



**APPENDIX F**

**Additional Materials**





*For more information:*  
CDC's National Prevention Information Network  
(800) 458-5231 or [www.cdcnpin.org](http://www.cdcnpin.org)

CDC National STD/HIV Hotline  
(800) 227-8922 or (800) 342-2437  
En Espanol (800) 344-7432  
[www.cdc.gov/std](http://www.cdc.gov/std)

Fact Sheet for Public Health Personnel:

## **Male Latex Condoms and Sexually Transmitted Diseases**

In June 2000, the National Institutes of Health (NIH), in collaboration with the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the United States Agency for International Development (USAID), convened a workshop to evaluate the published evidence establishing the effectiveness of latex male condoms in preventing STDs, including HIV. A summary report from that workshop was completed in July 2001 (<http://www.niaid.nih.gov/dmid/stds/condomreport.pdf>). This fact sheet is based on the NIH workshop report and additional studies that were not reviewed in that report or were published subsequent to the workshop (see "[Condom Effectiveness](#)" for additional references). Most epidemiologic studies comparing rates of STD transmission between condom users and non-users focus on penile-vaginal intercourse.

Recommendations concerning the male latex condom and the prevention of sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), are based on information about how different STDs are transmitted, the physical properties of condoms, the anatomic coverage or protection that condoms provide, and epidemiologic studies of condom use and STD risk.

**The surest way to avoid transmission of sexually transmitted diseases is to abstain from sexual intercourse, or to be in a long-term mutually monogamous relationship with a partner who has been tested and you know is uninfected.**

**For persons whose sexual behaviors place them at risk for STDs, correct and consistent use of the male latex condom can reduce the risk of STD transmission. However, no protective method is 100 percent effective, and condom use cannot guarantee absolute protection against any STD. Furthermore, condoms lubricated with spermicides are no more effective than other lubricated condoms in protecting against the transmission of HIV and other STDs. In order to achieve the protective effect of condoms, they must be used correctly and consistently. Incorrect use can lead to condom slippage or breakage, thus diminishing their protective effect. Inconsistent use, e.g., failure to use condoms with every act of**

intercourse, can lead to STD transmission because transmission can occur with a single act of intercourse.

While condom use has been associated with a lower risk of cervical cancer, the use of condoms should not be a substitute for routine screening with Pap smears to detect and prevent cervical cancer.

## ***Sexually Transmitted Diseases, Including HIV***

### ***Sexually transmitted diseases, including HIV***

*Latex condoms, when used consistently and correctly, are highly effective in preventing transmission of HIV, the virus that causes AIDS. In addition, correct and consistent use of latex condoms can reduce the risk of other sexually transmitted diseases (STDs), including discharge and genital ulcer diseases. While the effect of condoms in preventing human papillomavirus (HPV) infection is unknown, condom use has been associated with a lower rate of cervical cancer, an HPV-associated disease.*

There are two primary ways that STDs can be transmitted. Human immunodeficiency virus (HIV), as well as gonorrhea, chlamydia, and trichomoniasis – the discharge diseases – are transmitted when infected semen or vaginal fluids contact mucosal surfaces (e.g., the male urethra, the vagina or cervix). In contrast, genital ulcer diseases – genital herpes, syphilis, and chancroid – and human papillomavirus are primarily transmitted through contact with infected skin or mucosal surfaces.

**Laboratory studies** have demonstrated that latex condoms provide an essentially impermeable barrier to particles the size of STD pathogens.

**Theoretical basis for protection.** Condoms can be expected to provide different levels of protection for various sexually transmitted diseases, depending on differences in how the diseases are transmitted. Because condoms block the discharge of semen or protect the male urethra against exposure to vaginal secretions, a greater level of protection is provided for the discharge diseases. A lesser degree of protection is provided for the genital ulcer diseases or HPV because these infections may be transmitted by exposure to areas, e.g., infected skin or mucosal surfaces, that are not covered or protected by the condom.

