

Opinion on ethical problems raised by action to combat the spread of infection by the human immunodeficiency virus (HIV). Report

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Opinion

The Ministry of Solidarity, Health, and Social Protection referred a request for an opinion to the National Consultative Ethics Committee for Health and Life Sciences on the subject of ethical problems raised by the spread of HIV infection in the general population, in particular on the matter of whether there was justification for screening in certain circumstances (such as pre-nuptial examination, early pregnancy, admission to hospital - in particular for surgery), on the systematic or optional nature of screening, and on disclosure or non disclosure in case of HIV positivity.

Preliminary comments are called for :

1) The issues arising, considered from a broad angle, are substantial. Taking into account time constraints placed upon the Committee, it could only examine certain aspects of these issues, and intends to continue to reflect on them in the near future.

2) The whole subject is evolving. The Committee's comments can only be applicable to the present situation.

3) As regards the legality of the matter, the Government can act within existing legislation, particularly articles L. 18 and articles L.355-22 and those following of the Code of Public Health (*Code de la Santé Publique*), which provide abundantly for effective Government action for the purpose of preventing the disease and avoiding or limiting its extension. Such empowerment is only limited by general rules for keeping the peace, i.e. an obligation for the authorities to maintain a balance between the constraints of law and order, in this case fighting the disease, and safeguarding individual and collective liberties. From this standpoint, and for ethical purposes, the legitimacy of the steps taken or to be taken in the future depend on a continuing arbitration directed by the severity of the epidemic to be overcome. The Committee found that the authorities have already mustered considerable efforts to fight the spread of HIV infection with results which, although as yet limited, are far from trivial and which represent a step in the right direction.

We find ourselves confronted with an epidemic of indisputable severity, since there is reason to fear its spread at a time when no therapy is available and there is no likelihood of any for several years to come. The situation may therefore call for exceptional constraints. The effort to be undertaken must of course, in the present state of affairs, bear on limiting the spread of the disease and justify intensive action to prevent such transmission. Sacrifices, in financial terms and as regards some limitation of individual and collective liberties, may be needed.

4) In scientific terms, the global HIV pandemic, which appeared in the '70s, is in fact three epidemics :

The first epidemic concerns those infected : about 5 or 10 million people globally, 200,000 to 400,000 in France. The only easily available infection criterion is to test for HIV-positive serostatus. In the absence of any cure, preventing transmission is the only objective open to human society. The efficacy of preventive measures is shown by the diminishing curve of growth of the number of HIV-positive people.

The second epidemic concerns cases of full blown AIDS, i.e. the terminal phase of the infection : about 250,000 to 300,000 the world over, of which about 5,000 in France. These numbers are doubling every six to nine months, and this growth will continue for several years to come, however effective preventive measures may be, since it is no more than the natural history of infection in those who are already contaminated. AIDS is preceded by a period of incubation of anything between six months and fifteen years, and probably more.

The third epidemic is represented by social, cultural, economic, and political consequences. It is generated by the first and second epidemics and the fear they arouse, and will be reinforced by the statistics of the second epidemic, cases of full blown AIDS.

HIV infection is transmissible by blood inoculation during intimate sexual intercourse and by mother to child during pregnancy. Detection of carriers of the virus is based on risk factors such as homosexuality, bisexuality, multiple partners, history of sexually transmitted diseases, injecting drug use, residence in a highly endemic country, and ascertaining seropositive status. Thus, HIV-positive status is only discovered between six weeks and six months after infection. During this interim period, patients are contagious.

To combat dissemination of the disease, two types of action are required :

- Firstly, addressing the seronegative population as a whole. Although the Committee was

more specifically asked to consider screening for seropositives, it wishes to stress that in its view, education of the masses, and the young as a first priority, is even more important than screening.

- Avoiding contamination, apart from through blood, organ, cell and sperm donation, is an impossibility if men and women and their potential sexual partners do not modify their behaviour since control of sexual activity without the co-operation of those concerned is unthinkable. This applies to both seronegative and seropositive individuals.

Screening cannot be a substitute for education. On the contrary, it must be organised so as to support educational efforts; it must not induce a false sense of security in those who are found to be seronegative, nor must it engender a feeling of exclusion in those who are found to be seropositive.

Screening aims to contact those at risk, to inform them about risk factors and about the ways of lowering risk such as reducing the number of partners and using condoms, to get them to act responsibly and encourage them to change voluntarily and durably their partner's and their own sexual behaviour. If there is no such effort to inform, educate, and counsel, the undertaking may be ineffective. Effectiveness also depends very much on unstinting co-operation from the medical profession since they will be specially burdened when an HIV-positive result is returned.

Success or failure of the prevention campaigns for HIV infection will depend on individual and collective attitudes as regards individuals whose behaviour does not conform to accepted norms. Any discrimination or allocation of guilt, any process of notification, exclusion, or coercion would lead those already infected into avoiding tests or care and would encourage gradual and silent progression of the disease. If prejudice and rejection are replaced by tolerance, psychological social and medical counselling, information and education, then voluntary screening becomes feasible with the primary aim of helping the infected person to be aware of his/her condition, and to take voluntarily the necessary preventive steps since the only contaminating factors are sexual activity and inoculation with blood.

Medical confidentiality, or even anonymity, are prerequisites for mass screening. Spontaneous motivation is desirable : consent to screening is the first sign of responsibility on the part of the person concerned. If screening must be made an obligation then information and counselling must be provided.

In the present state of our investigations, there are three categories of questions :

- In the first category are questions which we have been able to examine fully and to which answers are submitted;
- In the second category are questions which are still under examination. Some data and meaningful information can be supplied, but further work, now ongoing, is required before specific answers can be given ;
- The third category includes questions which have not been studied due to lack of time.

Questions which have been fully examined and to which answers can be given and proposals made

Information, education

The Committee stresses once again the importance of education, which has already begun but must be critically evaluated whenever possible.

A continuation of education is required to gain fuller awareness of the disease, of its consequences, and particularly of how to avoid contamination.

Leaving aside those contaminated by blood transfusion up to 1985, and children of HIV-positive mothers to date, those concerned may be classified into two sets :

- on the one hand, those in "at-risk" groups (drug addicts, homosexuals, prostitutes);
- on the other hand, those who do not belong to the above set, in fact all sexually active age-groups.

A great deal of effort has been devoted to informing the first set, whereas this has not been the case for the second. As it happens, the AIDS threat is particularly related to an extension of contamination by the first infected groups to other groups, who are on the whole free of contamination at the present time. Danger is heightened by the fact that young men and women in our country are largely indifferent to it. Very earnest thought must be given to ways and means of surmounting this indifference, and of increasing awareness and a responsible attitude.

Working groups should be established (with the help, possibly, of youth associations, etc.). Educational methods and people most likely to be influential should be selected. Experiments could be of help.

Such action should target particularly members of the medical and para-medical professions, and social and professional categories most directly concerned.

Particular attention should be paid to informing and educating youngsters.

The general public must also be informed since it is only through their understanding and solidarity that any action can be successful.

The Committee also considered some problems of a general nature connected with preventing the transmission of HIV infection

When, a person is found to be HIV-positive by recognised scientific methods, that person must be told.

It is important, however, that this information should be given by a doctor during an interview, in terms fitting the psychology of the patient, including information on the consequences of the infection in the short, medium, and long term, and steps which the patient should take to limit or avoid repercussions to himself, to those close to him and to others. Medical and social management of these consequences and repercussions should also be discussed.

Results of screening tests are covered by medical confidentiality and no nominative information should in principle be communicated to anyone except the individual concerned, and then only by a physician.

Insofar as registers are kept, these must comply with conditions laid down by the Committee in a previous opinion on medical registers generally. For AIDS, particularly strict precautions must be taken to protect confidential information.

The information given to the patient who has been diagnosed as HIV-positive aims to make the patient aware of his/her responsibility as regards steps and precautions to avoid transmitting the disease, but the Committee does not feel that there is any necessity to legislate to that effect, since existing legislation should be sufficient.

A seropositive status must not prevent the person concerned from exercising a profession in the public or private sectors nor lead, for instance, to rejecting an application for work. In the future certain professions may be found to be incompatible for two reasons :

- because of a risk of transmission of the disease;
- because those concerned or third parties could be at risk due to certain pathological consequences of the situation.

Consideration of such situations, which are likely to be very exceptional, and consequent decisions should be on a case by case basis.

A private insurance company cannot have access to screening results, even if the data is given by its own doctors.

Notification

A decree in 1986, based on article L. 12 of the Code of Public Health, lists HIV infection when it has developed into AIDS, as one of the notifiable contagious diseases. After due consideration, the Committee sees no benefit in an extension to seropositive status since the constraints of such an obligation far outweigh the usefulness of the data collected for epidemiological knowledge, or as regards action to be taken to combat the spread of the disease.

Screening for the disease

The authorities have already adopted a course regarding screening. Through ministerial decrees and circulars, the authorities have specified cases where screening is mandatory and those where screening can simply be offered for duly informed consent.

Screening for disease, and more specifically for HIV infection, is mandatory for donors of

- blood,
- organs,
- cells,
- and, in particular, sperm.

The Committee approves this obligation which for that matter does not seem to raise any objections.

HIV-positive screening, according to official doctrine, must be offered, but cannot be performed without consent, to :

- patients entering a public or private hospital for surgery or endoscopy;
- future spouses requesting a prenuptial certificate;
- expectant mothers, during early pregnancy.

The issue is whether in these three cases, screening tests should not only be offered, but made mandatory.

If screening is mandatory, there is an obligation on physicians and on the patient. At risk groups and geographic areas are not singled out and everyone is on an equal footing. The physician has complied by prescribing the mandatory test or tests and must, once results are known, inform those concerned of possible consequences so that contagion can be avoided.

When screening must simply be offered, the physician must systematically propose the test or tests, and inform the person concerned of consequences for himself or for others of acceptance or refusal.

If it is refused, the physician cannot prescribe the tests.

If there is acceptance, his responsibility is as above : he is under obligation to inform his patient of test results.

The method adopted to implement a screening campaign is logical in either case.

The Committee approves the position taken by the authorities according to which a screening test would be offered systematically to patients admitted to hospital for surgery or endoscopy. It does not feel that compelling a patient who refuses the test is required since the risk of infection to medical or para-medical staff, or from one patient to another is too slight, and hardly justifies an imposition which would not be any great benefit for public health. Furthermore, the medical profession would be unlikely to welcome this.

Questions still under examination

These concern future spouses (prenuptial certificate), and pregnant women. There are two possibilities : mandatory screening, or systematic offer of a test which could only be performed with the consent of the person concerned.

Prenuptial certificate

A prenuptial certificate must be obtained before any marriage can be celebrated, by virtue of article 63 of the *Code Civil* . It is based on a medical examination during which, according to article 155 of the *Code de Santé Publique* , "the physician must pay special attention to contagious or chronic conditions which may have grievous consequences for the spouse or descendants".

This examination involves a set of tests defined at present by a decree dated 17th March 1978, including in particular a serum test for syphilis, but not for HIV infection. The authorities simply state that the test is to be offered to patients which implies that their consent is required.

