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MessageNo. 29457 Page 1 of 15 paga Datez81unel993
From: Chief, DIA 1’ To: Mr V.R. Mabope. Director, Project for HIVIS’ID Testing in
Offwe of Research - Soweto, Johannesburg, South Afrim ,
:53. GlobalegmnmeonADS
Ourref.
Fax No: (27 11) 932 5621
: GPA/RES/DIA/HT/ss Subject: PROJECT FOR HIV/STD TESTING IN SOWETO,
SOUTH AFRICA
DearMIMabope,
We tried to telephone you’in the United States on several occasions without success in
responsemfourrequesttovisiteenevaon lBAprIlmdiscusstheaboveprojecL.
AsyoumaybeamWHO’smlmomwhhSMAmcamustbemlinewithcertain
policies and practices of the United Nations system. We are free to exchange data.
information, experience and receive visits to discuss technical matters, such as your HIV
/STD
testing project.
We have studied your project outline for review and comment and have tried to
anticipate your needs to strengthen the docmnent based on the various subjects mentioned
in
you letter. The attached Annex lists the documents that have been dispatched under separa
te
COVCI’.
Regarding the project proposal, we wish to make the following comments: 77
1. You have mentioned that the motivation for the project is "surveillance? (under ,
point 5), but the proposal reads as a voluntary testing and caunseningW
with a cost recovery Component. When HIV testing is carried out for Surveillance
purposes, WHO recommends vollmtary unlinked anonymous testing. Voluntary
testing with counselling is recommended within a comprehensive range-of
measures for HIV/AIDS care and support. The anached "Statement from the
Consultation on testing for HIV infection and comelling (Geneva,
16-18 November 199 " and the GPA statement on Unlinked monymaus screeninV
for the public health meillance QfHIV bfections: pr0posed international
guidelines(sent1mderseparatecover) clarifytheabovepoint. WhenS’IDteeting
isnsedforsurvemanceitmustbeconiidendalandlinkedvdthmenameofme
personsothatthepersonmnbeidentiiiedforueaunmt. "
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smd:

Mr V-R- Mabope, Johannesbmg, South Africa 2 _ ,
GPA/RES/DIA/HT/ss - 8 June 1993
2. Although you imply that this project will be self-sustaining, it is not clear from the document how this will be achieved, even though this would be essential to the proper ftmctioning of the project It is also not clear whether we 30000 land annual budget includes training of counsellors, labmatory technicians or if there will be additional flmding available.
We hope that these comments and the documents pmv-ided will help you strenglhen your proposal. Please do not hesitate to contact us if you require further information. 4
Yours sincetely,
WM
Y/u Dr Hiko Tamashiro
Chief, Diagnosn’cs
OfEce of Research
Global Progmnme on AIDS

Annex
HIV testing
’ Comparative evaluation of 36 cammenzial assays for detecting antibodies to HIV;
Operational characteristics of commercially available assays to dam antibodias to I-IIV- 1 and/orI-IIV-Zinhuman 5612- Reports;
Simplified and less expensive coniirmatom HIV testing;
Recommendations for the selection and use of HIV antibody tats;
Proposed WHO criteria for inte1preting results from Western blot assays for HIVJ, HIV-z, H’ILV-I/HTLV-II;
Report on the meeting of a technical working group on the standardization of Western blot assays for HIV-1, EIV-Z, and HTLV-I/H’ILV-ll
Blood donation
Recommendations for! testing for HIV antibody on serum pools.
Surveillance
Unlinked anonymous screening for the public health surveillance of HIV infections: proposed intemational guidelines.
Partner notification
Consensus statement from the consultation on parhter notiiication for preventing HIV transmission.
STD control
Consensus statement from the consultation on global strategies for coordination of AIDS and STD control programmes;
Management of patients with sexually transmitted diseases;
Bench-level laboratory manual for sexually transmitted diseases.
General guidelines
Guidelines for the cliniml management of HIV infection in adults;
Guidelines on sterilization and disinfection methods effective against HIV;
Guidelines for nursing management of people with HIV;
Guide to planning health promotion for AIDS prevention and control;
Prevention of sexually transmission of HIV;
Guidelines for counselling about HIV infection and disease;
Biosafety guidelines for diagnostic and Issearch laboratories working with HIV;
School health education to prevent AIDS and sexually tmnsmined disuses;
Living with AIDS in the community.

