of HIV infection among African Americans and Latinos. Before 1988, only one research report focusing on a minority population had been published. In 1995, 41 reports, published (or accepted for publication) in peer reviewed journals, focused entirely or mainly on African Americans, Latinos, or both. (There still have been no studies published on Native Americans or Asian/Pacific Islanders.) Of these studies, 13 were randomized trials. In four of those, the interventions were very effective, and in five others, of moderate or mixed effectiveness. Even from this small literature, however, some general findings emerge, and they are consistent with interventions in other populations.

The most successful interventions were developed through extensive preliminary work with the target population, and used formal behavior change theory in their development. The preliminary work consisted mainly of focus groups and individual interviews. These exchanges provided information, for instance, about the barriers to safer behavior and about the level of skills that people had to deal with difficult situations. They also served to help develop and test the research

questionnaires and role playing materials before formal data collection began.

The four most effective interventions emphasized behavioral skills and practice (e.g., practice for teenagers in refusing to engage in unsafe behavior, negotiating about condom use, and putting on condoms), and were generally more interactive and less didactic than the less effective interventions. African American adolescents were the target of two of the particular programs that were most successful, and the interventions were, in one case, eight weekly group meetings of 90 minutes to two hours each, focusing on behavioral skills, condom use skills, and refusal skills; and in the second case, a five-hour program of information, videos, games, exercises, and skills practice. A third successful program, this one for high-risk mostly African American women, consisted of a series of group sessions with a variety of information, role playing, and other activities. The fourth program was for African American and Latino sexually-transmitted-disease patients, and consisted of culturally appropriate videos, 20-minute group sessions, skills building, role playing, and discussions.

There are large gaps in the AIDS prevention research for minority populations. Most strikingly, almost no work has been done with African American and Latino drug users or gay men, two groups affected heavily by the AIDS epidemic. Interventions targeting adult men who are not injection drug users have been rare, except for studies of STD patients. Adolescents have been studied to some extent in schools, but not in neighborhoods or juvenile

¹⁶This section is based largely on a paper prepared under contract to OTA by Marin (70).

detention settings, where many of these youth are more likely to be.

Research has gone slowly with African Americans and Latinos for several reasons. Funding agencies have not specially targeted these groups, and researchers may have shied away from taking on studies of high-risk, hard-to-reach populations. Few non-minority researchers have demonstrated interest in these groups, and there are too few minority researchers in positions to undertake the needed work.

PREVENTING HETEROSEXUAL HIV TRANSMISSION TO WOMEN¹⁷

Little is known about the effectiveness of AIDS prevention activities targeted towards women. Multiple counseling and skills sessions targeted at female injecting drug users, female sexual partners of injecting drug users, and inner-city or low-income women seem to provide a benefit in terms of increased condom use (26,87). A controlled study of a program of peer outreach combined with distribution of written material containing risk-reduction strategies increased condom use among female sexual partners of injecting drug users living in public housing projects (99). A methodologically sound HIV counseling and testing study found no benefit at either two weeks or three months (48).

¹⁷ This section is based largely on a paper prepared under contract to OTA by Ehrhardt, Exner, and Seal (25).

As with many other subpopulations, often studies enlisted very small samples, failed to provide enough information to be assessed, had unclear or very short follow-up periods, were not randomized, or did not use control or comparison groups. This deficiency is a serious matter given the rate of increase in AIDS cases among women. More work is needed in this area in order to develop effective prevention programs. The variety of techniques studied must be expanded, especially to include community-level interventions. Maintenance of non-risk behavior should be studied as well.

PREVENTING AIDS AMONG SCHOOL-AGED YOUTH¹⁸

There have been various studies evaluating school, community, and health clinic-based sex and AIDS education and prevention efforts targeted towards youth. The weight of the evidence indicates that sex and AIDS education programs, in general, increase the use of condoms (or other forms of contraception) by a small amount, and that more targeted programs can increase condom use by a greater amount. Still, overall, there are large gaps in knowing how to prevent HIV transmission among young people.

All 50 states either mandate or recommend AIDS education in their schools (15,34). Schools have the advantage of reaching almost every young person in society before he or she begins potentially risk-associated

¹⁸ This section is based largely on a paper prepared under contract to OTA by Kirby (59).

behavior. There is widespread public support for sexuality and AIDS education in the schools (32,33,67), but there has been conflict in some communities over the content of such education. Some believe that only abstinence until marriage should be discussed, while others believe that contraception and other sexuality topics should be covered as well. Those who favor only abstinence fear that further discussion would encourage youth to engage in sexual activity that they otherwise would avoid, thereby potentially increasing HIV transmission along with other undesirable outcomes. People who favor discussion of additional topics along with abstinence are concerned that abstinence alone is not a sufficient lesson, because many teenagers still would engage in sexual activity.

Studies have found no evidence that curricula focusing only on abstinence have an impact on delaying the onset of sexual intercourse. However, limitations in the design of these studies may have obscured program impacts. On the other hand, data strongly support the conclusion that sexuality and AIDS education that include discussions of abstinence and contraception in combination with other topics such as resistance skills do not hasten the onset of sexual intercourse for students who have not already initiated such activity (46,60,76,97,116). In fact, there is evidence that these more sexual educational and AIDS prevention programs result in a lower incidence of sexual intercourse, and for individuals who do engage in sexual activity, fewer sexual partners and greater use of contraception (46,60,64,68,115). At the

same time, none of the interventions resulted in increased or decreased frequency of intercourse for individuals sexually active prior to the beginning of the study.

Some other methods also have been found to have at least marginal value in reducing HIV transmission. Multiple-session counseling (5), counseling connected to other services (118), and a wide-ranging program of community prevention activities (61,113) all have some promise, but need additional refinement and evaluation.

PREVENTING AIDS AMONG CHILDREN

HIV can be transmitted from infected mother to her fetus during pregnancy, at birth, or during breast feeding. An estimated 7,000 births occur each year to HIV-infected women in the United States. All of these children initially test seropositive because they carry certain elements of their mother's immune system, though about three-quarters of them will become seronegative and suffer no manifestations of HIV disease. In fact, about 25 percent of these children are actually infected with HIV, and virtually all of them will develop AIDS.

HIV transmission among this population may be significantly reduced if the infected mother and newborn are treated with Zidovudine (AZT). In a randomized clinical trial, only 8 percent of the children born to HIV-infected mothers were born infected if the mother took AZT during pregnancy and birth. (37). The effectiveness of this

intervention in the community depends on the mother's knowledge of her serostatus, her access to prenatal care, her confidence in her doctor, and her ability and willingness to use AZT. The effect seen in the clinical trial also might be larger than it is likely to be in the community.

Studies have shown that a program of testing only pregnant women who appear to fall into a traditional exposure category for HIV infection will fail to identify many of the women who in fact are seropositive (22,37). Consequently, a program of voluntary testing might be a better method to screen for HIV among pregnant women. Most pregnant women who may be at risk for HIV infection will agree to be tested if they are in prenatal care and the service is offered. In an eight-month pilot study done in 1989 in six Los Angeles County public clinics, 76 percent of 9,069 women accepted voluntary HIV testing. Results also suggested that when the HIV antibody test was presented as a routine rather than a special, optional test, acceptance was nearly universal (12). In 1987, routine prenatal HIV screening was offered as part of a battery of tests to 3,472 women at Grady Memorial Hospital, which serves a poor, intercity population in Atlanta. The HIV test was singled out from the others and the women received written information about the test and its implications, along with a consent form agreeing to the test. Even though at the time there was no treatment known to prevent transmission from infected mother to child, 96 percent of the women agreed to be tested (66). Testing and counseling pregnant women can be an effective part of reducing perinatal HIV transmission if

seropositive women have access to AZT and to related medical care and support services.