On whether HIV testing should be made mandatory, the following arguments are put forward in favour :

- tests required for obtaining a prenuptial certificate must, according to article L. 155 of the *Code de la Santé Publique* , bear essentially on "contagious or chronic conditions which may have grievous consequences for the spouse or descendants". HIV infection is clearly one such condition;
- one or other of the future spouses may be HIV-positive without knowing it;

- the fact that there have been sexual relations before marriage does not necessarily mean that an HIV-infected partner has contaminated the other partner;

- it is essential that the couple should know beforehand of the possible consequences of HIV infection as regards both mutual contamination and childbearing.

Very substantial arguments can be put forward in favour of an obligation confined to offering the test :

- screening linked to delivery of the prenuptial certificate is of doubtful utility since a large proportion of couples nowadays have sexual relations before marriage, and the fact that doctors must prescribe the test could lead to seeing it as a mere administrative routine which would deter them from considering their patients' specific case before counselling;

- positions adopted by the Council of Europe and the World Health Organisation which reject any obligation are referred to in support of this view.

Pregnant women and health care for mothers and children

For women in early pregnancy, the problem is similar.

Due consideration must of course be given to the harmful effects of psychological repercussions when a hitherto unknown seropositive status is revealed to a future mother. However, in favour of mandatory measures, it can be said that it is important for her to know whether she is or is not HIV-positive so that she can take decisions,

as to whether pregnancy should be continued whereas elective abortion is an option at all times, by virtue of article L. 162-12 of the Code of Public Health "when there is a strong possibility that the unborn child will suffer from a particularly severe disorder, recognised as incurable at the time of diagnosis", which would include transmission of the mother's infection to the child;

and, should she decide to continue pregnancy, so that she can be aware of the consequences for herself of the birth of a sick child with a short life expectancy. Furthermore, as is the case for prenuptial examinations, public opinion would find difficulty in understanding that a very serious disease which can be transmitted from mother to child is not included amongst mandatory tests to protect their health.

In favour of a simple obligation to offer screening systematically, it has been pointed out that in fact the offer is almost always accepted, that psychologically a mother's deliberate decision is preferable to constraint, and that furthermore, transmission of the disease from mother to child does not always take place. Some members of the Committee consider that if all pregnant women were obliged to take the test, this would powerfully reinforce pressure in favour of elective abortion if a future mother is found to be HIV-positive.

Members of the Committee were divided on whether preference should be given to one or the other of the courses of action and cannot, therefore, propose a choice between the two.

In any case, a woman found to be HIV-positive who has been fully informed of the consequences of her condition, must be entirely free to choose or reject elective abortion. In the latter case, then as soon as possible after birth and in the following months, it is essential that the child be tested to check whether contamination has occurred.

Finally, as the authorities have stated, breast feeding by an HIV-positive woman must be totally prohibited, as must donation of mother's milk if an official milk collecting centre is not involved.

A conclusion is not possible in the short time allotted. The Committee will continue work on the subject and considers that further study should be organised.

The Committee will study specific problems created by transmission of the disease amongst members of a community.

In particular :

- members of the armed forces,
- boarders in schools,
- prison inmates.

Ethical Report

The Minister for Solidarity, Health, and Social Protection, in a letter dated 6th July, 1988, remarks that "the issue of justification for HIV infection screening in particular circumstances such as prenuptial examination, early pregnancy, admission to hospitals - particularly for surgery, raises ethical problems : should screening be systematic or optional, and should seropositive status be disclosed or not," and requests an opinion on these issues from the National Consultative Ethics Committee for Health and Life Sciences.

This request for an opinion calls for a preliminary comment. We are not concerned here with a problem related to the ethics of research, which is the Committee's own province. These are ethical problems which concern the policing of epidemics.

This does not preclude the Committee's competence. On the one hand, ethical problems raised by attempts to limit dissemination of HIV infection are closely connected to progress in its epidemiology, and thus to the ethics of research. On the other hand, on several occasions, the Committee has had to speak out on questions beyond the purview of research (surrogate mothers, disclosure to blood donors of their HIV-infected status). Finally, it is a prerogative of government to seek advice from those individuals and institutions who may be able to provide it.

However, it must be pointed out that, depending on whether the issue is research or fighting an epidemic, the approach to the problem will not be identical. For research, it is generally adequate to examine and collect representative samples of the population concerned and then extrapolate conclusions to be drawn from the study of these samples to establish statistics. When fighting the spread of an epidemic, ethical problems involve restrictions to be demanded as the case may be, either from the population as a whole, or at least from large segments of the population, in fact from all those who may transmit the disease individually. The outlook is very different.

In legal terms, existing legislation gives very broad powers to government. Not only do articles L. 11 and L. 12 of the Code of Public Health permit making it an obligation by decree to notify contagious diseases, but moreover article L. 18 of the same Code makes it possible, through a decree adopted after obtaining an opinion from the *Conseil Supérieur d'Hygiène Publique de France* (Supreme Council for Public Health), to "determine" the means required to prevent the propagation of an epidemic affecting all or part of the country, the cost of implementation being borne by the State. As in any matter connected with policing, the authorities - in this case the Government - must evaluate under judiciary supervision the constraints, i.e. the limitations to public liberties, which may be necessary to ensure the effectiveness of measures proposed, taking into account circumstances of time and place, and a satisfactory balance between these constraints and the preservation of

individual and collective liberties. Lawmakers would only need to intervene if penalties beyond those already included in existing legislation were to be required to enforce these measures.

As is the case for legal issues, in ethical terms a balance needs to be found between constraints imposed on individuals and safeguarding liberties.

On this issue, the scientific report supplies all that is known to date on HIV infection, its consequences, and risks of contagion. We know that, for the time being, no effective therapy has been found to prevent HIV infection or to cure those who are infected. As long as ongoing research has not arrived at concrete results - which is not likely for several years to come - all efforts must concentrate on preventing transmission of the viral agents which are now known to cause the disease.

This implies :

- knowing who has been infected and can transmit the disease;
- taking steps to avoid transmission of the infection.

Knowing who can transmit the virus, notification and screening

Those who can transmit the virus are either those who have visible clinical symptoms or those who are HIV-positive, that is who carry the virus but do not have AIDS. The latter, in much greater numbers than the former, may not know, and frequently do not know that they are HIV-positive. It is only with tests which are now available that they can be discovered.

Notification

As regards those who have symptoms of the disease, they should normally be known through the notification that the attending physician must make, by virtue of a 1986 decree which includes HIV infection on the list of notifiable contagious diseases, by implementation of article L.11 of the Code of Public Health. As to the seropositive status, it is not notifiable as yet. The question is whether it should be.

After due consideration, the Committee gave a negative reply, since the constraints of such an obligation far outweigh the usefulness of the data collected for epidemiological knowledge, or as regards action to be taken to combat the spread of the disease.

Screening and tests

The first essential is to decide who should be tested for HIV infection.

Existing tests involve blood sampling and biological analysis of the sample. In spite of best efforts, they are not totally reliable. Therefore, in view of the consequences of being found HIV-positive, when that is the case, a second confirmation test is considered essential.

Furthermore, several viruses are now known to cause the same infection. It would seem that for the present in France, only the test for the HIV-1 virus is required. There are, however, isolated cases of HIV-2 or HIV-S, and this cannot be ignored. In any case, article 355-23, added to the Code of Public Health by a law dated 30th July 1987, and a decree dated 18th January 1988, provide for cost of screening to be paid by the State and public health insurance organisations. They should not therefore entail any cost for patients. Each

of the French provincial areas (*départements*) is to organise a free screening centre open to patients.

Should screening be compulsory ?

It has been suggested that it should be compulsory for the population as a whole as is vaccination for an increasing number of diseases. This suggestion must be rejected in view of the cost and also because tests would have to be renewed frequently for seronegative individuals who could get infected at any time after testing. Costs and constraints would be out of all proportion with the present spread of the epidemic, since the total number of HIV-positive individuals is estimated at about 0.50 % of the total population of the country.

The authorities, however, have not remained inactive. A ministerial ruling dated 23rd July 1985 provides for compulsory HIV-infection screening in the following cases :

- blood donation
- organ donation
- tissue donation
- cell donation
- sperm donation.

The Committee approves this measure which, for that matter, does not seem to have raised the slightest objection.

The same ruling plus a circular dated 25th March, 1988, provide for screening to be also proposed :

- as part of the prenuptial examination
- to women in early pregnancy
- to patients entering a public or private hospital, in particular for surgery, gynaecology and obstetrics, and before any endoscopic exploration. However, the patient's consent must be obtained before testing.

One may for that matter entertain doubts as to whether a ministerial ruling or circular would suffice to make such testing mandatory.

In any case, is there any useful purpose served by extending the obligation beyond what is already planned ?

A Swiss Federal Commission considered that " serotesting for HIV infection interferes with the integrity of the patient's body and cannot therefore be performed without consent. Such consent is only valid if it expresses the patient's true and freely formed opinion which can only be arrived at once the patient has been fully informed, without which consent is ineffective.... It is probably the first time in the history of medicine that a simple laboratory test such as AIDS testing can lead to major consequences for the integrity of the individual, in particular unforeseen psychological morbidity and social upheaval" . The conclusion was that " unlike other forms of testing and screening, serotesting for HIV infection should only be offered in carefully selected situations and always after having discussed the decision with the patient" . For similar reasons, the competent bodies of the Council of Europe and of the World Health Organisation do not favour mandatory procedures.

These ethical principles are worthy of the highest respect. The problem is whether the risk in this case is so serious that diverging from them would be warranted, and if so, to what extent.

Three kinds of differentiation could be considered, according to :

- patients' usual residence;

- social and professional categories;
- circumstances warranting screening.

GEOGRAPHICAL DIFFERENTIATION

It is a fact that in France, HIV infection is very unevenly distributed. It is to be found mostly in the Paris area, Provence and on the Riviera, and in the vicinity of Toulouse in the south west. In the rest of the country, it is either rare or non-existent.

Should, therefore, special mandatory provisions be made for the areas infected which would not apply to the rest of the population ?

Some arguments can be found in favour of this course :

- the law itself (article L. 18 of the Code of Public Health) provides for the possibility of limiting measures to fight epidemics to certain infected areas;
- it hardly seems appropriate to enforce an obligation on people who are not or only slightly concerned by contagion, and to do so at great and doubtfully useful cost;
- in areas where contagion is rare, it could be more difficult to keep confidential the few cases which might be discovered and therefore, psychological consequences for those concerned could be more severe.

However, even though infection may be rare in certain areas, it is impossible to claim that it does not exist or will not in the near future in view of extensive and frequent travel from one end of the country to the other. One can hardly deprive regions which so far are disease-free of the protection to be expected of efforts to limit the spread of infection.

For this latter reason, it is not deemed desirable to limit geographically present or future obligations on a permanent basis.

SOCIAL AND PROFESSIONAL DIFFERENTIATION

HIV infection affects mainly certain social groups :

- drug abusers;
- homosexuals;
- prostitutes.

Is it desirable, or even legally and morally acceptable to limit mandatory screening to those segments of the population ?

To begin with, in practice the task of determining individually who belongs to any of these categories is extremely difficult. Furthermore, those who do belong to these groups are almost inevitably likely to contaminate people who do not belong to them, and who could then disseminate the disease to the rest of the population.

In this case also, the distinction does not seem fitting.

DIFFERENTIATION ACCORDING TO CIRCUMSTANCES WARRANTING SCREENING

As previously mentioned, there are already cases in which the authorities request that screening, although not mandatory, should be systematically offered. Confining ourselves to those cases only for the moment, we shall consider whether there is any justification for or against instituting mandatory screening instead.

