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STATEMENT FROM THE CONSULTATION
ON TESTING AND COUNSELLING
FOR HIV INFECTION

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WORLD
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Statement from the Consultation on Testing and Counselling for HIV Infection

Geneva, 16-18 November 1992

I. Introduction

A reliable test for antibody to HIV (human immunodeficiency virus) was first developed in 1984 and became widely available in many parts of the world by 1985. The development of this test enabled researchers to understand HIV infection and AIDS better, allowed health care workers to diagnose HIV infection in patients, and gave individuals the choice of knowing whether or not they were infected with HIV. HIV infection, including AIDS, has important characteristics that affect the usefulness of HIV testing and distinguish it from testing for many other health conditions:

- HIV infection is lifelong, as is infectiousness, and there is at present no drug known to render infected individuals non-infectious. Therefore, unlike diseases such as syphilis, early diagnosis does not lead to any medical treatment to prevent transmission.
- HIV infection is believed to be eventually fatal in virtually all cases, with no known cure, although early therapy, if available, may delay the onset of various HIV-related diseases, and prolong life.
- HIV infection is not transmissible by casual contact. Nevertheless, because of ignorance of this fact, and because HIV is a fatal disease spread mainly through sexual intercourse, individuals known to be HIV-infected are often stigmatized and discriminated against.
- Because HIV is transmitted through modifiable behaviours, providing individuals with their test results on a voluntary basis and with appropriate counselling can, in some cases, promote behaviour change that is beneficial to the individual, as well as to public health.

These special characteristics of HIV infection have important implications for the potential role of HIV testing in HIV/AIDS prevention and care programmes.

In order to identify issues that should be considered in planning and implementing an HIV testing programme, WHO organized a meeting in Geneva in May 1987 on "Criteria for HIV

screening programmes", which made recommendations on the role of various types of HIV testing programmes for HIV/AIDS prevention and care. More specifically, the meeting participants voiced concerns about the situation at that time with respect to HIV testing programmes, noting that:

[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 [testing] 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 clearly examined.

The participants also noted that:

readily available counselling and testing for 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 [testing] initiatives,

and noted, in conclusion that:

[testing] by itself does not result in behaviour changes that restrict transmission of HIV to others. ... For effective prevention, all persons who are potentially at risk of infection must be included in the programme to reduce or eliminate risk behaviour, regardless of whether they are infected and whether they have been tested.

Although these observations and conclusions remain valid, additional information and experience have been gained since 1987 and approaches to the prevention of HIV transmission and the provision of care to those affected by HIV/AIDS have changed. The availability and reliability of HIV antibody tests have improved, and the cost of these tests has decreased. In addition, the HIV/AIDS pandemic has expanded to affect far more people, in more parts of the world.

In order to offer national AIDS programmes up-to-date guidance on the role of HIV testing and counselling of asymptomatic people, a consultation was held at WHO headquarters on 16-18 November 1992. Its purpose was to review what is known about the advantages and disadvantages of HIV testing, and to develop recommendations on the role of testing and counselling in HIV/AIDS prevention and care programmes.

The consultation specifically focused on the role of testing and counselling for the early detection of infection in asymptomatic people. It did not aim to provide guidance on the other purposes for which HIV testing is done, namely:

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- Ensuring transfusion and transplantation safety by screening blood for transfusion, semen and ova for donation, and organs and tissues for transplantation (see: *Global Blood Safety Initiative. Consensus Statement on Screening of Blood Donations for Infectious Agents Transmissible through Blood Transfusion*. WHO/LBS/91.1).
 - Epidemiological surveillance (see: *Unlinked Anonymous Screening for the Public Health Surveillance of HIV Infections. Proposed International Guidelines*. WHO/GPA/SFI/89.3).
 - Research (see: *International Guidelines for Ethical Review of Epidemiological Studies* (Council for International Organizations of Medical Sciences [CIOMS], Geneva, 1991).
 - Diagnosis of symptomatic infection (see: *Guidelines for the Clinical Management of HIV Infection in Adults*. WHO/GPA/IDS/HCS/91.6).
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II. Mandatory testing and other testing without informed consent

HIV testing can be classified as being done with or without informed consent (see Glossary). **Mandatory testing and other testing without informed consent has no place in an AIDS prevention and control programme.** The Forty-fifth World Health Assembly noted that

there is no public health rationale for any measures that limit the rights of the individual, notably measures establishing mandatory screening (resolution WHA 45.35, 14 May 1992).