SOCIAL MARKETING¹⁹

People and their needs change constantly, and this includes the information and stimulation they need to practice healthy behaviors. Even proven methods may have to be tailored (e.g., through community-based planning) to be successful in different subpopulations and over time. An effective approach may be social marketing, which seeks to borrow consumer product marketing techniques from the private sector and use them for health promotion. Social marketing has been talked about but little used in AIDS prevention in the United States, though it has been used in other countries for AIDS prevention and for other health promotion campaigns. Social marketing takes the approach that prevention must be "sold" and that there may be a need to "resell" it even to the "converted" in order to maintain behavior change, just as there is with consumer products. "No one at Coca Cola would argue that selling Coke is something you accomplish once and forever, especially when everyone knows about Coke and likes it. Selling Coke is something you do every day, in ever new ways, to meet an ever changing consumer (92)."

Social marketing in an AIDS prevention context would use private-sector product marketing approaches to

¹⁹ This section is based largely on a paper prepared under contract to OTA by Rabin and Porter (84).

"sell" HIV prevention to the public. It would move beyond traditional health education to provide a framework for constantly adapting prevention efforts to new audiences and audiences who are always changing. It would employ market research, segmentation, diverse marketing channels, measurable outcomes, constant evaluation for continued efficacy and program redesign where needed. It would identify and attempt to meet a consumer need with the goal of sustaining behavior change over a period of time. In exchange for alterations in behavior, social marketing would offer a desired benefit, one that is found through rigorous consumer market research. Social marketing research has shown that desired benefits often have more to do with social acceptance or status than "health." For example, future health benefits may be insufficient to persuade teens to avoid smoking, but they may be willing to do so to escape current social stigma. With respect to AIDS, social marketing would seek to address questions such as: What is the benefit of abstinence for teenagers when sexual activity is considered a rite of passage by one's peer group? How can condom usage be increased when condoms often are associated with gay people, a stigma for some, or a lack of trust between partners? What is the benefit of avoiding certain sexual activities versus the risk of contracting a virus that may kill you in 10 to 15 years?

Social marketing considers perceived benefit, consumer acceptance, price (including monetary value, time, and social cost), sacrifice of behavior possibly considered pleasurable and convenience of outlets. It takes as a given that effective promotion requires a

wide array of creative tactics and repetition involving professional message design. For each AIDS prevention behavior, there is competing pressure to stray from that behavior, so a single exposure to even the most effective message or adopting the "right" behavior may not be enough. Social marketing would "sell" prevention again and again to the same target audiences.

Social marketing approaches have been used in cardiovascular risk reduction, smoking cessation and population planning, as well as in U.S.-funded AIDS prevention efforts in other countries. For example, the National Cancer Institute developed the 5-A-Day campaign to increase fruit and vegetable consumption. It employed marketing segmentation to define target audiences and followed a consumer-based approach to the design of media messages. Diverse marketing channels were chosen to deliver messages to key groups. Promotional materials were placed in over 30,000 retail establishments. There were television appearances by Olympic gold medalists.

In April 1993, the CDC established the Prevention Marketing Initiative (PMI), which uses a social marketing approach. CDC has worked with community-based organizations to develop demonstration projects targeted to young people in Phoenix, AZ, Sacramento, CA, Northern Virginia, Nashville, TN, and Newark, NJ. It also has produced 12 public service announcements for radio and television with messages about abstaining from sex and using condoms. As yet, there has been no outcome evaluation of PMI. The program entails considerable

expense, and many questions remain about whether it can achieve an acceptable level of effectiveness to make it worthwhile.

ECONOMIC EVALUATION²⁰

A central question for policymakers is which strategies are most cost-effective in preventing further HIV infection? The aim would, of course, be to choose the mix of interventions that would prevent the largest number of infections with the amount of money available for AIDS prevention programs. As is the case in most areas of medicine and health, the cost-effectiveness information that one would need ideally to make "rational" choices is quite limited. Only in recent years has sufficient evidence of the efficacy and effectiveness of interventions accumulated to begin to support such analyses.

A total of 25 economic evaluations of AIDS primary prevention interventions meeting minimum methodological criteria were found in the published literature in 1995 (90). Some of these studies look at interventions that are not basically "educational," such as screening donated blood, and screening health care workers, and are not discussed in this report. Interventions that do fall within the scope of this report and are the subjects of economic evaluations are:

- ◆ voluntary counseling and testing of injecting drug users, high- and low-

risk populations (based on a model), the general public, pregnant women, and women age 13-44;

- ◆ mandatory testing of marriage license applicants and premarital couples,
- ◆ notifying partners of infected people and injection drug users;
- ◆ bleach distribution to injection drug users;
- ◆ needle exchange for injection drug users; and
- ◆ treatment of drug dependency.

Many of the interventions--even some for which there is some evidence of efficacy and effectiveness--discussed earlier in this report have not been subject to economic analysis. This includes the important category of small group counseling (except as included in the studies of injection drug users) and virtually all the large-scale education programs aimed at the public and at various risk groups.

Findings From Economic Evaluations

The major types of economic evaluation--cost-effectiveness, cost-benefit, and cost-utility analyses--all take into account the costs and effects of interventions. In the case of AIDS prevention, as with many other preventive services, the costs of intervening occur in the present, and many, if not all, the benefits occur sometime in the future. Discounting is a technique used to allow all the costs and benefits to be expressed in current dollars, recognizing that money spent today is worth more than the same amount of money spent 10 years from now. Having everything in the same currency is necessary for making

²⁰ This section is based largely on a paper prepared under contract to OTA by Sisk (90).

comparisons, but money spent today must materialize in a particular budget, while money counted in the future need not.

Programs of counseling, testing, referral, and partner notification, as exemplified by the CDC-funded sites, produce benefits greater than their costs. If only about 7 percent of the infected people notified subsequently changed their behaviors to avert further transmission, savings in discounted lifetime AIDS treatment costs (about \$85,000 in 1990 dollars, 6 percent discount rate) would more than compensate for program costs. If savings in future earnings are added, net benefits would exceed costs if only slightly more than 1 percent of infected people notified averted further spread of HIV.

A similar pattern emerges for several interventions targeted to injection drug users. Savings in treatment costs avoided are likely to exceed program costs for counseling and testing, partner notification, and bleach distribution. Even using conservative assumptions about injection and sexual behavior for more controversial needle exchange programs, their savings in treatment costs are likely to outweigh program costs.

The results for testing marriage license applicants were less clear, partly because there is little information about how effective this type of testing would be in changing sexual behavior. Testing women of childbearing age would produce most benefits in preventing infection among adult contacts, and less in preventing the birth of infected

newborns, so it really reflects testing part of the adult population. Screening women could potentially produce more benefits than the costs of the program if it were targeted at high-risk women and the HIV prevalence were above a certain level.

Potential for Greater Use of Economic Evaluation

The use of cost-effectiveness analysis and other forms of economic evaluation in AIDS prevention policymaking is limited by the still meager literature on the topic and by the variability in analytic methods used. This situation is changing, however, as the potential value of this type of work is appreciated and more is being undertaken by independent academics and others. In addition, CDC is encouraging the use of economic analysis by the HIV Prevention Community Planning Groups that it funds. Developments in the field of cost-effectiveness analysis itself may also help solidify this work. The U.S. Public Health Service has formulated recommendations for economic principles to be applied in economic analyses, which should improve the rigor and comparability of future work.

