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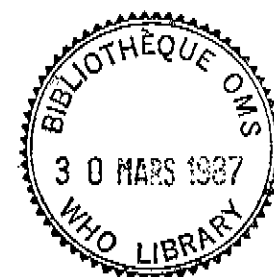
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A I D S, LEGISLATIVE MEASURES AND ETHICAL ISSUES

by

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# A I D S, LEGISLATIVE MEASURES AND ETHICAL ISSUES

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## INTRODUCTION

The AIDS epidemic continues to develop in Europe. Thus one of the most important public health questions in this Region today is: which measures are appropriate to curb the spread of the virus of AIDS.

The governments' responses are not easy, given the uncertainty of the scientific knowledge on some characteristics of the disease and also because of people's behavioural attitudes towards a problem of foremost personal and intimate nature but which is at the same time of intense public interest.

Another difficulty in finding a solution to this crucial public health problem, lies in the fact that it has to be dealt with at the international level with a consensus on policy judgements and a thorough coordinated action; it is not an easy task in a Region with such a diversity in traditional administrative patterns and such a variety in the lifestyle of the European societies reflected by their different cultural backgrounds and societal structure. Hence the reason for such a meeting.

This paper will comprise two main parts as implied in its title. First an overview of the legislative action taken to prevent the spread of the AIDS epidemic based on the measures taken mainly during the past 3 or 4 years. They have been collected from various surveys conducted by the Regional Office of WHO and by its Headquarter. The following key areas will be considered: notification and reporting, blood supplies and other donated items, high risk groups, health care personnel, other means of governments' support.

The second part of this paper will deal with ethical implications deriving from this new, rather sudden and complex medico-social problem of AIDS. The following areas will be explored: Confidentiality of information, tracing of contacts, information of the public and testing sites, problem of serological false results, perinatal transmission, patient-doctor relationship.

As may be expected at the present juncture, more questions will be raised than answered. It is hoped, however, that bringing the facts once more into the open may help all those concerned, and we are in fact all concerned, to reach the best possible decisions which will improve the odds for success towards the emerging ethical dilemmas of AIDS.

## I. Legislative measures

### 1.1 Notification and reporting of AIDS and HIV infection

This is a key area which required immediate action after the beginning of AIDS epidemic in 1981, cases being reported in many countries of the world, their incidence rising rapidly, the disease being fatal and its epidemiological nature and extent, a matter of speculation.

Governments in the European Region have therefore reacted very quickly in setting out arrangements for notification and reporting of AIDS. Already in 1982, the Federal Republic of Germany set up an AIDS working group which elaborated a notification procedure for the recording of patients. The general trend in the European Region is that the existing provisions of the Act on Communicable Diseases can be applied to AIDS, as they are often foreseen for all communicable diseases.

It is interesting to note that in 1985 several countries such as Malta, Norway, the Netherlands, Scotland, reported that no specific legislative measures to counter AIDS were envisaged since the existing legislation allowed the public health authorities to take the action considered necessary. However, quite a number of countries felt the urge to introduce new mandatory systems of notification and reporting.

Passing measures concerning the notification of confirmed cases of AIDS encountered relatively minor difficulties. However, serious controversy aroused when measures were passed requiring the reporting of cases on the basis of seropositivity also. The issue remains under a heated discussion. In this respect, many ministries of health have issued detailed circulars on diagnostic criteria applicable in the detection of cases of AIDS.

At present regulations, by and large, provide for the classification of AIDS as a communicable disease and for its designation as a notifiable disease. However, in some countries, like Sweden for instance, both the provisions of the Prevention of Infectious Diseases Act and of the Ordinance concerning venereal diseases are fully applicable to HIV infection, this raises ethical issues which will be considered later. At the very first stages of the epidemic there was clearly a hesitation as to whether to classify AIDS as a venereal disease. Once a disease is classified as being sexually transmitted it arouses strong negative emotional reactions that impair a fair and efficient approach to the problem and tends to victimize the afflicted persons.