Prenuptial certificate

A prenuptial certificate must be obtained before any marriage can be celebrated, by virtue of article 63 of the *Code Civil*. It is based on a medical examination during which, according to article 155 of the *Code de Santé Publique*, "the physician must pay special attention to contagious or chronic conditions which may cause grievous consequences for spouse or descendants".

This examination involves a set of tests defined at present by a decree dated 17th March 1978, including in particular a serum test for syphilis, but not for HIV infection. The authorities simply state that the test is to be offered to the patients which implies that their consent is required. On whether HIV testing should be made mandatory, contradictory arguments have been put forward :

In favour of simply offering to test, the usefulness of screening when the prenuptial certificate is delivered is disputed since a large proportion of couples nowadays have sexual relations before marriage, and the fact that doctors must prescribe the test could lead to seeing it as a mere administrative routine which would deter them from considering their patients' specific case before counselling. Positions adopted by the Council of Europe and the World Health Organisation are referred to in support of this view.

Arguments in favour of a mandatory testing are :

- 1) tests required for obtaining a prenuptial certificate must, according to article L. 155 of the *Code de la Santé Publique*, bear essentially on "contagious or chronic conditions which may cause grievous consequences for spouse or descendants". HIV infection is clearly one such condition;
- 2) one or other of the future spouses may be HIV-positive without knowing it;
- 3) the fact that there have been sexual relations before marriage does not necessarily mean that an HIV-infected partner has contaminated the other partner;
- 4) it is essential that the couple should know beforehand of the possible consequences of HIV infection as regards both mutual contamination and childbearing.
- 5) that the fact that the competent bodies of the Council of Europe and the World Health Organisation are not in favour of a mandatory test is not a determining factor since each country has to decide for itself and in view of its particular situation regarding the spread of the endemic and the psychological impact of steps taken.

Pregnant women and health care for mothers and children

For women in early pregnancy, the problem is similar.

In favour of a simple obligation to offer screening systematically, it has been pointed out that in fact the offer is almost always accepted, that psychologically a mother's deliberate decision is preferable to constraint, and that furthermore, transmission of the disease from mother to child is not inevitable.

Due consideration must of course be given to the harmful effects of psychological repercussions when a hitherto unknown seropositive status is revealed to a future mother. However, in favour of mandatory measures, it can be said that it is important for her to know whether she is or is not HIV-positive so that she can take decisions,

- 1) as to whether pregnancy should be continued whereas elective abortion is an option at all times, by virtue of article L. 162-12 of the Code of Public Health "when there is a strong

possibility that the unborn child will suffer from a particularly severe disorder, recognised as incurable at the time of diagnosis", which would include transmission of the mother's infection to the child;

2) and whether she should decide to continue pregnancy, as she is at liberty to do, so that she can be aware of the consequences for herself of the birth of a sick child with a short life expectancy. Furthermore, as for prenuptial examinations, public opinion would find difficulty in understanding that a very serious disease which can be transmitted from mother to child is not included amongst mandatory tests to protect their health.

For both the prenuptial certificate and the first prenatal examination, the members of the Committee are divided on whether one or the other of the courses of action should be adopted, and cannot, therefore, propose a preference.

In any case, a woman found to be HIV-positive who has been fully informed of the consequences of her condition, must be entirely free to choose or reject elective abortion. In the latter case, then as soon as possible after birth, it is essential that the child be tested to check whether contamination has occurred.

Finally, as the authorities have stated, breast feeding by an HIV-positive woman must be totally prohibited, as must donation of mother's milk if an official milk collecting centre is not involved.

Patients entering a hospital for surgery

The question of whether patients admitted to hospital for surgery or endoscopy should be made to take an HIV-infection test is a difficult one.

This has been advocated to protect hospital staff from contagion. Although this protection is of prime importance, this does not seem to be a decisive factor since experience has shown that HIV infection is no more contagious than many other diseases. In particular, it is less so than viral hepatitis, and general hospital hygiene is sufficient to practically eliminate any danger of contamination from an HIV-positive patient to hospital staff.

Nevertheless, it can be important for the patient, for other patients, and for the surgical team, to know if HIV infection is present or not. In fact, except in an emergency, any patient admitted for surgery goes through a battery of tests and it would obviously be useful for future therapy and simply for the patient's own edification if he was unaware of being HIV-positive, to include an HIV test.

A distinguished Parisian surgeon has declared that in his hospital department, he always included an HIV test in the set of tests all patients are given on admission and are presumed to have consented to when they agreed to go through with an operation. It would seem that this course of action has raised neither difficulty nor objection.

But this is probably a rather exceptional case and it would perhaps be difficult to make a general practice of it for the time being, in spite of the advantages of such a course if only to gain better knowledge of the spread of the disease. For the moment, the Committee feels it preferable to be content with what the authorities have already proposed, i.e. free and informed consent.

In ethical terms, it is debatable whether a screening test which is not an immediate clinical necessity can be performed upon a patient without his consent or knowledge. Such a practice is without doubt contrary to essential ethical rules. Except for special cases (such as venereal diseases, in which category HIV infection is not so far included) neither treatment nor any clinical procedure can be imposed on an unwilling patient. Are the dangers of HIV infection such that this rule should be overturned? This may or may not be the case, but in any event to do so would require either legislation or a decree with the

approval of the *Conseil Supérieur d'hygiène publique de France* (Supreme Council for Public Hygiene) with reference to article L. 18 of the Code of Public Health.

General ethical issues

The above considerations regarding notification and screening, possibly mandatory, of HIV infection, are far from being the only ones arising because of the spread of this infection. We shall mention a few of them, but the list is not exhaustive.

Information to patients regarding their seropositive status

When, with appropriate scientific methods, a person is discovered to be HIV-positive, should this person be informed of this fact if it was hitherto unknown ?

In a previous opinion, the Ethics Committee recommended that this be done for blood donors.

It would seem that this should be generalised. It is essential that HIV-positive individuals should take on the responsibility of choosing to adopt precautionary measures in order to avoid transmitting their infection. It is just as essential that this information should be imparted in suitably ethical conditions in view of the psychological and possibly social repercussions that this information may have on the patient himself and his entourage in all aspects of that individual's life. It is important that the information should be given by a physician, in an interview during which consequences in the short, medium, and long term must be discussed with composure, as well as steps which should be taken by the person concerned to avoid repercussions both for himself and for others. Information would be also be given at this time on medical and social management of these repercussions. It would be worth drawing the attention of the medical profession as a whole to this aspect of their duties so that suitable training courses can be organised.

Medical confidentiality

Results of screening tests are covered by the rule of medical confidentiality. There is nothing to prevent the establishment of anonymous statistics based on such results, but no nominative item of information must ever be communicated to anyone but the person concerned, and that via a doctor.

The inclusion of screening results in " registers" cannot be ruled out. They would be used for epidemiological research and to contribute to preventive action, individually or collectively. But as the Ethics Committee emphasised in its Opinion on medical registers, the information must remain strictly confidential , and in this particular field, safeguards are of special importance.

However, there is some justification for wondering whether the demands of fighting an epidemic of this severity might not motivate perhaps at least an adaptation of the principle of medical confidentiality.

It does seem that nominative test results should be passed on to some doctors, in particular those engaged in preventive action, who are themselves bound by the rules of confidentiality. But if so, how and how much ? This is one of the most delicate issues. It is possible, and perhaps desirable, to go a little further down this road than the Ethics Committee had advised on the general subject of medical registers in view of the importance of vigorous action to halt the spread of the disease. It should also be noted that the law dated 6th January 1978, on computerisation, registers, and individual liberties, in articles 15 and 26, provides for the possibility of ruling, after consulting the National Commission for Computerisation and Individual liberties (*Commission Nationale de*

l'Informatique et des Libertés), or else the *Conseil d'Etat* , that there could be a derogation to the normal rule of allowing the person concerned to oppose the processing of personal and nominative data. An exception is possible if data processing is to be performed for the State, a public institution, or private persons acting for a public service. Some such exception could probably be considered if it appeared to be essential to halt the spread of HIV infection.

Furthermore, the Presidential Commission which, in the United States was given the task of making a similar study of policy needed to fight the infection, considered that medical and para-medical staff should make known to the partner(s) and to others who might be in danger of contagion that a certain person was HIV-positive. Could such action be taken in France ? The Committee doubts whether any such extreme exception to the fundamental rule of medical confidentiality - which would require legislation - would be acceptable in the present state of affairs.

Awareness of responsibility

Should compulsion be used, and even more so if recommendations calling on the conscious will of those concerned are preferred, then it is essential that they accept to the largest extent possible the responsibilities entailed by knowing themselves to be infected.

The question arose of whether legislation should be devised to sanction any lack of responsibility. This is probably neither necessary nor desirable. Already, information given to the public has incited fair numbers of those concerned to make enquiries spontaneously and to submit to screening tests provided. New constraints might well be counter productive.

Furthermore, existing legislation is probably adequate to cover the more serious cases of non compliance.

General rules of third party liability are sufficient to incriminate in financial terms those who, knowing themselves to be HIV-positive, transmit the disease through failure to take the precautions which could have prevented transmission.

Penal liability could probably be invoked in such cases and dealt with in civil or even criminal courts on the basis of existing legislation. There does not seem to be any jurisprudence on these matters in France to date, but decisions have been taken by foreign courts and there is no obvious reason why civil and penal law should not apply to the subject we are dealing with.

HIV positives and professional activity

Based on transmission of the infection as we now know it, the presence of antibodies should not be an obstacle to exercising any profession in the public or private sectors. A refusal to hire for that reason or making a screening test a condition for employment should as a general rule be totally denounced. To act differently could only be allowable for certain professions to be defined and listed specifically where there is a serious risk of contact with the blood of another person or where pathological consequences of being HIV-positive could be hazardous for oneself or for others.

Professions should be considered with great care on a case by case basis.

Insurance and HIV-positives

The question of whether an insurance company could make a screening test a condition for signing a policy was raised.

This being in the domain of private contractual relations, there could not be any question of preventing a commercial enterprise from refusing a contract with someone who might represent in future a burden which it does not wish to take on. However, the company could certainly not have direct access, even through its own doctors, to screening test results.

Education

Taking into account the particular characteristics of the disease, the way in which it is transmitted, and the present lack of appropriate therapy, fighting the contagion largely rests on public awareness and individual responsible behaviour. Hence, campaigns to educate the public about the disease, the means to fight it and specially to avoid its spread, which have already begun, must be continued and amplified with unrelenting perseverance.

The campaigns should start by addressing the medical and para-medical professions whose members are probably uniquely able to explain to those at risk or afflicted what consequences they must accept and which precautions to avoid transmission they must adopt.

They should specially target those social and professional categories which are most at risk.

A special effort could be made in favour of the younger sections of the population who are prone to indifference or light-heartedness as regards risks and responsible behaviour towards others.

However, education must be extended to the public at large so as to develop, even in those who are HIV-negative, awareness of their own responsibility to avoid contagion on the one hand, and to encourage the united effort from the whole community which is the only guarantee of success.

Special problems

Transmission of the disease is a special problem for certain categories, in particular those who are members of a community.

A study should be made in this respect, particularly for :

- members of the armed forces,
- boarders in schools,
- prison inmates.

Technical Report

Introduction

The pandemic due to HIV and the Acquired Immune Deficiency Syndrome (AIDS) which it leads to, raises major ethical problems.

How can the epidemic be kept under control without encroaching on individual liberties ? Without discrimination ? Without being harmful to some individuals ?