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Judy Auerbach, Ph.D.
National Institutes of Health
Bethesda, MD

Lourdes Baezconde-Garbanati, Ph.D.
Institute of Preventive Research
University of Southern California School of
Medicine
Los Angeles, CA

Barbara Cambridge, Ph.D.
Department of Obstetrics and Gynecology
University of Texas Southwestern Medical
Center
Dallas, TX

James W. Curran, M.D. M.P.H.
Centers for Disease Control and Prevention
Atlanta, GA

Theresa Exner, Ph.D.
College of Physicians and Surgeons
Columbia University
New York, NY

Nicholas Freudenberg, Dr.Ph.
Center on AIDS, Drugs, and Community Health
School of Health Sciences
Hunter College
New York, NY

Robert Fullilove, Ed.D.
HIV Center for Clinical and Behavioral Studies
Columbia University School of Public Health
New York, NY

David Holtgrave
Center for AIDS Intervention Research
Medical College of Wisconsin
Milwaukee, WI

Jeffrey Kelly, Ph.D.
Department of Psychiatry
Medical College of Wisconsin
Milwaukee, WI

Ronald King
Whitman-Walker Clinic
Washington, DC

David L. Kirp, LL.B.
Graduate School of Public Policy
University of California at Berkeley

Len McNally, M.P.H.
The New York Community Trust
New York, NY

Walt Odets, Ph.D.
Berkeley, CA

Randy Pope
Michigan Department of Public Health
Lansing, MI

Mark Schuster, MD, PhD
Senior Natural Scientist, RAND
Assistant Professor of Pediatrics
University of California at Los Angeles

Jane Silver
American Foundation for AIDS Research
Washington, D.C.

Jeff Stryker
Center for AIDS Prevention Studies
University of California at San Francisco

Ron Valdiserri, M.D., M.P.H.
Division of STD and HIV Prevention
Centers for Disease Control and Prevention
Atlanta, GA

Prevention indicators for evaluating the progress of national AIDS programmes

Thierry Mertens, Michel Caraël, Paul Sato, John Cleland*,
Helen Ward† and George Davey Smith‡

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Introduction

Over the past decade pressure for the rapid introduction of high-profile HIV/AIDS programmes has often led to their inadequate evaluation. For example, in the United States, the Public Health Service requested that a panel be established to recommend strategies for evaluating the major AIDS prevention programmes sponsored by the Centers for Disease Control and Prevention in 1989 only — many years after the initial implementation of prevention programmes [1]. The growth of national programmes, and the participation of many governmental and non-governmental agencies, calls for evaluation methods that can provide a systematic overview of the programme's progress, in addition to a more specific assessment of the impact of discrete activities. While evaluation may appear to be a luxury, it is a crucial resource for programme reorientation. Unless plans for evaluation are made early enough, programmes run the risk of generating unfulfilled expectations, frustration and even disillusionment, due to lack of feedback on the impact of the work carried out. Increasingly, donors will, and should, demand evidence that funds are being spent effectively.

A global AIDS strategy was endorsed in 1987 and revised by the World Health Assembly in 1992 [2]. These documents describe guiding principles applicable to national and international actions relating to AIDS prevention and care. They also outline specific objectives for the prevention of HIV transmission and the reduction of the impact of the HIV/AIDS pandemic on individuals and

society. A priority task for evaluation is to determine whether activities meet these objectives, are appropriate and are implemented effectively.

Since the majority of HIV transmissions occur through sexual intercourse [3], two major interventions have been identified to reduce such transmission. The first is to increase knowledge about ways of preventing HIV transmission and to promote and facilitate sustained behavioural changes; and the second is to enhance the control of sexually transmitted diseases (STD), which are thought to increase the probability of HIV transmission. Activities have also been developed to prevent the transmission of HIV by blood; these include screening contaminated blood, donor selection and more rational use of transfusions, as well as application of universal precautions. Behavioural changes among injecting drug users have also been promoted.

This study provides recommendations for the evaluation of AIDS programmes, focusing on prevention of sexual transmission of HIV, and outlines the approach developed by the Global Programme on AIDS (GPA; Geneva, Switzerland) for use by national programmes.

Framework for evaluation of national programmes

Evaluation has been defined as the 'critical assessment, on as objective a basis as possible, of the degree to

From the Unit of Surveillance, Evaluation and Forecasting, Global Programme on AIDS, World Health Organization, Geneva, Switzerland, the *Centre for Population Studies, London School of Hygiene and Tropical Medicine, the †Academic Department of Public Health, St Mary's Hospital Medical School, London and the ‡Department of Public Health, University of Glasgow, Glasgow, UK.

Note: A methods package for the measurement of prevention indicators is available from the Global Programme on AIDS, World Health Organization, Geneva, Switzerland.

Requests for reprints to: Dr Thierry Mertens, Chief, Surveillance, Evaluation and Forecasting, Global Programme on AIDS, World Health Organization, Geneva, Switzerland.

which entire services or their component parts fulfil stated goals' [4].

It is useful to approach evaluation by questioning whether, and if so, how well it works. There are a number of approaches to evaluation, using different methodologies and objectives [5]. All share a number of common steps; the first is to state clearly the objective of the programme. In relation to AIDS prevention, the overall objective is to reduce HIV transmission, and thereby produce a fall in the incidence of HIV. But the programme may have a number of more focused objectives relating to particular time periods, such as increasing population knowledge about how HIV is transmitted, or improving the management of STD other than HIV.

For a specific set of activities, the objectives similarly need to be defined. For a community outreach activity, for example, the objectives may include reducing the incidence of STD in local sex workers, increasing their access to local health care, reducing unsafe sexual practices, and increasing the number of trained peer educators.

A common second step is to identify the indicators to be measured. These should relate to the stated overall objectives but may equally well include 'process measures', such as the number of pharmacies invited to take part in condom distribution or the number of staff trained in STD case management and qualitative assessments on strengths for, and constraints to, programme implementation.

A third stage is to decide how these indicators are to be measured, which methods to use for qualitative assessments and how often this will be carried out through routine monitoring or special surveys. Experimental techniques can be applied for focused interventions with a clearly defined outcome. This is how new drug treatments are evaluated, for example, through randomized controlled trials. Similar methods could be applied to other interventions or activities, such as the free provision of condoms. However, where the target of the intervention is not the individual but a community, the unit of randomization has to be the community. This has been suggested for measuring the impact of improved STD control programmes on the incidence of HIV [6]. However, such experimental designs are fraught with difficulties when applied at the population level, not least of which is the sheer scale of the study required.

It is useful to separate two different goals of the evaluation of health programmes: efficacy and effectiveness. Whether the efficacy of interventions, in ideal circumstances, can produce the desired outcomes can be most reliably ascertained by experimental studies. Quasi-experimental and purely observational methods are less robust techniques for evaluating efficacy, but are usually less costly and sometimes the only methods adaptable to a particular setting. Once efficacy has been formally evaluated, the interventions are implemented in circumstances that differ from those existing during experimental testing. The resources, the level of staffing, the

degree of human motivation and the level of auxiliary support may be less when programmes are implemented in real-world settings rather than during the conduct of formal trials. It is commonly found that the outcomes of health interventions are more favourable during trials than during routine practice. It is therefore necessary to evaluate the effectiveness of interventions, that is, the degree to which the potential benefits demonstrated in trials are realized in usual practice. The evaluation of the effectiveness of programmes will generally be carried out by purely observational methods. Since programme evaluation is carried out to inform choices between alternative courses of action, it is also important that the data required for assessment of goals and for supporting decision making are collected [7].

The evaluation of prevention aspects of national AIDS programmes has several dimensions. The first consists of understanding the context in which efforts are taking place to slow the spread of HIV, and thereby to assess the appropriateness of these efforts. Indeed, patterns of sexual behaviour are deeply embedded in social organization and culturally determined norms, and interpretation of changes requires an understanding of the constraints and opportunities imposed by local conditions. Second, once activities are underway, there is a need to examine whether they are being carried out as planned, are on schedule and are within budget. Third, the outputs and outcome of these activities should be examined against their stated objectives. In practice, however, each of these dimensions is closely interlinked and the sequence may change over time. Monitoring of implementation is a continuous process, while contextual analysis and programme evaluation are conducted at particular times.