In some instances amendments to the Communicable Diseases regulations have been made through ordinances to promulgate detailed provisions, covering in particular the notification form for reporting AIDS cases; in other instances decrees and ordinances introduced a revised version of the section dealing with the notification procedure. It is noteworthy that some countries have passed regulations making provisions for a different form of notification for AIDS cases, than the one normally used for notifying other diseases. The intention in producing a new form model is to maintain more easily confidentiality concerning the identity of the patient or deceased person, while enabling the medical officer to follow up the case. Some European countries also mention specifically that the system of compulsory notification

foresees measures to safeguard the anonymity and privacy of the individuals concerned. This is the case for instance in Austria, Sweden and in a Swiss bill in preparation.

To sum up this question of notification and reporting one could say that the main preoccupation of the governments in the legislative field has been to enable the health authorities to control contagion and to legalise the measures necessary to prevent the spread of AIDS. In most European countries the reporting of AIDS cases is now based on compulsory notification to the national health authorities, this is the case in Austria, Denmark, Finland, France, Greece, Hungary, Italy, Luxembourg, Monaco, Norway, Sweden. In a few countries the reporting of AIDS cases is part of a monitoring system based on voluntary notification, such as in Belgium, Ireland, and Scotland.

#### 1.2. Measures related to the protection of blood supplies and other donated items

The prevention of transmission of AIDS through blood transfusion is another key area which preoccupied at a very early stage the European countries and prompted the introduction of many measures to modify the rules for institutions dealing with blood supplies.

It should be underlined that the legislative and preventive measures to eliminate the possibilities of transmission of the AIDS virus through blood transfusion were the first ones to be largely taken in the fight against the spread of the AIDS virus. At present the eventuality of transmission of the AIDS virus through blood transfusion is very low compared to other means. A questionnaire on public health measures related to blood transfusion already sent to 22 countries in Europe in 1985 showed that systematic screening of blood donors became effective between June and November 1982 in 16 of the 21 countries which replied. This practice is now firmly established in all European countries and backed up by law. What has been made compulsory is the detection of AIDS antibodies by a laboratory test (ELISA). A second test and a confirmation test are either foreseen in regulations, or implemented in practice in many countries. Specialized consultations for the follow-up of sero-positive subjects is also organized in most countries.

Another type of measures to exclude at risk blood donors have been taken promptly in nearly all the countries. These measures were initiated in 1983 for seven countries, Belgium, Denmark, France, the Netherlands, Norway, Sweden and the United Kingdom, in 1984 for Luxembourg and in 1985 for seven others, Austria, Greece, Iceland, Italy, Poland, Spain and Yugoslavia.

Thus, due to systematic screening of AIDS antibodies in blood donors, prevention of transmission of AIDS through blood transfusion is now effective in all European countries. Even in those where no cases of AIDS have been officially declared.

A vast array of measures have been adopted for the protection of supplies of blood and blood products, in particular for the preparation and utilization of coagulants fractions for hemophylia treatment. Countries have issued detailed regulations obliging blood donation services to observe strict safety precautions that come in addition of course to the testing of blood donors; for instance special measures for the treatment of blood preparations, for the examination of available stored blood, for the screening and elimination of any questionable donors, for information on blood donors. Not only manufacturers, but also importers of blood and blood products are subjects to

the obligation of carrying out the appropriate tests. In view of the ever increasing international trade of medical products, one immediately wonders whether international agreements have been passed or are contemplated to that effect. Noteworthy is the consensus of action of the Member States of the Council of Europe whose Committee of Ministers passed two recommendations in 1983 and 1985 to take appropriate measures to prevent the transmission of AIDS virus through blood.

Turning now to another area of health care, relevant legislation has been introduced to ensure safety precautions to be taken by health care establishments, hemodialysis centers, transplantation centers, histocompatibility centers, concerned with donated organs, tissues and sperm. Mothers' milk depots have also been the target for precautionary measures. Needless to say, to cover the costs of these supplementary blood analysis, special measures have been necessary to allocate extra financial provisions.