**Epidemiologic studies** seek to measure the protective effect of condoms by comparing rates of STDs between condom users and nonusers in real-life settings. Developing such measures of condom effectiveness is challenging. Because these studies involve private behaviors that investigators cannot observe directly, it is difficult to determine

accurately whether an individual is a condom user or whether condoms are used consistently and correctly. Likewise, it can be difficult to determine the level of exposure to STDs among study participants. These problems are often compounded in studies that employ a “retrospective” design, e.g., studies that measure behaviors and risks in the past.

As a result, observed measures of condom effectiveness may be inaccurate. Most epidemiologic studies of STDs, other than HIV, are characterized by these methodological limitations, and thus, the results across them vary widely--ranging from demonstrating no protection to demonstrating substantial protection associated with condom use. This inconclusiveness of epidemiologic data about condom effectiveness indicates that more research is needed--not that latex condoms do not work. For HIV infection, unlike other STDs, a number of carefully conducted studies, employing more rigorous methods and measures, have demonstrated that consistent condom use is a highly effective means of preventing HIV transmission.

Another type of epidemiologic study involves examination of STD rates in populations rather than individuals. Such studies have demonstrated that when condom use increases within population groups, rates of STDs decline in these groups. Other studies have examined the relationship between condom use and the complications of sexually transmitted infections. For example, condom use has been associated with a decreased risk of cervical cancer – an HPV associated disease.

The following includes specific information for HIV, discharge diseases, genital ulcer diseases and human papillomavirus, including information on laboratory studies, the theoretical basis for protection and epidemiologic studies.

## ***HIV / AIDS***

### ***HIV, the virus that causes AIDS***

*Latex condoms, when used consistently and correctly, are highly effective in preventing the sexual transmission of HIV, the virus that causes AIDS.*

AIDS is, by far, the most deadly sexually transmitted disease, and considerably more scientific evidence exists regarding condom effectiveness for prevention of HIV infection than for other STDs. The body of research on the effectiveness of latex condoms in preventing sexual transmission of HIV is both comprehensive and conclusive. In fact, the ability of latex condoms to prevent transmission of HIV has been scientifically established in “real-life” studies of sexually active couples as well as in laboratory studies.

**Laboratory studies** have demonstrated that latex condoms provide an essentially impermeable barrier to particles the size of STD pathogens.

**Theoretical basis for protection.** Latex condoms cover the penis and provide an effective barrier to exposure to secretions such as semen and vaginal fluids, blocking the pathway of sexual transmission of HIV infection.

**Epidemiologic studies** that are conducted in real-life settings, where one partner is infected with HIV and the other partner is not, demonstrate conclusively that the consistent use of latex condoms provides a high degree of protection.

### ***Discharge Diseases, Including Gonorrhea, Chlamydia, and Trichomoniasis***

***Discharge diseases, other than HIV***

*Latex condoms, when used consistently and correctly, can reduce the risk of transmission of gonorrhea, chlamydia, and trichomoniasis.*

Gonorrhea, chlamydia, and trichomoniasis are termed discharge diseases because they are sexually transmitted by genital secretions, such as semen or vaginal fluids. HIV is also transmitted by genital secretions.

**Laboratory studies** have demonstrated that latex condoms provide an essentially impermeable barrier to particles the size of STD pathogens.

**Theoretical basis for protection.** The physical properties of latex condoms protect against discharge diseases such as gonorrhea, chlamydia, and trichomoniasis, by providing a barrier to the genital secretions that transmit STD-causing organisms.

**Epidemiologic studies** that compare infection rates among condom users and nonusers provide evidence that latex condoms can protect against the transmission of chlamydia, gonorrhea and trichomoniasis. However, some other epidemiologic studies show little or no protection against these infections. Many of the available epidemiologic studies were not designed or conducted in ways that allow for accurate measurement of condom effectiveness against the discharge diseases. More research is needed to assess the degree of protection latex condoms provide for discharge diseases, other than HIV.