Where is the demarcation line between respect for the human being and what is required to safeguard public health ?

Is restriction of individual liberties useful or necessary to win the battle against the HIV virus ?

As in every case of a transmissible disease, the first urgent strategy is to prevent transmission and break the sequence of contamination. The first human reflex is to locate and isolate the infected element. This is exactly what we do when we identify an infected blood donor and that blood is removed.

Can this simple and effective reflex apply to the entire human community afflicted by a sexually transmitted pandemic ?

In other words :

1) To what degree does screening the entire population for HIV help to control transmission of the virus and extension of the epidemic ? Is it justified by the beneficial effects on individuals and the community ?

2) How should screening be organised, knowing that simply being told there has been HIV infection is a source of anxiety and social upheaval and a shattering experience for the individual concerned. How can the principles of bio-medical ethics as set out by Beauchamp and Childress (1983) be respected :

- bring about well-being;
- be equitable and free of discrimination against any particular social group;
- respect individual liberties, and everyone's right to privacy.

Perhaps a fourth rule of ethics should be added to these three :

- ensure collective security in a context of solidarity. (Leroy-Walters. *Science* , February 1988).

Definitions

In humans, HIV infection is followed by an integration of the genetic information of the retrovirus into the chromosomes of infected cells. Integration is final and irreversible. Infection can be transmitted by the intimate contacts of sexual activities, by inoculation of blood, from mother to child.

The individual who has been infected may develop an acquired immuno deficiency syndrome (AIDS) because the virus infects those cells which are responsible for our immune defences, T-lymphocytes and macrophages. This syndrome is marked by encephalitis, the appearance of many opportunistic infections, and by the development of life threatening malignant tumours.

The infection is pandemic.

Screening is used to seek for the biological proof which signs infection by HIV. It is not used to find AIDS, which is the visible part, visible clinically, of an iceberg composed of infected individuals.

The French word "dépistage" (screening) is used erroneously in everyday language to mean both the search for specific infection criteria in an individual - and should then be referred to as "to do a test to find...", as in the English word "testing"; and is also used to mean the search for specific infection criteria in an entire population, which is what the word "dépistage" really means, as in the English word "screening".

To talk about "systematic" screening is very imprecise since this can mean anything from a simple prescription at the slightest risk of infection to generalised coercive action.

Screening for an infection can be :

- general for a whole population or targeted at certain higher risk groups;
- exhaustive or incomplete;
- voluntary or compulsory;
- nominative or anonymous, or even confidential protected information;
- performed without the subject knowing or with the subject's consent;
- free or for a charge;
- reliable or liable to error...

Epidemiological data

Even now, eight years after the first cases appeared in France, eleven years after they first appeared in the United States, thirty years after the virus appeared in Africa, detected retrospectively, it is difficult to count the number of cases of AIDS, of pathologies connected to HIV, and to evaluate the number of asymptomatic infections. The way in which the French health system is organised, partly public and partly private sector, makes a full analysis of the situation even more difficult.

The three epidemics

The epidemic nature of the virus gives us reason to agree with Jonathan M. Mann, Director of the special programme against AIDS in the World Health Organization, who defines three distinct, although closely connected, global epidemics.

The first of these epidemics numbers those infected. The dissemination of the virus is evaluated and the only effective criterion presently available to judge whether an apparently healthy individual is infected, is seropositive status, i.e. the presence of specific antibodies in the serum which signifies the virus has been acquired, though account must be taken of a small number of virus carriers who do not carry antibodies.

Presently available data comes from the blood transfusion centres where screening of blood donors is compulsory, by a ruling of 23rd July 1985,. However, measuring seroprevalence in blood donors is of limited utility since they are not representative of the population as a whole and biased for "new" donors for whom HIV positive seroprevalence is high because this is an anxious, at risk population who come to donate blood because they want to be screened and want to "know".

The proportion in the population of those who do not know they are carrying the virus is likely to diminish because of campaigns to inform and to encourage screening and because of the creation, by decree 88-61 of 18th January 1988, of 113 centres for screening anonymously and free of charge. They are too recent however for statistical data on their activities and results to be available for the time being.

Apart from these centres and data collected in hospitals and through targeted investigations, there is no obligation to report HIV-positives anonymously. If there were, it

would probably be counter productive and have the harmful effect of deterring those at risk from screening.

It is therefore only possible to make estimates of the numbers of those infected. A generally accepted figure is 100 HIV infected to one case of AIDS.

The second epidemic we must consider is the one which numbers AIDS cases. Unlike most acute viral infections, such as poliomyelitis and smallpox, in which symptoms appear a few days or weeks after infection, AIDS may delay its appearance for years, or even decades.

By decree n° 86-770 of 10th June 1986 (official publication 14th June), AIDS is now one of the compulsorily notifiable diseases, in conformity with article 11 of the Code of Public Health. With this system, which had lapsed before AIDS appeared, the obligation to notify concerns any doctor, or even in the absence of one, the head of the family or of the establishment in which the patient is to be found (article L.257). A circular of 19th November 1986 (n° 642), sent to departmental directors of hygienic and social affairs, sets out implementation rules for the decree. The notification does not give the patient's name, but initials for surname and first name, sex, date of birth, address, nationality and profession are requested. Also requested is diagnosis, serostatus, and modes of transmission. The document is therefore very patently epidemiological. It is sent to the *Direction Départementale des Affaires Sanitaires et Sociales* and then sent on weekly to the *Direction Générale de la Santé*. The number of notifications is published in the *Bulletin Epidémiologique Hebdomadaire (BEH)* each quarter and all this data is used for epidemiological surveillance. AIDS mortality figures obtained via death certificates, also anonymous, seem to be more exhaustive than morbidity figures emerging from mandatory notification.

The AIDS epidemic is progressing exponentially and the number of cases doubles every six to nine months. This can but continue for another four or five years whatever is done about prevention, since it is the result of the natural history of infection of those contaminated, on average, eight years ago. As far as we know, incubation takes from six to fifteen months before the AIDS syndrome appears. About 30% of those infected develop AIDS five years later, but the percentage varies with population. For infected haemophiliacs, the figure is 11%.

A drop in the curve for the first epidemic will be the only sign that preventive measures are beginning to take effect, at a time when the curve for the second epidemic will still be rising.

A third epidemic, concurrent with AIDS and HIV infection, is represented by social, cultural, economic, and political reactions. It is a new challenge for humanity, as tremendous a challenge as the virus itself. As the emerging pandemic develops and as understanding dawns about the :

- irreversible nature of the infection;
- lethal nature of the disease;
- transmission from mother to child;
- economic consequences;
- dissemination of infection on the African continent,

fear will deepen and will be intensified by statistics on the second epidemic, full blown AIDS.

Geographic distribution

France is the country in Europe which is most affected, and the one where numbers of AIDS cases are growing fastest. As of 31st December, 1988 and since March 1982, 5,874 cases of AIDS have been notified. Of these, 228 were children. The sex-ratio is 6.5 compared to 6.8 the previous quarter (BEH N° 33/1988). The Ile-de-France (Paris area) with 52% of cases on a cumulative basis, and the Provence-Alpes-Côte d'Azur (South East France) with 13.6% are the two regions with the highest rate of notification, followed by the Antilles-Guyanne region (4.3%).

Europe adds up to 14,684 cases, with 2,203 in the Federal Republic of Germany, 2,223 in Italy, 1,669 in Great Britain, 1,471 in Spain.

The United States are still way ahead with 71,171 cases.

In total, the World Health Organization recorded 111,854 cases at end of August 1988, in 140 countries, which leads one to suppose that there are about 250,000 to 300,000 cases of AIDS world-wide, a total of 6 to 10 million people infected at the very least, and that 1 to 3 million new cases of AIDS can be expected during the next five years.

Africa is particularly affected and in all likelihood, the number of AIDS cases could be as high as 500 to 1,000 per million inhabitants. African women are as afflicted as men. AIDS is setting off an explosion of the established endemics such as in particular, tuberculosis. It should not be forgotten that AIDS cannot be halted in one country if it is still rampant elsewhere.

Social and cultural distribution

The distribution of AIDS in French adults reflects the distribution of groups for transmission of the virus (homosexuals, drug abusers, recipients of transfusion, heterosexuals), which is also linked to social and cultural groups (age, profession, place of residence). Percentages relative to each group at risk are changing (with a lag correlated to the length of incubation) as and when people become more informed and depending on their capacity to draw the right conclusions (BEH n° 31 and 33/1988).

Five years after information first began to be given, homosexuals as a group only represent 49% of cases reported in the second quarter of 1988 as compared to 63% notified in the first quarter of 1987. Drug abusers accounted for 13.7% of cases reported in the first quarter of 1987, and numbers have risen to 18.7% in the second quarter of 1988.

Three years after compulsory screening for blood donors came into force, blood transfusion recipients numbers fell from 9.2% to 6.6% of reported cases for the same time period.

Median age is 36 for homosexuals, 27 for drug users, 54 for blood recipients, 33 for heterosexuals.

Numbers vary for AIDS in the different socio-professional groups.

Out of 217 cases of AIDS per million intellectuals and business people, 83% are homosexual. That socio-professional group's share drops from 36% in the period 1978-1984 to 25% in 1987.

Out of 104 cases of AIDS per million office workers, 72% are homosexual.

Of the 46 cases of AIDS per million manual and farm workers, 43% can be attributed to homosexuality.

Out of 37 cases of AIDS per million non-workers and pensioners, 26% are due to

homosexuality, and 30% to drug abuse. That share increases from 16% in the 1978-1984 period to 25% in 1987.

Notable facts are the broader distribution progressively starting with the upper social classes, and rapid growth in numbers of AIDS in drug abusers, correlated with extension of the disease in the Provence-Alpes-Côte d'Azur area.

Methods to diagnose the infection

Techniques and their significance

When one means that an individual has been infected by the acquired human immune deficiency virus, the expression habitually used is HIV-positive.

In fact, HIV-positive status is an indirect proof of infection which is based on detecting in the serum of an individual the markers of infection which are serum antibodies which are produced in response to the synthesis of antigenic viral proteins within three to twelve weeks, sometimes with a lag of several months to more than a year.

- before infection, an individual is HIV-negative;
- he is infected; the virus and viral proteins are present in his blood; genital secretions are potentially infectious;
- he produces antibodies and becomes HIV-positive;
- infection persists, chronic, permanent, incurable.

Seroconversion, (from HIV-negative to HIV-positive, detected in two sequential serum samples for the same person) signs and dates primary infection.

A seropositive status detected on one serum sample signs the infection but does not provide the primary infection date.

During a pre-serological phase lasting several weeks, the person is infected, but is HIV-negative, and potentially infectious.

Detection of the presence of antibodies in the serum is done since 1985 with an immuno-enzymatic test called ELISA (enzyme linked immunosorbent assay). This is now an inexpensive routine test, and takes about one and a half to three hours. Viral antigens and reagents are marketed in kit form with the approval of the *Laboratoire National de la Santé Publique*. There are many brands, new kits are frequently on offer and are increasingly easier to use, faster, more sensitive, and more specific.

Detecting direct markers of the infection would be preferable, but for the time being this is not available in a form suitable for mass screening.