To sum up this review on the legislative steps taken to protect blood supplies and other donated items, it should be recalled that this was the first action to be taken promptly and effectively against the propagation of AIDS. An incentive factor for the rapid adoption of these measures lies in the fact that this mode of transmission is directly linked with medical procedures. In addition there was a precedent in this pragmatic approach, on both its technical and legal aspects; this was facilitated by the evidence which had accumulated in successful similar measures taken to combat the viral transmission of infective hepatitis. The rapid emerging consensus of legal and public health authorities was also facilitated by the fact that only minor ethical problems were encountered which, unfortunately, is not the case when tackling, through possible legislative action, the thorny issue of the "high-risk groups".

### 1.3 Measures on preventing the spread of AIDS virus from high-risk groups

To date the epidemiological knowledge of the disease indicates that it is spreading mainly from so called "high-risk behaviour groups" to other sectors of society. High-risk groups are mainly homosexuals, drug addicts, prostitutes; hemophiliacs deserve to be mentioned apart. But being not confined to those "fringe elements" of society, AIDS represents a potential threat to everyone and future spread to the overall community cannot be excluded. Thus in view of taking preventive action against the transmission of AIDS, significant public health activity has taken place in a number of countries.

The measures are somewhat different from country to country depending on factors which characterize these societies and in particular their administrative traditions, their cultural conditions, and their religious peculiarities. The measures may vary considerably depending on whether the country involved is a liberal or a puritanical one. Thus the measures implemented in some countries of our Region may not be applicable in others and should therefore be taken as examples only.

As one might expect in a situation where a frightening disease of epidemic proportion threatens, with no known control measures, the handling of confirmed cases of AIDS has been approached drastically.

In some instances the law subjects patients to a variety of coercitive measures such as obligatory removal to a hospital, confinement in isolation of contagious AIDS persons, penalties for helping the spread of the disease.

This last measure may be the case in some countries where AIDS has been assimilated to venereal disease and where legal measures on the spread of venereal disease foresee such a penalty. In this respect Sweden mentions that the parliament has recently decided to abolish these provisions for AIDS sufferers.

Furthermore various safeguards have been foreseen regarding the disposal of the bodies of persons who died from AIDS. France issued in 1985 an order dealing with the procedures to be followed in such instances. The same year the United Kingdom made operational restrictions placed on the removal from hospitals of a body of an AIDS patient and to require steps to be taken to prevent persons coming into contact with or proximity to the body of an AIDS sufferer when not necessary.

The United Kingdom with a long tradition of being quarantine-minded has enacted measures which may seem severe to others, although recommended in exceptional circumstances. The public health regulations which came into operation in March 1985 make provisions such as: Allowing a justice of peace to make an order for a person believed to be suffering from AIDS to be examined by a registered medical practitioner; allowing a local authority, with the consent of appropriate health authorities, to make an application to a justice of peace for an order to remove a person suffering from AIDS to a hospital, when there is a risk to other persons; allowing a local authority to make an application to a justice of peace to have an AIDS patient detained in a hospital.

Focusing now on the high-risk groups, a two-part control strategy has been envisaged: measures to reduce the spread of the virus within the risk-groups, and, from the risk groups to the general population.

Regarding the drug addicts group, preventive action was first taken in those countries which have a rather liberal attitude towards adolescents and youth problems and it implies of course health information and health education which points out the special risk involved in such practice. A practical step was taken towards intravenous drug abusers sharing needles and syringes.

In countries, where syringes and needles are freely available in pharmacies and drugstores, like Austria, Belgium, the Federal Republic of Germany, Italy, Spain, Denmark, and the Netherlands, sometimes the pharmacists were in fact reluctant to sell them. In some cases the Government has found it necessary to remind the profession that no prohibition existed in the law and consequently they should respond to consumers request.

Two of the above mentioned countries i.e. Denmark and the Netherlands have developed their drug policy focusing on efforts to protect drug users from the effect of criminalization and marginalisation. In these two countries there is easy access to treatment and easy access to disposable syringes and needles as part of prevention efforts; for instance in Amsterdam the initiative was taken to implement an exchange system for syringes.