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Statement from the Consultation on Twang and Counselling for HIV Infection
Geneva, 16-18 November 1992
I.
Introduction
Amhablemstforanhbodymmvmnmmimmmodendencyvims)wasmstdevdopedin 1984andbemmewide1yavailahleinmanypaxtsoftheworldby1985.’Ihedeveloymentot mistestenabledreseaxchetstomdetstandHIVinfectionandAIDSbener, allowedhealthcare, workers to diagnose HIV infection tn patients. and gave individuals the choice ofknowing whether or not they were mm with HIV. HIV infection, including AIDS, has important characteristics that affect the usefulnm of HIV testing and distinguish it from testing f or 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 ts believed to be eventually fatal in virtually all uses, with no known 0 cure,a1though early therapy, if available may delay the onset of various I-iIV-related diseases, and prolong life.
HIV infection is not transmissible by casual contact Nevertheless, because of ignorance ofthisfacLandbecausePEVisafataldiseasespmdmainlythroughsexual intercourse, individuals known to be HIV-infected are often stigmatized and discriminated against.
Because HIV’ ts transmitted through modifiable behaviours, providing individuals with their test results on a voluntary basis and with appropriate counselling can, in some mses, promote behaviour change that is beneiicial to the individual, as wen as to public health.
These Special charactetistics of HIV infection have important implimtions for the potenti al role of HIV testing in HIVIAIDS 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
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screening programmes". whichmadereoommendations ontheroleofvatioustypesofI-Ilve testing programmes for HIVIAJDS prevention and care. Mme speciheally, the meeting participants voiced caneerns abbot the situati0n at that time with respect to HIV testing programmes, noting that: ’

(screening) efforts may be drivenby unfounded concerns about casual transmiss’on ’ofI-IIVoraneedtoappwmbetakingvistbleactionagainsttheI-Hmeblem. The pmposes of the Itestingl programmesandtheobjectivestobeachievedarenot always clearly dehned 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 m behaviour changes that connibute to the public health goal of reducing spread of HIV than are mandatory (testing) initiatives,

and noted, in conclusion that: e

(testingl by itself does not result in behaviour changes that restrict transmission of HIV to others. ... For effective prevention, all persons who are potentially at n’sk of infection must be included in the programme to reduce or eliminate 153k behaviour; regardless of whether they are infected and whether they have been tested.

Although these observations Qand conclusions remain valid, additional information and expen’ence have been gained since 1987 and approaches to the prevention of HIV transmission and the provision of are to those affected by HIVIAIDS have changed. The availability and reliability of HIV antibody tests have improved. and the cost of these t ests

has decreased. In addition, the HIV/AIDS pandemic has expanded to affect far more people, in more pans of the wodd.

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 an 16-18 November 1992. Its purpose was to review what 15 lmown about the advantages and disadvantages of HIV testing. and to develop recommendations on the role of- testing and counselling in HIV/AIDS prevention and are programmes.

The consultation specmwly focused on the role of testing and counselling fer 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 uansfusiom semen and ovafordo’nation, and organs andlissuesforuansplamation (see: Global Blood Sqfety Initiative. Consensus Statement on Screming of Blood Donations for ngfecziaus Agents Transmissible through Blood Truman. WHOILBSDI. 1).
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6-3 ’ . Epidemiological snrvaiIIance (we. Unlinked Anonymous Screaung for the Public . Health Surveillance of HIV Infections. Proposed Internammal Guidelines. WHOIGPA/SFII893) , .
. Research (see: Immauanal GtadelinesforMcalRm opridemiologicaI 5m (Council for International Organizations of Medical Sciences ICIOMSJ, Geneva, 1991). .
. Diagnosis of symptomuiuic infection (see: thdelinesfar the ClinicalMaizaganentof szmfecaou in Adam. WHOIGPAIIDSIHCSIQI.6).

