Statement of

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Good morning, Mr. Chairman and members of the Committee. I am Harvey Fineberg, president of the Institute of Medicine in Washington, DC. The Institute of Medicine is the health arm of the National Academies, which also include the National Academy of Sciences, the National Academy of Engineering, and the National Research Council. The Institute of Medicine serves as adviser to the nation to improve health, acting under the charter originally granted by Congress to establish the National Academy of Sciences in 1863.

I welcome this opportunity to discuss the effectiveness of sex education programs to prevent the sexual spread of HIV infection among youth in the United States. I will briefly summarize recent data on HIV infection and risk behaviors among youth in the U.S., discuss different types of sex education programs, and highlight findings from the 2001 Institute of Medicine report *No Time to Lose* (IOM, 2001) which examined this issue, as well as more recent research findings.

Risk of HIV Infection among Youth in the United States

Many young persons who contract HIV are infected through sexual exposure. In 2006, persons aged 13-24 accounted for 15% of newly diagnosed HIV/AIDS cases in the United States in the 33 states with confidential, name-based HIV reporting (CDC, 2008). An estimated 85% of U.S. females aged 13-19 with a diagnosis of HIV/AIDS during 2001-2005 in the 33 states with name-based HIV acquired HIV through high-risk heterosexual contact (CDC, 2007). Among U.S. adolescent males of the same age, approximately 77% with a new diagnosis of HIV/AIDS during the same time period and areas acquired the virus through male-to-male sexual contact, and an additional 11% were infected through high-risk heterosexual contact (CDC, 2007). In the decade between 1994 and 2003, new HIV/AIDS diagnoses declined by nearly 50% among people aged 25-34; however, new HIV/AIDS diagnoses among individuals aged 13-24 remained stable during that same period (CDC, 2006).

Sexual activity among teenagers is common and can lead to infections and unwanted pregnancy. In a 2005 survey, 47% of all U.S. high school students and 62% of high school seniors reported having had sexual intercourse (Kaiser Family Foundation, 2005). A recent national survey found that 1 in 4 teenage females—3.2 million—were infected with at least one sexually transmitted infection (STI) (Forhan et al., 2008). Nearly half of all African-American female teenagers in this study were infected with at least one STI. The STIs measured in this study were chlamydia, herpes simplex virus type 2 (HSV-2) (which causes genital herpes), trichomoniasis, and human papillomavirus (HPV). These STIs can be dangerous in their own right, including increased risk of cervical cancer associated with HPV infection, and the ulceration and inflammation caused by some infections can increase the risk of acquiring and transmitting HIV. Although teen pregnancy and birth rates in the U.S. have declined by approximately one-third since 1990, these rates remain high when compared to other developed countries. One worrying sign is that the teen birth rate increased between 2005 and 2006, the first rise since 1990 (NCHS, 2007).

These sober findings underscore the need for more effective deterrence of unsafe sexual practices among young persons that put them at risk for HIV, as well as other STIs, and unintended pregnancy.

Sex Education Programs in the United States

Sex education programs for adolescents in the U.S. vary considerably in their goals, content, duration and intensity, implementation setting, target age and population, the training and skill of the program facilitator, and other factors. Recognizing these variations, it will be convenient for our purposes to consider sex education curricula in two broad categories: abstinence-only programs and comprehensive programs. Abstinence-only programs (also referred to as "abstinence-until marriage" programs) teach and encourage young people to remain abstinent from sexual activity as the exclusive method to reduce their risks of HIV, other sexually transmitted infections, and unintended pregnancy. These programs provide little or no information about safer sex practices or contraception or emphasize their failure rates. Most comprehensive programs for youth (also sometimes referred to as "abstinence plus" programs) promote abstinence as the best means of preventing HIV, but also educate youth about correct and consistent use of condoms and other contraception to reduce unintended pregnancy, and to decrease the risk of contracting HIV or other infections (Underhill et al., 2007a,b).