In other countries, like Sweden, syringes and needles are not available freely but are only delivered on prescription from a physician. This has been discussed in the Swedish Government Commission on AIDS and forms part of a policy including a large treatment programme for drug abusers for which considerable financial resources have been freed. France has recently repealed the relevant decree dating back to 1972 and syringes and needles are now available without prescription.

Regarding homosexuals and bisexuals who represent the highest risk of infection, the most important means at present available of limiting the spread of infection within the group and to the community at large, is the provision of information about the disease, the probable routes of transmission, the possible ways and means of reducing the risk of contagion, and, in particular, the avoidance of multiple sexual partners. Measures have been taken by health authorities to fulfil and finance education campaigns. The risk of infection being reduced by the use of condoms, a precaution in any kind of multiple sexual contacts, more and more countries have taken measures not only to advertise its use, but also to make them easily available, specially in public places, to impersonalize a private desire.

Prostitution is a potentially dangerous road which leads to an increased risk with the AIDS virus. There is no doubt that much is known and much has been done in the legislative field about sexually transmitted diseases. This includes measures to improve vigilance specially in places and areas of greatest potential hazard, measures allowing systematic screening of prostitutes and closure of places of sexual practice.

Finally, most countries have urged people in all these high-risk groups to refrain from donating blood, plasma, body organs, other tissues and sperm and the law has confirmed the exclusion of these groups from these operations.

#### 1.4 Preventing the spread of infection to health care workers

Because of the gaps in knowledge, in the transmission of AIDS, in the first years of the epidemic, there has been much concern for the spread of infection to hospital staff and other health care workers, in particular those exposed, through accidental needle stick injury, to AIDS contaminated blood.

It seems that at present, in Europe, there is no clear evidence of cases related to that kind of exposure. Nevertheless, as this represents a hazard, there is still some concern over the occupational risk for health workers handling specimen from AIDS patients, but, to our knowledge, no special legislative measures have been taken. In fact, evidence has accumulated that measures taken to avoid the transmission of hepatitis B virus are sufficient to protect staff against AIDS infection.

#### 1.5 Other means of Governments' support

##### 1.5.1 The financial issue

Considerable funds will have to be made available to finance all sorts of activities linked to AIDS issues like those previously mentioned.

In countries such as European ones, the diagnostic and patient care procedure will be comprehensive and, consequently, very costly. We have pointed out that to cover the cost of many supplementary blood analyses for the detection of AIDS virus in blood supplies, large extra financial provisions had to be allocated. Expenditures are secured for the detection of AIDS in drug dependent persons, for the free distribution of syringes and needles, for establishing alternative diagnostic sites.

Financial resources have been made available for health education and health information campaigns. Large funds have to be allotted for AIDS research, which is now at its peak worldwide. In countries where the AIDS infection is spreading, the cost of the disease may have a marked impact on

health economy. Thus Governments have to take the legislative measures to divert a considerable part of their health care budget to support their special programme on AIDS. In this respect, noteworthy is the text adopted in 1986 by the European Parliament calling on Ministers of Health of their Member States to support action by joint decisions and by earmarking the necessary resources.

#### 1.5.2 The health education and information issue

A review of legislative measures to prevent the spread of AIDS epidemic must stress the importance of governmental support to health education and health information activities. They are well exploited in many places. An example of a health education campaign in full swing is the one actually organized in the United Kingdom. The French Ministry of Health is also launching a vast campaign. Many other countries have taken steps to prepare such health education and information campaign including the proper allocation of financial resources to support it.

In May 1986 a resolution was passed by the European Communities requesting their Member States and the Commission to examine what joint action can be developed in the field of health information and education to bolster the campaign against AIDS. It further requests the Commission to organize an exchange of information and experience in connexion with the main medical, psychological and social problems of persons with a positive serology and in particular suffering from AIDS.