II. Mandatorytwtingaridothertestingwidloutinformedconsent

HIV testing can be classified as being done with or without informed consent (see Glossary).

Mandatory testing md other tasting withont informed coment has no place In an AIDS prevention and control programme. The Foxty- -&fth World Health Assembly nored that there is no public health rationaie for any measures that limit the rights of the individual. notably musm 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 mm, such as voluntary testing and counselling.

Public health experience demonsuates that programmes that do not respect the- rights and dignity of individuals are not gffective. 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:

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smattmmtheConsulntiononTestingndCoumethformVInfection
Because of the stigmatizarion and discrimination directed at HIV-infected people, individuals who believe they might be infected tend to go "underground" to escape mandatory testing. As a tesult. 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 war or because they are infected but havenot yet developed detectable antibodies to HIV. Thus, mandatory testing can never identify all HIV-infected people. ’
Mandatory testing can create a false sense of wcurity 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 infecnion. Examples are health cane workers who do not follow Quiversal 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 measmes. ,
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 0: have been proposed by governments or legislative bodies. Of special note are programmes in which testing without infomed consent may be initiated by a health care worker. ’IVVo important’examples of populations tested in this way are:
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Women of negroductive age, including greggant women: Women who are, or who might become, pregnant have sometimes been subjected to testing without infomed consent, including mandatory testing, for the pmpose of preventing childbirth or breast-feeding among those who are HIV-positlve. However, testing without informed consenL even if provided contidentially, offers no advantage over voluntary testing and counselling programmes designed to assist women in making decisions about childan 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 itnnethical to pressme or force women to make reproductive or breast-feeding decisions for any reason, including their HIV infection stems, but those women most likely to be HIV-infected may try to avoid mandatory testing, precisely in order to avoid pressure in such decim’on-making. Such avoidance may have the additional unwanted result of discouraging pregnant women from attending antenatal services.
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Patients: Ambulatory and hospitalized patients have been subjected to testing without informed consent, including mandatory testing, on the groundsthat 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 preirention of HIV uansmission in the health can setting. Rather, the application of universal precautions in infection control procedures is the bestwaytominimizeHIVtransmissioninthehealmeeresetting. Theconeeptof universal promotions means that gag blood (and other potentially infectious body fluids) is assumed to be infectious, and standard infection control procedmes should therefore be applied for 311 patients, regardless of whether an HIV test is positive, negative, or hot done at all (see: Report of a WHO Consultation on the Prevauian of Human Immdejiciency V’u’us and Hepatitis B Virus T ransmission in th! Healdz Care Setting. WHO/GPAIDIRIQIS). The testing of patients, in particular those with sexually u-ansmitted 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 M testing and counselling (see Section ijbelow) The only other role of HIV testing for patients is to assist in making a diagnosis of HIV infection when this is suggested by ciiniml signs and symptoms. Testing without informed consent holds no advantage over testing with informed consent in such cases.
In many parts of the warld, other populations have been, or are being, subjected to manda tory or other testing without consent. Again, although the rationale for mandatory testing - w hen stated -- is often said to be related to health, in fact neither individual nor public he alth benehts result from such testing that cannot be better achieved through voluntazy testing .
Following is a non-exhaustive list of such groups:
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Population groups considered to be at high risk of HIV infection, such as injecting drug users, prostitutes, homosexual men, and prisoners (see: WHO Guidelbzes on HIV Infection and AIDS in Prisons. WHO/GPA/DIR/93.3)
Military,inc1uding applicants and those already in service
International travellers, including immig-ants, refugees, ramming emigrants (such as students), and guest workers (see: Staremazt on Saeening of International Travellers for Infection with Human Immunodeficiency Virus. WHOIGPA/INF/88.3)
People planning to many
Health care workers (see: Report of a M10 Consultation on the Prevention of Human Immunodeficiency Virus and Hepatitis B Virus Trwnzission in the Health Care Setting, cited above)