Qualitative assessment of the programme and understanding of the context is essentially achieved during programme reviews and case studies of specific projects. Reviews were conceived as management tools to assess the adequacy of the structure of national programmes and the progress of prevention activities, and to analyse the relevance of programme plans. The prime audiences for these reviews are programme managers and policy-makers [8]. However, many reviews have not completely fulfilled their objectives, mainly because of the lack of a framework to assess relevance and adequacy, and because of problems in the clarity and applicability of the recommendations.

Quantitative assessment of programmes can be achieved in a variety of ways using a wide range of process and outcome indicators (Fig. 1) [9]. Consideration must be given to ease of assessment, and to the feasibility, accuracy, reliability and validity of the measurements taken. Based on these considerations, 10 indicators of progress and outcomes of prevention activities have been developed by GPA (Table 1). These range from indicators of population knowledge regarding preventive practices, reported sexual behaviour and use of condoms in the general population, through STD service evaluation, to indicators of programme impact. The latter are meas-

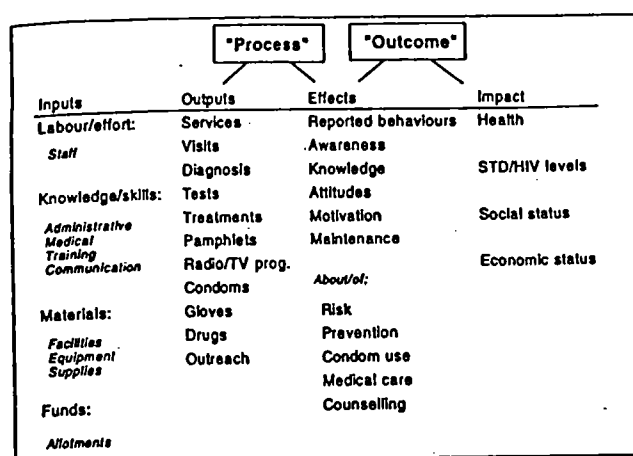


Fig. 1. Possible options for HIV/AIDS programmes monitoring and evaluation indicators. STD, sexually transmitted disease.

ured through the reported STD incidence in the general male population, and syphilis and HIV prevalence in women. This review outlines the reasoning behind the formulation of these prevention indicators, and describes the practical issues surrounding methods for their measurement. The four methods proposed for measuring the 10 core prevention indicators (PI) are shown in Fig. 2. Five indicators are measured during a population survey: reported knowledge of preventive practices (PI-1), condom availability at peripheral level (PI-3), reported frequency of non-regular sexual partners (PI-4), reported condom use during non-regular sexual encounters (PI-5) and reported STD incidence among men (PI-9). Condom availability at central level (PI-2) is assessed through a record review and key-informant interviews with major distributors. Structured observa-

Table 1. List of prevention indicators (PI).

Title	Calculation
PI-1: Knowledge of preventive practices	No. people citing at least two acceptable ways of protection from HIV infection / Total no. people aged 15-49 years surveyed
PI-2: Condom availability (central levels)	Total no. condoms available for distribution during the preceding 12 months / Population aged 15-49 years
PI-3: Condom availability (peripheral level)	No. people who can acquire a condom / Population aged 15-49 years
PI-4: Reported non-regular sexual partners	No. people aged 15-49 years who report having had at least one sex partner other than a regular sex partner(s) in the last 12 months / Total no. people aged 15-49 years who report having been sexually active in the last 12 months
PI-5: Reported condom use with non-regular sexual partner	No. people aged 15-49 reporting the use of a condom during the most recent act of sexual intercourse with a non-regular sex partner / Total no. people aged 15-49 years reporting sexual intercourse with a non-regular sex partner in the last 12 months
PI-6: STD case management	No. people presenting with STD in health facilities assessed and treated in an appropriate way (according to national standards) / No. people presenting with STD in health facilities
PI-7: STD case management	No. people presenting with STD or for STD care in health facilities who received basic advice on condoms and on partner notification / No. people presenting with STD or for STD care in health facilities
PI-9: STD incidence, men	No. reported episodes of urethritis in men aged 15-49 years in the last 12 months / No. men aged 15-49 years surveyed
Under development	
PI-8: STD prevalence, women	No. pregnant women aged 15-24 years with positive serology for syphilis / Total no. pregnant women aged 15-24 years attending antenatal clinics whose blood has been screened
PI-9: HIV prevalence, women	No. HIV-seropositive pregnant women aged 15-24 years / Total no. pregnant women aged 15-24 years attending antenatal clinics whose blood has been screened

STD, sexually transmitted disease.

tions during a health facility survey allow assessment of the appropriateness of STD case management (PI-6 and PI-7). Finally, a serosurvey among antenatal clinic attenders aged 15–24 years allows the measurement of HIV and syphilis seroprevalence in that population (PI-8 and PI-10). GPA recommends that such surveys be repeated after a period of 1 to several years, depending on the type of survey, the available resources and the level of programme implementation [10].

Methods for the measurement of PIs		Population Survey/ outlet visit	Health Facility Survey	Records	Sero-Survey
PI 1 - Knowledge of preventive practices		■			
PI 2 - Condom availability (central level)				■	
PI 3 - Condom access (peripheral level)		■			
PI 4 - Reported non regular sexual partners		■			
PI 5 - Reported condom use in relationships of risk		■			
PI 6 & PI 7 - STD case management			■		
PI 8 - STD prevalence, women					■
PI 9 - Reported STD incidence, men		■			
PI 10 - HIV prevalence, women					■

Fig. 2. Methods for measurement of prevention indicators (PI). STD, sexually transmitted disease.

The development of prevention indicators

There is much debate about what should be measured to provide evidence that a health programme 'has made the difference' [11–13]. Schrettenbrunner and Harpham [14] reviewed the limitations of evaluations focusing exclusively on health impact. First, it is important to establish that implementation of programmes actually occurs prior to seeking evidence of impact. Second, there is likely to be an important time-lag between programme initiation and detectable impact. Third, the complexities of health programme evaluation often lead to problems of interpretation: what is actually making the difference? Finally, a frequent objection relates to the use of resources in evaluating interventions already widely believed to be efficacious. In the context of HIV, for example, it can be argued that the question is not so much to confirm that the use of condoms prevents HIV transmission, but rather how to encourage people to use condoms.

An additional serious difficulty in assessing the impact of AIDS programmes arises because the prevalence of chronic infections such as HIV is a poor indicator of incidence. Similarly, where serological markers of past infection persist, as in syphilis, changes in prevalence of such markers may be hard to interpret. For predominantly sexually transmitted chronic infections it can be argued that in the immediately postpubertal age group, changes in prevalence closely reflect changes in incidence among those just beginning sexual activity. It is

not unreasonable to hypothesize that HIV or *Treponema pallidum* haemagglutination (TPHA) seroprevalence in 15-year-olds closely parallels HIV/syphilis incidence. In a public-health context, however, a community-based survey of (only) 15-year-olds would be extremely difficult. However, the underlying hypothesis may not be sufficiently robust to allow extrapolation to 15–24-year-olds (a 10-year age band), as is proposed in PI-8 and PI-10.

The difficulty may be illustrated by modelling the expected changes in HIV prevalence in a hypothetical high-incidence population, typical of East and Central Africa. In these conditions, a consistent and gradual 25% decrease in HIV incidence over 5 years due to a successful prevention programme would lead to minimal decrease in the observed HIV prevalence, if at all, after 5 years. Indeed, in many circumstances programmes are likely to face the problem of confronting a rise in seroprevalence for some years, even if the incidence is decreasing. To argue that a prevention programme has had an impact is therefore complex, as one has to compare an observed rise in prevalence with the hypothetical increase in the prevalence that would be observed, had there been no effective intervention. Conversely, the situation could occur where an apparent decrease in prevalence is misinterpreted as the result of programme efforts. In the initial years of the epidemic the vast majority of HIV-infected individuals are asymptomatic. Later, an increasing proportion develop AIDS, and mortality increases. Therefore, with a 10-year 15–24 age range, even if HIV incidence remains high, a fall in HIV prevalence may be seen as mortality rates increase among this age group with longer-term HIV infection.