To conclude this first part on legislative measures to reduce the spread of AIDS, it might be appropriate to quote from the "Guidelines on AIDS in Europe", published by the Regional Office for Europe of WHO in 1986: the most effective control measures will be somewhat different from country to country, they will depend on cultural and administrative traditions, they will however involve health information, health education and health legislation.

## II. Ethical issues

During the pasts two decades, the unprecedented advances and discoveries in biology and medicine have prompted a host of moral and ethical issues amongst both the professionals and society as a whole, to the point where governments have felt the need to install national ethical review committees to guide them and advise on measures to be taken.

However, nothing, up to now, in our societies, has amounted to the present challenge created by AIDS. Among numerous ethical issues the following ones have particularly retained out attention.

### 2.1 Confidentiality of information

It has become clear that some countries such as, for instance, Sweden, Switzerland, Austria, are endeavouring to ensure that personal data on AIDS remains strictly confidential, and that reported cases are mentioned in a way safeguarding anonymity, at the same time that these countries take care of the legitimate public health, epidemiological and research needs.

In spite of all precautionary measures taken, technical, administrative, legal, the possible threat to confidentiality, in health matters in general and particularly concerning communicable diseases and sexually transmitted diseases, is a very sensitive subject.

The seropositive persons are very much concerned and their fears are justified. Too many dramatic consequences have been reported involving cases of persons being heavily penalized for the stigma of their disease or because of the sexual preference it sometimes reveals.

Data about seropositive and AIDS patients should not be transmitted to third parties such as employers and the insurance companies. If data were transmitted they could be used to discriminate in hiring, promoting and retaining employees. This would create incommensurable social problems to those individuals who on the contrary are in need of help and social support. Moreover, the knowledge we have about the way the AIDS virus is transmitted does not provide any justification for mandatory screening. If such screening practices by employers and insurers would develop, the legislator would have to intervene in order to prevent seropositive persons from being discriminated.

Certainly individual human dignity has to be balanced against the health of the community but great harm can be inflicted to the society if individual human rights are compromised to a point where it disrupts the fabric of society.

## 2.2 The tracing of contact cases

Physicians are deeply concerned with the need to develop a strategy for tracing contacts of confirmed cases of AIDS. As soon as the notion of risk is involved, contact cases are a target for the preventive work of the epidemiologist. As HIV infection is frequently asymptomatic and the disease may develop only several years after the infection was contracted, it is important to get in touch with infected person's contacts. The question is, then, should designated contacts be systematically approached and directed to a physician who will decide what follow-up measures are necessary? If they wish so only, or should it be compulsory?

How will the reporting be done concerning persons who have been in contact with the AIDS sufferer? Will it be the same detailed requirements as for reporting an infected person? Will their identity be protected as well? Will it be necessary to collect further information about their lifestyle and eventual belonging to high risk-groups where sexual promiscuity exists, taking into account that this is the main means of propagation?

## 2.3 Information of the public and testing sites

There is also the problem of health information of the public at large. If blood receivers are rather well informed of the systematic preventive test enforced in 1985, unjustified fear may persist among people who may not have understood that only receivers are at risks. It may deter potential donors from giving blood, a serious situation in view of the constant increasing demand for blood transfusion. Hence the importance of the health information and the effective measures to organize it.

On the other hand, the fact that the test for AIDS infection is free of charge for blood donors may attract those, in particular from the high risk-groups, looking for free consultation to be informed about whether they are carriers or not. It certainly represents an added potential risk for blood transfusion centers. An interesting answer may be found in the creation of alternative testing sites for the diagnosis of AIDS. This proposal is already envisaged by many countries, albeit an expensive one. Austria for instance has already taken such steps and established testing sites with guarantee of strict confidentiality and subventioned by the Government although organised by non-governmental organizations.

## 2.4 The problem of serological false results

When serological tests are performed for the detection of AIDS laboratories are faced with the possibility of error. These fortunately are small in number but create serious situations. The laboratory may be faced with the dual problem of false-negative results (the virus is present but anti-bodies cannot be detected) and of false-positive results (accidental detection of anti-bodies although no virus is present). The problem is not easy to solve and in both instances troublesome.

