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Source: NIDA Cooperative Agreement Final Cohort Sites.

Introduction

Applied research in HIV prevention is a continual process of identifying changes in drug and sexual risk patterns, developing and evaluating appropriate interventions to respond to those changes, and finding ways to make effective use of new technologies as they are developed and new information as it becomes available. We offer here a real-world example of this process.

We have advanced the Standard Intervention developed for the Cooperative Agreement for AIDS Community-Based Outreach and Intervention Research (Coyle, 1993), a multi-site study funded by the National Institute on Drug Abuse (NIDA). The last six study sites funded collaboratively developed a Revised Standard Intervention designed to better address perceived needs in reducing HIV risk among substance abusers. To place the revision in context, we present a background summary of NIDA's HIV prevention efforts, a brief description of NIDA's Standard Intervention, and a discussion of the reasons for the revision. We then highlight the main points of difference between the Standard Intervention and the revision. The complete document describing the content and protocol of the Revised Standard Intervention is in Appendix A.

Background

In 1987, NIDA's Community Research Branch launched the first of its HIV/AIDS risk reduction programs: the National AIDS Demonstration Research project (NADR) (USDHHS, 1994). The objective of the project was to evaluate the efficacy of research-based interventions intended to reduce or eliminate risky behaviors for AIDS transmission, including needle sharing, polydrug abuse, and unsafe sexual activities. Analyses of the NADR intervention have shown that, while it was effective at reducing needle risk, it was less effective with sexual risk behaviors.

The NIDA Cooperative Agreement for AIDS Community-Based Outreach and Intervention Research was implemented in 1990. The overall goal is to prevent the further spread of HIV infection among injection drug users (IDUs), their sexual partners, and those at demonstrable risk for initiating injection behavior. The Cooperative Agreement (CA), with 23 sites in the U.S., Puerto Rico, and Rio de Janeiro, has three interrelated objectives:

- To establish a system for monitoring the nature and extent of drug use and HIV-related risk-taking behaviors in an out-of-treatment drug-using population.
- To assess the efficacy of established interventions in reducing drug and sexual risk-taking behaviors among out-of-treatment drug users and their sexual partners.
- To develop new initiatives and refine existing outreach and intervention research strategies.

As can be seen, the objectives of the two programs were essentially similar. However, because the CA had the benefit of NIDA's experience with NADR, the methodology differed in a number of significant ways:

- Although clients in both studies were recruited with outreach workers, the CA employed a targeted sampling strategy to reduce self-selection bias.

- The CA established more stringent eligibility requirements for clients.

- The CA instrumentation was more reliable, valid, and sensitive.

- While the CA sites were required to offer HIV antibody testing, not all NADR sites offered testing.

- Both the research design and the standard intervention for the CA were standardized across the sites; the research design and intervention for NADR were more site specific.

- The CA employed strategies to reduce attrition rates and set a minimum follow-up rate of 70%

- While the NADR methodology allowed only limited and uncoordinated analysis strategies across sites, the CA devised strategies to take advantage of reliable, valid, continuous outcome variables.

In summary, the CA drew from the methodology of NADR and the lessons learned from that study to build a more coherent and rigorous research and intervention program.

The Cooperative Agreement's Standard Intervention

NIDA's Standard Intervention as structured for the CA is a two-session educational and counseling intervention with HIV antibody testing. It consists of five parts:

- Outreach and recruitment of study participants (who are screened for eligibility), and completion of a Significant Contact Form.

- The intake process, which includes completion of an informed consent form and a locator form; drug use verification (inspection for recent needle tracks and a urine test); administration of the Risk Behavior Assessment (RBA), the primary data collection instrument; and completion of recruitment reports.

- Session I, an HIV prevention counseling session held the day of the RBA (or within 7 days), supported by cue cards. HIV antibody testing is also conducted (at the client's option).

- Session II, a booster session of additional counseling held within 21 days of Session I. Clients are assigned to a Track A (HIV negative/unaware) or Track B (HIV positive) counseling session.

- Random assignment of clients to a further "enhanced" intervention.

The protocol for the Standard Intervention was adopted by the CA Steering Committee in January 1992. In April 1995, a cohort of six CA sites (the last six funded: North Carolina, Washington DC, Lexington KY, St. Louis MO, Rio de Janeiro, and San Antonio, Texas) adopted a Revised Standard Intervention.

The Rationale for Revision

The need for a revised intervention was signaled by several developments relating both to the state of the knowledge of HIV transmission and to changing drug use patterns. First, research indicated that indirect routes of transmission (sharing of cookers, cotton, water) were potentially as dangerous as direct sharing of needles (Koester, 1994). For that reason, it became important to stress both the dangers of indirect sharing and the latest thinking on the best methods for cleaning injection equipment to reduce the chance of transmitting HIV through sharing. Second, the growing use of crack cocaine posed a different kind of threat. Because crack is often associated with frequent and unprotected sexual activity (Tims & Leukefeld, 1993; Washton & Stone-Washton, 1993), it became important to emphasize even more strongly the importance of safer sex behaviors. Further, because negotiating safer sex often becomes a power issue between men and women (Amaro, 1995), it became important to stress the need for effective communication and to suggest some ways to bring that about. A related side issue is the introduction of information on the female condom, which has the potential to give women more control over their own sexual safety.

The Revised Standard

- *The revision process took working with other cohort sites to make the revisions and standarize our plans and materials.*

The Revised Standard Intervention follows the same five-part structure specified for the Standard Intervention. We highlight here the key points of revision.

More specific instructions for outreach workers. The content of the outreach recruitment activity as specified in the Standard Intervention remains the same. However, the Revised Standard includes a detailed script for the outreach workers to follow. The script lists the points the outreach workers are expected to cover as they a) discuss the risk factors for transmission of HIV, b) explain ways to reduce risk, and c) attempt to recruit individuals into the study. Particular emphasis is placed on explaining the dangers of sharing needles and "works," the dangers of unprotected sex, how to clean works with bleach, and how to use condoms.

Forms for monitoring outreach. In addition, the Revised Standard specifies the use of a Screener Form for an initial determination of a potential recruit's eligibility for the study, and a Significant Contact Form documenting any contact with a potential recruit lasting more than 5 minutes. This documentation supports information on ineligibles and dosage of the contact.

Samples of both these forms are included in Appendix B, although they can be adapted to the requirements of the individual sites. Individual sites have developed additional forms to monitor outreach activity, and samples of these are also provided in Appendix B.

Prepackaged hygiene kits and other materials. The Standard Intervention specifies the distribution of condoms and bleach, but the Revised Standard specifies prepackaged kits containing condoms, bleach, rinse water, an alcohol swab, a Band-Aid, instructions, brochures and local community referral list of drug treatment, social service and health agencies.

Revised cue cards. The cue cards used in Session I of the Standard Intervention, which all clients receive, present the basic HIV risk reduction message. We thoroughly revised the standard cue cards to more accurately reflect our increasing understanding of HIV risk behaviors and risk reduction strategies. We added four new cards, as follows:

- Routes of Indirect Sharing. This card stresses the fact that HIV can be transmitted by means other than direct sharing of needles (e.g., sharing rinse water, cookers, and cotton).

- Bleach, Bleach, Water, Water. This card, which specifies how to clean needles, is a logical supplement to the card that discusses why you should clean needles. We recommend using only full strength bleach two times and water two times. We also stress dumping the waste in an appropriate place.

- What About Female Condoms? This card presents information on the female condom, a relatively new technology and an alternative means of protection that has the potential to give women more power to protect themselves.

- How to Talk With Your Partner About Safer Sex. This card stresses the importance of making an effort to talk about safer sex, finding an appropriate time to do it, and making appropriate decisions.

In addition to the new cards, we made numerous additions and changes to the original cards. The changes were designed to make the messages on the cards more immediately understandable and to emphasize key points related to safer sex, the use of condoms, and needle cleaning. The revised cue cards for Session I (the "A" series of cards) are included in Appendix C.

The cue cards used in Session II for HIV posttest counseling (the "B" series for those clients who are seronegative and the "C" series for those who are seropositive) were also revised. In addition to wording changes designed to make the message more forceful, two other important changes were made:

- Reduce Your Risk and Stop the Spread of HIV and AIDS. The message on this card was changed to reflect the reality that most clients are not going to stop using drugs or stop having sex. The intent of the revised card is to convey quickly what clients can realistically do to reduce their risk.

- HIV Control Measures. This card was added to the "C" series. It explains the measures that HIV positive clients should take to prevent the spread of the virus.

In addition, the Revised Standard provides a detailed script for the counselor to follow in discussing the cue cards. Detailed instructions are also provided for the rehearsals of condom use and needle cleaning.

Crisis Intervention. The Revised Standard recognizes that some crisis intervention may be needed in Session II when a client has been informed that he or she is seropositive for HIV. We provide general guidelines for the counselor.

Conclusion

Our experience with the Revised Standard Intervention has been encouraging. However, we recognize that the field is constantly changing, both because drug use and sexual risk patterns change and because research discloses new approaches to reaching at-risk populations and more effective means of helping them to reduce their risk behaviors. The continuing challenge for applied research is to respond proactively to these changes to build better interventions.

We also recognize that an intervention like the Revised Standard, which is intended to serve a heterogeneous substance-abusing population, may not be the most effective means of reducing risk behaviors. Our research suggests that next step may be to design interventions that target specific groups of substance abusers (e.g., women, minorities, crack users).

References

Amaro, H. (1995). Love, sex and power: Considering women's realities in HIV prevention. American Psychologist, 50(6), 437-447.

Coyle, S. (1993). The NIDA counseling and education intervention model (NIH pub. No. 93-3508). Rockville, MD: National Institute on Drug Abuse.

Koester, S.K. (1994). Copping, running, and paraphernalia laws: Contextual variables and needle risk behavior among injection drug users in Denver. Human Organization, 53, 287-295.

Tims, F.M., & Leukefeld,, C.G. (1993). Treatment of Cocaine abusers: Issues and perspectives. In F.M. Tims & C.G. Leukefeld (Eds.), Cocaine Treatment: Research and Clinical Perspectives, 135, National Institute on Drug Abuse Research Monograph Series, 1-14.

