grams of diagnosis and treatment of these infections into AIDS prevention programs.

REFERENCES


Criteria for HIV Screening Programs

Screening for infection or disease indicators has undoubtedly benefited many public health programs, screened individuals, and the community at large—both when it has been used to detect treatable diseases which are otherwise difficult to recognize and also when it has been used to detect conditions for which there is no therapy. It is not surprising, then, that proposals for screening often arise in the context of the AIDS epidemic and of public health efforts to control its causative agents, human immunodeficiency virus (HIV) and related retroviruses.

Without question, the pandemic spread of HIV infection warrants close monitoring and public health planning. However, any HIV screening program raises delicate and difficult logistical, le-
gal, technical, personal, social, and ethical questions that must be addressed and resolved if the program is to be successful. Because of the restricted modes of HIV transmission, the privacy of the behavior usually involved, and the current absence of any specific therapy, screening programs must be approached extremely carefully. Otherwise, these programs could be intrusive and costly, and could divert human, material, and financial resources from education programs that, to date, have been the most effective weapon against the spread of HIV.

To help ensure that these issues are systematically addressed whenever HIV screening is considered, the WHO Special (now Global) Program on AIDS convened a meeting on “Criteria for HIV Screening Programs” in Geneva, in May 1987. Twenty-one participants from 17 countries attended, including epidemiologists, virologists, experts in legal medicine and ethics, social and behavioral scientists, and disease control specialists. This report outlines criteria which should be considered in planning an HIV screening program, and points out areas that must be addressed before successful and effective public health outcomes can be achieved. Both public health and human rights will best be served by addressing these issues prior to implementing any HIV screening program.

BACKGROUND

In response to the spread of HIV that the world has experienced during the 1980s, many authorities are considering or implementing programs to halt transmission of the virus. With neither a vaccine nor effective drug therapy in sight for the near future, these programs offer the greatest hope for halting the spread of the disease.

HIV transmission. Epidemiologic studies in Europe, the Americas, and Africa repeatedly have documented only three modes of HIV transmission: heterosexual or homosexual intercourse; contact with blood, blood products, or donated organs and semen (most cases of contact with blood involve transfusion of unscreened blood or the use of unsterilized syringes and needles); and from mother to child before, during, or shortly after birth. HIV is not transmitted by close but nonsexual contact or by food, water, air, or insect vectors. The documented routes of HIV transmission should be considered whenever public policies are developed; for this discussion, it is particularly important to keep in mind that HIV is not transmitted by casual contact with an infected person.

HIV infection. Almost all HIV-infected persons develop antibodies against the virus within a few months. Even though infected persons may appear healthy at the time of testing, laboratory studies have shown that the presence of antibodies indicates current and persistent HIV infection, and these infected persons can potentially transmit the virus to others by sexual contact or through blood by, say, sharing injection equipment. Infants born to HIV-infected mothers have passively acquired antibodies to HIV which may persist for up to one year; about 50% of these infants will themselves be infected, and their antibodies to HIV will persist indefinitely.

HIV serologic testing. Tests to detect antibodies to HIV have been available commercially since 1985, and they have been used for several different purposes. Most countries have first and primarily used them to screen donated blood and plasma and to discard units inadvertently collected from infected persons. Epide-
miologists have used the tests to assess the prevalence and incidence of infection in different geographic areas and populations, as well as to better understand the infection's natural history. With this information, areas and groups which need to be targeted with specific educational programs and other prevention efforts can be determined. Health officials and physicians in some countries also have used these tests to help individuals determine whether they have been infected. This sort of testing should be coupled with individual counseling and education, so that persons at risk can reduce their own risk of infection or the risk of transmitting the infection to others.

**HIV screening.** Several testing and screening programs have been proposed, aimed at reaching as many HIV-infected persons as quickly and as thoroughly as possible. While a well-designed testing program might reduce the incidence of new HIV infections, some screening efforts may be sparked by unfounded concerns about casual transmission of HIV or by the need to appear to be actively fighting the HIV problem. The purposes and objectives of these programs have not always been clearly defined, and the practical, economic, and social costs of implementing them may not have been sufficiently examined.

If testing programs are to be effective, the major problem of disclosing personal information that may result in ostracism or discrimination must be carefully considered and resolved. Alternative approaches should be explored whenever the risks are too many, too great, or when they outweigh the benefits. Failure to do this may lead persons at high risk of infection to avoid testing and would ultimately result in counterproductive programs.