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’ Other workets (see: Statement fan; the Consultation on AHJS and the Worlqdace’. WHO/GPA/INF/88J)
0 Athletes (see: Comm Statement from Consultation on AIDS and Sports. WHO/GPA/INF/SQZ)
Blood for transfusion should be screened for HIV. If screening is not anonymous and unlinked-Les ifpersonal identifying dataarekeptwith the specimen andthe testresalls are to be made known tothedonor-then the donormustbe told thisin advance and must give informed consent to such testing. Blood donation should not be mandatory nor canied out in such a way that people are pressured to donate, Or are stigmatized if they seif-de fer
(see: Global Blood Safety Initiative. Comm Statement on Screening of Blood Donations for Infectious Agents Transmissible through Blood Tramjiuion. WHO/LBS/9Ll).
Theterm "routine testing" is oftenusedtoreferto testingthatisean’iedoutmtlessthepatient 0: client explicitly refuses -3 or is conducted without the subject even knowing. When routine testing carries either of these meanings, it represents an approach to testing th at does
not require pretest coanselling and explicit consent. As a form of testing without inform ed
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 testi ng
may be of net benetit for those individuals who wish to know whether or not they are HIV-infected. However, it shonld 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 tast ed. 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-reducuon behaviours
having risk-reduction behaviours reinforced
receiving referral to additional medical or social support services.

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These beneEts are likely to be enhanced where preventive measures (e.g., condom supply) a
nd
supportive measures (e.g., provision of food. shelter, home eare)a1e available and where
the
social environment is favourable towards people affected by HIV. h
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Voluntary testing with counselling has the following potential advantages over and above
counselling alone:
- having the knowledge: of ones serostams
- relieving anxiety associated with uncertainty
0 if HIV-infected, being referred’to clinical care and mceiving speciiic drug therapy,
where this is available ’
. planning for the fumre-- e.g., for we care of children and the setting of ’onets affair
s
in order, and making decisions about childbearing. b1east-feeding.. and future ’
relationships . ’
- possibly enhanced motivation for risk reduction. and a more informed choice
concerning personal preventive strategy.
Some individuals may _1;_o_t want to know whether or not they are HIV-infected, for vario
us
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 i
f
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 (Le, where one partner is infected and the
omer
minfected), in whom it has been show to result in less dsky behaviour in those settings
Studied. Testing in itself is not a preventive measure; it could in pn’nciple aid prevent
ion in
other settings only if it succeeds in motivating individuals to adopt or maintain safer
behaviours. Individuals are more Rely to be thus motivated if they believe thatI-IIV test
ing
is of great beneEt 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 Voluntgg Testing and Counselling
To be benehcial, voluntary HIV testing, whether client- or health worker-initiated. must
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Stamem from the Coagulation 0; Testing and Coumdhng for HIV Infection
1. part of a comgrehensiVe counselling meme, in which trained counsellors provide counselling before a decision is made about testing (pre-test counselling), and provide ecunsemng along with other supportive services (such as the provisiontof condoms and safer injecting equipment, where appropziate) or referral after testing (postetest counselling). The objectives of counsenmg should be:
. to allow the expression of concerns and emotions about individual risks and
- behaviour
- toclarifytechnicalaspecmoftestingandassessrheneedfortesting’
. to explore the implications of the test results for the individual, and to assess the individuaTS capacity to cope with such implications
- to provide support. guidance, and refetral, 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 (Le, 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 panicula: time. There must be no coercion or pme 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 anonmous; any potential or real breach of conEdentiaJity 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 labomto ry
practices.
Planning Issues for National AIDS Frommes
Voluntary HIV testing and counse ’ g is of benefit in the cane and support of individuals .
It may therefore have an important role in national AIDS programmes within the spectrum of HIV/AIDS cane and support strategies. However, further research is needed to determine with data on other preventive interventions to determine its relative cost-effectiveness.

