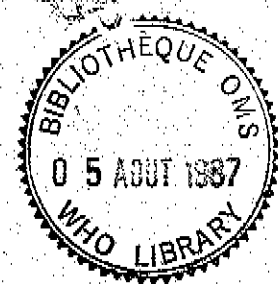

SPECIAL
PROGRAMME
ON AIDS

REPORT OF THE MEETING
ON CRITERIA FOR HIV
SCREENING PROGRAMMES

GENEVA
20-21 MAY 1987



WORLD
HEALTH
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1. INTRODUCTION

Screening¹ for indicators of infection or disease has been useful in a variety of public health programmes. When deployed as a detection instrument for treatable diseases, which are otherwise difficult to recognize, screening has a clear beneficial impact for the person screened as well as for the community at large. In the absence of therapy for a condition, screening still may serve a useful function by identifying affected persons in order that specific actions might be taken to prevent other persons from being affected. This latter use of screening, however, often raises complex social issues that are difficult to resolve. Thus, it is natural that proposals for screening arise frequently in the context of the epidemic of acquired immunodeficiency syndrome (AIDS) and the public health response to control its causative agents, human immunodeficiency virus (HIV) and related retroviruses. The usefulness of these proposed screening programmes, however, must be weighed carefully against their potential deleterious effects.

HIV screening programmes present broad problems beyond the simple recognition of infected individuals. Because of the extremely restricted modes of spread of HIV, the privacy of the behaviour usually involved in transmission, and the current lack of any specific intervention, screening programmes must be approached with great caution. Such programmes may be intrusive and cost-ineffective, and may divert human, material and financial resources from education programmes that are acknowledged to be the primary and most effective preventive measure currently available.

In order to help ensure that these issues are systematically addressed whenever HIV screening programmes are considered, the WHO Special Programme on AIDS convened a Meeting on 'Criteria for HIV-Screening Programmes' in Geneva on 20-21 May 1987. Twenty-one participants from 17 countries attended the meeting, including epidemiologists, virologists, experts in legal medicine and ethics, social and behavioural scientists and disease control specialists.

The meeting was chaired by Professor A. Pompidou (France) on the first day and Dr I. Gust (Australia) on the second day; Dr Mukunyandela (Zambia) and Dr J. Allen (USA) acted as rapporteurs.

Two working groups were convened to examine technical and psychosocial issues. The working group on psychosocial issues was chaired by Professor L. Kallings (Sweden) and Dr J. Osborne (USA) was rapporteur; Dr A. Pinching (UK) was chairperson and Dr R. Couthino (NL) was rapporteur of the working group on technical issues.

¹Definition of HIV Testing and Screening for the Purpose of this Report

Testing is defined as a serologic procedure for HIV antibody (or antigen) for an individual person, whether recommended by a health-care provider or requested by the individual.

Screening is defined operationally as the systematic application of HIV testing, whether voluntary or mandatory, to any or all of the following: entire populations; selected target populations; donors of blood/blood products and cells/tissues/organs.

2. BACKGROUND

AIDS and medical conditions associated with HIV infection were not recognized until 1981. HIV was not isolated and identified until several years later. Although HIV (and perhaps other related retroviruses) was present in some countries for several years before AIDS was recognized, the extent of HIV infection throughout the world has emerged only during the 1980s. Many authorities are considering or implementing programmes to curb the spread of HIV. This is appropriate because, at present, the sole means of controlling the epidemic spread of AIDS is to prevent further transmission of HIV; neither vaccines nor effective chemoprophylactic drugs are likely to be available in the immediate future.

2.1 HIV Transmission

Epidemiological studies in Europe, the Americas, Africa and Australia have documented repeatedly only three modes of HIV transmission:

- i) sexual intercourse (heterosexual or homosexual);
- ii) contact with blood, blood products, or donated organs and semen. The vast majority of contacts with blood involve transfusion of unscreened blood or the use of unsterilized syringes and needles;
- iii) mother to child - before, during or shortly after birth (perinatal transmission).