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**CRITERIA FOR PLANNING AND IMPLEMENTING HIV SCREENING PROGRAMS**

**What Is the Rationale of the Proposed Program?**

The rationale and desired public health outcome of any proposed screening plan should be carefully articulated. Depending on the program's objectives, it should be determined from the outset what counseling and follow-up services will be provided to those who are to be identified and notified of their HIV antibody findings. Addressing social, legal, and ethical ramifications of screening and follow-up programs is a critical part of this assessment. A cost/benefit/risk analysis is also recommended at this initial stage.

Since there is no effective treatment for HIV infections, the public health rationale for HIV screening programs rests on the premise that identifying infected individuals will reduce HIV transmission; HIV screening programs also may help reduce the incidence of new HIV infections by reaching and counseling persons at risk. To do this, however, the type of voluntary or mandatory screening program to be used must both effectively identify persons at high risk of HIV infection and also motivate them to voluntarily change their high-risk behaviors.

Another public health objective is to obtain data on the pattern and prevalence of HIV infection, critical information in drawing up measures to slow the spread of HIV in a given area. Screening of total or selected populations in a newly involved area has been proposed as a way to monitor the silent, early spread of HIV and thus be able to implement specific control measures early on. Some countries have conducted this kind of epidemiologic surveillance by using sam-
ples previously collected for other purposes and which have been rendered anonymous.

Even after an HIV screening program is considered justified and necessary for prevention, the following criteria must be resolved before implementing the program. At each stage, the rationale and the possibility of achieving the goals of the program may need to be reconsidered in light of new information on costs, risks, and benefits. Furthermore, it must be borne in mind that screened individuals who are found uninfected but who continue to engage in high-risk behavior remain at risk—the screening program cannot identify persons who become infected after testing unless screening is repeated at intervals.

What Population Is To Be Screened?

Identifying and selecting the target population is a critical aspect of a successful screening program. Each of the following questions must be adequately answered before continuing to design the program.

- What population should be screened?
- What is the relative risk of HIV infection in this population?
- Is the proposed program voluntary or mandatory?
- Does the proposed program allow anonymity or does it require and plan to retain identifying information?
- Can the screening program readily reach the population?
- How will individuals in the target population be identified for screening?
- How will people be notified of the need or obligation to be tested?

- What sanctions would apply to persons failing to comply with obligatory testing?
- Can persons in the target population be reached through traditional medical care sources or is there need for a separate access system?
- Is the site for screening, including pre- and post-test counseling and/or specimen collection, suitable for the target population?
- What is the plan for confirming that a given test result applies to the person being informed?
- How will those already tested be identified?
- What plan has been made for periodic retesting of the screened population?

What Test Method Is To Be Used?

Since no single test, or series of tests, fits all circumstances, the chosen test methods should be tailored to the setting where they will be used. In choosing both primary screening and confirmation test systems, the technical nature of the test system, the availability and disposition of necessary resources, and the characteristics of the target population should be considered. Other, more specific aspects also should be considered in selecting a test or tests:

- Desired characteristics of the test(s), such as whether the test(s) should detect antigens or antibodies, HIV-1, HIV-2, or other related retroviruses; the type and source of test materials required.
- Technical aspects of the test(s), such as design of the test system, type and complexity of required equipment, time and laboratory space required, storage characteristics and
stability of reagents, technical skill and training required by technicians.

- Support aspects of the test(s), such as source and reliability of test kits and reagents, stability or electrical source for electronic equipment, calibration requirements, spare parts and availability of service for special equipment.

- Interpretation characteristics of the test(s), such as sensitivity and specificity of the test(s) in the target population (these values and the prevalence of HIV infection in the population determine the predictive value of positive and negative test results).

- Quality control and proficiency evaluation systems to be established in the laboratory.

Wherever system is ultimately selected, there must be access to a regional reference laboratory resource that can evaluate and assess how appropriate assay systems are for the given setting or use, that can provide validation or confirmation testing, that can oversee quality control at screening centers, and that can train staff for local screening centers.

Where Is the Laboratory Testing To Be Done?

Implementing a screening program also will require that an appropriate site be determined for laboratory test facilities. Factors to be considered in making this decision include the scope of the program, its geographic extent, its duration, the percentage of the population to be screened, the existing distribution of technical and human resources, and supply constraints. In addition, the following issues need to be resolved:

- Is the screening test to be conducted where specimens are collected or at a laboratory away from this site?
- Is the test site under national or local government or under private jurisdiction?
- Will the screening tests be processed by a centralized laboratory or by multiple local laboratories?
- What laboratory sites will be used for supplemental tests?
- How will the proposed screening program affect existing laboratory functions?
- Are existing multipurpose serologic facilities suitable or will a separate new facility be needed?
- What safeguards will be taken in labeling and transporting specimens to retain both convenience and confidentiality?
- Are quality control systems for tests and procedures adequate?
- Who is responsible for testing costs?