Finally, when HIV infection is introduced for the first time into a country or region, the age and sex distribution of new infections is predominantly determined by age- and sex-specific patterns of sexual behaviour. With the passage of time, this distribution of new HIV infection changes, as adolescents and other newly sexually active age groups begin to predominate in the pool of individuals who are uninfected with HIV and possess HIV-associated risk behaviours and practices. Therefore, if HIV prevalence in adolescents and young adults (15–24-year-olds) is monitored, under such conditions a rise in prevalence in this age group may be observed, whether or not overall HIV incidence was on the increase or on the decrease.

In developing a framework for the evaluation of the prevention aspects of national AIDS programmes, GPA has recognized the problems of using HIV prevalence as an indicator of programme success, and proposes that the examination of impact should take place only in selected settings in the context of broader knowledge about the dynamics of the epidemic. Therefore, methods of measuring surrogate outcomes and mediating variables have also been developed, focusing on the programme implementation process.

These methods were extensively field-tested in 1992–1993 in eight countries of Africa, Central and South America, and Asia (Tables 2 and 3). We examine in turn the design of each prevention indicator and discuss issues relating to their measurement and interpretation.

Table 2. Field tests of population survey*, 1992–1993.

City/country	Geographical areas	No. people interviewed	Total fieldwork duration (months)
Dar-es-Salaam, Tanzania	Capital city	378	2
Colombo, Sri Lanka	Capital city	438	2
Burundi (national)	1 city & 1 rural	2300	3
Ethiopia	4 largest cities	6400	4

*Prevention indicators (PI) 1, 4, 5, 9. Measuring of PI-2 is carried out along with the population survey by collecting information from the major donors and commercial distributors of condoms. In addition, condom distribution outlets are visited to measure PI-3, as explained in the text.

Table 3. Field tests of health facility survey and antenatal clinic survey, 1992–1993.

City/country	Geographical areas	No. health facilities	No. observations‡
Honduras*	2 largest cities	16	79‡
Côte d'Ivoire*	2 urban and 1 rural areas	39	64‡
Madras, India*	5 urban areas	89	108‡
Ethiopia*	4 largest cities	20	350‡
Brazil†	1 city	30§	1500††
Ethiopia†	4 largest cities	25§	3000††

*Sexually transmitted disease (STD) health facility survey (PI-6 and PI-7); †syphilis/HIV serosurvey (PI-8 and PI-10); ‡number of times a health-care provider-patient encounter(s) was observed; §antenatal clinics; ††number of people tested. PI, prevention indicator.

Assessment of condom availability

Two of the prevention indicators (PI-2 and PI-3; Table 1) measure progress in the area of condom availability [15]. The first indicator estimates the average number of condoms (centrally) available per person (aged 15–49 years) in the past 12 months. Interviews with key informants from donors and major commercial distributors are used to estimate the number of condoms supplied in the past year to the national AIDS control programme, family planning programmes and those, through private commercial channels, that are available for sale.

In Ethiopia, where distribution is organized primarily through regional health bureaux, 1.3 condoms were available per adult in 1993. In Tanzania, where a social marketing programme has been in operation for

several years, 3.2 condoms per adult were available in 1992. This is of course a crude measure and ideally PI-2 should reflect the number of condoms at hand for distribution in relation to national condom needs. However, to date there is no satisfactory method to determine condom needs for HIV prevention. The sexually active population varies widely between countries, as does the proportion in mutually monogamous unions and the proportion using condoms for contraception. Finally, condoms may also cross national boundaries and even when sold or distributed may remain permanently unused. Therefore, taken on its own, PI-2 yields little information and needs to be interpreted in conjunction with the other indicators, particularly with PI-3.

Information on condom availability at peripheral level (PI-3; Table 1) is collected during the population survey. This survey involves interviewing household members within a series of randomly selected clusters. In each cluster, an investigator identifies condom outlets of three major types: medical or family planning clinics, shops and pharmacies, bars and hotels. The investigator then selects three sources for each type, usually identified through key informants during the population survey, that are most likely to stock condoms. A visit is made to three of each type of outlet to assess whether condoms are currently available and whether there was an uninterrupted supply in the previous 12 months. If at least one outlet has condoms available and had an uninterrupted supply in the previous 12 months, the total population of the cluster (calculated on the basis of the population survey sampling frame) is considered to have a supply of condoms regularly 'available'. This low threshold is motivated by the fact that few programmes have been active in the logistics of condom distribution until recently. The threshold can be changed once condom availability at the peripheral level has improved, although the basic measurement should be maintained for comparison purposes. Figure 3 shows condom availability in 1993 by type of outlet in Ethiopia. The low level of condom availability in the health-care system is noteworthy.

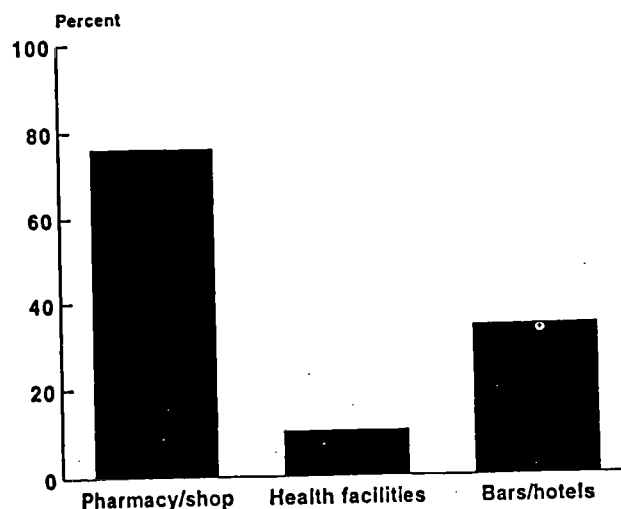


Fig 3. Condom availability at the peripheral level. Four major cities, Ethiopia 1993. (■), Percentage of population covered.

The cost of assessing these two indicators is minimal, as one person is required to visit central distribution facilities for PI-2 and visits at peripheral level are conducted during the population survey. For PI-2 it is recommended that the information is collected annually, while the frequency of data collection for PI-3 depends on the frequency of population surveys.

Evaluation of STD case management

Two other prevention indicators (PI-6 and PI-7; Table 1) monitor the quality of the management of individuals presenting to health facilities for care of STD. PI-6 measures the proportion of such individuals who are assessed and treated appropriately, according to predefined standards; PI-7 measures the proportion who receive basic advice on condom use and partner notification.

GPA recommends that a survey of a sample of health-care facilities providing care to people presenting with STD complaints is conducted, with the following methods of data collection: enumeration of all health-care facilities providing STD care; interviews with health-care providers; and observation of the practices of health-care providers with individual patients [16]. These methods provide an overview of the facilities that deliver STD care to a significant part of the population (enumeration), allow the identification of constraints in supplies and areas for improvement in health-care provision (interviews), and the evaluation of the quality of case management (observation). During the observation a score (positive or negative) is given for each consultation between a patient and a health-care provider in order to assess the quality of case management. Up to 300 observations are required to compute PI-6 and PI-7 and measure an improvement of 50% in the original score on repeating the survey, taking into account the fact that observations made on the same health-care provider are not independent. Such surveys are best undertaken at a regional level and can be repeated at an interval of 1–2 years, depending on the results of the baseline survey and the resources available.