- Evidencing the virus by culture in human lymphocytes requires a high security laboratory installation, special qualifications, and ten to thirty days. It is costly and reliability percentages are respectively only 80% for AIDS and 30 to 50% for a non-symptomatic HIV-positive.
- Evidencing the presence of the P24 viral protein in the blood by enzyme immunoassay testing is easy and only takes two or three hours. But these antigens are only detected in the blood of 30% of HIV-positives. In spite of this low sensitivity, this test can in certain cases diagnose infection at onset when the patient is still HIV-negative.
- Evidencing the presence of the HIV genome by molecular hybridisation with a marker

probe (with optical signalling of position) is not very sensitive either since not very many peripheral blood cells are infected. However, it is possible to detect a single HIV genome present in a million lymphocytes if one of its nucleotide sequences is amplified using primers through a rapid polymerase chain reaction or PCR. At present, this can be done in three days but only by a few highly skilled laboratories.

This could become the best method for a highly sensitive direct diagnosis test for HIV infection at onset.

Diagnosis of newborns is particularly difficult. Thirty to forty per cent of children born to seropositive mothers are infected, as several years of experience has demonstrated. But all newborns with HIV-positive mothers test seropositive even if they are not infected because maternal antibodies are transmitted passively and will persist for several months. Furthermore, an infant born to an HIV-positive mother may remain seronegative after eliminating the mother's antibodies because it is unable to produce its own antibodies, whereas the presence of the virus in the blood is demonstrated. In such cases, it is only through detection of direct markers that infection can be discovered and this is the best indication for PCR.

Reliability of results detecting seropositivity

Criteria demanded for the evaluation of tests are, above all, sensitivity and specificity. Both are at 99%, or even more.

A false negative result because of insufficient sensitivity or a technical mistake, means an erroneously reassured individual, unaware of being infective. For this reason, serum is always tested twice with techniques based on two different principles. For transfusion, the risk is estimated at 1/40,000, excluding labelling errors. It would probably be difficult to reach such a high level of security with mass screening which would call on a multiplicity of laboratories not all as fully aware of the risk of technical mistakes producing false negatives. Finally, an individual's serum may be a false negative because he is in the pre-seroconversion phase. The test therefore needs to be repeated at a later date.

Between 1985 and 1988, thirteen cases of seroconversion after transfusion were recorded by the Center of Disease Control in Atlanta. These were due to transfusion with blood from seven HIV-negative donors who later turned out to be HIV infected. When these donors were interviewed, six of them were found to present risk factors. Five were homosexual and one woman had had sex with an HIV-positive drug user. This information is an illustration of the fragility of mandatory screening and also of the importance of a medical examination which can only be of use if it is conducted in a spirit of mutual trust.

A false positive, through lack of specificity or technical error leads to a person who has not (or not yet) been infected thinking he is infected. Considerable harm would be done. That is why serum is always tested with two techniques, any positive result is checked by getting a second serum sample from the person concerned to avoid any risk of error due to label switching between two different patients, and finally, a positive serum is checked with a confirmation test, Western-blot or radioimmunoprecipitation. These are analytical techniques permitting specific and separate detection of different antibodies targeting different proteins coded by different viral genes. It is only after these three costly and arduous phases are completed that the HIV-positive status is averred and can be revealed to the patient.

In some cases, results are doubtful. A search for antibodies to HIV-2 and/or repeating tests at a later date reveal whether a patient is uninfected, in the early stages of seroconversion, or infected by HIV-2.

The number of false positives depends not only on test specificity and technical skill, but also on the prevalence of infection in the population. It must be noted that when

seroprevalence is low, for instance a true positive infected individual in 3,000, about ten false positives will be found in a population of 10,000 (0.1% of 9,997). Out of thirteen positive results obtained in a laboratory, 77% will be false positives, so that numerous repetitions of complementary tests will be needed and their psychological repercussions cannot be ignored. On the contrary, when seroprevalence is high in a population, the probability of a positive result being a true-positive, i.e. the positive predictive value of the test, increases.

The specificity of the most recently marketed tests in which antigens are recombinant proteins or synthetic peptides instead of complete virions, and increasing skill of laboratories which were mostly new to these techniques in 1985, contribute to better reliability. A sequential study, such as the one described above and performed in the best possible conditions in a reference laboratory, revealed only one false positive out of 135,187 tests, i.e. a specificity of 99.999% . In such circumstances (a voluntary population and a reference laboratory), the existence of false positives would not be a valid argument against screening in a population with low seroprevalence (New England Journal of Medicine, 13th October 1988).

The individual faced with HIV infection

Revealing infection

A great deal has been said about AIDS, but not enough about the discovery of HIV infection, about the moment when a physician has to reveal to the person sitting opposite him that infection is irreversible and that he is powerless to cure. This revelation of HIV infection has a devastating effect : the emotional shock and psychological consequences which ensue are, so doctors tell us, greater than those following a cancer diagnosis. In some cases, the result was self destruction and quite clearly the patient needs looking after even before test results are ready. The *Conseil de l'Ordre des Médecins* (French Medical Association) and the National Ethics Committee as early as 1985 considered that in the presence of a properly confirmed HIV-positive test result, a doctor loses "the right to keep silent" which article 42 of the French Medical Code of Deontology allows for a serious disease. However, although the physician is under obligation to tell his patient that he is HIV-positive and encourage him to take steps to avoid contamination, he is also duty bound to assess for each particular case his patient's capacity to endure the disclosure and the most appropriate time for disclosure. For the moment, this obligation has no legal foundation but it is considered to be an ethical obligation because of the need to avoid contamination. It is on the whole well observed in spite of difficulties experienced by practitioners : too compassionate an attitude, fear of contamination, social prejudice against sexually transmitted diseases and homosexuality, doubts about their own sexuality, feeling of professional failure.

Disclosure of seropositivity, evidence of HIV infection, is experienced by the person concerned to be an indelible mark inducing discrimination in a society whose rejection is dreaded on two counts : through fear of contamination, and rejection of what is considered to be deviant behaviour (homosexuality, bisexuality, sodomy, drugs). To be HIV-positive is to fear losing one's job (if disease is discovered) and salary (in case of sickness), it means not being able to travel to certain countries and not being able to take out life insurance... Most HIV-positives suffer these trials and anxieties in solitude and do not confide to any member of their family or to close friends, some of whom frequently are not aware of certain particulars of their lives up to that point. Even beyond the time when symptoms begin to appear, secrecy is maintained in a third of cases. The environment in which a seropositive can fill the need to communicate is too frequently provided solely by the attending medical staff. Communication between carers powerless to cure and patients who need psycho-social assistance full time is moving towards greater humanity. Many voluntary associations are helping the medical profession to cope in this respect.

A seropositive person must shoulder the burden of being infective. He must warn partners,

get them to see a doctor and to take a test. More often than not, the person's whole sex life is devastated. Dentists must be warned and it may become difficult to get professional attention. Feelings of guilt or injustice, revolt, are frequent. In some cases, a voluntarily contaminating behaviour is adopted.

Procreation is no longer advisable. There is the risk of contaminating the mother. A seropositive woman has a mere even chance of producing a child with a future. In one out of two cases, an apparently healthy child at birth, will cease to develop, progressively lose psychomotor accomplishments, and will die in a state of cachexia, an advance illustration of the progressive and inexorable degradation of body image which threatens her own life.

A seropositive person knows that chances of progressing to AIDS within five years are 30%, even though it is carefully explained that this is not always the case and everything done to reassure and de-dramatise. The patient will henceforth have to live with unrelenting anxiety, on the alert for the slightest symptom, wary of test results, under permanent and inevitable medical supervision.

The right "not to know"

It is hardly surprising in the circumstances that some people are fearful of the stress of disclosure, and consider they have a right not to know and to refuse testing. They feel it will be time enough when symptoms appear.

Should the fundamental right of self governance and free choice for an individual be scrupulously maintained ? Can or must society continue to recognise this right in the absence of any cure, and therefore prohibit compulsory screening without an individual's consent, by either physician or government departments. Such prohibition would affect two other categories of people connected to the non-consenting, or even unknowing, patient.

The doctor offering a screening test

Can a doctor be legitimately prevented from using all the aids to diagnosis available to him for a patient who asks for his opinion or care ? Does he not have any responsibility to those who are at risk ? Can a mother who learns that her one or two year old child has AIDS not be allowed to complain about the doctor who did not offer screening in her early pregnancy, at a time when she could have chosen abortion ? Should refusal to take a test in some cases give rise to the establishment of a signed document proving that screening was offered ? The General Medical Council adopted the following rule : "It is only in the most exceptional circumstances, when testing is essential for the safety and protection of persons who are not the patient, and when it is impossible to obtain prior consent, that there may be justification for testing without the explicit consent of the person concerned".

In France, routine screening unbeknown to the patient has been banned by a circular dated 28th October 1987, but it must be systematically offered with a guarantee of medical confidentiality to pregnant women, at the time of the prenuptial examination, or when ceasing contraception, and to patients entering a hospital for invasive examination, surgery, and for gynaecological and obstetrical care.

It would be useful to know the percentage of refusers in particular circumstances or in a given population.

In Parisian maternity clinics, refusal represents about 1%. In other circumstances in hospitals, according to physicians, it is as low. The figures for private practices are unknown. Refusal here depends on the doctor's own beliefs, the amount of time and effort he is willing to devote to convincing his patients. If an anonymous screening centre was set up in each district, this should encourage population at risk to take a test.

Those at risk of being infected

Complaints from such persons that they have not been protected might well be justified. But can a test protect? If results are negative, that is only so at this moment and if the person concerned is not in the pre-seroconversion phase. A false sense of security will have been induced. If a person tests positive, prevention of transmission can only be achieved by a modification of the behaviours of those tested and their partners who cannot be identified without their help.

If tests were performed in violation of the right not to know, which is claimed by only a very small fraction of the population, any kind of screening policy would be ineffective, since success depends on a climate of trust between those who test and those who are tested.

The duty to know

In the present state of knowledge, medical science cannot offer an HIV carrier any guarantee of effective cure. All it has on offer is a therapeutic trial, generally randomised and double blinded as compared to placebo. However, medical follow-up is mandatory in all cases since it can provide :

psychological support which is, probably, the most effective weapon in the doctor's armoury to achieve prevention;

repeatedly, advice on prevention ; by ceasing high risk behaviour to avoid transmission to partners, a seropositive patient also avoids the risk of reinfection to himself and falling prey to bacterial, viral, and parasitic sexually transmitted diseases which are all co-factors facilitating virus replication, destruction of the immune system and progress to AIDS;

the possibility of tracking the chain of contaminators and contaminees upstream and downstream, and see to it that at-risk partners get tested, informed, and motivated to change behaviour. Tracking of partners which implies neither identification nor notification, makes it possible to contact people who are unaware of being HIV-positive. In this way, an effective technique for prevention can be developed, as has been the case in homosexual communities. For women, it has made it possible to avoid pregnancy by using contraception and possibly AIDS in children through abortion, if the mother requests it.

early treatment of the first symptoms of opportunistic infections or of other complications (Kaposi's sarcoma, tumours...).

Although for the moment disclosure of seropositivity appears all too frequently to be more informative than helpful to those who have taken a test, it is likely that in the near future the effectiveness, albeit relative, of specific treatment for HIV infection will be an added argument available to physicians to help convince those who do not want to know or who refuse or neglect medical follow-up.

Usefulness of screening

The National Consultative Ethics Committee for Health and Life Sciences has always maintained since its creation that only what is scientifically sound can be ethical. Necessary conditions for legal action for the prevention and dissemination of a contagious disease to be ethical, must be effectiveness.