## ***Genital Ulcer Diseases and Human Papillomavirus***

### ***Genital ulcer diseases and HPV infections***

*Genital ulcer diseases and HPV infections can occur in both male or female genital areas that are covered or protected by a latex condom, as well as in areas that are not covered. Correct and consistent use of latex condoms can reduce the risk of genital herpes, syphilis, and chancroid only when the infected area or site of potential exposure is protected. While the effect of condoms in preventing human papillomavirus infection is unknown, condom use has been associated with a lower rate of cervical cancer, an HPV-associated disease.*

Genital ulcer diseases include genital herpes, syphilis, and chancroid. These diseases are transmitted primarily through “skin-to-skin” contact from sores/ulcers or infected skin that looks normal. HPV infections are transmitted through contact with infected genital skin or mucosal surfaces/fluids. Genital ulcer diseases and HPV infection can occur in male or female genital areas that are, or are not, covered (protected by the condom).

**Laboratory studies** have demonstrated that latex condoms provide an essentially impermeable barrier to particles the size of STD pathogens.

**Theoretical basis for protection.** Protection against genital ulcer diseases and HPV depends on the site of the sore/ulcer or infection. Latex condoms can only protect against transmission when the ulcers or infections are in genital areas that are covered or protected by the condom. Thus, consistent and correct use of latex condoms would be expected to protect against transmission of genital ulcer diseases and HPV in some, but not all, instances.

**Epidemiologic studies** that compare infection rates among condom users and nonusers provide evidence that latex condoms can protect against the transmission of syphilis and genital herpes. However, some other epidemiologic studies show little or no protection. Many of the available epidemiologic studies were not designed or conducted in ways that allow for accurate measurement of condom effectiveness against the genital ulcer diseases. No conclusive studies have specifically addressed the transmission of chancroid and condom use, although several studies have documented a reduced risk of genital ulcers in settings where chancroid is a leading cause of genital ulcers. More research is needed to assess the degree of protection latex condoms provide for the genital ulcer diseases.

While some epidemiologic studies have demonstrated lower rates of HPV infection among condom users, most have not. It is particularly difficult to study the relationship between condom use and HPV infection because HPV infection is often intermittently detectable and because it is difficult to assess the frequency of either existing or new

infections. Many of the available epidemiologic studies were not designed or conducted in ways that allow for accurate measurement of condom effectiveness against HPV infection.

A number of studies, however, do show an association between condom use and a reduced risk of HPV-associated diseases, including genital warts, cervical dysplasia and cervical cancer. The reason for lower rates of cervical cancer among condom users observed in some studies is unknown. HPV infection is believed to be required, but not by itself sufficient, for cervical cancer to occur. Co-infections with other STDs may be a factor in increasing the likelihood that HPV infection will lead to cervical cancer. More research is needed to assess the degree of protection latex condoms provide for both HPV infection and HPV-associated disease, such as cervical cancer.

### **Department of Health and Human Services**

For additional information on condom effectiveness, contact  
**CDC's National Prevention Information Network**  
**(800) 458-5231 or [www.cdcnpin.org](http://www.cdcnpin.org)**



Notice to Readers**CDC Statement on Study Results of Product Containing Nonoxynol-9**

During the XIII International AIDS Conference held in Durban, South Africa, July 9–14, 2000, researchers from the Joint United Nations Program on AIDS (UNAIDS) presented results of a study of a product, COL-1492,\* which contains nonoxynol-9 (N-9) (1). N-9 products are licensed for use in the United States as spermicides and are effective in preventing pregnancy, particularly when used with a diaphragm. The study examined the use of COL-1492 as a potential candidate microbicide, or topical compound to prevent the transmission of human immunodeficiency virus (HIV) and sexually transmitted

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*Notices to Readers — Continued*

diseases (STDs). The study found that N-9 did not protect against HIV infection and may have caused more transmission. The women who used N-9 gel became infected with HIV at approximately a 50% higher rate than women who used the placebo gel.

CDC has released a "Dear Colleague" letter that summarizes the findings and implications of the UNAIDS study. The letter is available on the World-Wide Web, <http://www.cdc.gov/hiv>; a hard copy is available from the National Prevention Information Network, telephone (800) 458-5231. Future consultations will be held to re-evaluate guidelines for HIV, STDs, and pregnancy prevention in populations at high risk for HIV infection. A detailed scientific report will be released on the Web when additional findings are available.