There are no benefits either to the individual or for public health arising from testing without informed consent that cannot be achieved by less intrusive means, such as voluntary testing and counselling.

Public health experience demonstrates that programmes that do not respect the rights and dignity of individuals are not effective. It is essential, therefore, to promote the voluntary cooperation of individuals rather than impose coercive measures upon them.

Furthermore, testing programmes that do not require and secure an individual's informed consent can be damaging to efforts to prevent HIV transmission — and are therefore not in the interest of public health — for the following reasons:

- Because of the stigmatization and discrimination directed at HIV-infected people, individuals who believe they might be infected tend to go "underground" to escape mandatory testing. As a result, those at highest risk for HIV infection may not hear or heed education messages about AIDS prevention.
- Testing without informed consent damages the credibility of the health services and may discourage those needing services from obtaining them.
- In any testing programme, there will be people who falsely test negative — for example, because of laboratory error or because they are infected but have not yet developed detectable antibodies to HIV. Thus, mandatory testing can never identify all HIV-infected people.
- Mandatory testing can create a false sense of security especially among people who are outside its scope and who use it as an excuse for not following more effective measures for protecting themselves and others from infection. Examples are health care workers who do not follow universal precautions when all hospital patients are tested, and clients of sex workers who do not use condoms when they believe that all prostitutes are being tested.
- Mandatory testing programmes are expensive, and divert resources from effective prevention measures.

Despite strong evidence that mandatory testing is not in the interest of public health, a number of mandatory testing programmes and other programmes not involving informed consent are currently in place or have been proposed by governments or legislative bodies. Of special note are programmes in which testing without informed consent may be initiated by a health care worker. Two important examples of populations tested in this way are:

- Women of reproductive age, including pregnant women: Women who are, or who might become, pregnant have sometimes been subjected to testing without informed consent, including mandatory testing, for the purpose of preventing childbirth or breast-feeding among those who are HIV-positive. However, testing without informed consent, even if provided confidentially, offers no advantage over voluntary testing and counselling programmes designed to assist women in making decisions about childbearing and/or breast-feeding. Those women who want to know if they are infected before making such decisions generally would participate in voluntary testing and counselling programmes. Furthermore, not only is it unethical to pressure or force women to make reproductive or breast-feeding decisions for any reason, including their HIV infection status, but those women most likely to be HIV-infected may try to avoid mandatory testing, precisely in order to avoid pressure in such decision-making. Such avoidance may have the additional unwanted result of discouraging pregnant women from attending antenatal services.

- **Patients:** Ambulatory and hospitalized patients have been subjected to testing without informed consent, including mandatory testing, on the grounds that this is necessary in order to allow health care workers to take precautions to prevent themselves and other patients from becoming infected. However, there is no role for testing without informed consent in the prevention of HIV transmission in the health care setting. Rather, the application of universal precautions in infection control procedures is the best way to minimize HIV transmission in the health care setting. The concept of universal precautions means that all blood (and other potentially infectious body fluids) is assumed to be infectious, and standard infection control procedures should therefore be applied for all patients, regardless of whether an HIV test is positive, negative, or not done at all (see: *Report of a WHO Consultation on the Prevention of Human Immunodeficiency Virus and Hepatitis B Virus Transmission in the Health Care Setting*. WHO/GPA/DIR/91.5). The testing of patients, in particular those with sexually transmitted disease, has also been advocated so that those who are infected can be offered appropriate counselling and other care. However, this purpose can be accomplished through voluntary testing and counselling (see Section III, below). The only other role of HIV testing for patients is to assist in making a diagnosis of HIV infection when this is suggested by clinical signs and symptoms. Testing without informed consent holds no advantage over testing with informed consent in such cases.