Screening, aimed at an individual or at a population, is one of the tools available to health authorities to control a disease.

When effective treatment exists which can be of benefit to those infected, propagation of an infection in a population is controlled by the determination of those contaminated and

capable of contaminating. In these circumstances, authoritarian measures such as those once taken for tuberculosis and syphilis are fully justified in the best interests of the population as a whole : mandatory testing for those infected, compulsory therapy with, in some cases, isolation until infection has been eliminated.

In the absence of any known cure for HIV infection, prevention of transmission can only be achieved by a modification of circumstances bringing about infection on the part of contaminators and potential contamineds.

HIV infection is not transmitted by the ordinary contacts of everyday existence, nor by water, air, food, nor by vectors such as insects. The virus can only be transmitted by heterosexual or homosexual intercourse, or by blood. "Infection by HIV is therefore avoidable, it is not ordained by fate".

Why screen ?

Detecting those who can transmit the disease should normally lead to specific action to avoid contamination. But the benefit to public health by identifying and counting those infected must be considered in the light of, on the one hand, means of transmission, and on the other, potential damaging effects of such disclosures on the effectiveness of means of prevention. Although there is no disputing the fact that the fight against AIDS requires some administrative measures, and possibly legislation, care must be taken not to indulge in hasty decisions which might be useless or even harmful, and furthermore extremely costly, so that much needed funds for more effective preventive measures would no longer be available.

Screening activities, however popular such measures may be, because everyone thinks they are necessary or even essential for prevention and also because people feel that they concern " others" and not themselves, are not sufficient as such to prevent sexually transmitted diseases, because it is impossible to control sexual intercourse without the cooperation of those concerned. It seems hardly likely that partners, male or female, engaged in a sexual relationship, are going to ask each other for an HIV-negative certificate, which for that matter would be valid with three or six months' delay, or are going to bother to consult a register listing positives, supposing there was such a thing and it was kept up to date if it did exist, whereas such a register might be used for other purposes which would be socially and morally unacceptable. For these reasons, some people have gone so far as to suggest intimate tattooing revealing HIV-positives, so that those who can transmit the disease can be identified and avoided.

The object of screening is to contact individuals at risk, to inform them of risk factors, of effective means of reducing risk, to make them aware of their responsibilities, and get them to deliberately and voluntarily modify their behaviour.

Screening is an excellent occasion to inform and make responsible people at risk at the very first consultation if, and only if, prevail conditions promoting trust between the physician and the person being screened, confidentiality or even anonymity, and willingness.

To recommend screening in this context is useful. To impose screening as the essential weapon for prevention might be nothing more than the posturing of authorities keen to take spectacular action to fight the most threatening scourge of our times, but only capable of pretence.

Epidemiological data numbering those infected can only be provided on the basis of programmes for screening of HIV infected individuals and an analysis of systems for collecting data with the help of a minimal medical and social case file, which would be computerised, anonymous, and common to all screening facilities. Such information is indispensable to establish prevalence and incidence, geographical and socio-cultural distribution of epidemic centres, and to understand the natural history of the infection. On

the basis of that data, preventive action can be planned; financial, human, and equipment resources to be devoted to AIDS estimated; and designs made for facilities such as anonymous, free of charge, screening centres, telephone hot lines, medical consultation and laboratory installations, hospital beds and alternatives to hospital care, for instance day hospital and therapeutic housing.

Who should be screened ?

Screening the whole population is unrealistic. The cost would be considerable and the yield poor. Groups at risk would elude screening for fear of being singled out and rejected, the recently infected in the latency phase before seroconversion would not be detected, and tests would have to be repeated at regular intervals. Any screening is only of value for a very limited period insofar as screening per se does not modify behaviour and therefore does not reduce HIV transmission.

The only screening campaigns which could conceivably be programmed are those which target persons exposed to risk factors or who expose others to them.

Screening is mandatory for donors of blood, organs, cells, sperm, and products of human origin used for therapy since entry into force of a ruling dated 23rd July 1985, complemented by a circular dated 1st June 1987. This is because transmission by the blood of an HIV-positive donor is close to 100%. The compulsory aspect of screening is not disputed, nor is information to donors, since there is no obligation to be a donor nor therefore to be screened. Programmes for voluntary screening of blood recipients who had had transfusions between 1978 and 1985 in the United States in order to detect cases of infection in recipients, their partners, or their offspring, revealed that 13% of these recipients did not know they had had a blood transfusion. All recipients should be informed in writing, and all the more so because contamination by transfusion persists, in particular from the blood of HIV-negative donors before seroconversion. To avoid contamination through sperm donation, as far as is presently known, requires the product to be frozen several months before use and after testing the donor again to verify that he is still HIV-negative. It is worth noting that there is no regulation concerning fresh donated sperm, which is frequently used in private practices.

When doctors encounter recognised risk factors during a consultation, they generally prescribe an HIV screening test. Such factors are homosexuality or bisexuality, a history of sexually transmitted diseases, prostitution, multiple partners, originating or residing in an endemic country (central Africa, Caribbean). Recipients of blood or blood components, particularly if treatment was given before 1985, are at risk as are partners of the above categories of people. Drug abusers are at risk twice over because of needle sharing and prostitution.

In all such circumstances, testing for HIV antibodies must be repeated at regular intervals.

Screening at certain pre-programmed times in a person's life is useful both for supplying epidemiological data and contributing to halt transmission of the disease. Furthermore, since such screening reflects the situation of an entire population in the presence of an epidemic, it helps to inform and infuse a sense of responsibility. Men are screened when they are called up for preliminary examination before conscription. Screening is offered to women by most physicians in the more infected areas when they are seen in early pregnancy, or when they cease to use contraceptives, and is always offered as part of a work up for infertility before medically assisted reproduction. For couples, prenuptial examination is the occasion.

Screening methods

Screening is a tool to prevent transmission which is more or less effective depending on the way it is used. Screening programmes raise many technical, social, economic, and ethical problems which must be discussed before any decision is taken to undertake targeted screening.

The cost of the ELISA test for detecting HIV antibodies is 123.20 FF (reimbursed by Social Security). A positive test result must :

- be confirmed by Western Blot, 316.80 FF;
- be repeated using a second serum sample, 123.20 FF.

If there is any doubt about the Western Blot result, a radioimmunoprecipitation test will be required : cost 466.40 FF (not, as a rule, reimbursable by Social Security) Sometimes, it is only by repeating these procedures or testing for the presence of HIV 2, that a diagnosis can be made. It is clear then that in a low prevalence population, detecting an HIV-positive is expensive.

Detecting those who may transmit the disease is arrived at not just through biological exploration. Clinical pursuit of risk factors such as homosexuality, bisexuality, multiple partners, a history of sexually transmitted diseases, drug abuse and originating or residing in an endemic country. If that is neglected, there is a danger of contamination by an as yet seronegative but contagious person as is demonstrated by persisting contamination through transfusion which could almost always have been prevented by the discovery of risk factors which are as much a reason for elimination from a list of donors as is the presence of HIV antibodies.

Ethical conditions of screening

Tracking a contaminator is certainly of value preventively. There is therefore no reason to argue for or against. But in every case motivation and objectives must be defined, whether screening is intended for an individual or a target population. What is the cost-to-benefit ratio ? Who will do the screening ? Why and how ? To whom will results be reported and what use will be made of them ?

Screening is a simplistic word for a complex action whenever :

- detection of infection or even simply investigating risky behaviour, classifies individuals according to sexual practices, social groups, race, life style;
- disclosure of infection encroaches upon the body, the psyche, or the social position of the person concerned;
- making screening a routine, systematically prescribed, is a risk of losing the preventive value gained by increased knowledge and sense of responsibility within a population.

The special programme to fight AIDS (SPA) created by WHO on 1st February 1987, after an analysis of data supplied by countries in response to complex issues raised by AIDS : screening, housing, care, education, employment, came to the following conclusions :

- AIDS can be prevented and HIV infection checked without violating human rights;
- prevention of HIV infection depends on the quality of information, education and counsel given to those infected;
- public health considerations do not justify any steps to isolate afflicted persons or discriminate against them;

- the interests of public health are better served by allowing infected individuals to remain in their own social environment and by helping them to protect others from contamination;

- screening for HIV infection must be based on free and informed consent, counsel, and with a guarantee of total confidentiality.

In order to improve understanding of issues raised by the organisation of a screening programme, twenty one experts - epidemiologists, virologists, sociologists, three legists, and ethicists, met in Geneva at WHO in May 1987, to consider criteria which should be taken into account when organising screening programmes in order for them to be successful and beneficial to public health.

Information, counsel, consent, offered free of charge

Since identification of HIV-positives can only reduce the spread of infection if it is correlated to behavioural changes which can only be voluntary, it seems that the most effective prevention policy should be based on encouraging voluntary screening. The advantage is not just discovering the serostatus, but more importantly it gives an opportunity for prior consultation. The doctor can discuss with the patient reasons for testing, the significance of test results, and problems arising when interpreting results; he can explain modes of transmission and give advice for preventive action which is useful whether results are positive or otherwise, either for protecting oneself from contamination or one's partners. He can elucidate how sexual intercourse can be made safe using a condom and explain the technicalities, advises on a reduction of the number of sexual partners whilst making it clear that partial reduction is no safeguard and that monogamy is the only way to reduce risk. This consultation is an excellent opportunity to further the aims of a policy for informing, giving health education, and a sense of responsibility to people at risk and has proved of benefit in mature-minded populations.

It is at this point, before test results are returned, that the population at risk is most receptive to explanation and advice. The information given at this time has a maximum effect because it serves to prevent contamination of the person being tested and not only of that person's partners : selfish self-interest and sense of responsibility are equally implicated.

This interview, during which the consequences of a possible positive result are discussed, makes it possible for the test to be taken by a fully consenting patient, by which is meant free and informed. It is true that for other tests of major importance for the health of the patient, the physician does not ask for consent, but the personal and social consequences of discovering an HIV-positive are such that this cannot be considered like an "ordinary" test. Furthermore, the fact that the doctor must obtain consent guarantees that essential information and advice are given and discussed.

Disclosure of results, necessarily face to face, is a further occasion for post-screening consultation during which advice for prevention can be reiterated. If the person tested turns out to be HIV-negative, it must be made quite clear that seroconversion is still a possibility and that the risk of infection endures if there is no change in behaviour. If an HIV-positive result is reported and disclosed after a second test to confirm and with a different test method, a smooth transition to regular medical follow-up will be much facilitated by the groundwork already accomplished during the earlier consultation.

It is regrettable that screening is not always free of charge even when it is prescribed by a doctor.

Since 1985, detection of antibodies to HIV is coded B70 (French social security codes for reimbursement of expenses) for the first test (123.20 FF), B180 for the confirmation test (316.80FF) of which 65% is reimbursed by French social security (in the general scheme

which covers a majority of workers). The only facilities where voluntary screening is totally free of charge are certain clinics for venereal diseases (CISID) and the anonymous screening centres set up to comply with law n° 87-588 of 30th July 1987 (article L. 355-23) and decree n° 88-61 dated 18th January 1988. So, outside these centres and when it is not anonymous, screening, which is recommended, costs 43.40 FF at least (if the result is negative), including when a pregnant woman is advised to take the test in a public or private maternity clinic.

Reimbursement of 100% of medical expenditure by French social security is applicable solely for full blown AIDS since 31st December 1986.

