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OPINION AND RECOMMENDATION

SCREENING

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HIV TESTING DURING PREGNANCY AND THE PERINAAL PREVENTION OF MOTHER-TO-CHILD TRANSMISSION

SUMMARY

Drafted and submitted by the Ad hoc Committee on Screening and Testing Approved at the plenary session of March 14th 2002.

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The present statement, complete with recommendations, was established at the request of the investigators of the French Perinatal Survey (FPS). Professor Stéphane BLANCHE, MD[1], having observed that perinatal HIV transmission from mother to child still exists, asked for the Council's opinion on the advisability of compulsory routine testing of pregnant women.

The National AIDS Council examined the possibility of a change in the policy of voluntary and informed consent not only in terms of benefits and risks incurred but also as regards actual testing procedures applied to pregnant women in gynecologic and obstetrical wards. The Council's statement as a whole only deals with women who complete pregnancies.[2]. The Council's investigation has indeed gone beyond prenatal testing and considered conditions of care and follow up during pregnancy.

After briefly retracing the outstanding items of the issue submitted to the Council, the statement delineates reasons why the Council is opposed to compulsory testing for pregnant women. This is followed by various recommendations designed to improve efficiency of HIV mother-to-child transmission prevention measures.

1 TESTING PREGNANT WOMEN IN FRANCE : BENEFITS AND LIMITATIONS

1.1 A DECLINING MOTHER-TO-CHILD HIV TRANSMISSION RATE BUT STILL TOO HIGH CONSIDERING AVAILABLE MEDICAL TECHNOLOGY

Since 1991, the prevalence of HIV infection seems to be stabilized among pregnant women having given birth in France (roughly 0.25 % in Ile-de-France and Provence-Alpes-Côte¬d'Azur regions)[3] ; the mother-to-child transmission rate is now only 2 % to 3 % of births from HIV positive mothers[4].

Available surveys show that a vast majority of HIV infected pregnant women receiving care in France are nowadays infected through heterosexual intercourse. They tend to be younger and have more babies than other pregnant women. Several sources show that HIV prevalence is much higher among pregnant women born in Sub-Saharan Africa : in 1997 the prevalence rate was 7.9 times higher than among pregnant women born in France[5].

Vertical transmission from mother-to-child and through breast-feeding is one of the transmission routes of HIV. Still particularly high in most developing countries, mother-to¬child transmission (MTCT) has considerably decreased in France over the past decade. Progress is evidenced by data from the cohort of pregnant women considered in the FPS and from the epidemiological and clinical data supplied by the yearly reported new AIDS cases[6].

[1] Necker-Enfants malades Hospital, Paris.

[2] A relatively high proportion of HIV positive pregnant women have abortions.

[3] Couturier et al., 1998.

[4] Delfraissy, 2000.

[5] Couturier et al., 1998.

[6] Lot, 2000.

The decrease in the MTCT rate, which was 7 to 8 times higher before the implementation of appropriate treatments, is due to the combination of possible treatment for women during pregnancy, prevention measures during delivery and infection prophylaxis for the newborns.

When the immunological and especially virological condition of the pregnant woman already receiving antiretroviral treatment for herself is satisfactory, that treatment enables to substantially reduce the risks of infection for the infant. In opposite cases (virological failure or lack of treatment for the mother-to-be) a treatment initiated during the third trimester of pregnancy can effectively prevent MTCT. Even when this type of preventive treatment has not been initiated, it is still possible to reduce MTCT risks in a significant way for women accessing late medical care or during delivery, through short antiretroviral regimens. Lastly, routine treatment of the neonate for six weeks after birth also helps minimize risks of infection[7].

Medical technology does therefore enable efficient intervention on the risks of viral MTCT and infection risks to the neonate, whatever time treatment is inititaed, through various therapeutic, preventive and prophylactic strategies. It is possible, when requirements are respected and breast-feeding avoided, to reduce the MTCT rate to under 2 % of births from HIV positive women.

The important progress made in that area field has however been made possible through an efficient monitoring system of HIV infection in pregnant women. The French Perinatal Survey shows that in 1999, in the cohort of HIV positive mothers, 28 % had been diagnosed during pregnancy. According to the national perinatal survey carried out over one week in 1998 on all the women who had given birth in France, 89.4 % of those who had not been previously tested for HIV said that they had had the test because of pregnancy[8] .

Improvement of care has therefore been undeniably successful. But the actual rate of HIV transmission from mother-to-child is still higher than it could be if all HIV positive pregnant women benefitted from appropriate measures. The overall difference (under 1 %) may seem slight. But the often dramatic impact of perinatal HIV infection on the child and its family, is such that preventing it remains a major objective.