United States Department of Health and Human Services (USDHHS). (1994). Outreach/risk reduction strategies for changing HIV-related risk behaviors among injection drug users: The National AIDS Demonstration Research (NADR) project. Rockville, MD: Author.

Washton, A.M., & Stone-Washton, N. (1993). Outpatient treatment of cocaine and crack addiction: A clinical perspective. In F.M. Tims & C.G. Leukefeld (Eds.), Cocaine Treatment: Research and Clinical Perspectives, 135, National Institute on Drug Abuse Research Monograph Series, 15-30.

Appendix A

THE STANDARD INTERVENTION OF THE COOPERATIVE AGREEMENT PROGRAM FOR AIDS COMMUNITY-BASED OUTREACH/INTERVENTION RESEARCH

REVISED VERSION FOR NEW COHORT SITES APRIL 1995

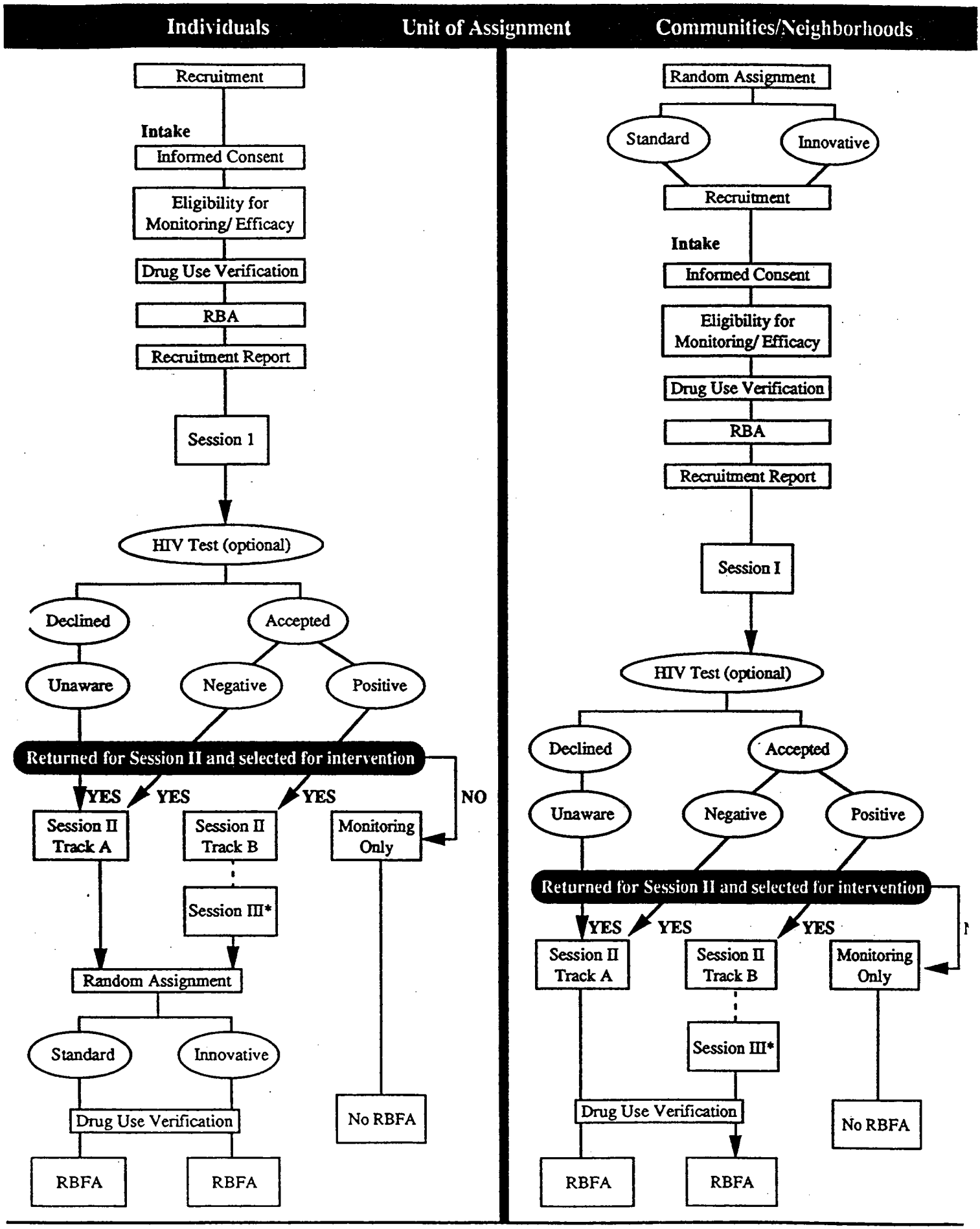
The Cooperative Agreement intervention study involves a multisite evaluation of AIDS prevention projects by means of a controlled experiment and a commonly-applied set of survey and tracking instruments. Before the evaluation, however, a standard format of outreach activities is undertaken in each community, using a specific set of HIV prevention and educational materials and information about participation in the study. The research design calls for: (1) the random assignment of clients to either a standard or an innovative intervention; (2) the administration of screeners and Significant Contact Forms to monitor eligibility, contacts who are ineligible, service delivery, and competing service delivery; (3) the administration of the Risk Behavior Assessment (RBA) and the Risk Behavior Follow-up Assessment (RBFA) questionnaires to monitor behavioral outcomes; and (4) the administration of any additional questions that may be site specific. (These forms and instruments are in the Appendices.)

For the cooperative agreement experiment, investigators must choose one of two possible units of assignment to randomize: individuals or communities (neighborhoods, census tracts). If a site chooses to assign individuals, it should make the assignment after the standard intervention has been completed; if a site chooses to assign communities, it should make the assignment prior to recruiting participants into the interventions.

Note that client referrals will be written (passive) regardless of randomization unit. Active referrals should be undertaken only when ethically or otherwise necessary, and all active referrals must be documented on a Significant Contact Form (standardized or site-specific).

This document describes the content and protocol of the research design, beginning with a schematic of the research protocols.

COOPERATIVE AGREEMENT STUDY PROTOCOLS/RESEARCH DESIGN



*Session III will be offered in communities that elect to provide active referrals to clients with confirmed seropositivity.

I. The Individual Assignment Standard

For sites that choose to randomize individuals and to offer written referrals to seropositive clients, the standard intervention consists of parts A, B, C, D, and E shown in the first column of Figure 1, that is:

(A) outreach to and recruitment of study participants[1] and completion of a Significant Contact Form;

(B) the intake process, which includes informed consent, locator form, drug use verification (inspection for recent needle tracks and an ONTRAK urine test), administration of the RBA, recruitment trailer, and site-specific instruments;

(C) Session I, an HIV prevention counseling session held the day of the RBA;

(C.1) HIV testing (at client's option);

(D) either a track A or track B Session II, a booster session of additional counseling which should occur within 21 days of Session I for 90% of clients; and

(E) random assignment of clients (individual assignment sites only).

By delaying random assignment of individual clients until after the intervention has been completed, the debilitating effects of attrition will be reduced because early project dropouts will not become members of the experimental or control groups. Early dropouts can, however, continue to function as monitoring subjects.

II. The Community Assignment Standard

For sites that choose to randomize communities and offer written referrals to seropositive clients, the standard intervention consists of parts A, B, C, D, and E shown in the second column of Figure 1, that is:

(A) the random assignment of communities or neighborhoods[1];

(B) the recruitment of study participants and completion of a Significant Contact Form.

(C) the intake process, which includes informed consent, locator form, drug use verification (inspection for recent needle tracks and an ONTRAK urine test), administration of the RBA, recruitment trailer, and site-specific instruments;

(D) Session I, an HIV prevention counseling session held the day of the RBA;

(D.1) HIV testing (at client's option); and

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[1] Any recruits eligible for a project's monitoring study (i.e., confirmed out-of-treatment users of crack or injection drugs) are also eligible for the intervention study. Each site must recruit a minimum number of 35 people a month from their master target samples for the monitoring study; for the intervention study, however, each site must determine the minimum number of study participants needed to detect outcome differences between participants in its standard and innovative interventions.

(E) either a Track A or Track B Session II, a booster session of additional counseling held within 21 days of Session I for 90% of clients.

Prior to recruiting study participants, sites will randomly assign communities or neighborhoods to either the standard intervention (i.e., the control condition) or the innovative intervention (i.e., the experimental condition).

III. Procedures and Guidelines for Outreach Workers

The following procedures and guidelines apply to outreach workers at all sites, whether they choose the individual or community assignment standard.

A. Recruitment

Outreach workers serve dual roles as both street educators and recruiters. As street educators, workers circulate within communities to become familiar with neighborhood patterns of drug use, to establish their own trustworthiness, and to foster general awareness of HIV risks and prevention steps that drug users can take. As recruiters, workers make additional overtures to potential study participants to describe the purpose of the project's study, its eligibility requirements, and the benefits of participation.

Recruiters' interactions with study participants must be limited specifically to street outreach activities, brief data collection (screener and contact form), and recruitment. Recruiter/outreach workers may not be used to interview clients or to provide the standard or innovative interventions (except where staff are rotated such that no staff provides outreach, interview, or intervention to the same client).

A.1 Protocol

COMMUNITY ENTRY

Outreach workers first familiarize themselves with the study community (copping sites, housing, etc.), then establish credibility by visiting businesses, congregations, tenant associations, etc., to explain the study. In addition, credibility is generally enhanced by being seen in the community. During this stage, outreach workers will raise awareness of the project by distributing handouts, posting fliers, and leaving literature on doorknobs, at health fairs, and at other locations.

(THIS STAGE MAY ONLY BE MEASURED BY AN EXAMPLE OF AN OUTREACH LOG.) **(see Appendix)**

OUTREACH AND RECRUITMENT

Initial screeners may be used to find potential subjects. Initial recruitment contacts with potential study participants will be limited in number to five active overtures/contacts lasting up to 15 minutes each (GOAL: 15 minute limit for 90% of such contacts). A Significant Contact Form will be completed for every individual contact lasting more than 5 minutes. Recruiters may continue outreach activities with drug users disinclined or ineligible to participate, but workers should no longer try to recruit them actively into the intervention study. [NOTE: Drug users may always choose to participate in the intervention without having been actively recruited or after active recruitment has ended. See Section B for more information.]