*Reference*

1. van Damme L. Advances in topical microbicides. Presented at the XIII International AIDS Conference, July 9–14, 2000, Durban, South Africa.





# MMWR<sup>TM</sup>

## Morbidity and Mortality Weekly Report

Weekly

May 10, 2002 / Vol. 51 / No. 18

### Nonoxynol-9 Spermicide Contraception Use — United States, 1999

Most women in the United States with human immunodeficiency virus (HIV) become infected through sexual transmission, and a woman's choice of contraception can affect her risk for HIV transmission during sexual contact with an infected partner. Most contraceptives do not protect against transmission of HIV and other sexually transmitted diseases (STDs) (1), and the use of some contraceptives containing nonoxynol-9 (N-9) might increase the risk for HIV sexual transmission. Three randomized, controlled trials of the use of N-9 contraceptives by commercial sex workers (CSWs) in Africa failed to demonstrate any protection against HIV infection (2–4); one trial showed an increased risk (3). N-9 contraceptives also failed to protect against infection with *Neisseria gonorrhoeae* and *Chlamydia trachomatis* in two randomized trials (5,6), one among African CSWs and one among U.S. women recruited from an STD clinic. Because most women in the African studies had frequent sexual activity, had high-level exposure to N-9, and probably were exposed to a population of men with a high prevalence of HIV/STDs, the implications of these studies for U.S. women are uncertain. To determine the extent of N-9 contraceptive use among U.S. women, CDC assessed data provided by U.S. family planning clinics for 1999. This report summarizes the results of that assessment, which indicate that some U.S. women are using N-9 contraceptives. Sexually active women should consider their individual HIV/STD infection risk when choosing a method of contraception. Providers of family planning services should inform women at risk for HIV/STDs that N-9 contraceptives do not protect against these infections.

CDC collected information on types of N-9 contraceptives purchased and family planning program (FPP) guidelines for N-9 contraceptive use. The national FPP, authorized by Title

X of the Public Health Service Act, serves approximately 4.5 million predominantly low-income women each year. Program data for 1999 were obtained from all 10 U.S. Department of Health and Human Services (HHS) regions on the number of female clients and the number of female clients who reported use of N-9 contraceptives or condoms as their primary method of contraception. CDC obtained limited purchase data for 1999 for specific N-9 contraceptives and program guidelines from eight state/territorial FPPs within six HHS regions. State health departments, family planning grantees, and family planning councils were contacted to request assistance in collecting data on purchasing patterns of the 91 Title X grantees; of the 12 FPPs that responded, eight provided sufficient data for analysis.

In 1999, a total of 7%–18% of women attending Title X clinics reported using condoms as their primary method of contraception. Data on the percentage of condoms lubricated with N-9 were not available. A total of 1%–5% of all women attending Title X clinics reported using N-9 contraceptives (other than condoms) as their primary method of contraception (Table 1). Among the eight FPPs that provided purchase data, most (87%) condoms were N-9-lubricated (Table 2). All eight FPPs purchased N-9 contraceptives (i.e., vaginal films

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#### Notifiable Disease Morbidity and 122 Cities Mortality Data

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and suppositories, jellies, creams, and foams) to be used either alone or in combination with diaphragms or other contraceptive products. Four of the eight clinics had protocols or program guidance stating that N-9-containing foam should be dispensed routinely with condoms; two additional programs reported that despite the absence of a clinic protocol, the practice was common. Data for the other two programs were not available.

**Reported by:** *The Alan Guttmacher Institute, New York, New York. Office of Population Affairs, U.S. Dept of Health and Human Services, Bethesda, Maryland. A Duerr, MD, C Beck-Sague, MD, Div Reproductive Health, National Center Chronic Disease and Public Health Promotion; Div of HIV and AIDS Prevention, National Center HIV/AIDS, STDs, and TB Prevention; B Carlton-Tobill, EIS Officer, CDC.*

