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GLOBAL
PROGRAMME
ON AIDS

UNLINKED ANONYMOUS SCREENING FOR THE PUBLIC HEALTH SURVEILLANCE OF HIV INFECTIONS

PROPOSED INTERNATIONAL GUIDELINES

GENEVA
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WORLD
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I. Introduction

The development of tests to detect infection with the human immunodeficiency virus (HIV) has made it possible to determine the prevalence of HIV infection, and to monitor trends of the infection in populations. This surveillance information is of great value in designing, implementing, and monitoring public health programmes for the prevention and control of HIV infection and the Acquired Immunodeficiency Syndrome (AIDS). However, testing of any population for HIV infection requires careful prior consideration of a variety of issues including logistic, laboratory, operational, legal, and ethical1. The design of an HIV surveillance methodology should maximize the likelihood of obtaining useful and accurate epidemiological information about the distribution of HIV infection in the community. Simultaneously, the design should minimize the likelihood of adverse individual or community consequences.

All surveillance methods have their limitations. The purpose of these proposed international guidelines is to describe the strengths and weaknesses of unlinked anonymous screening or testing (UAS), and to provide criteria and points for consideration important for the successful implementation of UAS.

II. Choice of surveillance method

Unlinked anonymous screening or testing (refer to definitions in Annex) is generally considered to be an accurate and effective method for public health surveillance of HIV infection. However, the selection of an HIV surveillance method must take into account the epidemiological objectives of the public health surveillance of HIV infection, and other relevant considerations.

A. Epidemiological objectives

One of the primary epidemiological objectives of the public health surveillance of HIV infection is to obtain information on the prevalence and incidence of the infection in selected population groups in a manner that is as free as possible of participation and selection bias.

1. **Voluntary HIV testing or screening** is directed to the individual. Its primary objective is to provide to HIV-infected persons the medical and psychosocial support they need to help them assume their responsibility to prevent HIV transmission. Therefore, such testing requires some mechanism of conveying the results of HIV testing to individuals. The public health surveillance of HIV infection may be a secondary objective, but the resulting HIV prevalence

estimates are usually subject to unpredictable participation and selection bias. The reason for the participation bias is that persons at increased risk of HIV infection, or members of stigmatized population groups, may be more or less willing to accept HIV testing, in different places and at different times. The degree of selection bias will depend on how groups of individuals are chosen and asked to participate voluntarily in HIV testing after informed consent and counselling. An advantage of voluntary HIV testing is that the opportunity would exist for follow-up of HIV infected persons to obtain more detailed information on risk behaviour, as well as the opportunity to obtain additional blood specimens to resolve inconclusive serological results.

The identification of HIV-infected individuals should be carried out with caution. This is because of the dangers of discrimination and stigmatization of HIV-infected individuals by the community. When testing will identify individual HIV-infected persons, careful attention to pre-test and post-test counselling, informed consent, and confidentiality is essential.

2. **Unlinked anonymous screening or testing** for HIV infection is not directed to the individual, but has as its objective the public health surveillance of HIV infection. It is an epidemiological method for measuring HIV prevalence in a selected population with the minimum of participation bias. By minimizing participation bias, UAS offers a distinct epidemiological advantage over voluntary or mandatory HIV testing for the public health surveillance of HIV infection. If properly conducted anonymity is not endangered, and the individual cannot be identified. UAS involves use of blood already collected for other purposes (see *A. Criteria* below); therefore the effect of selection bias will remain and will depend upon the time, location, and other details of blood collection for these other purposes. It is important that prevalence estimates distorted minimally by participation bias be available for the identification of areas and populations where HIV testing programmes directed to the individual should be developed. In this way, UAS can meet an important need in the prevention and control of HIV infection and AIDS, as well as in the provision of medical and psychosocial support to HIV-infected persons.

3. **Mandatory testing or screening** will not provide information of sufficient accuracy or completeness for public health surveillance purposes, as persons at risk of HIV infection may selectively avoid contact with health services or testing activities. This creates unpredictable participation bias. The importance of selection bias would depend upon the populations chosen for mandatory testing.

B. Other considerations

1. **Voluntary testing or screening** (confidential or anonymous) clearly offers individuals the opportunity to determine their HIV-infection status and to receive counselling in an appropriate setting.

2. **Mandatory or compulsory testing** for HIV infection is ethically questionable under most circumstances. The reactions among those HIV infected and others may be counterproductive to the objectives of AIDS prevention and control[2]. It is highly unlikely that a benefit to public health would be sufficient to justify the interference in human rights involved in mandatory or compulsory HIV testing.

III. Criteria and points for consideration in UAS programmes

Certain criteria must be observed if UAS is to be carried out. In addition, several points for consideration are relevant to ensuring that the criteria and the standards of the surveillance programme are respected.

A. Criteria

1. Prior to implementing public health surveillance through UAS, it is essential to conduct a thorough discussion of the ethics of UAS in the social and cultural context of the country where it is to be implemented. If it is against established national public health policy UAS should not be implemented. UAS can be regarded as being consistent with the existing global guidelines on human rights in biomedical research[3,4]. If the proposal for UAS originates in one country but is conducted in another, it should be reviewed by both an ethical review committee of the country of origin, as well as its equivalent of the host country.