Projects may engage in secondary "marketing" activities to recruit intervention participants (e.g., recruitment at health fairs, local clinics, jails, etc.). However, only clients in the study catchment area should be recruited. All others should be excluded. Otherwise, follow-up will be difficult if not

impossible. In addition, IDUs/clients may refer potential subjects for recruitment, again as long as they reside within the study catchment area.

Outreach/recruitment activity must be limited to the following activities:

- introduction of outreach worker and explanation of focus of outreach effort;
- brief educational discussion which includes the active distribution of elementary HIV/AIDS-related literature, including written HIV-related referrals;
- the active distribution of hygiene materials;
- description of the project, completion of the screener and contact form;
- provision of written referrals[2] for treatment, social/health services, etc., when appropriate; and
- recruitment into the study.

A.2 Content

This section describes the content and materials used for each of the above outreach/recruitment activities. It is intended to be used as a guide or "script" for outreach workers:

INTRODUCTION

Introduce yourself to potential recruits. Explain the project's name and purpose, who is conducting it, and the location of the project site. Raise the issue of AIDS as a general problem, but one that especially affects communities with pervasive drug use. Focus on building rapport.

EDUCATION MESSAGE

Briefly discuss specific risk factors for transmission of HIV: a) transmission through sharing, borrowing, or renting needles or syringes, and through sharing cotton, cookers, and rinse water, as well as through indirect practices such as "backloading," etc.; b) transmission through unprotected sex--particularly with someone who injects drugs or has multiple sex partners. Note that HIV transmission through unprotected sex is facilitated by the presence of other STDs (herpes, gonorrhea, syphilis, PID, etc.).

Explain that the risk of HIV transmission can be reduced by: a) use of condoms during sex; and b) cleaning works with full strength bleach and not engaging in indirect sharing. Using literature/pictures, briefly describe how to use condoms and how to clean injection equipment (making clear that works need to be rinsed twice for 30 seconds in full strength bleach). Do not conduct actual demonstrations during the outreach contact. If asked to, inform contacts that such demonstrations will be presented in the intervention sessions.

DISTRIBUTE MATERIALS

Following the educational discussion, give the respondent: a) literature concerning HIV/AIDS and the study; and b) prepackaged hygiene materials.

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[2] If, for ethical reasons, an active referral is necessary during outreach/recruitment, it must be documented on the Significant Contact Form.

The literature will include the following information:

- basic, primer-type information about HIV transmission;
- a description of the study;
- a local referral list for HIV prevention and testing; and
- a local referral list of drug treatment agencies and other social services (if available).

Examples of HIV-related literature that conforms to these study guidelines can be found in **Appendix B**.

The culturally-specific, pre-packaged hygiene kits will include:

- condoms;
- one bottle of bleach;
- one rinse water bottle;
- alcohol swab;
- band-aid; and
- instructions on proper use of the materials, including disposal of used rinse water.

RECRUITMENT

Finally, wrap up the contact by attempting to recruit the individual into the study. The individual should be informed of:

- eligibility requirements for participating;
- usual amount of time required;
- the necessity of providing a urine sample for drug testing (if recent needle tracks are not visible);
- the location of the study site; and
- the benefits of participating, including reimbursement for study time and availability of free HIV testing.

A Screener Form should be completed at this point (see **Appendix A** for suggested form--sites may adapt as necessary, as long as essential information is obtained).

In addition, ask recruits if someone they know would be interested in participating. When appropriate, offer assistance in getting to the intervention site.

Following any recruitment contact that lasts 5 minutes or longer, complete a Significant Contact Form (see **Appendix A** for suggested form--sites may adapt as necessary, as long as the indicated information is obtained).

OTHER SERVICE REFERRALS

Recruiters may provide passive referrals to other services. This means that, if requested, recruiters should provide written materials regarding non-HIV related services (e.g., welfare, shelter, food pantries). Do not, however, provide active referrals--except (as noted previously) where there is an ethical imperative, in which case the active referral should be documented on a Significant Contact Form.

B. Intake and Data Collection for the Standard Intervention

B.1 Protocol

An Intake Form to verify eligibility is to be completed for people who come to the project site. For those who are eligible, the first step of the interview process will be the administration of an Informed Consent Form (content discussed below) and a Locator Form to contact participants for follow-up. Interviewers will ask recruits for informed consent in one-on-one interview formats.

The second step involves drug use verification. For injection drug users, verification consists of a physical examination for recent needle tracks and an ONTRAK urine test. Non-injection drug users complete only the ONTRAK urine test. Urine testing should occur before the administration of the RBA.

The third step is administration of the RBA questionnaire in one-on-one interviews. Project personnel provide reimbursement to participants upon completion of the RBA.

In the fourth step, interviewers record participants' self-reports about the number of times they were contacted for recruitment. A trailer form to the RBA is suitable for collecting these reports, which can then be checked against the recruiters' reports.

The last step in the interview process is the administration of site-specific instruments. [NOTE: administration of such instruments may be divided between Sessions I and II.]

Interviewers' interactions with a given study participant must be limited specifically to interviewing and (optionally) collecting urine or blood specimens. Interviewers may not be used to recruit participants into the study or to provide the standard or enhanced interventions. [However, a site may rotate staff between recruiter, interviewer, and intervention roles, as long as no staff interacts with the same study participant in more than one role.]

B.2 Content

Intake forms should contain a short series of questions to check the person's eligibility for the project before starting the interview process. The form will vary across sites according to the specific requirements of each project. Criteria for eligibility in the Cooperative Agreement are:

- at least 18 years old;
- injected drugs or smoked crack/cocaine and/or heroin within the past 30 days; and
- has not been in drug treatment for the past 30 days.

In obtaining informed consent, interviewers or other project staff must explain the following, in accordance with 45 CFR 46: (1) the purposes and procedures of the research (include here the randomization procedure and the expected duration of participation, including multiple office visits and follow-up; (2) any foreseeable discomforts (e.g., urine or blood testing); (3) the expected benefits of participation; (4) the extent to which records will be held confidential; (5) the reimbursement schedule for project participation; (6) the identity of a contact person for answers about research subjects' rights;

and (7) a declaration that participation is voluntary and may be discontinued at any time without penalty. (Note: A given site's Institutional Review Board may require additional terms in an informed consent document.)

C. Session I: HIV Prevention Counseling

C.1 Protocol

Session 1 of the standard intervention will take place immediately following the RBA. Like the RBA, Session I will be conducted in private, one-on-one interview formats of 20 to 30 minutes duration. No group session formats or video segments are allowed.

Conducting the session. Provide your client a comfortable place to sit in a private setting, and introduce yourself by name and role as a health educator/interventionist. Summarize what you are going to talk about and why. While a large portion of the material to be covered seems didactic in nature, remember to pace the session to allow questions and interaction. By asking and encouraging questions, listening for concerns, and offering support, you can personalize this session for each of your clients.

Session I will be restricted to:

- a discussion of HIV prevention material listed on the attached set of 14 "A" cue cards;
- a rehearsal of how to use condoms;
- a rehearsal of how to clean injection equipment;
- the distribution of hygiene products (condoms, bleach, water, etc.);
- a discussion of the HIV test;
- the distribution of HIV-related literature; and
- written non-HIV service referrals, if requested.

Counselors' interactions with a given participant must be limited specifically to counseling and (optionally) to drawing blood for HIV testing (C.1, discussed below). Counselors may not be used to recruit participants or to interview clients--except where staff are rotated such that no counselor recruits or interviews the same client(s) he/she counsels.

C.2 Content

In brief, the 14 "A" cue cards provide the following talking points: (1) basic information about HIV/AIDS disease; (2) truths and myths about how someone gets infected; (3) behaviors that put people at risk; (4) how and why to use condoms; (5) how and why to clean injection equipment and avoid indirect sharing; (6) risks related to cocaine; (7) the benefits of drug treatment; (8) the meaning of the HIV test; and, (9) healthy behaviors to practice if infected. The cue cards (in **Appendix C**) should be presented as follows:

HIV DISEASE

Cue Card A.1 provides basic information about AIDS and its viral source. Discuss global and local statistics, making the point that AIDS is a community problem. Talk about the destructive effect of HIV on the immune system, and explain Cue Card A.2, which describes HIV disease symptoms.

TRANSMISSION ROUTES

Cue Card A.3 prompts you to outline the various ways HIV is transmitted (semen, blood, pregnancy, and so on) and to debunk myths about HIV transmission (such as by casual contact, saliva, tears, toilet seats, and insect bites).

RISKY BEHAVIORS

Cue Card A.4 prompts you to describe behaviors that put people at risk. Ask the client to assess his or her own risk situation as you discuss this card. Emphasize the risks associated with the common practice of sharing drug paraphernalia (needles, syringes, cookers, cotton, rinse water). Cue Card A.5 describes the risks of indirect sharing. Explain how "frontloading," and using a "donor" syringe also present significant transmission risks.

Also emphasize the risks of unprotected sex, especially with persons who have a history of drug use or multiple sexual partners. Warn against the disinhibiting effects of drugs and alcohol that may lead to risky behavior or even jeopardize the immune system. Discuss the common risk factors for HIV and STDs, and the effect of STDs on HIV transmission.

RISKS ASSOCIATED WITH CRACK OR COCAINE

Cue Card A.6 prompts you to point out the risks related to cocaine. Emphasize especially the link between using cocaine, crack, and rock[3] and losing the ability to practice safer sex, and also how the drugs may compromise the immune system. Advise clients to get off the drug. If they believe they cannot, urge them to practice safer sex and to be sure not to start injecting the drug.

Crack cocaine has become a leading drug of choice among many drug users. Trading or bartering or exchanging sex for money, crack, or other drugs is on the increase with greater risk for HIV among heavier users. Many of these people at risk are women. Therefore there is a seriously deadly relationship between drugs and sex.