Compulsory screening, through legal or administrative means, through a nominative test, without the patient's knowledge, using serum sampled for other purposes, is a violation of human rights.

Such practices would loosen the bonds of mutual trust which now exist between people at risk and the medical profession or any other social structure. People at risk would elude screening.

Furthermore, any compulsory screening will result in the doctor's role being reduced to routine prescribing. It is so much easier and faster to write a prescription than to obtain consent after a discussion suited to each patient and it must be remembered that the major objective of this dialogue is to inform and encourage a more responsible attitude in sexual relationships because this is the only means of prevention available to us.

Although it is desirable to recommend screening in certain circumstances to avoid contamination (pregnant women), it must be the physician who is under obligation to propose a test. Screening which a physician is obliged to offer - in a way which remains to be defined - will facilitate the dialogue which is needed to obtain consent. It is difficult even for a doctor to ask questions about risky behaviour (adultery, sodomy, drugs...) and/or to obtain information about a patient's past which the person concerned would rather forget than confess. To make the offer an obligation on the doctor could contribute to prevent the spread of infection by giving the medical profession a greater sense of involvement in preventive policy.

Medical confidentiality or anonymity

Since HIV infection spreads by sexual transmission, and the fact that it predominates in the homosexual, bisexual, and drug user populations, and because prognosis is life-threatening, any disclosure to the patient's entourage of HIV infection is a violation of privacy. Frequently, discovery of infection also reveals a life-style, sexual practices, a history of drug abuse, hitherto in most cases unknown to spouse, family, employer, or the social environment of the person concerned. It is of paramount importance to that person to keep both infection and personal matters out of the limelight. There are two ways of keeping that secret : medical confidentiality and anonymity.

MEDICAL CONFIDENTIALITY

Confidentiality is an obligation on all physicians. Violation is punishable by article 378 of the Penal Code and by article 11 of the Code of Deontology. If there is prejudice to the patient, the physician's third party liability is involved. Medical confidentiality extends to anything which has been confided, seen, heard, or understood by the doctor and his medical assistants. It persists after the death of the patient and must be kept in scientific publications. It is general and absolute; a hospital clinician is not allowed to inform the family's attending physician that one of his patients is HIV-positive. It is up to the doctor to ensure protection of information and in particular, when records are computerised, he must make a nominative written statement to that effect addressed to the *Commission Nationale*

de l'Informatique et des Libertés whose mission it is to "preserve, in our times as they were in the past, personal privacy and liberties, and maintain a balance between the rights of the individual and those of society".

Respect of medical confidentiality in the presence of AIDS and HIV infection has to be strictly observed in France where a very rigid view of medical confidentiality is upheld by the Medical Association (*Ordre des Médecins*). If an HIV-positive patient refuses to follow advice to protect sexual partners, a physician can neither reveal the information nor warn those under threat of infection.

The only legal exception to medical confidentiality in the case of HIV infection is anonymous notification of cases of full blown AIDS to the head physician of DASS (public health authorities) (decree dated 1986 based on article L.12 of the Code of Public Health).

In some quarters it is thought that a priority measure should be a notification of HIV-positives so that there can be proper follow-up and an opportunity to enforce observance of preventive measures to protect partners. But it is neither useful nor necessary to organise mandatory notification on a grand scale in order to supply required information and advice to prevent transmission and ensure follow-up. The drawbacks of such mandatory measures outweigh by far any epidemiological advantage.

A law dated 31st December 1942, articles 255 to 262 of the Code of Public Health, lists four venereal diseases : syphilis, gonorrhoea, chancroid, and lymphogranuloma venereum during the contagious phase, for which notification is mandatory, albeit anonymous. It can however become nominal when the patient is engaged in prostitution and refuses treatment. Sanctions, forced admission to hospital, fines, or prison sentences may be imposed. Specialist social services must carry out an epidemiological enquiry in compliance with article 262, under the responsibility of the head physician of the clinic or the consultant physician of the administrative area. For many reasons, implementation of this law has lapsed :

- the four venereal diseases can be cured easily and speedily, and they are not the main sexually transmitted diseases out the twenty or more that are known today;
- when doctors treat them in private practices, they do not notify;
- patients refuse to cooperate in tracking a chain of contamination when there is an element of police enquiry;
- prostitution is increasingly casual and there is much less official and recognised prostitution.

One can only draw the conclusion that compulsory measures which touch upon the privacy of individuals are ineffective.

The practice of medicine implies truthfulness. Truthfulness means trust. Trust needs confidentiality.

On 18th February, 1988, the *Conseil National de l'Ordre des Médecins* , issued a reminder about the sacrosanct nature of medical confidentiality, except in cases covered by legal exemption : "Doctors could be put under pressure to reveal the existence of HIV infection or AIDS. Such disclosures would transgress the rights everyone has to privacy, leading perhaps to concealment and deterring the sick from seeking medical help. This would be contrary to the interests of the infected person and those of public health". Compulsory medical follow-up of any kind, which would very probably mean notification, or even nominative reporting of HIV-positives, would not be very ethical and would incite individuals at risk to evade tests. Furthermore, medical confidentiality and trust are the prerequisites for discovery and tracking of contacts.

Past experience to prevent gonorrhoea and syphilis has demonstrated the futility of mandatory notification policies in private practices, unless it remains anonymous and organised through a voluntary network of "watchdog" doctors. This is the method followed by anonymous free screening centres established in 1988.

Observance of medical confidentiality conditions a patient's trust. Confidentiality is not a privilege granted to the medical profession; it is a basic right of patients.

ANONYMITY

As we all know, it is frequently difficult to observe medical confidentiality in a hospital or a restricted community. In such circumstances, an individual at risk would hesitate to undergo screening. A comparative study of the yield of nominative screening protected by medical confidentiality and anonymous screening, with prior consultation and questionnaire in both cases, was made in a hospital in Oregon. The result was an increase of 50% in favour of anonymous screening with the following breakdown : 125% increase for homosexuals and bisexuals, 56% for women prostitutes, 17% for drug abusers, and 32% for miscellaneous others. Twice as many HIV-positives were discovered in the 31 months which followed the adoption of anonymous screening and it seems that these individuals at risk were able to get earlier information and advice from the medical consultation before the test because of anonymity.

In France, when the test for HIV infection became available in 1985, those who wished to discover their serostatus went first of all to the blood transfusion centres where identity was not verified. A harmful consequence was an inflow of donors at risk, some of which, although they were still HIV-negative, had been recently infected and were a source of contamination. In order to supply an alternative to this possibility of voluntary, secret, and free of charge screening for those who preferred for financial or psychological reasons not to go to their own doctor, nor to a nearby laboratory, nor to a public hospital, private initiative led to the creation of free and anonymous screening centres as of 1987 in Paris and later by government action in each French administrative area (*département*). The first free and anonymous screening centre opened by *Médecins du Monde* , rue du Jura in Paris, saw 2,968 people who wanted to take the test, between July 1987 and September 1988, of which 233, i.e. 8% turned out to be HIV-positive. 47% went to the Centre because it was anonymous and free, 30% because of anonymity alone, 14% purely because it was free of charge. However, 20% of those who were HIV-positive never returned to fetch their test results. Anonymous screening does respond to a need, in spite of its drawbacks : positive results unknown and lack of follow-up in some cases, impossibility of correcting errors by recontacting patients.

Other anonymous modes of screening have been suggested for epidemiological purposes : testing serum samples collected for other reasons but so coded that they cannot be identified. An experiment in the Centre for Information and Therapy in Human Immunodeficiency (CISI) in Marseilles, involving the development of a system for collecting strictly confidential medical information by irreversibly coding an identity, should help to improve the collection of epidemiological data.

Guarantee of non discrimination

In every country, AIDS provokes fear and irrational rejection reactions. An immediate reflex is to reject the infected, the "aliens", for the sake of protection. This is instinctive logic on the part of people who fear contamination (for themselves or their offspring whose sexual behaviour they cannot control) and who wish to identify and eliminate the source of contamination. Answers to surveys have shown that most people consider that an HIV-positive individual who does not refrain from sex with an unknowing partner without the protection of a condom should be treated like a criminal. Many doctors feel that observing medical confidentiality when they have dealings with the uninformed partner is on a par

with abetting homicide. Cases of refusal to give medical assistance have been reported, and the medical association was obliged to issue a reminder of rules of deontology to the effect that "medical attention must be given even if dangers of contamination cannot be avoided" which is not the case, "and given to all patients with the same degree of conscience and respect".

Many parents refuse to allow their children to be with HIV-positive school-fellows, although the great majority are well aware that the only avenues of contamination are sex or blood inoculation.

Such reactions, in their most extreme forms : tattooing HIV-positives, total exclusion like lepers in the Middle Ages, are accepted and even wanted by respectively 29% and 17% of people interviewed in a survey in the United States. The fact that AIDS affects certain social groups more than others : homosexuals, drug abusers, coloured men or women, is one of the reasons for these discriminatory reactions. A survey revealed that 75% of people felt sorry for AIDS sufferers, but numbers dropped to 36% if the virus was transmitted through homosexual intercourse, and 26% if the disease was caused by using contaminated needles to inject drugs. This association of death, blood, and sex which is at the core of AIDS and HIV infection, awakens in all of us subconscious reactions related to branding the guilty, sexual permissivity and punishment, fears of divine retribution, rejection of the impure.

It is to be feared, as this scourge develops over the next five years and impacts on the awareness of the masses, that there will be outbreaks of an epidemic of increased discrimination, social and popular violence, and/or political turmoil, against which the only available weapons are objective analysis, communication and information, social education and possibly anti-discrimination laws.

The greatest number of people must become aware that AIDS is everyone's problem and is not limited to certain social groups and that it is up to each and everyone of us to avoid exposing ourselves or others to the risk of HIV infection. The major impediment to voluntary screening and progress in public health policies is the fear of discrimination, loss of social status, of family, home, job, and free movement. Any discriminatory measures of exclusion stoke up these fears so that people at risk refuse to face facts, infected individuals neglect to inform their partners, and behave as though nothing had happened for fear of being found out. Urging voluntary screening would be more successful if HIV infection once discovered did not lead to rejection from relations, employers, and authorities.

WHO considers that "the respect of human rights and of the dignity of those infected by HIV, who suffer from AIDS, and of members of particular groups is essential for the success of national anti-AIDS programmes and global strategy" and requests member states inter alia :

- to promote understanding and support for those affected by HIV and AIDS, by means of programmes for information, education, and social action;
- to protect the human rights and dignity of those affected by HIV and AIDS and members of particular groups and to avoid taking any discriminatory steps or being prejudiced against them as regards the supply of services, employment, and travel ;
- to guarantee confidentiality of HIV screening tests and promote the establishment of confidential consulting services and other services to support those affected by HIV and AIDS ;
- to include in any report to WHO on national strategies adopted to combat AIDS, information on steps taken to protect human rights and the dignity of those affected by HIV and AIDS".

Fighting discrimination in all its forms must be part of any programme to combat AIDS and

HIV infection . Such programmes will be all the more effective if legislation keeps discrimination at bay because information and education cannot alone modify discriminatory behaviour on the part of the public particularly at a time when AIDS is increasingly visible in the public eye. Anti-discrimination laws will probably be needed to create for those infected and those at risk conditions in which they can safely survive, get medical care, and social support. Courts will need to distinguish between inequitable discrimination and legitimate decisions required because of the encephalopathic repercussions of HIV infection and essential efforts to halt dissemination.