Funding for abstinence-only programs has increased significantly in the past decade since the enactment of the Personal Responsibility and Work Opportunity Reconciliation Act ("welfare reform act") in 1996 (Pub. L. No.104-193). This legislation created a new State Abstinence Education Program, funded through section 510 of the Social Security Act for abstinence-only education, appropriating \$50 million per year for five years (FY98-FY02). The program has been reauthorized under extensions of the welfare reform act. Other significant sources of federal funding for abstinence-only education include the Community Based Abstinence Education (CBAE) program and the Adolescent and Family Life (AFL) Program. Together, these three programs (Title V, CBAE, and AFL) totaled \$176 million in federal funding for abstinence-only education in FY2007 (state funding excluded)—compared to the \$9 million in federal funding in FY1997 prior to the enactment of the welfare reform act. Obtaining comparable estimates of expenditures on comprehensive sex education programs is difficult because funding for these programs comes from multiple state, local, federal and private funding streams that are mixed with funding for other services. In light of what are surely substantial expenditures for both types of programs, it is reasonable to ask how well they achieve their goals.

Effectiveness of Sex-Education Programs in Preventing HIV infection

In the 2001 IOM report *No Time to Lose: Getting More from HIV Prevention*, an expert committee reviewed the scientific evidence on the effectiveness of abstinence-only and comprehensive sex education programs targeting youth in preventing HIV infection. At the time, the committee concluded that evidence was insufficient to determine whether abstinence programs were effective in reducing sexual activity, in part because many programs had yet to be rigorously evaluated (Kirby 2000, Maynard, 2000). In contrast, multiple reviews concluded that comprehensive sex education programs were effective in reducing self-reported high-risk sexual behaviors among adolescents and that they did not increase self-reported sexual activity (Kirby, 2000; IOM, 1997; IOM, 1995; Kirby, 1995).

Today we have an opportunity to assess what the cumulative evidence in 2008 tells us about the effectiveness of these programs in preventing HIV transmission. I want to stress the high degree

of variability that exists in the research methods, outcomes, populations, control groups, and quality of evaluations of these programs. This heterogeneity limits our ability to draw comparative conclusions about the effectiveness of different programs.

The discussion below highlights findings from two recent, published, systematic reviews of studies evaluating the impact of abstinence-only and comprehensive ("abstinence-plus") programs on biological and behavioral outcomes related to HIV prevention (Underhill et al., 2007a,b). Researchers from the Cochrane Collaboration conducted these reviews using established methodological and review guidelines to assess the strength of the body of evidence. The reviews include only randomized or quasi-randomized controlled trials which provide the strongest evidence about the effectiveness of a program. Trials were excluded from the review if they did not list HIV prevention as a specific goal of the program. While there may be other studies that could be referenced, the advantage of relying on these reviews is that they used reasonable inclusion criteria to reveal the overall pattern of results.

Relatively few rigorous scientific studies have evaluated the effectiveness of abstinence-only sex education programs. In 2006, the U.S. Government Accountability Office (GAO) issued a report on efforts to assess the accuracy and effectiveness of three major federally-funded abstinence education programs administered by the U.S. Department of Health and Human Services (DHHS). They found that while efforts had been made to evaluate abstinence-only sex education programs, most evaluation studies failed to meet minimum scientific criteria—such as randomization and use of control groups, sufficient follow-up time, or adequate sample sizes—that are necessary to support scientifically valid conclusions about a program's effectiveness. Another recently completed, methodologically rigorous evaluation by Mathematica Policy Research of four federally funded abstinence-only studies provides additional insight into the effectiveness of these programs (Trenholm et al., 2007).

Impact of programs on biological outcome measures

Incidence of HIV

To date, no studies have directly measured the impact of abstinence-only or comprehensive sex education programs on HIV incidence (Underhill et al., 2007a,b). This is in part due to the fact that the incidence of HIV in the United States is relatively low compared to other diseases, and very large sample sizes or very long follow-up periods would be required to be able to detect the impact of a prevention program on HIV incidence, making trials more complicated and costly. The impact of these programs on HIV disease is thus undemonstrated.