REHEARSAL OF CONDOM USE

Cue Card A.7 asks "Why Use Condoms?" Review the benefits of condoms to prevent the spread of AIDS (and other sexually transmitted diseases, which in turn can promote the transmission of HIV). At this point, stop your presentation and offer an unopened latex condom to the client. Open the package carefully and advise how to avoid tearing the product as you do so. Explain that the tip of the condom should be pinched to release the air and allow room for the ejaculate. Unroll the condom over a penis model, explaining that condoms are never to be pulled on. A vibrator is a preferred penis model, being less realistic (and less anxiety provoking) than a dildo, but more realistic than a vegetable. **This demonstration should be done at least once for every client.**

When demonstrating condom use, explain that, to be effective, the condom must be worn before penetration and all the way through sex; it must also be positioned all the way down on the shaft of the penis.

Explain that, after orgasm, one partner should hold on to the condom at its base to keep it from slipping off. Talk about the correct removal and disposal of the condom after use. Ask the client to demonstrate his or her proficiency by fitting a condom on the model. Continue such playback until proficiency is achieved. [NOTE: It is anticipated that 90% of clients will be proficient by the first rehearsal.]

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[3] Local terminology may differ and cue cards should be modified to reflect local usage. The cards may need to be periodically updated.

Discuss the types of condoms that protect against HIV transmission and the types of lubricants that can be safely used with condoms. Show how a condom can be cut to make a barrier for oral sex, and explain that plastic wrap without air holes (not for use in a microwave) can also be used as a barrier. Briefly introduce the female condom, using Cue Card A.8.

Explain that the female condom has several advantages over the male condom, both as a contraceptive and as an STD prevention method. First, it is primarily woman-controlled. With the female condom, women are not as dependent on the cooperation of sex partners to protect themselves from HIV and other sexually transmitted diseases. Second, the female condom is inserted before intercourse, providing additional protection against infections from pre-ejaculated fluids. Third, the female condom protects a greater proportion of the vagina, which also provides further protection against STDs. Fourth, The Reality™ condom has less risk of rupture than the male condom. Other advantages are that it causes less loss of sensitivity (because of its loose fit), it permits penetration before complete erection of the penis, and it permits continued intimacy in the resolution phase of intercourse since it need not be removed immediately.

You can also explain that tests have shown that the female condom has a lower leakage rate than the male condom, and that it has been found to be as effective as other barrier methods at preventing conception. Furthermore, in simulated laboratory testing of the Reality™ condom, there was no viral leakage for HIV.

Answer any questions.

STOPPING UNSAFE SEX PRACTICES

Clearly, condoms are not the only way to reduce the risk of infection through sexual behavior. To personalize the session, offer a flexible array of risk reduction practices, such as:

- abstinence;
- non-penetrative sex;
- mutual masturbation, massage; and
- a reduction in the number of sexual partners.

HOW TO TALK WITH YOUR PARTNER ABOUT SAFER SEX

Cue Card A-9 offers some suggestions on talking about safer sex. Since this kind of communication may be difficult for many clients, stress that having unprotected sex with a person infected with HIV is one of the main ways of contracting this disease; therefore, your life may depend on your ability to discuss practicing safer sex.

Lead into a discussion of the points on the card by explaining the following to the client:

Talking to your partner(s) about practicing safer sex is an important first step in the process of protecting yourself from HIV. However, it may not be easy to talk to your partner about having safer sex. Just the thought of bringing this issue up with your partner(s) may make you feel uncomfortable or embarrassed or you may worry about how your partner(s) will react. These are all normal concerns that we all share.

In order to make it easer to talk to your partner(s) about practicing safer sex, you must first make a firm decision and commitment to yourself that the only kind of sex you will have is protected sex. This will make it easier to stand firm, if your partner tries to convince you that you don't need to use protection with him/her.

Discuss the points on the card. When you have finished, emphasize again the importance of talking about safer sex. Remind the client that HIV is a fact of life in the 90s: not talking about it will not make it go away, and talking about it and practicing safer sex may save your life.

NEEDLE AND SYRINGE CLEANING AND DISINFECTION GUIDELINES

Much remains to be learned before practical disinfection guidelines for IDUs can be established without qualification. Until then, recommendations for cleaning and disinfecting procedures are likely to abound. Such techniques should be promoted as a means of reducing but not eliminating the risk of HIV transmission. Clearly, it is preferable for injectors to not share and always use sterile supplies. When this is not possible, cleaning and disinfection techniques should be considered.

It is important for clients to attempt to disinfect all injection paraphernalia that is known or suspected to have been used by someone else. It is also extremely important for clients to be aware of risks from indirect sharing practices (e.g., frontloading, using one syringe to measure/distribute drug, extracting drug from the used cotton), and to avoid engaging in any of those practices.

Full-strength bleach is one of the more effective disinfectants. If bleach is not available, a mixture of detergent and water, alcohol, or even vinegar may be used in an attempt to clean injection equipment as thoroughly as possible. This may not offer 100% protection, but it is likely to reduce the risk of contaminated supplies spreading infection.

Cleaning and disinfecting are best accomplished immediately after injection equipment has been used. Once any residual blood in needles, syringes, or cookers has clotted, both thorough cleaning and disinfection are more difficult to achieve. Studies to date suggest that an effective bleach disinfection procedure requires all contaminated surfaces to be exposed twice to full-strength bleach for at least 30 seconds.

REHEARSAL OF NEEDLE AND SYRINGE CLEANING

Cue Card A.10 asks "Why Clean Needles and Syringes?" Review the health risks associated with using drugs and, especially, sharing works, cookers, cotton, and rinse water. When clients believe that they cannot stop drug use or equipment sharing, tell them that needle cleaning is imperative and repeat the importance of avoiding indirect sharing. Stop your presentation and demonstrate how to use water and bleach to clean drug paraphernalia. **This demonstration should be done at least once with every client.**

The following needle and syringe cleaning materials should be available:

- cup with rinse water;
- container with full-strength, household bleach; and
- empty cup.

Stress that only full-strength, household bleach and clean, never-used water should be used for bleach disinfection of needles and syringes.

Draw full-strength bleach through the submerged needle to fill the barrel of the syringe. Shake and/or tap the barrel with your finger to agitate the contents for 30 seconds. Squirt out the bleach to dispose of it, or discharge it into the cooker if this is also being cleaned. REPEAT.

After using the bleach, rinse the syringe and needle. Draw clean water through the submerged needle to fill the syringe and squirt out to dispose of it. REPEAT. If the cooker is also being cleaned, water can be used to flush out the residual bleach. DO NOT REUSE WATER OR BLEACH!

Emphasize that all injection equipment should be cleaned after each use. Make sure to add that CLEANING WATER/BLEACH SHOULD ALWAYS BE DISCARDED INTO A SINK, TOILET, SEWER, OR DISCARD BOTTLE. IT IS HAZARDOUS WASTE!

NOTE: Suggest that clients take the syringe apart (remove the plunger) to improve the cleaning/disinfection of parts that might not be reached by flushing with water and bleach.

Ask the client to demonstrate his or her proficiency by cleaning the needle and syringe as directed. Continue such playback until proficiency is achieved. [It is anticipated that at least 90% of clients will be proficient by the first rehearsal.]

STOPPING UNSAFE DRUG USE

Clearly, cleaning needles is not the only way to reduce the risks associated with using drugs. To personalize the session, offer several possible ways to control unsafe drug use. Urge your client to:

- Stop using drugs, or at least reduce the frequency of use.

- Stop sharing, borrowing, lending, or renting equipment--including indirect sharing.

Review cleaning points using Cue Card A.11.

Emphasize that while stopping these behaviors is best, reducing their frequency will give the client a greater degree of protection against AIDS than he or she has now.

BENEFITS OF DRUG TREATMENT

Cue Card A.12 prompts you to highlight the benefits of drug treatment—to get off drugs, to provide social support for coping with AIDS or kicking the habit, and to connect clients with health and social services. Mention the opportunity to connect with other people like themselves, too.

Discuss the different types of locally available treatment programs and, if appropriate, how they may serve different needs (e.g., methadone programs only treat opiate addicts, but your locality may also have therapeutic communities that treat other kinds of substance abuse). Remind clients that even if they can't get into drug treatment now, they can get on a waiting list.

HIV ANTIBODY TESTING

Cue Card A.13 prompts you to review the HIV antibody testing procedure and the meaning of HIV antibody test results, including the uncertain nature of negative test results and the uncertain prognosis of positive results. Discuss both the advantages and disadvantages of testing, and pay special attention to early medical treatment and confidentiality issues.

Inform clients that public health officials recommend testing and that this official position is based on the belief that potential benefits far outweigh potential drawbacks. Note that the benefits include early treatment for HIV infection and the ability to plan a health strategy that is best for the client and his or her family and community. Despite the benefits, you must also assure clients that HIV antibody testing is voluntary.

INFECTION

Cue card A.14 prompts you to outline healthy behaviors for a client to practice if infected. Encourage early medical intervention, and explain the dangers of taking in more virus by unsafe

practices. Stress that practicing safer sex is important even if you are infected. Review ways for your clients to take good care of their health.

LITERATURE, REFERRALS, AND HYGIENE KIT

Before wrapping up the session, probe for questions and provide written material about the information discussed in the cue card session. In addition to factual information about HIV disease, HIV transmission, and risk reduction, the literature should include a local referral list to drug treatment agencies (if available) and a local referral list for other HIV prevention and testing agencies. See **Appendix B** for examples of the types of literature that should be distributed. In addition, give all clients a hygiene kit as specified in Section A.2. At this time, sites should also distribute literature on the female condom, which includes availability information.

As in the recruitment phase, counselors will provide written referrals to non-HIV social or economic services if requested by the client. If any active referrals are made due to ethical necessity, these must be documented on a Significant Contact Form.

D. HIV Testing (Voluntary)

D.1 Protocol

For those subjects who are willing, blood should be drawn for HIV testing on the same day as Session I (immediately following, if possible). Blood may be drawn at the study location or at a referred location in accordance with state and local requirements. Before drawing blood, the phlebotomist or counselor should ask for informed consent in a one-on-one interview format. In eliciting informed consent, explain (1) any foreseeable discomfort, (2) the expected benefits of testing, (3) the extent to which records will be held confidential, and (4) a declaration that the blood test is voluntary.