**Editorial Note:** The findings in this report indicate that in 1999, before the release of recent publications on N-9 and HIV/STDs (4,6,7), Title X family planning clinics in the U.S. purchased and distributed N-9 contraceptives. Among at least eight family planning clinics, most of the condoms purchased were N-9-lubricated; this is consistent with trends in condom purchases among the general public (8). The 2002 STD treatment guidelines state that condoms lubricated with spermicides are no more effective than other lubricated condoms in protecting against the transmission of HIV infection and other STDs (7). CDC recommends that previously purchased condoms lubricated with N-9 spermicide continue to be distributed provided the condoms have not passed their expiration date. The amount of N-9 on a spermicide-lubricated condom is small relative to the doses tested in the studies in Africa and the use of N-9-lubricated condoms is preferable to using no condom at all. In the future, purchase of condoms lubricated with N-9 is not recommended because of their increased cost, shorter shelf life, association with urinary tract infections in young women, and lack of apparent benefit compared with other lubricated condoms (7).

Spermicidal gel is used in conjunction with diaphragms (1); only diaphragms combined with the use of spermicide are approved as contraceptives. The respective contributions of the physical barrier (diaphragm) and chemical barrier (spermicide) are unknown, but the combined use prevents approximately 460,000 pregnancies in the United States each year (1).

The findings in this report are subject to at least two limitations. First, data on specific products and patterns of contraceptive use were limited; CDC used a nonrepresentative sample of regions and states that voluntarily provided data, and specific use patterns of the contraceptives could not be extrapolated from these data. Second, data correlating use of N-9 contraceptives with individual HIV risk were not available.

Prevention of both unintended pregnancy and HIV/STD infection among U.S. women is needed. In 1994, a total of

**TABLE 1. Number of women using male condoms or nonoxynol-9 (N-9) products as their primary method of contraception, by Title X Family Planning Region — United States, 1999**

Region*	No. of women served	Male condoms		N-9 products†	
		No.	(%)	No.	(%)
I	179,705	27,726	(15)	1,251	(1)
II	404,325	73,069	(18)	21,515	(5)
III	487,502	73,088	(15)	4,807	(1)
IV	1,011,126	93,011	(9)	29,630	(3)
V	522,312	61,756	(12)	2,489	(1)
VI	478,533	40,520	(8)	11,212	(2)
VII	238,971	15,949	(7)	1,386	(1)
VIII	133,735	15,131	(11)	4,885	(4)
IX	672,362	109,678	(17)	14,547	(2)
X	186,469	17,320	(9)	1,275	(2)
<b>Total</b>	<b>4,315,040</b>	<b>527,248</b>	<b>(12)</b>	<b>92,997</b>	<b>(2)</b>

\* Region I=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont; Region II=New Jersey, New York, Puerto Rico, Virgin Islands; Region III=Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia; Region IV=Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee; Region V=Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin; Region VI=Arkansas, Louisiana, New Mexico, Oklahoma, Texas; Region VII=Iowa, Kansas, Missouri, Nebraska; Region VIII=Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming; Region IX=Arizona, California, Hawaii, Nevada, American Samoa, Guam, Mariana Islands, Marshall Islands, Micronesia, Palau; Region X=Alaska, Idaho, Oregon, Washington.

† Primary method of contraception reported by these women was one of the following: spermicidal foam, cream, jelly (with and without diaphragm), film, or suppositories.

**TABLE 2. Number of nonoxynol-9 (N-9) contraceptives purchased by Title X Family Planning Programs in selected states/territories, 1999**

State/territory	No. of clients served	Physical barrier method		N-9 chemical barrier methods					
		Condoms with N-9	Condoms without N-9	Gel	Vaginal			Jelly	Foam
					Film	Insert			
Puerto Rico	15,103	148,072	5,000	12,900	0	NA*	12,841	2,400	
New York†	283,200	1,936,084	NA	0	73,788	NA	3,112	23,830	
West Virginia	60,899	1,300,000	9,360	0	0	NA	1,200	9,900	
Florida	193,784	3,920,000	560,000	0	468,720	NA	5,760	25,920	
Tennessee	111,223	2,865,160§	717,088	0	94,500	12,528	756	2,758	
Michigan	166,893	631,000	254,000	0	0	NA	1,000	1,200	
Oklahoma	58,392	708,480	0	0	394,560	NA	1,200	0	
Oregon	57,099	151,900	276,000	345	25,764	2,074	272	3,007	

\* Not available.