Appropriate STD assessment and treatment are defined in terms of the health-care provider's adherence to certain standards in history-taking, examination and treatment. Clinicians may diagnose and treat on a clinical (presumptive), aetiological (with laboratory confirmation of the diagnosis), or syndromic basis. During field tests, it became apparent that it was unrealistic to think that an observer could check the diagnosis of the clinician without re-examining the patient and having access to available diagnostic tests. Diagnosis, therefore, does not contribute to the scoring of PI-6, but the way diagnosis is made (using a clinical, aetiological or syndromic approach), and its results are recorded in order to assess the appropriateness of treatment. The criteria for appropriate treatment will have a big impact on the outcome score. In the South India field test, using minimum

treatment criteria (not requiring syndromic treatment) the PI-6 score revealed that 67% of observed health-care provider-patient encounters met the requirement of appropriate case management (Fig. 4). But a more strict interpretation for PI-6 is that all patients be given syndromic treatment, unless a positive aetiological diagnosis is made, because this approach ensures that the patient is treated for most pathologies making up a syndrome. Using such a strict scoring method, the PI-6 was positive in only 10% of the observations in South India.

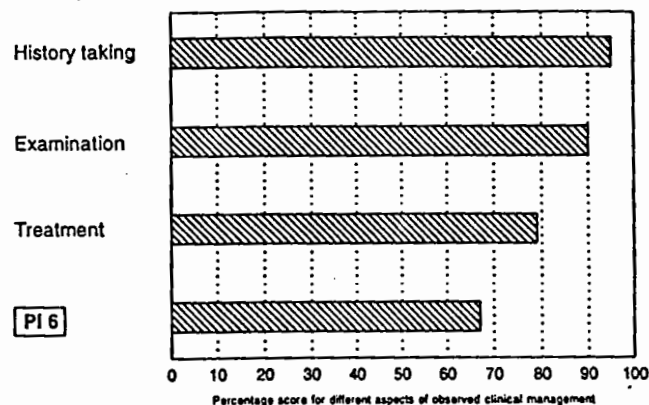


Fig 4. Sexually transmitted disease (STD) case management, India. Percentage of observed encounters in which different aspects of clinical management were handled appropriately (with criteria for scoring PI-6 involving clinical diagnosis and treatment). If criteria for scoring PI-6 involves syndromic diagnosis, then PI-6 = 10%. PI, prevention indicator.

For PI-7, basic advice refers to the promotion of condom use, and a request that partners be informed and referred for treatment. The provision of condoms at the clinic is recorded but is not part of the scoring. Health-care providers are expected to discuss the use of condoms in preventing STD and provide basic instructions on condom use. If this were included in the PI-7 score it appears that most clinicians would score very poorly (Fig. 5), potentially leading to frustration, discouragement and lack of motivation for change. As the evaluation process evolves it is anticipated that the technique of lot quality assurance (LQA) [17] might be considered, in which basic minimum thresholds are described and the standards of care are gradually raised.

It is recognized that patients with symptomatic STD consult a wide range of health-care providers, including public, private, informal and traditional sources of care. For logistic reasons, however, the protocol explicitly focuses on the measurement of the indicators in health facilities (public and private) and does not address the quality of care provided by other health-care providers, such as traditional healers and pharmacists.

A limited amount of information is usually collected on STD care provided to women as, in general, numbers of women with genital ulcers are small. On the other hand, most other syndromes are asymptomatic in women. Therefore, more work is needed in the area of STD services for women before meaningful indicators can be developed.

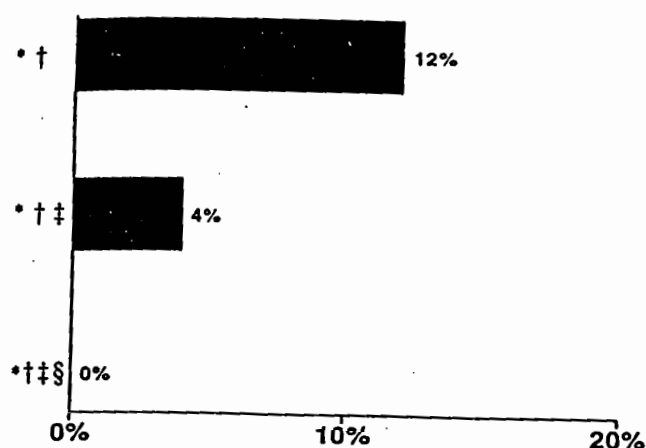


Fig 5. Sexually transmitted disease (STD) case management, India. Percentage of observed encounters in which different aspects of prevention were handled appropriately under a variety of criteria. *Condoms promoted for prevention of STD or HIV/AIDS; †patient urged to refer partner(s) for treatment; ‡instructions on how to use condoms offered; §condoms provided or sold to patient.

Assessment of STD case management can be conducted in the same area annually or every other year. The cost of the survey is between US\$4000 and 8000, depending on the country, the sample size and the honoraria of fieldstaff.

Evaluation of behavioural outcomes

Repeat interview surveys of the general population can measure change in two of the proximate determinants of HIV transmission [18]: reported number of sexual partners and condom use during intercourse (PI-4 and PI-5, Table 1). In addition, the survey is designed to estimate the reported incidence of symptoms of urethritis in adult men (PI-9) and also to identify the level of knowledge of preventive practices in relation to HIV/AIDS among the general population (PI-1) [19].

The population survey uses a clustered probability sample design. The sample is selected in two stages: an area stage and a household selection stage. Every adult aged 15–49 years is interviewed in each household sampled. Sample size is set at a level sufficient to measure changes of a meaningful magnitude in behaviours over time. With an urban and a rural sector, the achieved sample size required is 3200 individuals in total or 1600 for each sector.

The questionnaire is designed to be used as a verbatim instrument. Such standardization is essential to achieve reasonable response reliability. This approach demands careful translation into local languages and thorough pretesting. Although linguistic adaptation to specific cultural settings is essential, the substantive content of the instrument should be appropriate for the vast majority of countries. Such surveys are to be repeated after 3–4 years.

The target population for the survey consists of men and women aged 15–49 years. The lower limit is fixed at 15 years partly for social acceptability reasons. There are often objections from the family if younger people are questioned about their sexual behaviour. The upper limit of 49 years is fixed in the light of studies that suggest risk of HIV infection falls off rapidly in those aged 40 years or more in many settings.

Further narrowing of the age range is not recommended for a variety of reasons. First, in many countries, risk behaviours occur among all age groups and usually older men may have sexual associates younger than themselves [20]. Second, the median age at first sexual intercourse among men varies between countries from 15.9 to 26.8 years [20]. Third, the age range of 15–49 years is typical of demographic surveys that also collect data on condom knowledge and use. Comparison of results from these surveys with HIV programme evaluation surveys is highly desirable.

Measurement of knowledge (PI-1) can take two main forms: an open-ended question and a checklist approach. Neither method is satisfactory. The former is vulnerable to recall problems, vagueness of answers and reluctance to mention potentially embarrassing or sensitive topics. The checklist approach, although more simple, suffers from suggestion and its inability to establish the relative salience of different preventive means in the mind of the respondent. In 1992, in Colombo, Sri Lanka, using a checklist approach, 58% of respondents reported at least two acceptable methods of protection against HIV infection. Using an open-ended question, the results were lower, with 47% of respondents able to cite at least two methods. This pattern has been observed consistently in other settings. Levels of knowledge from a subsample of the population survey conducted in Burundi in 1993 are shown in Fig. 6. Because of its simplicity for analysis and its suitability to measure change over time, the checklist approach was adopted for evaluation purposes.