Sites should record on the Client Eligibility and Assignment Form whether a client is tested. Two types of persons may elect not to be tested: those who are truly sero-unaware and those who have been previously tested. The project will assign to standardized Track A those individuals who test seronegative, who are sero-unaware, or who self-report that they previously tested negative[4]. The project will assign to standardized Track B those individuals who test positive or, if the project can obtain written confirmation of their serostatus, those who self-report that they previously tested positive. If projects cannot confirm seropositive self-reports, the clients must be assigned to Track A.

Note that sero-unaware individuals have the option of changing their minds about HIV testing. Participants who elect not to be tested at the time of the RBA may ask to be tested after Session II and prior to the RBFA. Projects should refer these participants elsewhere for testing and follow-up. The project will treat these participants for analytic purposes as having received the Session II standardized Track A services.

E. Session II: HIV Booster Counseling

E.1 Protocol

Although the informed consent process will apprise study participants of a second session, projects may need to institute follow-up efforts (i.e., active search through locator information) to bring clients to Session II of the standard intervention. Since reimbursement appears to be an attractive incentive in this population, sites may elect to collect additional data at Session II, for which they may

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[4] Individuals who previously tested negative may, of course, have seroconverted by the time of this study. However, they are unaware of their serostatus, and thus fit the criteria for Track A.

reimburse clients for their research time. Sites may split their reimbursement budgets between Sessions I and II.

Session II provides, in effect, HIV posttest counseling to people who have been tested, and a risk reduction booster session to all participants whether or not they have been tested. Projects will offer one of two sets of counseling materials to study participants: track A is designed for participants who are not tested (the sero-unaware group) or who test negative for the virus (the seronegative group), and track B is designed for participants who test positive for the virus or whose self-report of seropositivity has been confirmed in writing by the project.

Session II of the standard intervention must be held within 42 days of the scheduled HIV testing. However, it is expected that 90% of clients will receive Session II within 21 days. Subjects not followed up for Session IIA by 42 days will be considered lost to follow-up and retained for monitoring only.

Session II shall be conducted in private, one-on-one interview formats. No group session formats are allowed, and no video segments are allowed. The expected duration of track A is 20 to 40 minutes. The duration of track B can be longer but will probably vary according to client needs; a range of 30 to 60 minutes is suggested.

E.2 Content: Track A, Seronegative and Sero-unaware Subgroup

The content of Session II will be the same for study participants who test negative for the virus and for those who are sero-unaware. The content will include:

- provision of the test result, if applicable;
- a discussion of risk reduction and the meaning of HIV positive and negative test results, based on the attached set of three "B" cue cards;
- a review of HIV prevention, based on a subset of nine "A" cue cards (cards A.3 through A.11);
- distribution of literature about HIV and HIV referrals; and
- non-HIV service referrals.

PROVISION OF TEST RESULTS

When applicable, inform the participant of the result of the HIV test and show the lab slip. Allow time for the client to react and to verbalize feelings.

HIV TEST RESULTS CUE CARDS

Explain what negative and positive results mean and how clients can reduce the spread of HIV. In brief, the "B" cue cards provide the following talking points: (1) seronegative results mean that HIV antibodies have not been detected but can show up later, (2) seropositive results mean that a client (and possibly friends and sexual partners with whom risk behaviors have been practiced) is infected and can infect others, and (3) many drug and sex behaviors carry the risk of spreading HIV and can be modified.

HIV PREVENTION CUE CARDS

Review the material from Session I on HIV prevention using the subset of "A" cue cards that discuss how someone gets infected (A.3); behaviors that put people at risk (A.4, A.5, and A.6); why to use condoms and an introduction to the female condom (A.7, A.8); how to talk with your partner about safer sex (A.9); why to clean injection equipment and reminders (A.10, A.11); and the benefits of drug

treatment (A.12). Condom and bleach rehearsals will accompany the discussions of cue cards A.7, A.10, and A.11.

DISTRIBUTION OF LITERATURE, HYGIENE KIT, AND REFERRALS

Provide written literature about the information discussed in the cue card session. In addition to factual information about HIV disease, HIV transmission, and risk reduction, the literature will include a local referral list to drug treatment agencies (if available) and a local referral list for other HIV prevention and testing agencies. See **Appendix B** for examples of the types of literature that should be distributed. In addition, give all clients a hygiene kit as specified in Section A.2. At this time, sites should also distribute literature on the female condom, which includes availability information.

Non-HIV Service Referrals. Unlike the recruiting phase or Session I, in Session II you should provide written materials (names, addresses, phone numbers, hours, etc.) regarding non-HIV related social or economic services (e.g., welfare, shelter) without waiting for a specific client request. However, counselors may not actively intervene by contacting referral agencies on behalf of participants or providing transportation to service providers. If any active referrals are made due to ethical necessity, these must be documented on a Significant Contact Form.

E.3 Content: Track B, Seropositive Subgroup (Written Referrals Option)

The content of Session II for study participants who test positive for the virus, or whose self-report of seropositivity has been confirmed in writing by the project, will include:

- provision of the test result, when applicable;
- a discussion of the meaning of HIV positive test results, based on the attached set of three "C" cue cards;
- a discussion of medical follow-up and early treatment;
- the distribution of literature about HIV and HIV referrals; and
- non-HIV service referrals.

PROVISION OF TEST RESULTS

When applicable, you will need to inform the participant of the result of the HIV test and show the lab slip. In these situations, allow time for the client to react and to verbalize feelings.

Some crisis intervention may be needed when a client has been informed that he or she is seropositive. A helpful response should include empathy, warmth, a positive regard for the client and his or her feelings, and an effort to help the client understand the situation and options clearly. Your specific goals should be to

- listen actively and with concern;
- encourage open expression of feelings (unless the client is out of control and more affect would be dangerous);
- help the client to understand the crisis;
- help the client to gradually accept reality;
- encourage the client to explore new ways of coping with problems;

- link the client to a support network; and
- reinforce newly-learned coping devices and follow up after the immediate crisis is resolved.

HIV TEST RESULTS CUE CARDS

Explain what positive results mean and what actions should be taken next. In brief, the three "C" cue cards provide the following talking points:

- seropositive results mean that a client (and possibly friends or sexual partners with whom risk behaviors have been practiced) is infected;
- healthy behaviors to practice if infected with HIV; and
- partner notification issues.

MEDICAL TREATMENT ADVICE (SUPPLEMENTS CUE CARD C.2)

Inform all participants that it is important for seropositive individuals to seek medical care, especially for lab tests to tell how the immune system is functioning and for early treatments that may prevent infections and slow the progression of HIV disease. Discuss approved medical treatments that are locally available (AZT, aerosolized pentamidine) that can help avert symptoms and opportunistic infections.

Emphasize the importance of staying in a medical treatment program to get regular check-ups and learn about new medical procedures. Note that infected people can probably stay healthier by reducing drug use, getting good nutrition, sleep, and exercise, and by cultivating a positive attitude (with support groups, counseling, etc.).

DISTRIBUTION OF LITERATURE, HIV REFERRALS, AND HYGIENE KIT

Provide written literature about the information discussed in the cue card session. In addition to factual information about the meaning of test results (a copy of Cue Card C.1), healthy behaviors (a copy of Cue Card C.2) and local partner notification laws, the literature should include:

- a local referral list to medical treatment agencies, clinics, and physicians in the area who treat HIV/AIDS (if available);
- a local referral list of drug treatment agencies (if available); and
- a local referral list for HIV prevention and testing agencies (see **Appendix B** for examples of literature).

In addition, give all clients a hygiene kit as specified in Section A.2.

Non-HIV Service Referrals. Unlike the recruiting phase or Session I, in Session II you should provide written materials (names, addresses, phone numbers, hours, etc.) regarding non-HIV related social or economic services (e.g., welfare, shelter) without waiting for a specific client request. However, counselors may not actively intervene by contacting referral agencies on behalf of participants or providing transportation to service providers. If any active referrals are made due to ethical necessity, these must be documented (on a Significant Contact Form).

F. Random Assignment of Participants

At the conclusion of Session II, sites will randomly assign individuals to the standard intervention (i.e., the control condition) or the innovative intervention (i.e., the experimental condition).

Sites may make the random assignment prior to this step, provided that the assignment is blind.

If assignment is made to the standard intervention, only written materials may be offered to the participant between Session II and the conclusion of the RBFA follow-up survey. Between the time of random assignment and the RBFA, the content of these written materials shall include (if available) names, addresses, phone numbers, hours, etc., of: (1) drug treatment facilities (2) anonymous HIV testing sites, (3) shelters, (4) food and clothing banks, and (5) welfare services (AFDC, food stamps, etc.).

Note: On some few occasions, clients will present special needs that cannot be satisfied by participating in the standard intervention. When a counselor recognizes such needs, she or he should provide the special services and arrange for the client to be dropped from the analysis. This action does much less harm to the intervention study than the alternative of breaching the random condition to assign a client to an innovative intervention.

Appendix B

QUICK OUTREACH SCREENER

(Version 10-OCT-95)

SITE ID: . . . . . |__|__|-|__|__|__|__| SITE NAME:_____

STAFF ID: . . . . . |__|__| STAFF NAME:_____

LOCAL ID: . . . . . |__|__|__|__|__|__| ALIAS:_____

DATE: . . . . . |__|__|/|__|__|/|__|__|

Hello, my name is _____, and I'm from the NC Coop Research Program. I'm working on a study of drug use and health in _____ County for the Public Health Dept. I would like your permission to ask you some questions that will take less than 3 minutes to find out if you might be eligible. Your answers will be kept strictly confidential and you do not need to give me your name unless you later decide to participate in the study.

A. SCREENER

A1. **[FROM OBSERVATION IF POSSIBLE]** (Are you male or female?)

MALE 1

FEMALE 2

A2. What is your date of birth? . . . . . |__|__|/|__|__|/|__|__|
M M D D Y Y

a. And how old are you now? . . . . . |__|__| 18+ ☐

A3. Do you consider yourself Black (African American), White, Hispanic (or Latin), Asian, Native American, or another race or ethnic group?