† 41 of 61 grantees responded.

§ Purchasing by family planning and sexually transmitted disease programs are combined and cannot be separated.

49% of all pregnancies were unintended (9). Furthermore, 26% of women experience an unintended pregnancy during the first year of typical use of spermicide products (1). In 1999, a total of 10,780 AIDS cases, 537,003 chlamydia cases, and 179,534 gonorrhea cases were reported among U.S. women. Contraceptive options should provide both effective fertility control and protection from HIV/STDs; however, the optimal choice is probably not the same for every woman.

N-9 alone is not an effective means to prevent infection with HIV or cervical gonorrhea and chlamydia (2,7). Sexually active women and their health-care providers should consider risk for infection with HIV and other STDs and risk for unintended pregnancy when considering contraceptive options. Providers of family planning services should inform women at risk for HIV/STDs that N-9 contraceptives do not protect against these infections. In addition, women seeking a family planning method should be informed that latex

condoms, when used consistently and correctly, are effective in preventing transmission of HIV and can reduce the risk for other STDs.

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## **The ABCs of Smart Behavior**

*To avoid or reduce the risk for HIV*

**A** stands for abstinence.

**B** stands for being faithful to a single sexual partner.

**C** stands for using condoms consistently and correctly.







CONTENT OF AIDS-RELATED WRITTEN MATERIALS,  
PICTORIALS, AUDIOVISUALS, QUESTIONNAIRES, SURVEY



INSTRUMENTS, AND EDUCATIONAL SESSIONS IN CENTERS FOR  
DISEASE CONTROL AND PREVENTION (CDC) ASSISTANCE PROGRAMS

Interim Revisions June 1992

1. Basic Principles

Controlling the spread of HIV infection and AIDS requires the promotion of individual behaviors that eliminate or reduce the risk of acquiring and spreading the virus. Messages must be provided to the public that emphasize the ways by which individuals can fully protect themselves from acquiring the virus. These methods include abstinence from the illegal use of IV drugs and from sexual intercourse except in a mutually monogamous relationship with an uninfected partner. For those individuals who do not or cannot cease risky behavior, methods of reducing their risk of acquiring or spreading the virus must also be communicated. Such messages can be controversial. These principles are intended to provide guidance for the development and use of educational materials, and to require the establishment of Program Review Panels to consider the appropriateness of messages designed to communicate with various groups.

- a. Written materials (e.g., pamphlets, brochures, fliers), audio visual materials (e.g., motion pictures and video tapes), and pictorials (e.g., posters and similar educational materials using photographs, slides, drawings, or paintings) should use terms, descriptors, or displays necessary for the intended audience to understand dangerous behaviors and explain less risky practices concerning HIV transmission.
2. Written materials, audiovisual materials, and pictorials should be reviewed by Program Review Panels consistent with the provisions of Section 2500 (b), (c), and (d) of the Public Health Service Act, 42 U.S.C. Section 300ee(b), (c), and (d), as follows:

*"SEC. 2500. USE OF FUNDS.*

*(b) CONTENTS OF PROGRAMS. - All programs of education and information receiving funds under this title shall include information about the harmful effects of promiscuous sexual activity and intravenous substance abuse, and the benefits of abstaining from such activities.*

*(c) LIMITATION. - None of the funds appropriated to carry out this title may be used to provide education or information designed to promote or encourage, directly, homosexual or heterosexual sexual activity or intravenous substance abuse.*

*(d) CONSTRUCTION. - Subsection (c) may not be construed to restrict the ability of an education program that includes the information required in subsection (b) to provide accurate information about various means to reduce an individual's risk of exposure to, or to transmission of, the etiologic agent for acquired immune deficiency syndrome, provided that any informational materials used are not obscene."*

*c. Educational sessions should not include activities in which attendees participate in sexually suggestive physical contact or actual sexual practices.*

*d. Messages provided to young people in schools and in other settings should be guided by the principles contained in "Guidelines for Effective School Health Education to Prevent the Spread of AIDS" (MMWR 1988;37 [suppl. no. S-2]).*