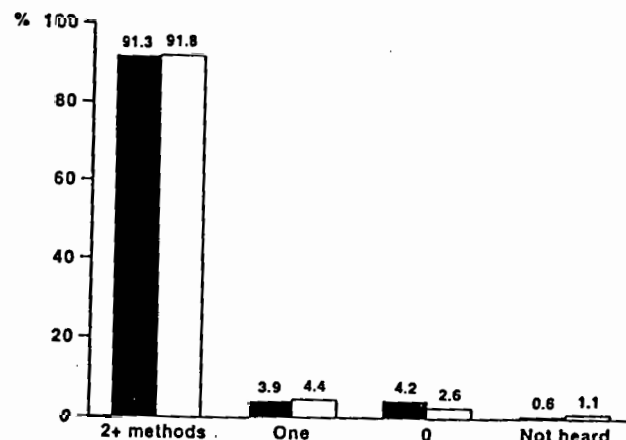


Fig 6. Prompted knowledge of preventive practices in Burundi, 1993. PI-1 = 91.7%. (■), male; (□), female. PI, prevention indicator.

Sexual partnerships take a multitude of forms and a strict definition of these forms is required for the measurement

of PI-4: the period prevalence of any non-regular sexual contact. While the extreme opposites, legally sanctioned cohabiting marriage and anonymous one-off commercial sex encounters are relatively easy to define, the range of possible intermediate relationships defies any typology. These relationships may vary in duration, expected future duration, frequency of sexual contact, degree of economic and social dependency, social visibility and legitimacy. Different types of relationships yield different degrees of risk of HIV transmission. At one end, stable and mutually monogamous relationships yield no risk if neither partner is infected; at the other end, commercial sex with multiple partners may yield a high risk of HIV transmission as the probability of meeting an infected partner increases with the number of different partners. Within the limits of simple standardized surveys, a blunt approach is required. For evaluation purposes, any sexual relationship that has lasted for at least 12 months is classified as regular and others as non-regular. While there is no pretence that this dichotomy is entirely satisfactory, a classification based on duration may represent the most important dimension of sexual relationships from the viewpoint of potential HIV transmission. In the national survey in Burundi, 20% of men and 5% of women reported non-regular sexual relationships in the previous 12 months.

A large difference between men and women in reported sexual behaviour has been observed in most surveys to date [20,21], generating much discussion. Differential reporting by men and women, differences in perceptions of what constitutes a regular as opposed to a non-regular partner, and probable omission from the sampling frames of female sex workers, are the most plausible reasons for the discrepancy. However, it is likely that none of these explanations account entirely for the reported differential. In some settings, one factor may be under-reporting by women of 'non-marital' relationships under the pressure of social norms. Further research is required on the validity of reports of sexual behaviour, in order to determine which indicators are most reliable.

Reported use of a condom during the most recent act of sexual intercourse with a non-regular sex partner (PI-5) raises no great difficulties in measurement. However, it presents problems of interpretation, because it does not take account of variations between respondents in their frequency of non-regular sex. In Dar-es-Salaam, Tanzania, although the availability of condoms was estimated to be 100% in 1992, only 27% of respondents reported the use of a condom during their last sexual intercourse with a non-regular partner. These results illustrate that although condom availability is an enabling factor, other social and cultural aspects of condom use are critical to use in appropriate circumstances. Changes in reported condom use in Uganda between 1991 and 1992 according to the type of sexual relationships [18] are shown in Fig. 7.

Self-reported incidence of STD (PI 9) raises a number of definitional and measurement problems. Even if diag-

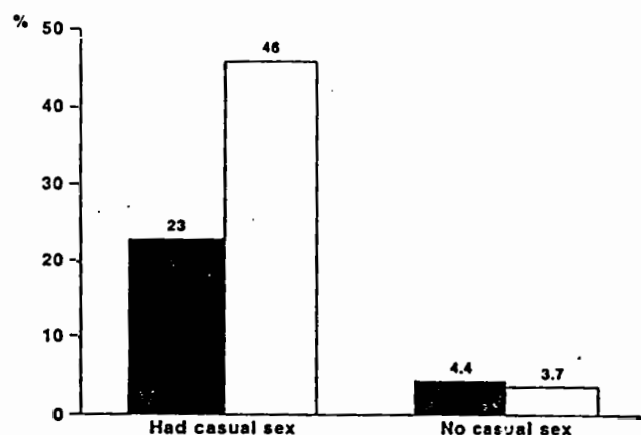


Fig. 7. Change in the proportion who reported ever using condoms by type of sexual relationship in the last year; Uganda, 1991 (■) and 1992 (□).

noses have been made by competent practitioners, most respondents are unaware of the correct medical terms for different STD. Furthermore, many episodes of STD will have passed undiagnosed. All questioning must therefore be about symptoms. For women, many infections may be asymptomatic for long periods and difficult to diagnose; hence, self-reported data for women are of little value and PI 9 is restricted to men. There may also be problems in distinguishing one episode from another, in so far as symptoms may largely disappear, but recrudescence if the infection is untreated. In Dar-es-Salaam, 6% of men reported at least one episode of urethritis in the previous 12 months. A comparison with the estimated period prevalence of urethritis from another source in the same area would be required to validate such information.

General population surveys should be repeated in the same area only after a period of about 3–4 years as it is anticipated that behavioural changes are unlikely to be detected in shorter intervals, unless very large sample sizes are used. The cost of conducting the survey in a single area is between US\$20 000 and 35 000. However, the additional cost of conducting the survey in several areas of the same country is, in relative terms, less, because some costs are fixed and are unrelated to sample size or number of sampling points. Since these surveys are repeated at 3–4-year intervals, such a cost will usually represent a small fraction (<3%) of the yearly cost of the overall prevention programme.

Evaluation of HIV/syphilis prevalence

PI-8 and PI-10 measure the prevalence of HIV antibodies and markers for syphilis infection in pregnant women aged 15–24 years attending antenatal clinics, as an indirect estimate of HIV/syphilis incidence in this population. The method proposed is an unlinked anonymous HIV/TPHA filter paper serological survey of 20–40 urban/peri-urban antenatal clinics, the sites being randomly selected by the 'probability proportional to

size' technique [22]. A total of 75 (if 40 clinics are selected) to 150 (if 20 clinics are selected) pregnant women aged 15–24 years are consecutively sampled from each of the selected antenatal clinics for a total sample of 3000 women. Since women with similar demographic characteristics will attend the same antenatal clinic, some clustering will occur within antenatal clinics and such a sample cannot be assumed to be equivalent to a randomly selected population sample. To account for this, a 'design effect' relating to the degree of clustering can be estimated and built into sample size calculations. Assuming a design effect of 1.5 (a relatively small clustering effect), a clustered sample of 3000 (120 women from 25 clinics) gives an 'effective' sample size (in terms of precision) of about 2000. The precision obtained from such a sample size also varies according to HIV prevalence [23].

The blood for HIV/TPHA testing is 'leftover' blood originally collected for syphilis screening (using a test other than TPHA) of pregnant women. This original purpose of the venepuncture is unaffected; all pregnant women sampled who are seropositive on syphilis screening are notified and treated for syphilis according to routine standards of care.

The protocol differs radically from the methods recommended by GPA for sentinel surveillance purposes. Sentinel surveillance uses convenience sampling, with sites (for example, antenatal clinics) chosen non-randomly for reasons such as willingness of staff to cooperate with surveillance, access to higher risk groups, or high attendance rates [24]. As one consequence of the convenience sampling method, sentinel surveillance data cannot be aggregated across several different sites (antenatal clinics), without correcting for selection bias inherent in the method. Such corrections are not easily made without recourse to broad assumptions that are likely to negate the utility of the results [25].

The requirement for representative data for evaluation purposes predicates random sample surveys. Since pregnant women attending antenatal clinics are a 'low-risk' population, the magnitude of changes in 15–24-year-old prevalence rates (as a consequence of changes in HIV incidence in 15–24-year-olds) will be relatively small, necessitating higher precision estimates and, therefore, large sample sizes. Otherwise, changes observed may not achieve statistical significance even with 3–5 years of separation between two surveys.