How Will the Data Obtained from the Testing Be Used?

Since the social and personal consequences of known HIV seropositivity are so profound, exceptional care must be taken in handling laboratory and medical data from HIV testing. If the program has a surveillance function, the suitability of the data for demographic purposes must be assessed at the outset. In addition, the following questions must be resolved:

- What identifying information about screened persons will be collected and maintained with test records?
- How will an individual's data be recorded and how will the cumulative records from the screening program be managed and stored?
- Will the person tested have direct ac-
cess to the test results and other recorded information?

- How will confidentiality be assured; what legal measures are available or can be introduced to assure it?
- Under what circumstances will persons other than the person tested be allowed to seek and obtain access to the data?

What Plan Will Be Used to Communicate Results to the Person Tested?

On being informed that they are HIV seropositive, persons often experience a profound psychological disturbance, particularly if they were unaware that they were being tested or if they are unprepared for the implications of positive test results. To offset the potential psychological damage, counseling should always be provided before HIV testing is conducted and HIV test results are communicated. Whenever possible, test results should be communicated in person by a trained counselor. In addition to the above-mentioned counseling, other factors to consider and resolve include the following:

- Who will communicate the information?
- At what stage in the screening and laboratory confirmation process will persons be contacted with results?
- If it is impossible to convey results in person, will the information be conveyed by telephone, by mail, or by some other means? Will this differ for positive and negative test results?
- What written record of test results, whether positive and negative, will be provided to the person tested?
- Other than the person tested, who will be informed of test results—physician, spouse, household members, sexual partners? Will program personnel decide this or does control rest with the person tested?

How Will Counseling Be Accomplished?

Counseling is so important that WHO held a separate consultation about it in May 1987. In countries or areas where there are no available counseling services, these need to be developed as soon as possible. It should also be considered that the magnitude of the epidemic has already stressed available counseling services in many countries, and that the demands created by a screening program may compete with those of other programs for scarce counseling personnel. Other considerations include:

- Who will conduct the counseling?
- How will counselors be trained and the adequacy of their performance be assured?
- Where will services be provided?
- How will confidentiality be achieved and maintained in the counseling setting?

What Is the Social Impact of Screening?

Even when test results are negative, the adverse social consequences of participating in a screening program can range from social isolation to economic losses, insurance cancellation, and restrictions in employment, schooling, housing, health care, and social services. These potential outcomes underlie the urgency of dealing with confidentiality and with informed consent prior to beginning testing.
What Legal and Ethical Considerations are Raised by the Proposed Screening Program?

Since HIV screening involves the collection of sensitive medical information, it could result in the infringement of a person’s human and legal rights. Someone’s right to privacy could be violated if information about HIV test results, or even about the fact that testing was sought or required, is disclosed without the person’s authorization or without a clear public health benefit. Human rights are best respected by using the least intrusive measures to accomplish public health objectives. The following legal and ethical questions regarding HIV screening programs must be resolved:

- Is informed consent for the HIV screening test required?
- Are screening test results validated to ensure correct identification of a person with a positive test result?
- Are appropriate supplemental laboratory test procedures used to minimize false positive results that inevitably occur in screening tests? Individuals falsely assumed to be seropositive may suffer severe and unjust consequences.
- Are there laws and regulations to safeguard against breaches of confidentiality or intentional disclosure of personal information not necessary for public health purposes?
- Will tested individuals be deprived of their legal or social rights?
- Are there laws or regulations to protect against discrimination in employment, housing, insurance, or health care and that provide redress for those who have suffered such discrimination?
- Will all personal identifying information be removed from specimens collected for other purposes before they are tested for HIV?

CONCLUSIONS

The meeting participants concluded that ready access to counseling and voluntary HIV antibody testing were more likely to contribute toward reducing the spread of HIV than were universal or targeted mandatory screening approaches. On the one hand, a single screening effort would yield only limited benefits, since screening alone does not result in behavioral changes that ultimately curb HIV transmission to others, and screening of targeted populations might not reach all persons at potential risk of infection, thereby becoming an inadequate public health measure.

The complex issues raised by mandatory screening efforts must be recognized and resolved. If epidemiologic data must be gathered, it should be obtained through methods that do not compromise human rights.