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The current availability of HIV/AIDS counselling, of voluntary HIV testing, t’ and of HIV counselling combined with voluntaxy testing varies greatly around the world. Where voluntary HIV testing is net yet widely available, national AIDS progmmmes should proceed cautiously in introducing it in order to ensure that con5dentiality or anonymity is guaranteed and that the service can be delivered in a manner most likely to result in beneiits 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 uial 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. 4
In areas where voluntary testing and counselling, or counselling alone, is already available, the impact of the exiSting progmmme should be evaluated. in tenns of both its planned 0: 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 agains: human rights abuses for those tested and those who learn that they are seropositive.
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IV. Summary
- Testing without informed consent should net 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 seropositlve individuals. can provide reassurance and support to semnegative 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, tindings are inconsistent, and more research is needed.
. National AIDS pregammes 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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client The person seeking or receiving HIV counselling andlor msting. In the case of a child or other person unable to consent to testing on his/her own behalf, the clientris the parent or other adult with the ethiul and legal competence to do so. .
mumelling: A ceniidential dialogue between a client and a care provider aimed at enabling .. the client to cope with stress and take personal decisions related to HIVIAIDS. The counselling process includes an evaluation of personal tisk of HIV transmission and facilitation of preventive behaviour.
pre-test comellingzg dialogue between a client and a care provider aimed at discussing the HIV test and the possible implications of knowing one’s HIV serostatm, which leads to an informed decision to take or not take the test.
postwm counselling: dialogue between a client and a care provider aimed at discussing the HIV test result and providing approptiate information, support and refemtl, and at encouraging tisk-reduction behaviours
. .
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(2)
Laboratory testing, Le, application of an assay (e.g., ELISA) for laboratory matkers 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 n-ansplantation (see screening). or in order to test an individual (see testing (2)).
More broadly, the testing of individuals with the intention to determine their HIV infection status. A11 testing in this sense can be categodzed 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 pm’poses;
(b) with or withouthinformed consent; and
(c) anonymous, conftdential, or non-conftdential. These terms are defined below.
client-initiated testing: HIV taming requested by a client on hislher own ittitiahm.
health care provider-initiated testing: HIV testing initiated by the chenfs health can worker.

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testing initiated or required by a third party for other than health purposes: HIV testing for other purposes, such as immigration, employment or insurance.
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testing with informed consent: HIV testing performed only after the client has given infonned 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. Coment 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 Mthhold consent.
testing without informed commit: 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 undergoi 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 ptior to employment or marriage.
anonymous testing: HIV testing in which the blood sample and tea result are identitied 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 pn’or removal of all personal idEIlt’iflCIS, so that retrospective identihcation is impossible.
’ "Routine testing" is sometimes used to mean the HIV tesdng 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 ante natal
or STD clinics. This term should not be used because it does not specify whether informed consent is requested and granted.
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nfidential testing: HIV testing in which only the client and the health professionals involved in the clienfs 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, inmrs, schools or other third parties without the patienfs explicit consent.
non-confidenu’al tasting: HIV testing conducted neither anonymously nor comdentially.
voluntary testing: Anonymons or conflдential testing initiated by either the client or his/her health care provider and performed with tha c1ienfs informed consent. ’
screening: The systematic laboratory testing of donated blood, blood products, tissue (includmg sperm) and organs for the purpose of preventing HIV transmission to the recipients. Other specimens, such as saliva, may also be used.