Transmission of HIV to adults by sexual or parenteral exposures is preventable provided persons have access to information and educational materials about the risks of infection, as well as the effective means and support to reduce or eliminate those risks. Preventing infection in women also prevents perinatal infections. Epidemiological evidence is firm that HIV is not spread by close inter-personal contact of a non-sexual nature or by food, water, air, or insect vectors. In developing public health policies, it is important to consider the documented routes of HIV transmission. It is especially relevant to this discussion that HIV is not transmitted by casual contact with an infected person.

2.2 HIV Infection

Persons infected with HIV almost universally develop antibody against the virus within a few months. Laboratory studies have shown that the presence of antibody indicates current and persistent infection with HIV even though the person may appear to be healthy at the time of testing. Infected persons, however, potentially are able to transmit the virus to others by sexual contact or through parenteral inoculation of blood (e.g., by sharing injection equipment). Infants born to HIV-infected mothers have passively acquired antibody to HIV which may persist for up to one year. Approximately 50 per cent of these infants will themselves be infected and their HIV antibody will persist indefinitely.

2.3 HIV Serologic Tests

Tests to detect antibody to HIV have been commercially available since 1985. In many countries, the initial and primary use of the antibody tests is to screen donated blood and plasma so that units inadvertently collected from infected persons are discarded. Epidemiologists have used HIV antibody tests to assess the prevalence and incidence of infection in different geographic areas and populations and to further understanding of the natural history of infection. This information is important in order to assess the areas and groups that need specific educational programmes or other prevention efforts.

In some countries health officials and physicians have used these tests to help persons determine if they have been infected. Counselling and education, with or without testing, allows persons who continue to be at risk to reduce their own risk of infection or their risk of transmitting infection to others. This type of individual counselling and testing effort should be made readily available in all countries regardless of whether the request for services is primarily initiated by patients or by health-care providers.

2.4 HIV Screening

To reach rapidly and completely as many HIV-infected people as possible, a variety of HIV antibody testing and screening programmes have been proposed. A carefully designed testing programme may reduce the incidence of new HIV infections by reaching and educating persons at risk. However, screening efforts may be driven by unfounded concerns about casual transmission of HIV or a need to appear to be taking visible action against the HIV problem. The purposes of the screening programmes and the objectives to be achieved are not always clearly defined and the practical, economic and social costs of implementing such programmes may not have been carefully examined.

Balanced also against any potential benefits of HIV antibody testing is the major problem of disclosure of personal information that results in social ostracism or discrimination. This factor must be considered carefully and resolved if testing programmes are to be effective. If the risks are substantial or outweigh the benefits, alternative measures to achieve the same objectives must be explored. Failure to consider and resolve these issues may result in programmes that, if they lead persons at high risk of infection to avoid testing, would be counterproductive.

This report sets out criteria which should be considered when an HIV screening programme is being planned. The criteria point to areas of concern that must be addressed and resolved for each programme being considered to provide the best potential for a successful and effective public health result.

3. CRITERIA THAT MUST BE CONSIDERED IN PLANNING AND IMPLEMENTING HIV SCREENING PROGRAMMES

3.1 What is the rationale of the proposed programme?

a) In considering screening of any population, the rationale and desired public health outcome should be carefully articulated. Depending on the objective(s), if persons are to be identified and notified of their HIV antibody findings it should be determined from the outset what counselling and follow-up services will be provided. Addressing and resolving the social, legal, and ethical ramifications of screening and follow-up programmes are a critical aspect of this assessment. It is also highly desirable to perform a cost/benefit/risk analysis as part of this initial exercise.

b) In the absence of effective treatment for HIV infections, the public health rationale for HIV screening programmes is based upon the premise that identification of infected individuals will result in a reduction of HIV transmission. The screening of blood donors, in order to discard units which have been inadvertently collected from HIV infected persons, has been a success where implemented. Other HIV screening programmes may be helpful to reduce the incidence of new HIV infections by reaching and educating (counselling) persons at risk. To achieve this objective, the type of screening programmes (whether voluntary or mandatory) needs to be carefully considered to determine which type would be more effective in identifying and motivating persons at increased risk of HIV infection to voluntarily change their HIV risk behaviours.