In many parts of the world, other populations have been, or are being, subjected to mandatory or other testing without consent. Again, although the rationale for mandatory testing — when stated — is often said to be related to health, in fact neither individual nor public health benefits result from such testing that cannot be better achieved through voluntary testing. Following is a non-exhaustive list of such groups:

- Population groups considered to be at high risk of HIV infection, such as injecting drug users, prostitutes, homosexual men, and prisoners (see: *WHO Guidelines on HIV Infection and AIDS in Prisons*. WHO/GPA/DIR/93.3)
- Military, including applicants and those already in service
- International travellers, including immigrants, refugees, returning emigrants (such as students), and guest workers (see: *Statement on Screening of International Travellers for Infection with Human Immunodeficiency Virus*. WHO/GPA/INF/88.3)
- People planning to marry
- Health care workers (see: *Report of a WHO Consultation on the Prevention of Human Immunodeficiency Virus and Hepatitis B Virus Transmission in the Health Care Setting*, cited above)

- Other workers (see: *Statement from the Consultation on AIDS and the Workplace*. WHO/GPA/INF/88.7)
- Athletes (see: *Consensus Statement from Consultation on AIDS and Sports*. WHO/GPA/INF/89.2)

Blood for transfusion should be screened for HIV. If screening is not anonymous and unlinked — i.e., if personal identifying data are kept with the specimen and the test results are to be made known to the donor — then the donor must be told this in advance and must give informed consent to such testing. Blood donation should not be mandatory nor carried out in such a way that people are pressured to donate, or are stigmatized if they self-defer (see: *Global Blood Safety Initiative. Consensus Statement on Screening of Blood Donations for Infectious Agents Transmissible through Blood Transfusion*. WHO/LBS/91.1).

The term "routine testing" is often used to refer to testing that is carried out unless the patient or client explicitly refuses — or is conducted without the subject even knowing. When routine testing carries either of these meanings, it represents an approach to testing that does not require pretest counselling and explicit consent. As a form of testing without informed consent, it is ineffective and unethical.

III. Voluntary testing and counselling

Voluntary testing accompanied by counselling has a place within a comprehensive range of measures for HIV/AIDS prevention, care and support. However, it must always be justified in terms of the balance of advantages and disadvantages to the individual who is tested. Within the context of a well-designed confidential counselling programme, voluntary testing may be of net benefit for those individuals who wish to know whether or not they are HIV-infected. However, it should be borne in mind that counselling on its own is a valuable intervention even if HIV testing is not available or if the client decides not to be tested. The potential benefits of **counselling** to the individual include:

- receiving accurate information about HIV
- becoming more able to cope with anxiety
- receiving emotional support
- learning methods of risk reduction
- becoming motivated and/or empowered to initiate risk-reduction behaviours
- having risk-reduction behaviours reinforced
- receiving referral to additional medical or social support services.

These benefits are likely to be enhanced where preventive measures (e.g., condom supply) and supportive measures (e.g., provision of food, shelter, home care) are available and where the social environment is favourable towards people affected by HIV.

Voluntary testing with counselling has the following potential advantages over and above counselling alone:

- having the knowledge of one's serostatus
- relieving anxiety associated with uncertainty
- if HIV-infected, being referred to clinical care and receiving specific drug therapy, where this is available
- planning for the future — e.g., for the care of children and the setting of one's affairs in order, and making decisions about childbearing, breast-feeding, and future relationships
- possibly enhanced motivation for risk reduction, and a more informed choice concerning personal preventive strategy.

Some individuals may not want to know whether or not they are HIV-infected, for various reasons — for example, because they believe that this knowledge would have little impact on their behavioural decisions, and/or might lead to greatly increased anxiety (especially if infected). Counselling should be provided for these individuals if they so desire.