2. Program Review Panel

- a. Each recipient will be required to establish or identify a Program Review Panel to review and approve all

written materials, pictorials, audiovisuals, questionnaires or survey instruments, and proposed educational group session activities to be used under the project plan. This requirement applies regardless of whether the applicant plans to conduct the total program activities or plans to have part of them conducted through other organization (s) and whether program activities involve creating unique materials or using/distributing modified or intact materials already developed by others. Whenever feasible, CDC funded community-based organizations are encouraged to use a Program Review Panel established by a health department or another CDC-funded organization rather than establish their own panel. The Surgeon General's Report on Acquired Immune Deficiency Syndrome (October 1986) and CDC-developed materials do not need to be reviewed by the panel unless such review is deemed appropriate by the recipient. Members of a Program Review Panel should:

- (1) Understand how HIV is and is not transmitted; and
  - (2) Understand the epidemiology and extent of the HIV/AIDS problem in the local population and the specific audiences for which materials are intended.
2. The Program Review Panel will be guided by the CDC Basic Principles (in the previous section) in conducting such reviews. The panel is authorized to review materials only and is not empowered either to evaluate the proposal as a whole or to replace any other internal review panel or procedure of the recipient organization or local governmental jurisdiction.
  3. Applicants for CDC assistance will be required to include in their applications the following:
    - (1) Identification of a panel of no less than five persons which represent a reasonable cross-section of the general population. Since Program Review Panels review materials for many intended audiences, no single intended audience shall predominate the composition of the Program Review panel, except as provided in subsection (d) below. In addition:
      - (a) Panels which review materials intended for a specific audience should draw upon the expertise of individuals who can represent cultural sensitivities and language of the intended audience either through representation on the panels or as consultants to the panels.
      - (b) The composition of Program Review Panels, except for panels reviewing materials for school-based populations, must include an employee of a State or local health department with appropriate expertise in the area under consideration who is designated by the health department to represent the department on the panel. If such an employee is not available, an individual with appropriate expertise, designated by the health department to represent the agency in this matter, must serve as a member of the panel.
      - (c) Panels which review materials for use with school-based populations should include representatives of groups such as teachers, school administrators, parents, and students.
      - (d) Panels reviewing materials intended for racial and ethnic minority populations must comply with the terms of (a), (b), and (c), above. However, membership of the Program Review Panel may be drawn predominately from such racial and ethnic populations.
    - (2) A letter or memorandum from the proposed project director, countersigned by a responsible business official, which includes:
      - (a) Concurrence with this guidance and assurance that its provisions will be observed;
      - (b) The identity of proposed members of the Program Review Panel, including their names, occupations, and any organizational affiliations that were considered in their selection for the panel.
  4. CDC-funded organizations that undertake program plans in other than school-based populations which are national, regional (multi state), or statewide in scope, or that plan to distribute materials as described above to other organizations on a national, regional, or statewide basis, must establish a single Program Review Panel to fulfill this requirement. Such national/regional/State panels must include as a member an employee of a State or local health department, or an appropriate designated representative of such department, consistent with the provisions of Section 2.c.(1). Materials reviewed by such a single (national, regional, or state) Program Review Panel do not need to be reviewed locally unless such review is deemed appropriate by the local organization

planning to use or distribute the materials. Such national/regional/State organization must adopt a national/regional/statewide standard when applying Basic Principles 1.a. and 1.b.

5. When a cooperative agreement/grant is awarded, the recipient will:
  - (1) Convene the Program Review Panel and present for its assessment copies of written materials, pictorials, and audiovisuals proposed to be used;
  - (2) Provide for assessment by the Program Review Panel text, scripts, or detailed descriptions for written materials, pictorials, or audiovisuals which are under development;
  - (3) Prior to expenditure of funds related to the ultimate program use of these materials, assure that its project files contain a statement(s) signed by the Program Review Panel specifying the vote for approval or disapproval for each proposed item submitted to the panel; and
  - (4) Provide to CDC in regular progress reports signed statement(s) of the chairperson of the Program Review Panel specifying the vote for approval or disapproval for each proposed item that is subject to this guidance.