Several problems limit the wide implementation of this antenatal clinic protocol. The problems relating to the use of prevalence among 15–24-year-olds have been discussed earlier. For evaluation of HIV or syphilis incidence trends in the general population, the use of HIV and syphilis seroprevalence in 15–24-year-old antenatal clinic attenders poses some further difficulties. First, women with infertility are excluded, and STD are a major cause of infertility in some developing countries. Second, since 15–24 years is a 10-year age band, a significant number of women infected with HIV in early adoles-

cence may have progressed to AIDS or severe HIV-related ill health, which in turn is associated with infertility.

Randomly selecting 25 or 40 antenatal clinics, and then obtaining 120 or 75 samples of sera from women aged 15–24 years who are screened for syphilis over a limited data collection period, may require centrally orchestrated and specially trained survey teams. These may have to include personnel withdrawn from their routine activities for a minimum of 3–4 months. An additional operational constraint is the contribution of the private, semi-private, or non-health ministry public sector to overall antenatal care; where their contribution to antenatal care is large, and the possibility of accessing their facilities is small, the selection bias engendered may limit the value of the resulting data. However, if the patterns of antenatal care do not change over time, the survey results may be used for comparison over time.

In countries where a field test has been attempted, it has been necessary to ensure an adequate supply of serological tests for syphilis in the selected clinics. Otherwise, some form of selection may occur, as health workers decide which antenatal patients are screened for syphilis, and which are not, in an attempt to husband inadequate supplies. The field test in Brazil proved necessary to supply penicillin for the treatment of syphilis.

In the field test conducted in Ethiopia an important selection bias requiring consideration was that estimated antenatal care coverage is as low as 30–50%. The results will therefore not be representative of all pregnant women aged 15–24 years in urban areas of Ethiopia. If the studies are repeated in the same cities/regions using the same methods, changes in prevalence rates will represent true changes in HIV infection rates, provided that antenatal coverage does not change significantly, and that populations accessed are more or less stable. One check on the magnitude of the likely bias is to ask women in the population survey whether they received antenatal care for their last baby.

In view of the difficulties relating to the implementation and interpretation of impact evaluation, it is suggested that estimation of HIV and syphilis seroprevalence in randomly selected antenatal clinics be limited to selected countries where the local situation guarantees that interpretable data can be collected.

Discussion

The prevention indicators provide a quantitative, although incomplete, picture of outcomes of some of the efforts to prevent HIV transmission. A comparison of all the PI estimates can aid interpretation of programme effectiveness. To infer an association between, for example, an increase in PI-1 (knowledge of preventive practices), and a decrease in PI-10 (HIV prevalence in antenatal clinic attenders aged 15–24 years) is invalid unless an analysis of the scores of all the PI and their

trends over time, combined with a contextual analysis, is performed. Such a close assessment is required before conclusions about the impact of programme activities on outcomes can be drawn.

A fuller understanding is required of the context within which programmes operate and to interpret results provided by PI. This necessitates multilevel approaches using broad and flexible field research methodologies. The first step is to collect relevant published data, at national and local levels, on the political and administrative context, demography, and the economy and the health-sector system. Emphasis should be on factors relevant to sexual behaviour and situations enhancing risk during sexual encounters, as well as on the health and social services infrastructure. A second key area is the documentation of programme targets and level of implementation. The kinds of data that may be relevant here relate to the content and quantity of information, education and communication materials, educational efforts by various sectors, resource allocation and availability of condoms and drugs to treat STD. Eventually it may be possible to develop an overall score of the strength of HIV control programmes, as has been done for family-planning programmes. Finally, it is essential that a thorough analysis of each of the surveys is conducted, beyond the simple computation of indicators. Breakdown by sex, age, and geographical location is an essential component of the interpretation of each prevention indicator.

Little is known about the reliability and validity of survey data on sexual risk behaviours, particularly in developing countries. Results from 15 knowledge, attitude and practices surveys suggest that a moderately high proportion of men (but less women) report casual or commercial sex, with plausible variations by age and rural-urban residence [20]. These results cannot, however, allay concerns regarding potential under-reporting. It is known from surveys concerning socially disapproved behaviours, such as alcohol consumption, smoking and theft, that under-reporting is common. There is every reason to expect a similar tendency in the reporting of certain sexual behaviours, particularly among cultures where strong social norms exist. Direct validation of self-reports using external sources of information is difficult, although not impossible [26]. Checks on consistency of response across repeat measures on the same individuals are easier to perform and a number of such reliability studies have been undertaken with encouraging results. High reliability does not guarantee high validity, since consistent under-reporting is possible. Further estimates of validity can be obtained through triangulation of complementary methods, such as the combination of survey questions with ethnographic methods, for example. However, for the purposes of basic evaluation it is clear that the quality of sexual behaviour data from surveys can be improved by standardized procedures. Poorly translated instruments, inadequately trained staff, lack of privacy for the interview itself and similar shortcomings are all likely to erode the reliability and validity of response.

The implicit assumption of the evaluation strategy is that surveys, if well performed, provide information of sufficient validity and accuracy to guide programmes and monitor progress.

There are two methods of obtaining information for the assessment of STD case management: observations and interviews. It is unlikely that interviews with health-care providers can replace observations. The field tests did not demonstrate with any certainty that the two methods produced comparable results. Therefore, both methods of data collection should be retained and viewed as complementary. The interviews are useful in measuring knowledge held by the clinicians together with the specific constraints they consider most important in their work, such as poor drug and condom availability.

The process of observation is likely to influence the behaviour of clinicians. Despite this, the field tests demonstrated generally poor scores on the PI. Even if these are overestimates due to the 'Hawthorne effect' [27], the exercise is useful in identifying that even the maximal standard is low. To investigate the problem of the Hawthorne effect, it is proposed to use individuals with fictitious symptoms (simulated patients) in a few settings, perhaps on a subsample basis, to obtain an estimate of the quality of STD case management with the potential bias of known observation removed. This technique has been used in the evaluation of health-care for children [28] and family planning services [29].

In most field tests conducted by the GPA to date, the experience mobilized programme managers, clinicians and other participating sectors to plan for improved efforts in the area of condom supply, STD case management, and interventions for behavioural change. This illustrates the necessity of integrating evaluation into programme formulation.

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CAIR NEWS

*Center for AIDS Intervention Research
Department of Psychiatry &
Behavioral Medicine
Medical College of Wisconsin
Milwaukee, Wisconsin*

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Vol. 2

Stopping AIDS With Community-Level Interventions: CAIR Research Identifies New Strategies to Mobilize Communities to Prevent AIDS

Between 40,000 and 80,000 Americans—and millions of people in the world—will contract HIV infection this year. While the rate of new HIV infections has slowed in the United States since the 1980's due to more effective AIDS prevention efforts, too many Americans are contracting HIV infection, and AIDS remains the most devastating infectious disease epidemic of modern times. Better HIV/AIDS prevention models are needed, especially those that can bring about changes in entire communities that remain vulnerable to AIDS. But, how do you go about mobilizing risk reduction behavior change in an entire community of people to change their behavior?

Seed Corn and Safer Sex

It all began in a corn field in Iowa. Back in the 1960's, sociologist Everett Rogers was studying the corn planting habits of farmers. Rogers found that like most of us, farmers are creatures of habit and would plant the same variety of corn each year because—well, just because they always planted that kind of corn. When new varieties of disease-resistant seed corn became available, they weren't immediately adopted because they were different and a little unknown.

Rogers discovered that if you want farmers to change from planting one variety of corn to an-



Denise Crumble, CAIR Project Coordinator, and CAIR faculty members Dr. David Wagstaff and Dr. Kathleen Sikkema are undertaking an evaluation of community-level HIV prevention interventions in 18 public housing developments.

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