With regard to false-negative results the possibility of establishing early diagnosis is missed, thus depriving the patient of the necessary follow-up measures. In the case of blood donors the detection of potentially infective persons is missed thus providing the possibility to transmit the disease. Although, at present, the risk of such transmission remains very low, nevertheless it is still a worry to the medical profession which while trying to cure a disease may in fact happen to transmit it.

With regard to false-positive results the problem is quite different and of a more psychological nature. Unnecessary anxiety, fear and other unfortunate reactions are aroused when the person being tested is informed. By and large in European countries faced with positive or doubtful results the approach is to have the first "routine test" systematically followed by a "confirmation test" using a different technique before the positive result is announced. However, that has not always been the case, and regrettable practices may still be going on. It is an issue which stresses the importance of rigorous confidentiality procedures. While it may be simple to correct faulty technical procedures, it is not so easy to eliminate the discomfort of a residual fear in a person's mind, or the persistent damage of the stigma of a false information.

There is also a financial aspect to this question. Routine tests are already costly, confirmatory tests need specialized laboratories and are quite expensive, only countries economically advanced can afford the supplementary cost. This is an issue which creates serious health economics difficulties outside Europe.

## 2.5 Perinatal transmission

One of the most dramatic situation is that of babies and children with AIDS who represent a high percentage of cases. It is a distressing problem specially concerning pregnant women. If they host the virus they can infect their child, not only during breast feeding, but also during their pregnancy.

The issue is particularly distressing on the one hand because many cases of AIDS occur amongst women in their reproductive years and on the other hand the child is contaminated in about 50% of the cases.

A serie of questions is therefore raised. Faced with an AIDS infected pregnant woman has the attending physician taken all the necessary measures to avoid parents finding themselves with an infected newborn child? What in fact should the doctor recommend to the expectant women after having fully informed her of what is actually known, including the gaps in medical knowledge. In the absence of a specific treatment should abortion be envisaged? What if the case represents the last chance of pregnancy? How forcefully should it be put to the couple? Parents may have to face some of the most difficult decisions

that could be imposed on anyone. Since prevention is at present the only way to fight AIDS, one could resort to prenuptial tests as in the case of the detection of syphilis. Should it be recommended only or systematically imposed?

## 2.6 Patient-doctor relationship

A fundamental principle that appears is a responsibility or even more an obligation for anyone, who has a reason to believe he or she has been infected, to contact a physician. The choice of the physician or institution is free or not, this varies between countries.

Then obligations are foreseen for the physician who sees this patient. The doctor is duty bound to carry out an examination. He has to inform health authorities (local, central) and other institutes (e.g. National Blood Transfusion Institute) so that measures of prevention are taken (e.g. risks to other persons). The physician has to give the proper information to the patient. Some legislation foresees that if the doctor feels he is unable to give an infected person the psycho-social support needed, he must arrange for the patient to be transferred to a doctor who is able to do so. So there is a responsibility of the first contact physician and a responsibility of other health authorities.

The information given to the patient is also seen as an incentive for a responsible behaviour and for collaboration in avoiding the spread of the disease. In some countries provisions were made that the need for counselling of persons with positive blood tests can be filled even better, not so much by creating any special institution for that, but rather by the traditional way of treating persons whose health is in danger, i.e. by the personal physician.

It seems that taking into consideration the specific psychological, social and ethical aspects of this new disease, the situation calls for a new type of doctor-patient relationship in order to bring additional social and moral comfort to AIDS sufferers.

## CONCLUSION

These were only some of the numerous ethical and closely related social and political issues deriving from the AIDS challenge to science, medicine and society. AIDS problems can be seen from a variety of perspectives. What seems to be at present the main issues have been reported with the aim of contributing to the discussions of this meeting. Being aware of the problems and having the courage to face them as well as their consequences is more important than rushing into quick solutions that may preserve egoistic interests but overlook the responsibility of the collectivity towards AIDS sufferers.