BLACK (NOT OF HISPANIC ORIGIN) 1

WHITE (NOT OF HISPANIC ORIGIN) 2

HISPANIC/LATINO 3

ASIAN OR PACIFIC ISLANDER 4

NATIVE AMERICAN OR ALASKAN NATIVE 5

OTHER **[SPECIFY:]** 99

v._____

A4. What is your zip code? . . . . . |__|__|__|__|__| **ELIGIBLE ZIP CODE** ☐

A4a. Do you live <u>inside</u> or <u>outside</u> the _____ city limits?

INSIDE 1

OUTSIDE 2

Next, I'd like to ask you about AIDS services, materials, and referrals you may have received from this program or other outreach programs.

A5. Including today, on how many days have you met with an outreach worker or staff from NC CoOp?

DAYS ..... |__|__|

SKIP: IF 0, GO TO A7

		NO	YES	
A6a.	Before this time, have you talked about AIDS with someone from NC CoOp?	0	1	**[IF NO, GO TO A7]**
A6b.	Were you asked to give blood or urine samples? ...	0	1	
A6c.	Did you participate in an interview that took about 45 minutes?	0	1	
A6d.	Do you have or recall your ID number? ..... (SPECIFY: |__|__|__|__|__|__|)	0	1	**NOT ALREADY A PARTICIPANT** ☐
A6e.	In the past 90 days, on how many days have you talked to someone from NC Coop? ..... |__|__|			

A7. Prior to today, on how many days have you met with an AIDS outreach worker or staff from some other program? (Which program were they from?)

DAYS ..... |__|__|

v._____

A8a-c. In the past 30 days, have you done any of the following?

	NO	YES	
a. Used crack cocaine?	0	1	**YES TO A8a OR A8b** ☐
b. Used a needle to inject drugs?	0	1	
c. Been in a drug or alcohol treatment program?	0	1	**NO TO A8c** ☐

[ADDITIONAL SPECIAL TOPICS MODULE] 000

END OF SCREENER

[IF ANY BOXES (☐) NOT CHECKED, READ:]
Those are all of the questions I have for you, thank you very much for your time and participation. Let me assure you again that all of the information you have given will be kept confidential.

[IF ALL BOXES (☐) CHECKED, READ:]
Based on your answers you may be eligible for a study we are conducting to try and slow the spread of AIDS and other health problems among drug users who are not in treatment. If you have a moment now, I would like to tell you a little more about that study.

SIGNIFICANT INDIVIDUAL CONTACT (SIC)

(Version 10-OCT-95)

SITE ID: . . . . . |__|__|-|__|__|__|__|

STAFF ID: . . . . . |__|__|

LOCAL ID: . . . . . |__|__|__|__|__|__|

NIDA ID: . . . . . |__|__|__|__|__|__|

SITE NAME:_____

STAFF NAME:_____

ALIAS:_____

DATE: . . . . . |__|__|/|__|__|/|__|__|

S1. WHICH OTHER STAFF WERE PRESENT?:

NONE 00

a. |__|__| b. |__|__| c. |__|__| d. |__|__| e. |__|__|

f. |__|__| g. |__|__| h. |__|__| i. |__|__| j. |__|__|

S2. WHAT WAS THE PURPOSE OF THE CONTACT? **[CIRCLE ALL THAT APPLY]**

OUTREACH/SCREENER 1

RBA & SESSION I TRAILERS 2

INTERVENTION SESSION I 3

SESSION II TRAILER 4

INTERVENTION SESSION II 5

OTHER INTERVENTION **[SPECIFY:]** 6

v._____

RBFA & FOLLOW-UP TRAILERS 7

HIV PRETEST COUNSELING AND BLOOD DRAW 8

HIV POSTTEST COUNSELING 9

SYPHILIS BLOOD DRAW 10

OTHER **[SPECIFY:]** 99

v._____

S3. WHERE DID THE CONTACT PRIMARILY TAKE PLACE?

STREET 1

PUBLIC HOUSING 2

OTHER RESIDENCE 3

BUSINESS 4

COMMUNITY CENTER 6

PUBLIC FACILITY (BUS TERMINAL, PARK) 5

MOBILE UNIT 7

INTERVENTION FIELD STATION 8

TREATMENT FACILITY 9

OTHER **[SPECIFY:]** 99

v._____

S4. WHICH TOPICS DID YOU DISCUSS? **[CIRCLE ALL THAT APPLY]**

RECRUITMENMT/STUDY/DATA COLLECTION 1
CASUAL CONVERSATION 2
HOW HIV AND AIDS ARE RELATED 3
HOW HIV AND OTHER SEXUALLY TRANSMITTED DISEASES ARE RELATED 4
DIRECT RISK BEHAVIORS FROM INJECTING DRUG USE 5
INDIRECT RISK FROM SHARING THE COOKER, COTTON, WATER, OR RINSE WATER 6
INDIRECT RISK FROM USING CRACK AND OTHER DRUGS 7
HOW TO CLEAN NEEDLE AND SYRINGE 8
SAFER SEX PRACTICES AND USING CONDOMS 9
RISK OF HAVING MULTIPLE SEX PARTNERS 10
GOING INTO DRUG TREATMENT 11
HIV ANTIBODY TESTING, SUPPORT, OR HIV TREATMENT 12
ANY OTHER TOPICS **[SPECIFY:]** 99

v._____

S5. HOW MANY TIMES DID YOU PERFORM THE FOLLOWING DEMONSTRATIONS?

a. HOW TO PROPERLY CLEAN NEEDLES . . . . . |__|__|
b. HOW TO PUT ON A MALE CONDOM . . . . . |__|__|
c. HOW TO USE A FEMALE CONDOM . . . . . |__|__|
d. HOW TO USE A DENTAL DAM . . . . . |__|__|
e. INDIRECT TRANSMISSION WITH NEEDLES . . . . . |__|__|
f. ANY OTHER DEMONSTRATIONS **[SPECIFY:]** . . . . . |__|__|

v._____

S6. HOW MANY TIMES DID THE RESPONDENT PRACTICE OR REHEARSE THE FOLLOWING?

a. HOW TO PROPERLY CLEAN NEEDLES . . . . . |__|__|
b. HOW TO PUT ON A CONDOM . . . . . |__|__|
c. ANY OTHER REHEARSALS **[SPECIFY:]** . . . . . |__|__|

v._____

S7. HOW MANY OF EACH OF THE FOLLOWING MATERIALS DID YOU GIVE THE RESPONDENT

a. HIV INFORMATION . . . . . |__|__|
b. STD INFORMATION . . . . . |__|__|
c. TREATMENT INFORMATION . . . . . |__|__|
d. STANDARD KIT WITH BLEACH, WATER, ALCOHOL SWAB, BANDAID, MALE CONDOMS, & CONDOM USAGE INFO . . . . . |__|__|
e. MALE CONDOMS . . . . . |__|__|
f. FEMALE CONDOMS . . . . . |__|__|
g. DENTAL DAM . . . . . |__|__|
h. BLEACH . . . . . |__|__|
i. ANY OTHER MATERIALS **[SPECIFY:]** . . . . . |__|__|

v._____

S8. WHICH OF THE FOLLOWING REFERRALS DID YOU GIVE THE RESPONDENT? **[CIRCLE ALL THAT APPLY]**

NONE 0
HIV ANTIBODY TESTING 1
SYPHILIS TESTING 2
OTHER STD TESTING 3
HEPATITIS B TESTING 4
TB TESTING 5
DRUG TREATMENT 6
HEALTH CLINIC OR SERVICES 7
ANY OTHER REFERRALS **[SPECIFY:]** 99
v._____

S9. HOW MANY OF THE FOLLOWING VOUCHERS OR ASSISTANCE DID YOU GIVE THE RESPONDENT?

TRANSPORTATION ASSISTANCE . . . . . |__|__|
TREATMENT COUPONS . . . . . |__|__|
ANY OTHER VOUCHERS OR ASSISTANCE
[SPECIFY:] . . . . . |__|__|
v._____

S10. DID YOU ATTEMPT TO COMPLETE A SCREENER?

NO 0
YES BUT REFUSED/BROKE OFF 1
YES BUT RESCHEDULED 2
YES AND R WAS INELIGIBLE 3
YES AND R COMPLETED AND WAS ELIGIBLE 4

S11. DID YOU ATTEMPT TO COMPLETE A SESSION I TRAILER QUESTIONNAIRE?

NO 0
YES BUT R REFUSED/BROKE OFF 1
YES BUT R RESCHEDULED IT 2
YES AND R COMPLETED IT 3

S12. DID YOU ATTEMPT TO COMPLETE AN RBA?

NO 0
YES BUT R REFUSED/BROKE OFF 1
YES BUT R RESCHEDULED IT 2
YES AND R COMPLETED IT 3

S13. DID YOU ATTEMPT TO COMPLETE A SESSION II TRAILER QUESTIONNAIRE?

NO 0
YES BUT R REFUSED/BROKE OFF 1
YES BUT R RESCHEDULED IT 2
YES AND R COMPLETED IT 3

S14. DID YOU ATTEMPT TO COMPLETE AN RBFA?

NO 0
YES BUT R REFUSED/BROKE OFF 1
YES BUT R RESCHEDULED IT 2
YES AND R COMPLETED IT 3

S15. DID YOU ATTEMPT TO COMPLETE A SESSION III TRAILER QUESTIONNAIRE?

NO 0
YES BUT R REFUSED/BROKE OFF 1
YES BUT R RESCHEDULED IT 2
YES AND R COMPLETED IT 3

S16. HOW MANY MINUTES WERE SPENT ON:

a. ENGAGEMENT & RAPPORT BUILDING ..... |__|__|
b. INFORMATION/DEMONSTRATION/REHEARSAL ABOUT AIDS/HIV/STD ..... |__|__|
c. INFORMATION ABOUT NC COOP STUDY ..... |__|__|
d. DATA COLLECTION WITH RESPONDENT ..... |__|__|
e. PAPERWORK WITHOUT RESPONDENT ..... |__|__|
f. TRANSPORTING THE RESPONDENT ..... |__|__|
g. HIV ANTIBODY TESTING & COUNSELING ..... |__|__|
h. SYPHILIS TESTING ..... |__|__|
i. REFERRAL/APPOINTMENTS ..... |__|__|
j. OTHER **[SPECIFY]** _____ ..... |__|__|

S17. HOW MUCH OF THE FOLLOWING COSTS ARE ASSOCIATED WITH THIS CONTACT?