The evidence that voluntary HIV testing may play a role in the prevention of transmission is not conclusive, except for discordant couples (i.e., where one partner is infected and the other uninfected), in whom it has been shown to result in less risky behaviour in those settings studied. Testing in itself is not a preventive measure; it could in principle aid prevention in other settings only if it succeeds in motivating individuals to adopt or maintain safer behaviours. Individuals are more likely to be thus motivated if they believe that HIV testing is of great benefit to themselves, such as when testing is provided in the context of a comprehensive counselling programme, with care and support services available, in a favourable social environment, and when the test is client-initiated.

Essential Components of Voluntary Testing and Counselling

To be beneficial, voluntary HIV testing, whether client- or health worker-initiated, must be:

1. part of a comprehensive counselling programme, in which trained counsellors provide counselling before a decision is made about testing (pre-test counselling), and provide counselling along with other supportive services (such as the provision of condoms and safer injecting equipment, where appropriate) or referral after testing (post-test counselling). The objectives of counselling should be:
 - to allow the expression of concerns and emotions about individual risks and behaviour
 - to clarify technical aspects of testing and assess the need for testing
 - to explore the implications of the test results for the individual, and to assess the individual's capacity to cope with such implications
 - to provide support, guidance, and referral, as needed.
2. entirely the choice of the individual whether or not to be tested; only the individual, assisted by information provided by a counsellor, can make a decision regarding the relative advantages and disadvantages of HIV testing for him or herself (i.e., informed consent). The person's individual circumstances, and the larger social context, will affect the balance of advantages and drawbacks of testing for that individual at a particular time. There must be no coercion or pressure to be tested — otherwise HIV testing may be counterproductive for the individual and/or society and cannot be considered to be truly voluntary.
3. confidential or anonymous; any potential or real breach of confidentiality greatly diminishes the value of HIV testing for an individual.
4. technically sound in terms of the laboratory tests used and the quality of the laboratory practices.

Planning Issues for National AIDS Programmes

Voluntary HIV testing and counselling is of benefit in the care and support of individuals. It may therefore have an important role in national AIDS programmes within the spectrum of HIV/AIDS care and support strategies. However, further research is needed to determine what role voluntary HIV testing and counselling could play as part of national AIDS prevention activities. This should be studied in a variety of population groups and compared with data on other preventive interventions to determine its relative cost-effectiveness.

The current availability of HIV/AIDS counselling, of voluntary HIV testing, and of HIV counselling combined with voluntary testing varies greatly around the world. Where voluntary HIV testing is not yet widely available, national AIDS programmes should proceed cautiously in introducing it in order to ensure that confidentiality or anonymity is guaranteed and that the service can be delivered in a manner most likely to result in benefits to the individual and the public health. In the process of developing a national policy on HIV voluntary testing and counselling, where such services are not already available, a trial programme should ideally be initiated and evaluated to determine the demand for client-initiated services, programme cost, potential sustainability, and efficacy in supporting the client and/or facilitating preventive behaviour.

In areas where voluntary testing and counselling, or counselling alone, is already available, the impact of the existing programme should be evaluated, in terms of both its planned or intended effects and any unforeseen benefits or harm.

There are additional issues which should be considered in the decision to implement or maintain a voluntary testing and counselling programme. One is the level of HIV knowledge in the local population: in general, testing will offer greater benefits in communities where levels of awareness and knowledge are already high. Another important consideration is the existence of safeguards against human rights abuses for those tested and those who learn that they are seropositive.