2. Specimens for UAS should have been taken with appropriate consent for other purposes. To take blood primarily or solely for UAS would raise serious ethical concerns. The volume of blood taken should be the minimum necessary and should be, at most, only marginally greater than that required for the other tests for which the blood was originally obtained.

3. No information should be requested in addition to that normally collected for the primary purpose for which the blood specimen was obtained.

4. All data that could potentially identify the individual must be removed from the specimens set aside for UAS before they are tested by the laboratory.

5. Protocols for UAS should be carefully reviewed to ensure:
   (a) that there is no possible way in which test results could be traced back to individuals;
   (b) that studies are designed to maximize the likelihood of obtaining data useful for surveillance purposes, given the estimated prevalence in the population under surveillance; and
   (c) that staff are trained to adhere to the UAS protocol, and supervised to avoid breaches of anonymity.

6. Voluntary testing (confidential or anonymous) with counselling should be available wherever possible to populations in which UAS is being carried out, so that those individuals who wish to know their HIV-infection status can do so. This is particularly important if the population is estimated to have a moderate to high prevalence of HIV infection. However, such testing should be offered through a separate system.

7. The resources devoted to UAS should be commensurate with its value for surveillance, as one part of a comprehensive HIV/AIDS prevention and control programme. UAS should not detract from other important public health objectives, including the primary purpose for which the specimens were obtained.

8. Health care providers should be made aware that the specimens drawn by them from patients may be used for unlinked anonymous HIV screening.

9. In areas with low HIV prevalence, pooling of sera collected for UAS might be considered.

B. Points for consideration

1. How will the public be informed of UAS in a way that they will not be deterred from using health care services where specimens may be obtained for UAS?

2. How will health care providers and the public be informed and assured of the appropriateness and anonymity of UAS?

3. How will services be targeted to population groups found to include HIV-infected individuals?

4. What information (e.g., age and sex) will be retained with the blood sample, given the need to guarantee anonymity and yet to obtain the most useful data for surveillance purposes? In general, the maximum useful information should be retained without jeopardizing anonymity. Aggregation of information retained with the sample (e.g., age information by age group only) may be of value.

5. How will UAS findings be presented in order to reinforce other HIV/AIDS prevention and control activities?

IV. Conclusions

Unlinked anonymous screening or testing is generally considered to be an accurate and effective method for public health surveillance of HIV infection. However, UAS has inherent limitations, so that it cannot be considered a complete solution to all problems of public health surveillance of HIV infections. Whenever UAS is being contemplated as part of a comprehensive HIV/AIDS prevention and control programme, careful attention should be paid to the criteria and points for consideration outlined in this document. It is emphasized that the quality of UAS, and its contribution to public health surveillance will depend as much on how UAS is implemented as on protocol design. Subject to these provisions, unlinked anonymous screening can provide accurate surveillance data to HIV/AIDS prevention and control programmes without endangering or compromising the broad principles of public health and human rights.

Selected references

1. *Report of the meeting on criteria for HIV screening programmes (1987);* Unpublished WHO document WHO/SPA/GLO/87.2.

2. Forty-first World Health Assembly resolution WHA41.24, *Avoidance of discrimination in relation to HIV-infected people and people with AIDS* (1988).

3. World Medical Association. *Declaration of Helsinki: Recommendations guiding medical doctors in biomedical research involving human subjects.* Adopted by the 18th World Medical Assembly, Helsinki, Finland (1964) amended by the 29th World Medical Assembly, Tokyo, Japan (1975) and the 35th World Medical Assembly, Venice, Italy (1983). In: Council for International Organizations of Medical Sciences (CIOMS). *Proposed international guidelines for biomedical research involving human subjects,* p. 35-50; CIOMS and the World Health Organization (1982).

4. *Proposed international guidelines for biomedical research involving human subjects.* Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (1982).

Annex

Definitions

1. **Public health surveillance** is the collection of information of sufficient accuracy and completeness regarding the distribution and spread of infection to be pertinent to the design, implementation, or monitoring of prevention and control programmes and activities.

2. **Unlinked anonymous screening** is the testing of specimens for markers of infection after elimination (unlinking) of all personal identifying information from each specimen.

3. **Bias**: Two forms of bias are pertinent to a discussion of unlinked anonymous screening for public health surveillance purposes; participation bias and selection bias. The occurrence of either type of bias leads to inaccuracies in the results relative to the true situation in the community.

   - **Selection bias** occurs when those persons selected to participate in a study differ in some important way from those not selected to participate.
   - **Participation bias** occurs when in a selected group, those persons who elect to participate in a study differ in some important way from those persons who elect not to participate in the same study.

4. **Mandatory testing** or screening occurs where testing is required of all individuals who voluntarily decide they wish to avail of a service or activity (such as attending a clinic). This is to be distinguished from compulsory testing, where both the testing and the service or activity are required (such as testing of new prison inmates).

5. **Voluntary testing** or screening occurs where participation in both the testing, and the service or activity, are up to the individual to decide.