INCENTIVES ..... $|__|__|__|.00
TRANSPORTATION: ..... MILES |__|__|__| OR COST $|__|__|__|.00
OTHER **[SPECIFY:]** ..... $|__|__|__|.00
v._____
ADDITIONAL COMMENTS/REQUESTS
[SPECIFY:] ..... $|__|__|__|.00
v._____

S18. WHAT WAS THE PRIMARY LANGUAGE USED?

ENGLISH 1
SPANISH 2
OTHER **[SPECIFY:]** 99
v._____

S19. POTENTIAL PROBLEMS **[CIRCLE ALL THAT APPLY]**:

NONE	0
NOT INTERESTED IN INTERVENTION	1
DENIAL/MISREPRESENTATION	2
GOING OR COMING FROM SOMEPLACE	3
ENGAGED IN REGULAR WORK	4
ENGAGED IN PROSTITUTION	5
ENGAGED IN DRUG DEALING OR HUSTLING	6
ENGAGED IN OTHER ILLEGAL ACTIVITIES	7
UNDER INFLUENCE OF DRUGS OR ALCOHOL	8
PHYSICALLY ILL OR IN PAIN	9
HOMELESS OR UNSTABLE HOUSING	10
MENTALLY DISABLED OR RETARDED	11
CONFUSED OR OTHER INCOHERENT	12
OTHER **[SPECIFY:]**	99

v._____

S20. OTHER COMMENTS

v1._____

v2._____

v3._____

v4._____

DATE: _____ STAFF NAME: _____

SITE ID: _____ STAFF ID: _____

OUTREACH ACTIVITY LOG

	1	2	3	4	5	6	7	8	9	10
Time Started										
Time Ended										
# of People										
DISCUSSION TOPICS:										
Focus of Outreach/Research Interests										
Basic information on HIV										
HIV antibody testing/testing sites										
HIV and drug use										
STDs and sexual risk										
Rick of direct sharing equipment										
Risk of indirect sharing equipment										
Risk of crack use										
Information on cleaning needles/syringes										
Safer sex practices/condom usage										
Risk of multiple partners										
Eligibility/participation in research										
MATERIAL DISTRIBUTED: (HOW MANY?)										
Basic information - HIV/AIDS/STDs										
Description of study										
Local community referral list										
Risk reduction kit										
Coupon for treatment										
Referral card										
Additional condoms										
Merchant coupons										
PAPERWORK COMPLETED:										
Quick Outreach Screener										
Significant Contact Form										

OUTREACH DAILY REPORT

NAME: _____ **STAFF ID:** _____

DATE: _____

	Time Spent On:	Hours	Minutes
1.	In-service training (formal training on HIV/AIDS/project)		
2.	Meeting with supervisor/staff (Administrative inhouse meetings)		
3.	Agency contacts (Networking with other service providers)		
4.	Subjects contact (Total time with contacts < 5 min)		
5.	Canvassing areas (scouting, security screening sweeps) (on foot, in car or van)		
	Group engagements (any time > 5 min):		
6.	• street		
7.	• door to door		
8.	• community center		
9.	• laundromat		
10.	• bar		
11.	• beauty parlor/barber shop		
12.	• other _____		
	Individual engagements (any time > 5 min):		
13.	• street		
14.	• door to door		
15.	• community center		
16.	• laundromat		
17.	• bar		
18.	• beauty parlor/barber shop		
19.	• other _____		
20.	Community presentations (e.g., speaking at a community center)		
21.	Other _____		
22.	Other _____		
23.	Total hours worked today (this should add up to the total on your timesheet and/or activity log):		

Appendix C

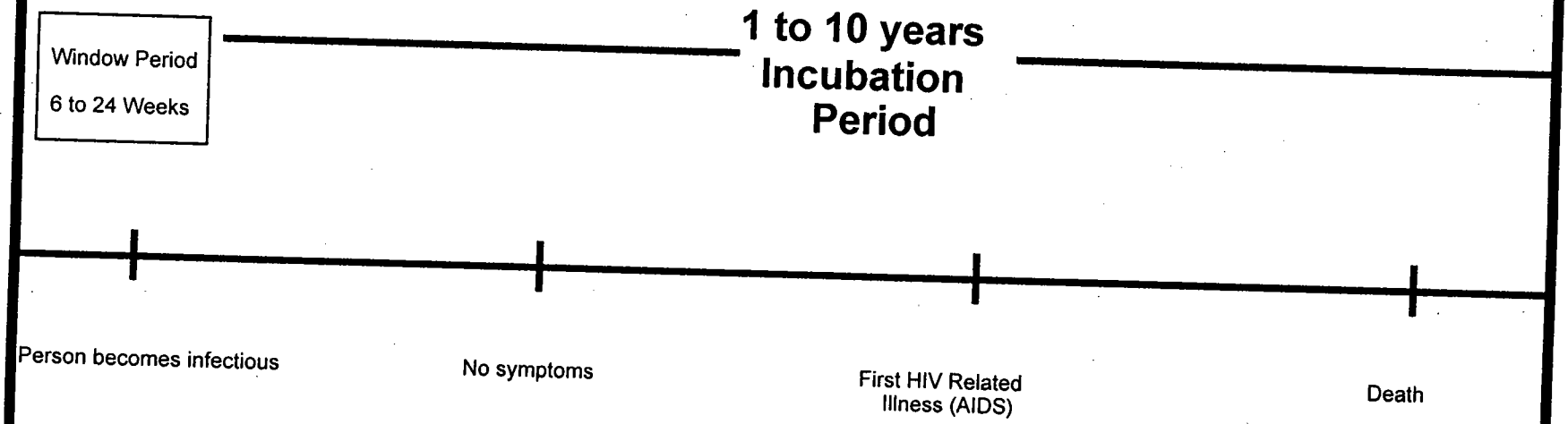
Standard Cue Cards For Session I

A.1: Basic HIV/AIDS Information
A.2: HIV/AIDS Symptoms
A.3: How does someone get infected?
A.4: Risk Behaviors
A.5: Routes of Indirect Sharing
A.6: Cocaine Risks
A.7: Why Use Condoms?
A.8: New Female Condom Information
A.9: Benefits of Discussing Safer Sex Practices
A.10: Why Clean Needles and Syringes?
A.11: Cleaning Points to Remember
A.12: Benefits of Drug Treatment
A.13: HIV Testing
A.14: Healthy Behaviors of HIV+

What is AIDS?

- AIDS stands for Acquired Immune Deficiency Syndrome. This disease is a serious health problem in our country and around the world.
- National and Local Statistics.
- AIDS is caused by the human immunodeficiency virus, commonly known as HIV.
- HIV can destroy the body's ability to fight off infections and disease.

Usual Course of HIV Infection and AIDS



How Does Someone Get Infected?

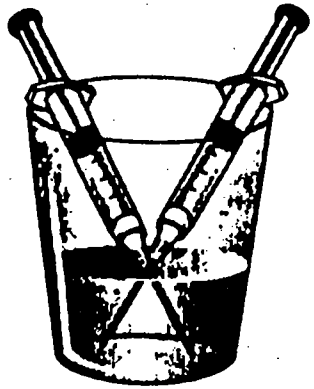
- HIV, the AIDS virus, is present in semen, blood, and vaginal fluid.
- HIV is transmitted
  - by sexual acts like oral, anal, and vaginal intercourse
  - by sharing needles and other drug injection equipment,
  - or by receiving blood from an infected person.
- HIV is transmitted from mother to child during pregnancy or the birth process. It is possibly also transmitted by breastfeeding.
- You <u>can't</u> get HIV through everyday contact such as shaking hands or hugging.
- You <u>can't</u> get HIV from saliva, sweat, tears, urine, or feces.
- You <u>can't</u> get HIV from clothes, a telephone, or a toilet seat.
- You <u>can't</u> get HIV from a dry kiss.
- You <u>can't</u> get HIV from a mosquito bite or other insect bites.

What Behavior Puts You at Risk?

- Sharing needles and syringes.
- Sharing cookers, cotton, and rinse water.
- Not using a condom or barrier during vaginal, oral, or anal sex.
- You increase your chances of getting HIV if you have unprotected sex with:
  - someone who has several sex partners; or
  - someone who injects drugs.
- Using alcohol or other drugs can be risky because:
  - alcohol and drugs may increase your desire to have sex and make you less careful;
  - alcohol and drugs may weaken your immune system, making it easier to get HIV and other infections.

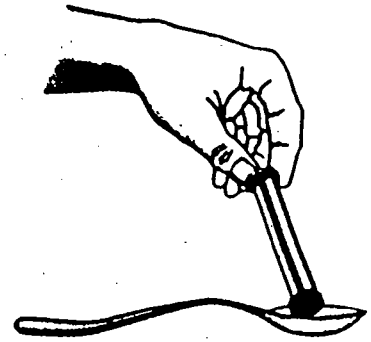
ROUTES OF INDIRECT SHARING

1. SHARED INFECTED CONTAINER

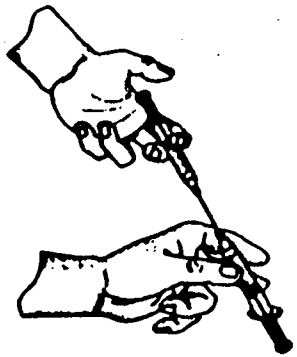


2. USING INFECTED SYRINGE

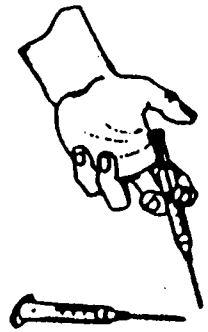
3. USING "DIRTY" PLUNGER TO MIX DRUG SOLUTION



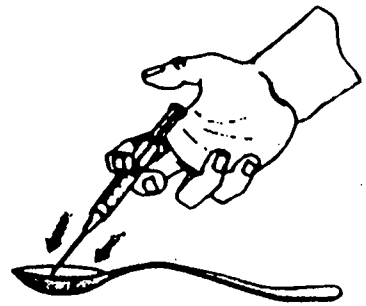
4. USING INFECTED SYRINGE TO DISTRIBUTE OR RETURN DRUG



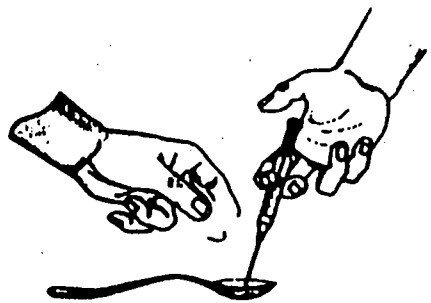
5. DRAWING DRUG FROM SHARED COTTON FILTER



6. RETURNING THE DRUG TO SHARED COOKER



7. "BEATING THE COTTON" AND "SCRAPING THE COOKER"



8. RINSING IN OTHERS WATER

What About Cocaine and Crack?