IV. Summary

- Testing without informed consent should not be done, regardless of its rationale, the population group tested, or the term used to designate the testing programme.
 - Voluntary testing and counselling can be useful in the care and support of seropositive individuals, can provide reassurance and support to seronegative individuals, and can relieve anxiety in both groups.
 - Several studies have indicated that voluntary testing and counselling may be effective in preventing HIV transmission among discordant couples when both members of the couple voluntarily participate in the testing and counselling. For other groups or situations, findings are inconsistent, and more research is needed.
 - National AIDS programmes that decide to develop voluntary testing and counselling services where none now exist should proceed cautiously by initiating and evaluating a trial project. Where such services already exist, their impact should be evaluated.
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Glossary

client: The person seeking or receiving HIV counselling and/or testing. In the case of a child or other person unable to consent to testing on his/her own behalf, the client is the parent or other adult with the ethical and legal competence to do so.

counselling: A confidential dialogue between a client and a care provider aimed at enabling the client to cope with stress and take personal decisions related to HIV/AIDS. The counselling process includes an evaluation of personal risk of HIV transmission and facilitation of preventive behaviour.

pre-test counselling: dialogue between a client and a care provider aimed at discussing the HIV test and the possible implications of knowing one's HIV serostatus, which leads to an informed decision to take or not take the test.

post-test counselling: dialogue between a client and a care provider aimed at discussing the HIV test result and providing appropriate information, support and referral, and at encouraging risk-reduction behaviours.

testing

- (1) Laboratory testing, i.e., application of an assay (e.g., ELISA) for laboratory markers of HIV infection such as HIV antigen or antibodies. The assay may be used in order to screen blood for transfusion, or organs or tissue for transplantation (see **screening**), or in order to test an individual (see **testing (2)**).
- (2) More broadly, the testing of individuals with the intention to determine their HIV infection status. All testing in this sense can be categorized according to three sets of criteria:
 - (a) client-initiated, health care provider-initiated, or initiated or required by a third party for other than health purposes;
 - (b) with or without informed consent; and
 - (c) anonymous, confidential, or non-confidential. These terms are defined below.

client-initiated testing: HIV testing requested by a client on his/her own initiative.

health care provider-initiated testing: HIV testing initiated by the client's health care worker.

testing initiated or required by a third party for other than health purposes: HIV testing for other purposes, such as immigration, employment or insurance.

testing with informed consent: HIV testing performed only after the client has given informed consent to it. **Informed** in this context means that in discussion (pre-test counselling) the client has been made aware of all the ramifications of HIV testing, including the risks and benefits, as well as of alternatives to such testing, in language he/she can understand. **Consent** means the giving of express agreement to HIV testing in a situation devoid of coercion, in which the client should feel equally free to grant or withhold consent.

testing without informed consent: HIV testing in which informed consent, as defined above, has not been requested and given.*

mandatory testing: HIV testing without informed consent which the individual is compelled to undergo. The term refers both to situations in which the individual clearly has no alternative — as when prisoners are tested involuntarily — and to situations in which refusal of testing is not realistic or would cause the individual undue hardship, as when HIV testing is required prior to employment or marriage.

anonymous testing: HIV testing in which the blood sample and test result are identified only by code, not by name, with no personal identifiers to link the sample to the donor source.

linked anonymous testing: HIV testing in which the code is known only to the client.

unlinked anonymous testing: HIV testing (e.g., for surveillance purposes) after prior removal of all personal identifiers, so that retrospective identification is impossible.

* "Routine testing" is sometimes used to mean the HIV testing of individuals without their knowledge or unless they specifically refuse such testing. Examples are routine testing policies applied by hospitals to patients, and sometimes applied to people attending antenatal or STD clinics. This term should not be used because it does not specify whether informed consent is requested and granted.

confidential testing: HIV testing in which only the client and the health professionals involved in the client's direct care know that the test was performed and have access to the test results. This information is not furnished under any circumstances to other health care providers, health authorities, employers, insurers, schools or other third parties without the patient's explicit consent.

non-confidential testing: HIV testing conducted neither anonymously nor confidentially.

voluntary testing: Anonymous or confidential testing initiated by either the client or his/her health care provider and performed with the client's informed consent.

screening: The systematic laboratory testing of donated blood, blood products, tissue (including sperm) and organs for the purpose of preventing HIV transmission to the recipients. Other specimens, such as saliva, may also be used.

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