c) Another public health objective is to obtain data on the pattern and prevalence of HIV-infection. In order to effectively plan preventive measures to slow the spread of HIV in any area, data on the distribution of HIV-infection are needed. The early spread of HIV in a newly involved area occurs silently, and it is especially important to monitor the spread of HIV at this stage to allow the design of specific control measures at the earliest opportunity. Screening of total or selected populations has been proposed to provide such information. In some countries, this type of epidemiologic surveillance has been carried out by using serum samples collected for other purposes that have been rendered anonymous and all links to identifying information have been eliminated.

d) If it is determined that a screening programme for HIV is justified and necessary for effective prevention, each of the following additional criteria must be considered and specific decisions reached before proceeding with implementation of the programme. At each step, it may be necessary to reconsider the rationale and achievability of the proposed programme in light of current information on the associated costs, risks and benefits. In addition, it must be recognized that persons who are screened and found uninfected and engage in some risk-taking behaviour will remain at risk of infection unless they change their behaviour to reduce their risk. The screening programme will not identify persons who become infected after they are tested unless the screening is repeated at intervals.

3.2 What population is to be screened?

An important determinant for success of any prevention strategy based on screening is the selection and identification of the target population. Each of the following must be adequately resolved before continuing with design of the programme.

- a) What population is to be screened?
- b) What is the relative risk of HIV infection in this population?
- c) Is the proposed programme voluntary or mandatory?
- d) Does the proposed programme allow persons to remain anonymous or will identifying information be required and retained?
- e) Can the population be reached readily through screening programmes?
- f) How will persons in the target population be identified for screening?
- g) How will people be notified of the need or obligation to be tested?
- h) If testing is obligatory, what sanctions would apply if persons fail to comply?
- i) Can persons in the target population be reached through traditional sources of medical care or is a separate system of access required?
- j) Is the locale for screening, including pre- and post-test counselling and/or specimen collection, suitable for the intended population?
- k) What is the plan for validating that the screening test result applies to the person to be informed?
- l) How will those already tested be identified?
- m) What is the plan for periodic retesting of the population screened?

3.3 What test method is to be used?

No single test or sequence of tests is appropriate for all situations. The choice of test methods depends on the setting in which the tests are to be used. Factors influencing selection of both primary screening test systems and supplementary (validation or confirmation) test systems include:

- * the technical nature of the test system;
- * the availability and disposition of necessary resources;
- * the characteristics of the target population.

Whatever system is considered, access to a national or regional reference laboratory resource is an essential prerequisite for any screening or testing programme in order to perform the following functions:

- * to evaluate and assess the appropriateness of assay systems for the particular setting or proposed use;
- * to provide supplemental (validation or confirmation) testing;
- * to oversee quality control at screening centres;
- * to train staff for local screening centres.

Aspects of test selection that must be considered and resolved after appropriate expert advice include the following:

- a) Desired characteristics of the test(s): e.g., to detect antigen or antibody; to detect HIV-1, HIV-2, or other related retroviruses; type and source of test materials (e.g., recombinant or disrupted virus antigens, cell line used for virus replication, etc.).
- b) Technical aspects of the test(s): e.g., design of the test system; simplicity, type and complexity of required equipment; time and laboratory space required; storage characteristics and stability of reagents; technical skill and training required by technicians; etc.
- c) Support aspects of the test(s): e.g., source and reliability of test kits and reagents; stability of electrical source for electronic equipment; calibration requirements, spare parts, and availability of service for special equipment.
- d) Interpretation characteristics of the test(s): e.g., sensitivity and specificity of the test(s) in the population to be studied. (These values and the prevalence of HIV infection in the population determine the predictive value of positive and negative test results).
- e) Quality control and proficiency evaluation systems to be established in the laboratory.