Targeted screening

Before hospital procedures

A circular of the Ministry of Social Affairs and Employment, dated 28th October 1987, issued a reminder that "general screening to test for HIV antibodies of all patients staying in or transiting through a public or private health establishment is definitely out of the question", but allowed that a screening test could be offered in certain hospital departments, such as surgery, gynaecology and obstetrics, and endoscopy".

This circular obviously leaves room for interpretation. In fact, some senior medical staff have ruled that anyone admitted to hospital will be tested, in most cases with the patient's prior consent. However, we have found, to our certain knowledge, that in some cases patients are not warned, which is a violation of one of the rules in the 28th October 1987 circular which states that the patient will be given prior notice and be asked for consent.

This trend to make a general practice of screening, according to the few contacts we have had so far, seems to be confined to surgical departments specialised in long and invasive operations involving copious bleeding, such as cardio-vascular or orthopaedic surgery. The same is true for obstetrics. It is true of course that in these situations the full spectrum of transcutaneous contamination by per-operative or pre-existing cuts is present. It should be noted however, that the risk also exists in other situations : a nurse performing a simple intra-venous jab, or a laboratory assistant handling any sample in any medical establishment, not necessarily a hospital, also run similar risks . The same is true for dentists.

However, available information to date is sufficiently convincing for us to be able to evaluate the risk at true and more modest proportions. In fact, the number of professional HIV contaminations is very low compared to the number of wounds which occur in a health care situation. In 1987, nine cases were known to exist, and it seems that now the number has risen to slightly more than ten.

Further reassuring data has been reported by prospective surveys connected to various populations of health care professionals. In particular, a CDC Atlanta study focusing on workers who had been specifically at risk through exposure to blood or contaminated fluids because of wounds to skin or mucous membrane, found that the danger of contamination was less than 1% in the case of parenteral inoculation.

However low the risk may be, the precautions which are widespread in health care environments are justified. They must always be applied because it is impossible to know every patient's serostatus at all times. It might be acceptable to reinforce them when the patient is known to be contaminated, as long as identification of these patients does not entail any segregation which would open the door to discrimination all the more detrimental since it would be stamped with the approval of the medical profession.

Prenuptial examination

Screening at the time of the prenuptial examination is useful because, as is the case for the prenatal examination, a vast and fairly young population is involved. A further advantage is that both men and women are concerned. Finally, at least theoretically, it takes place at a time which is particularly suitable for avoiding contamination of a partner and pregnancy if one of the couple turns out to be HIV-positive.

However, it must be noted that one high risk group, homosexuals, is obviously not involved. It is also frequently the case for some drug abusers, particularly those whose life style is the least conventional. The test, however, could be a valuable indication of the spread of the epidemic amongst young heterosexual adults, although the increasing trend not to get married must be taken into account. Annual figures at this time are 270,000 marriages, but there has been a drop of 30% between 1975 and 1985 with a parallel multiplication by 2.5 of the number of illegitimate births.

Mandatory prenuptial screening therefore would not reach the whole target population. There would also be other drawbacks. We shall not dwell here on the risk of error leading to false positives since the subject has been dealt with in the general context earlier. But emphasis should be placed on the particularly serious consequences of such errors in this specific context where the fact that a person was HIV-positive would be divulged to a third party other than the physician.

It is even more difficult to ignore the argument of the cost of the operation. For 270,000 weddings annually, screening would cost 75 million FF. This amount must be viewed in the light of :

- the number of cases which could be detected;
- the number of people who would be protected from contamination.

These two figures are not identical, contrary to what one could expect.

As regards the number of cases detected, an evaluation on the high side can be based on the prevalence found in nine Parisian maternity wards, i.e. 4%. On that foundation, about 2,100 cases could be detected. However, there are the already known cases. In the above enquiry, those represented about 50% and numbers are growing because of all the facilities for screening which are open to the public. So the number of new cases discovered would only be about 1,000 at best, which is not trivial of course if an equal number of partners were protected as a result. Such an outcome might be hoped for if the ideal traditional type marriage with future spouses about to begin sexual relations, still prevailed.

Unfortunately, this is becoming increasingly rare according to the latest population surveys. In a recent publication, (*Les nouveaux couples; nombre, caractéristiques et attitudes*, Population 1988) (Modern Couples: numbers, characteristics, attitudes), Leridon points out that 57% of weddings from 1980 to 1985 were celebrated after the couple had been living together, on average for almost two years. This already high proportion of prenuptial cohabitation might still increase if one extrapolates the curve which started at 10% for weddings in the 1960 to 1969 period. There is a noteworthy difference between geographic regions and in Paris, the figure reaches 75%.

Although prenuptial screening has lost some of its potential usefulness for protecting a spouse, perhaps it is still valuable for pre-conception protection. But there again, the situation has changed. In 1986, out of 778,000 births, approximately 170,000, i.e. 22% were illegitimate. However, the figure rises to 30% when only first pregnancies are considered. It may well be even higher in groups thought to be at risk for HIV. Data drawn from the nine Parisian maternity wards point in that direction, since for those pregnant women who were HIV positive (216 cases), 69% were unmarried.

It can therefore be said that the prenuptial examination has lost a great deal of its value and significance for preventive purposes. In view of the cost, and the low yield that can be expected of it, compulsory screening does not seem worthwhile. Of course, one might argue that it is at least as useful as screening for syphilis which is still compulsory. But it might be well to change that. In the United States the measure has been mostly dropped on the basis that studies have shown for instance, that only 1% of cases were discovered by screening at the prenuptial examination.

Reservations about mandatory screening should not lead to disregarding the value of screening left to the initiative of the doctor on the basis of information gathered during a personal interview with the future spouse. If one considers the highly important counselling role the doctor will have to play to avoid behaviour which would endanger the partner if positive serostatus is discovered, it does seem that the most effective environment is non mandatory.

Pregnancy

There is general agreement that a woman's serostatus must be known during pregnancy. We shall go into the reasons and then consider the effectiveness of what is now being done.

UTILITY OF KNOWING THE SEROSTATUS

1) In the first place, it is useful for the mother herself to detect HIV-positive status and to follow that up with an investigation into the state of her immune system, because although pregnancy does not seem to be an added risk for a woman who is simply HIV-positive, it could hasten the progress of disease when the system is already severely immunocompromised.

2) However, apart from the woman's status, we must also be concerned about possible contamination of the child. The probability of this event is variously appreciated (20 to 50% in different studies), but when it occurs, progression of the disease is particularly swift and severe. It is also known that probabilities of developing the disease increase when the mother herself has clinical symptoms. In the circumstances, it is apparent that a mother must be clearly informed of the risks her child will run at the earliest possible opportunity so that she can decide - and the decision is entirely and exclusively her own - whether she wants to continue pregnancy.

3) If pregnancy is continued, the child must be given paediatric care immediately after birth. The first problem is to discover whether there has been contamination, which with our presently available tests, is no easy matter. In fact, all children born of HIV-positive mothers, are also HIV-positive at birth, since the mother's antibodies pass through the placenta. Until direct tests are available, only antibody developments during the first months of the child's life can provide indications of contamination, so that medical supervision must begin as early as possible.

4) Another important reason for knowing the mother's serostatus, is that it may be necessary to ban breast feeding which, although to a lesser degree than the transplacental path, seems nevertheless to offer a possibility of contamination.

5) Some obstetricians also point out that as more information is gained on chronological aspects of transplacental contamination, there may be reason to choose certain obstetrical options, such as premature delivery or caesarean section.

6) Identification of HIV-positive mothers enables carers to take special precautions throughout procedures before and during delivery which naturally produce loss of blood and body fluids which are a likely source of contamination.

7) Finally, it has been pointed out that pregnant women are a young, sexually active population, and that this group would be very useful as a "reference" population indicative of the evolution of the epidemic. This point merits discussion. The group is not a uniform set and there is serious disparity of the risk depending on geographic location and the presence of a large or small proportion of high risk women, drug abusers in particular. Furthermore, the fact that women at risk will be, one hopes, increasingly screened before pregnancy, may lead them to either abstain from childbearing altogether or practise early abortion. If that should be the case, and all other factors being equal, the result would be an artificial under-evaluation of the number of HIV-positives, which would give a false impression of stabilisation or even regression of the epidemic.

PRESENT MEASURES AND THEIR EFFECTIVENESS

A circular issued by the Ministry for Social Affairs and Employment, dated 28th October 1987, specified that : " a screening test could be offered in certain hospital departments, such as surgery, gynaecology and obstetrics... to all patients admitted".

On 25th March, 1988, a letter from the Minister in charge of Health and Families in the Ministry of Social Affairs and Employment, went further and urged that "screening must be offered if there was the slightest doubt, after a comprehensive and careful interview during prenatal examination". One notices, however, that it does not say that this should be at the time of the first of the three mandatory prenatal examinations.

What has been the effect of these recommendations ? Gaps in the collection of information must be emphasised at this point. If only in the public hospital sector, it would be useful to find out how many of the gynaecological and obstetrics departments organised screening and how they went about it. But we have no official statistics on this vital matter.

Fortunately, two medical initiatives give some interesting figures. The first of these is an enquiry launched by Professor Henrion who contacted 244 departments in the whole country, of which 213 replied and of these, 40 (16%) state that they systematically offer screening to all pregnant women. An interesting point is that those departments most committed to screening are mostly in the Paris area or in Provence-Alpes-Côte d'Azur, i.e. the high risk regions. Although this is a very interesting enquiry, it gives no information on how many refuse to take advantage of this systematic offer. The second enquiry does give information on this point. This is a multicentric study conducted in nine maternity wards of the Paris area. The Saint-Antoine Hospital's Centre for Perinatal Hemobiology is responsible for co-ordinating the data, in co-operation with the Virology Laboratory in Tours. The enquiry began in February 1987 and is ongoing. More than 30 000 women are involved so far. There have been two preliminary publications bearing respectively on the first 7,000 and 15,000 cases. Refusals on the part of women who came for prenatal care amounted to 1.6% in the first series and 1% in the second. As the second series included those in the first, the percentage is now less than 1. However, closer inspection reveals that refusals vary according to the maternity wards under study. These figures fit in with figures from personal contacts between the rapporteurs and physicians in charge of maternity wards in the Paris area and Marseilles who said they no longer had any refusals since very thorough explanations were given to mothers about the usefulness of screening. It would therefore seem to be demonstrated that thanks to the powers of conviction of the medical staff and to information given to patients, it is possible to gain satisfaction on essential generalised screening during pregnancy without resorting to any compulsion.

It is true that when results are analysed, a loss as small as 1% may skew considerably statistical interpretations because refusers turn out to be a specially high risk population. Any epidemiological study must respond to the imperative need for exhaustive analysis of the sample, and this is specially true when seroprevalence is low, which is still the case for HIV. One could, to respond to that need, discuss the possibility of performing totally anonymous tests on the blood samples of those women who refused. This is the only

supplemental measure compared to the present situation that we feel empowered to submit for discussion, but strongly emphasise that it should be only used for research.

There is a possibility which, however uncommon, must be considered : refusal on the part of a woman whose symptoms are indicative of AIDS, or who simply seems at risk for several reasons. A physician would then probably be justified in referring to regulations concerning prenatal examinations, according to which "he must search for medical or obstetrical risk factors which may be a threat for the health of mother or child". The examination must "include screening for pathologies which may be brought about or aggravated by gestation or compromise its progression".