- Sometimes people smoke crack or snort cocaine rather than inject it. But that doesn't mean they are safe. Even if they only smoke or snort, heavy cocaine users are still increasing their risk for HIV infection. Here's why:

  - People often have more sex when they use cocaine, and they often forget to wear latex condoms or to ask their partner to wear a condom.

  - Some people sell sex to get cocaine or to get money for cocaine. This may mean they have more sex or unprotected sex.

  - Crack and cocaine may weaken the immune system, making it easier to get HIV and other infections.

- If you are a crack or cocaine user, you can decrease your chances of getting HIV by getting off drugs.

- If you can't get off drugs, be sure to wear latex condoms or make sure your partners do. Your life depends on it!

Why Use Condoms?

- Condoms, used all the way through sex, help prevent the spread of sexually transmitted diseases including HIV, the virus that causes AIDS.
  - Lambskin, sheepskin, and other natural condoms do not protect you from HIV.
- Sexually transmitted diseases often cause lesions or sores. When these occur, it's easier to get infected with HIV.
- Besides not having sex, the best ways to protect yourself against AIDS are non-penetrative sex or mutual masturbation (not oral sex). Using latex condoms is the next best way to protect yourself.
- For receiving oral sex, men should use condoms, and women should use dental dams or a barrier such as Saran Wrap.
- To reduce your risk of getting HIV/AIDS:

  Best method: no sex.
  Next best: no sex involving penetration.
  Next best: use condoms with all sex involving penetration.
- Spermicides like diaphragm jelly and contraceptive sponges do not kill HIV.
- Demonstration and rehearsal.

What About Female Condoms?

- Female condoms have been shown to reduce the risk of getting sexually-transmitted diseases and pregnancy.
- Female condoms (like Reality®) are polyurethane, bag-like devices that are placed in the vagina to catch the male ejaculate (cum).
- Female and male condoms should never be used together at the same time.
- Each female condom can be used only one time. It must be thrown out after each sex act.

How to Talk With Your Partner About Safer Sex

- Learn as much as you can about HIV. That will make it easier to talk.
- Decide when you want to talk. The best time is not just before having sex.
- Decide in your own mind what you will and won't do during sex.
- Give your partner time to think about what you're saying. Don't rush.
- Pay attention to how your partner is understanding what you're saying. Slow down if you need to.
- Talk about the times that make it hard to have safe sex. These are times when you don't have condoms or have used alcohol or drugs. Try to decide what to do at those times so you can both be safe from HIV.
- If your partner does not want to practice safe sex, ask yourself if this is the type of person you really want to have sex with.

Why Clean Needles and Syringes?

- You can get infected with HIV by sharing works another person has used. You can also get HIV by sharing cookers, cotton, or rinse water.
- Merely rinsing used works in water, even hot water, will not kill HIV. You must use bleach.
- To reduce your risk of infection:

  Best method: stop using drugs.

  Next best: stop using needles.

  If you can't stop using needles, don't share needles. Use a new needle or a needle only you have used before.

  If you do share needles, clean the needle every time before you inject drugs. Clean it the way we are showing you today.

- Do not put your needle in someone else's rinse water, cotton, or cooker. HIV can live in blood in all these places.
- Demonstration and rehearsal.

Bleach, Bleach, Water, Water

- Always clean with full strength bleach
- Keep bleach in syringe by tapping 30 seconds
- Always discard into sink, toilet, or sewer
- Bleach again
- Always rinse with clean water and discard into sink, toilet, or sewer
- Rinse again
- After you finish with bleach, bleach, water, water, <u>then</u> remove plunger from syringe and clean both parts again with bleach and water
- Never share your other equipment (cooker, cotton, cooking water, or rinse water)
- Clean your cooker with full strength bleach and rinse with clean water

The Benefits of Drug Treatment

- Can help you get off drugs and teach you ways to stay off drugs.
- Can change your life, improve your health and reduce your risk for HIV.
- Can provide counseling and support for you and family members who may also need help.
- Can provide referrals for other health and social services.
- Can provide support for dealing with AIDS and other problems.
- Even if you can't get into treatment now, you can be given information on support groups that will help you until a treatment program can be found for you.

The HIV Test

- The test screens for the presence of antibodies that have developed in your system in response to the virus.

- A positive test shows that you are infected with HIV and can give it to others.

- A negative test may mean that you are free of the virus. There is a period of time between infection and when the test shows that you are infected. This is called the window period. During this time, you can test "negative" for HIV but you may really be "positive." It's a good idea to have another HIV test in 6 months to be sure you don't have the virus. (Between testing, if you have sex, make sure you use latex condoms. If you use needles, make sure you don't share works - use clean works.)

- We recommend you take the test and learn your test results because:

  - Treatment is available for HIV infection.

  - You can plan a course of action that is best for you, your family and friends, and your community.

- Some people are anxious about taking the HIV test or gettings results. Our staff are prepared to discuss all concerns you may have about getting tested. Please feel free to ask any questions, so you can feel better about getting the test.

If You Are Infected with HIV

- It is important to get early medical treatment to control the disease.
- Be safe. Don't take in more virus--it can make you sicker. Do everything you can to reduce your risk.
- Some things you can do:
  - reduce drug use,
  - eat healthy foods,
  - get proper rest,
  - get proper exercise,
  - think positively--consider joining a support group,
  - get regular preventive medical care.

Partner Notification

- Partners may want to consider changing their behaviors, too.
- Partners may want to seek HIV testing and medical treatment if they are infected.
- The health department can help locate and counsel partners.
- Partner notification laws.

Meaning of Seronegative Results

- Negative results mean that HIV antibodies have not been found in the blood.
- Individuals who test negative may be infected with HIV. This can happen if your body hasn't yet produced enough antibodies to be detected.
- It usually takes 2 weeks to 6 months after you are infected for your body to produce a detectable level of antibodies. In a small number of people, it can take up to 3 years. A very small number of people never show antibodies, even though they are infected.
- Anyone who has engaged in risky behaviors in the last 6 months should be retested for HIV in the next 6 months. (Between testing, if you have sex, make sure you use latex condoms. If you use needles, make sure you don't share works - use clean works.)
- Anyone who has engaged in risky behaviors since 1977 should not donate or sell blood.

Meaning of Seropositive Results

- A person who tests positive is infected with the virus and can infect others.
- A person who tests positive may not have symptoms of AIDS. These symptoms may not develop for 5 to 10 years.
- People who are infected can take in more virus and get sicker unless they protect themselves with safe behaviors.
- The sexual partners, shooting buddies, or children of people who test positive may also be infected.
- A seropositive person should not donate or sell blood.
- A seropositive person should seek and receive regular medical care.
- A seropositive woman risks passing the virus to the fetus if she is pregnant and to her child if she is breastfeeding.
- Early medical treatment such as taking AZT may prevent passing the virus from mother to fetus.

Reduce Your Risk and Stop the Spread of HIV and AIDS

Drugs

- Don't use drugs.
- If you cannot stop using drugs, don't share needles and works.
- If you can't stop sharing, clean needles and works with bleach, bleach, water, water.
- Don't share cookers, cotton, and rinse water.

Sex

- Decrease number of sex partners.
- Use condoms.

Meaning of Seropositive Results

- A person who tests positive is infected with the virus and can infect others.
- A person who tests positive may not have symptoms of AIDS. These symptoms may not develop for 5 to 10 years.
- People who are infected can take in more virus and get sicker unless they protect themselves with safe behaviors.
- The sexual partners, shooting buddies, or children of people who test positive may also be infected.
- A seropositive person should not donate or sell blood.
- A seropositive person should seek and receive regular medical care.
- A seropositive woman risks passing the virus to the fetus if she is pregnant and to her child if she is breastfeeding.
- Early medical treatment such as taking AZT may prevent passing the virus from mother to fetus.

If You Are Infected With HIV

- Don't take in more of the virus by having unprotected oral, anal, or vaginal sex. Getting exposed to the virus again can make you sicker.

- Some things you can do: Stop using drugs. Reduce your number of sex partners. Get drug treatment. Join an HIV support group. Eat healthy foods. Get proper rest. Get proper exercise. Think positively. Get regular preventive medical care.

- Getting medical treatment is very important. Proper treatment can keep AIDS symptoms from developing as quickly as they would without it.

- Review local treatment resources.

Partner Notification

- Partners may want to consider changing their behaviors, too.
- Partners may want to seek HIV testing and medical treatment if they are infected.
- The health department can help locate and counsel partners.
- Partner notification laws.

HIV Control Measures

To help prevent spreading HIV to others, people with HIV should:

a. refrain from sexual intercourse unless condoms are used, and exercise caution when using condoms due to possible condom failure;

b. not share needles or syringes, or any other drug-related equipment, paraphernalia, or works that may be contaminated with blood through previous use;

c. not donate or sell blood, plasma, platelets, other blood products, semen, ova, tissues, organs, or breast milk—all of these things may contain HIV;

d. have a skin test for tuberculosis; and

e. notify future sexual partners of infection. (If the time of initial infection is known, notify persons who have been sexual and needle partners since date of infection; and, if the date of infection is unknown, notify persons who have been sexual and needle partners for the previous year.)

North Carolina Cooperative Agreement for AIDS Outreach and Risk Reduction Research

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