Incidence of other STIs

The goals of sex education programs generally include reducing the occurrence of STIs. This is important in its own right and as a surrogate biological outcome measure for HIV infection. Still, few evaluations of abstinence-only or comprehensive programs have examined the incidence of non-HIV STIs as outcome measures. All studies in the Cochrane reviews relied on self-reported incidence of STI diagnoses or treatment rather than biologically confirmed disease incidence (Underhill et al., 2007a,b). Self-reported STIs do not necessarily reflect STI incidence accurately because self reports depend in the first instance on a person's access to and willingness to seek STI screening, and self reports are susceptible to recall and other biases.

In the Cochrane review of abstinence-only programs in the U.S. to prevent HIV infection, 7 of 13 trials assessed participants' reports of STI diagnosis by a doctor or nurse (Underhill, 2007a). None of the trials found a significant short term or long term benefit of the programs compared to usual care, and one trial found significant adverse effects of the adult-led program on reported STI incidence after three- and 17- months of follow-up. However, the authors point out that the higher incidence of reported diagnosed infection in this study could have been due to differences in reporting, frequency of testing, or actual risk.

In the second Cochrane review of comprehensive (abstinence plus) programs in North American countries (primarily the U.S.) to prevent HIV infection, only three trials (of 39 included in the review) examined the impact of programs on STI-related outcomes (Underhill et al., 2007b). Two trials measured self-reported STI diagnosis by a doctor or nurse and one trial measured self-reported receipt of STI treatment. None of the three trials found significantly protective effects compared to control groups.

In reporting that neither abstinence-only nor comprehensive programs demonstrably reduce the incidence of STIs, the authors note that the trials may have been too small or too brief to detect a positive effect.

Incidence of Pregnancy

Pregnancy is an indicator of unprotected vaginal sex—an important risk behavior for HIV infection. Reduction in unintended pregnancies is a desirable outcome in itself, though it does not reflect all the risk behaviors that can lead to HIV, including, of course, the homosexual risk behaviors that account for three out of four newly infected males age 13 to 19 years. While pregnancy can be reduced through abstinence or correct and consistent use of effective birth control, reductions in HIV and STIs require other behavioral changes such as consistent use of condoms, reduction in number of partners, and screening and treatment for STIs, among others.

The Cochrane reviews included only those studies that explicitly listed HIV prevention as a goal—programs focusing exclusively on pregnancy prevention were not included. Studies in the reviews measured self-reported occurrence of pregnancy (females) or causing a pregnancy (males) rather than actual pregnancy incidence among teens (Underhill et al., 2007a,b).

In the Cochrane review of abstinence-only programs, 8 of 13 studies measured the impact of the programs on self-reported pregnancy rates (Underhill et al., 2007a).. None found a significant benefit compared to either usual care or no treatment One trial of a peer-led program found harm when compared to usual care at a 17-month follow up, but this result was isolated to a subset of males at a particular school and was not reflected in long-term behavioral measures.

In the Cochrane review of comprehensive programs, 7 of 39 trials measured the impact of programs on self-reports of becoming pregnant (females) or getting someone pregnant (males) (Underhill et al., 2007b). One unpublished study found a significantly protective effect of the program on female participants. Three studies suggested a positive outcome, but the studies had methodological flaws (e.g., limited statistical analyses or high rate of participant attrition) that limit their utility.

In sum, there is no good basis from these systematic reviews to conclude that abstinence-only programs have a positive effect on self-reported pregnancy. The reviews found limited evidence from a single unpublished study that comprehensive programs may reduce self-reported pregnancy incidence.

Impact of programs on behavioral outcome measures

The majority of studies on the effectiveness of abstinence-only and comprehensive programs examine self-reported measures of behavior rather than attempting to measure reductions in the incidence of disease or pregnancy. Self-reported behavioral outcome measures are not as strong as objective biological measures because they are an imperfect reflection of actual behavior and subject to bias.

Relevant behavioral outcome measures for programs to prevent HIV include: abstinence (or return to abstinence) from sex; reductions in the frequency of unprotected vaginal, anal, and oral sex or increases in condom use; reductions in the number of sexual partners and avoidance of concurrent partners; regular screening and treatment for STIs; and vaccination for certain STIs (HPV and hepatitis B).