3.4 Where is the laboratory testing to be done?

The implementation of a screening programme will also involve a determination of the most appropriate site for laboratory test facilities. This will be determined by the scope of the programme, its geographical extent, its duration, the proportion of the population to be screened, the existing distribution of technical and human resources, and supply constraints. The following issues need to be addressed:

- a) Is the screening test to be performed at the point of specimen collection or at a laboratory separate from this site?
- b) Under what jurisdiction (e.g., national or local government, private) is the test site?

- c) Will centralised or multiple local laboratories be used to process the screening tests?
- d) What laboratory sites will be used for supplemental tests?
- e) What impact will the proposed screening programme have on existing laboratory functions?
- f) Are existing multipurpose serological facilities suitable or will a separate new facility be required?
- g) What safeguards will be taken in the labelling and transport of specimens to prevent possible conflict between logistic convenience and confidentiality?
- h) Are quality control systems for tests and procedures adequate?
- i) Who is responsible for the costs of testing?

3.5 What is the intended disposition of data obtained from testing?

The social and personal consequences of known HIV seropositivity are so profound that the HIV test cannot be considered "just another test." Exceptional care, therefore, must be taken in handling laboratory and medical data. For instance:

- a) What identifying information about persons screened will be collected and maintained with the test records?
- b) How will the data for an individual person be recorded and how will the cumulative records from the screening programme be managed and stored?
- c) Will the person tested have direct access to the test results and other recorded information?
- d) How will confidentiality be assured? What legal measures are available or can be introduced to secure confidentiality?
- e) Under what conditions will individuals other than the person tested be permitted to seek and obtain access to the data?

Additionally, if the programme has an intended surveillance function, suitability of the data for demographic purposes should be assessed at the outset.

3.6 What plan will be used for communicating results to the person tested?

Persons informed that they are HIV seropositive often experience profound psychological disturbances. This is particularly true if they were not aware that testing was being conducted or were not prepared for the implications of the test results. For this reason, it is strongly urged that pre-test counselling always be provided before HIV testing is performed and that communication of HIV test results be accompanied by post-test counselling; whenever possible, test results should be communicated in person by a trained counsellor. Even with the provision of pre- and post-test counselling, other factors must be considered and resolved, including:

- a) Who will transmit the information?
- b) At what point in the screening and laboratory confirmation process will persons be contacted about results?

- c) If test results cannot be conveyed in person, how will the information be conveyed (e.g., by telephone or mail)? Will this differ for positive or negative test results?
- d) What written record of either positive or negative results will be provided to the person tested?
- e) Other than the person tested, who is to be informed of the test result (e.g., physician, spouse, other members of the household, sexual partners)? Are programme personnel responsible for this decision or does control of this remain with the person tested?

3.7 How is counselling to be accomplished?

Counselling is of such importance that a separate WHO consultation (May 1987) dealt with this area in depth. As noted above, the psychosocial impact of test results requires that post-test counselling be initiated at the time the person is informed of a positive HIV test result. Briefly, other considerations include:

- a) Who will counsel?
- b) How will counsellors be trained and the adequacy of their performance be assured?
- c) Where will such services be provided?
- d) How will confidentiality be achieved and maintained in the counselling setting?

Finally, it should be noted that the magnitude of the epidemic has already stretched available counselling resources in many countries and the additional demands imposed by a broad screening programme may well compete with more targeted programmes for scarce counselling personnel. In some areas, virtually no counselling services are available. Such services need to be developed as soon as resources permit.

3.8 What is the social impact of screening?

Adverse social consequences to participation in screening programmes can be profound (sometimes even if the results are negative), and may include social isolation, economic loss, cancellation of insurance, and restriction of opportunities for employment, schooling, housing, health care and social services. These potentially destructive outcomes lend special urgency to the issues of confidentiality and informed consent prior to initiation of testing.