Abstinence-Only Sex Education Programs

In the Cochrane review of abstinence-only programs, no program showed an effect on incidence of unprotected vaginal sex, number of sex partners, condom use or sexual initiation compared to controls. One trial favored an abstinence-only program over usual care for incidence of vaginal sex, but this was limited to two-month follow-up and was offset by measurement error and six other studies with non-significant effects. One evaluation found several significant adverse program effects: abstinence-only participants in this program were more likely than usual-care controls to report sexually transmitted infections, pregnancy and increased frequency of vaginal sex. Overall, the authors concluded that abstinence-only programs neither reduced nor exacerbated HIV risk among participants in the U.S. (Underhill et al., 2007a).

One of the most rigorous recent evaluations of federally funded abstinence-only programs was completed in 2007 by Mathematica Policy Research, Inc. (Trenholm et al., 2007). This was a multi-year, experimentally-based impact evaluation of four federally-funded abstinence-only sex education programs funded under from Title V, Section 510 of Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Pub. L. No.104-193). These four programs vary in their strategies, settings, and population characteristics. Participants in these programs were randomized to abstinence-only program or control conditions. Based on follow-up data collected 4-6 years after enrollment, youth in the abstinence-only program group were no more likely to have abstained from sex compared to those enrolled in the control group. Among those who reported having had sex, the group receiving abstinence-only education reported having similar numbers of sexual partners and similar timing of onset of sexual debut to those in the control group. The abstinence-only program participants were no more likely to have engaged in unprotected sex than youth in the control group.

Comprehensive Programs

In the Cochrane review of comprehensive sex education programs for youth in high-income countries, 23 of the 39 trials found a positive effect on at least one self-reported behavioral outcome including sexual abstinence, condom use, and unprotected sex (Underhill et al., 2007b). While the specific features that contribute most to success are difficult to discern because of the variable design in these programs, the review found many comprehensive sex education programs appear to reduce self-reported short-term and long-term HIV-risk behaviors among young people in high income countries. These findings of positive behavioral outcomes are consistent with a prior independent review of the same body of literature (Kirby, 2007).

Conclusions and Observations

In the seven years since *No Time To Lose* was published, there is little additional evidence about the impact of sex-education programs that rely on biologically verified reductions in the incidence of HIV and other STIs. The growing body of literature on the impact of sex education programs on behavioral outcomes, however, provides more information.

Based on the relatively small number of rigorous evaluations, abstinence-only programs do not reduce the risk of HIV as measured by self-reported behavioral outcomes. Studies indicate that abstinence-only programs do not result in a delay in the initiation of sexual activity, a reduction in the frequency of unprotected vaginal sex, or a reduction in the number of sexual partners. Among sexually active teens, abstinence-only programs have not been shown to increase the return to sexual abstinence nor to affect condom use.

Comprehensive sex-education programs appear more promising. Several studies found a positive effect on a number of behavioral outcomes. Comprehensive programs have reduced the self-reported incidence and frequency of unprotected sex and the number of sex partners. These programs have also been demonstrated to increase reported condom use and to delay initiation of sexual activity.

The available evidence on the impact of sex education programs is limited to a relatively small number of well-executed, controlled studies. Future evaluations should endeavor to improve study quality in such areas as program specification, outcome measures, length of follow-up, and retention of study participants. Studies that validated behavioral measures against biological outcomes would be a valuable addition. Especially useful would be studies that compared abstinence-only and comprehensive programs head-to-head in the same target population at the same time.

I believe public funds should support programs that are well grounded in evidence. By this standard, public financing and wide deployment of abstinence-only programs does not constitute sound fiscal or public health policy. Comprehensive sex education programs appear to be more effective, although this conclusion is based mainly on self-reported behavior change rather than on direct biological measures of outcome. Encouraging innovation and flexibility in the design of future sex education programs coupled to a systematic evaluation strategy is the most promising path to reducing HIV and other sexually transmitted infections among adolescents.

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