3.9 What legal and ethical considerations are raised by the proposed screening programme?

HIV screening involves the collection of sensitive medical information that may infringe upon human and legal rights.

A person's right to privacy can be infringed if information about HIV test results (or even 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 measure(s) which are necessary to accomplish specific public health objectives.

The following legal and ethical questions relevant to HIV screening programmes must be resolved:

- a) Is informed consent for the HIV screening test required?
- b) Are screening test results validated to assure correct identification of the person with a positive test result?
- c) Are appropriate supplemental laboratory test procedures used to minimize false-positive results that are an inevitable part of screening tests? Persons falsely assumed to be seropositive may suffer severe and unjust adverse consequences.
- d) Are statutes or regulations in place that safeguard against breaches of confidentiality or intentional disclosure of personal information that is not necessary for public health purposes?
- e) Will persons who are tested be deprived of legal or social rights that otherwise are protected?
- f) Are statutes or regulations in place to safeguard against discrimination in employment, housing, insurance or health care and that provide redress for those who have suffered such discrimination?
- g) Will specimens collected for other purposes be tested with personal identifying information removed (eliminated)?

4. CONCLUSIONS AND RECOMMENDATIONS

The pandemic spread of HIV infection merits close monitoring and public health planning. Universal screening of donors of blood/blood products and of cells/tissues/organs is entirely warranted. In any area where therapeutic injection apparatus or other instruments that pierce the skin are used for more than one person, scrupulous attention to cleaning and sterilization of the equipment is necessary to prevent potential HIV transmission. Because the other modes of HIV transmission (sexual intercourse and/or sharing of injection apparatus and perinatal infection) are a consequence of private behaviour, the effectiveness of additional public health programmes will depend largely on voluntary participation and educational counselling designed to effect personal behavioural change.

It was the opinion of the participants at the meeting that readily accessible counselling and testing for antibody to HIV, provided on a voluntary basis, are more likely to result in behaviour changes that contribute to the public health goal of reducing spread of HIV than are mandatory screening initiatives. There are more effective, less intrusive and less costly measures for preventing HIV transmission than the use of mandatory universal screening. In addition, any single screening effort will have value for a very limited period of time since screening by itself does not result in behaviour changes that restrict transmission of HIV to others. There was also consensus that mandatory screening of targeted populations is less likely than voluntary programmes to reach effectively those persons whose behaviour can be influenced to reduce the risk of infection. For effective prevention, all persons who are potentially at risk of infection must be included in the programme to reduce or eliminate risk behaviours, regardless of whether they are infected and whether they have been tested.

Identifying persons infected with HIV in certain target populations, such as intravenous drug abusers, may be a desirable public health objective because of the high risk of infection associated with their behaviour and the risk of transmission to their sexual partners and offspring. In this instance, the actual design and execution of such programmes are difficult because the target population is ill-defined and not easily reached or identified. Drug abuse is illegal in almost all countries, and coercive approaches and/or police action may conflict with efforts to reach addicts and change their behaviour.

Similar considerations pertain to almost all other populations whose behaviour places them at high risk of infection. In some target populations, focussing attention only on a segment of the population that is readily accessible is likely to be an inadequate public health measure. For example, screening only licensed female prostitutes ignores the large population of unlicensed prostitutes, both male and female, who are difficult to reach and potentially at high risk of HIV infection from either sexual or drug abuse exposures. Furthermore, such a programme does not emphasize either education about risks or the need for screening clients of prostitutes who place themselves and their spouses or other sexual partners at risk of infection through their behaviour.

Epidemiological surveillance data can be obtained, as needed, by methods that do not compromise human rights. The complexity of logistic, technical, personal, social, legal and ethical issues generated by mandatory screening of targeted populations must be recognized. To facilitate full awareness of these inherent complexities, this report includes an extensive list of criteria that must be considered and resolved as an integral part of the process of planning any HIV screening programme.

The interests of both public health and respect for human rights will best be served by addressing all of these issues with care prior to the initiation of screening programmes as an element in HIV control policies.

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