1.2 THE ELEMENTS OF THE ISSUE AS REFERRED TO THE NATIONAL AIDS COUNCIL: QUESTIONING THE BASIC PRINCIPLE OF INFORMED CONSENT TO HIV TESTING

France's policy on prenatal HIV testing of pregnant women is based on the principle of compulsory offer by a physician during the first prenatal visit, with the possibility for the woman to accept or refuse. As stipulated by the regulations of 1993[9], prior to the test information on transmission risks must be provided; whether this relates to possible infection of the woman, her partner or her child is not specified.

The FPS investigators reported to the National AIDS Council that some physicians, so as to reduce as much as possible the number of children born with HIV infection, suggest that compulsory testing of pregnant women at the outstart of pregnancy would be an appropriate solution.

Several reasons were put forward to justify a possible modification of the law. First, women would no longer be able to refuse the test. Second, it would raise physicians' awareness of transmission risks and of the necessity of carrying out prenatal HIV screening. These two elements would guarantee the offer of preventive treatment of MTCT for each and every pregnant woman going to prenatal visits.

The National AIDS Council examined this suggestion very carefully, in the light of the elements which enable to evaluate its consequences as compared with current testing policies. The Council does however regret the lack of data - which was needed to back up its investigation - on the estimated number of children born to HIV positive women who are unaware of their serostatus[10].

[7] Delfraissy, 2000 and Berrebi, 2001.

[8] Vayssière et al., 1999

[9] Law n° 93-121 of January 27th 1993 on various social measures, published in the French Official Journal of January 31st 1993. Article 48 establishes as follows article L 2122-1 (new nomenclature) of the Public Health Code : « At the first prenatal visit, following information on risks of infection, an HIV test is offered to the pregnant woman ».

[10] The FPS's perinatal cohort only includes women whose seropositivity is known.

2 PRINCIPLES, TESTING PROCEDURES, AND CONSEQUENCES OF COMPULSORY TESTING OF PREGNANT WOMEN

Testing pregnant women in France follows a general rule of voluntary and informed consent of the person to HIV testing. The administrative regulations that establish precise testing modalities therefore apply to all testing procedures. The National AIDS Council acknowledges that there may well be epidemiological and health situations, such as the protection of another person's health, which can occasionally justify a test without consent[11] . The National AIDS Council nonetheless considers that testing practices in France being what they are nowadays, compulsory testing of pregnant women, where the benefit would be unlikely, is an ethical risk that could jeopardize overall informed consent to testing.

2.1 VOLUNTARY TESTING OF PREGNANT WOMEN IN FRANCE: CURRENT FRAMEWORKS AND OBJECTIVES

ORGANIZATION OF TESTING PROCEDURES FOR PREGNANT WOMEN

Modalities and, to some extent, objectives of prenatal HIV testing of pregnant women were established in a circular of January 29th 1993 sent to all local health authorities[12].

This document is a reminder of general testing procedures for HIV and it highlights certain aspects for physicians' benefit, particularly as regards prenatal testing :

- testing is voluntary (it can be refused);

- it must be offered during a « personalized counselling » session which is part of a medical visit. The visit is an « ideal time to inform the patient on HIV infection, identify with the patient any possible risk factors and provide advice on prevention. The physician must also explain the significance of and obtain consent for, the test. During the prenatal visit, depending on the results of the test, the physician must broach, with the woman, « the consequences on the pregnancy's outcome »;

- « results, whether positive or negative, must always be communicated to the patient during a personalized medical counselling visit ». This must be an opportunity to raise

- awareness of prevention behaviours and the physician must, if the result is positive, urge the woman to receive early medical and psycho-social care;

- any testing visit must allow for « referral to one or several visits designed to provide medical care to HIV positive people » and « referral to settings specializing in psychological and social support »;

- at prenatal visits in MCH (mother-and-child health) centres, patients who are offered or ask for, a test are entitled to free testing.

In this document, the Health Authority deliberately emphasized various principles and the strong belief that voluntary and free testing is an essential contribution to a prevention objective, when it is carried out in the required conditions. That however is not its sole function.

VOLUNTARY AND INFORMED CONSENT TO TESTING : OBJECTIVES AND PURPOSES OF THE PROCESS

Choosing to encourage the free-will of a person likely to have a test, is designed, except in some rare cases[13], to meet objectives of individual empowerment and education in care and prevention which the National AIDS Council firmly believes in. It is also, when testing implies a specific blood sample, an ethical choice of respect for body integrity, which is guaranteed by law[14].

Counselling must help the patient to make a decision according to his or her behaviour; the physician must therefore not only explain how the virus is transmitted but also make sure that explanations are correctly understood so that the patient's choice is truly informed.

[11] See the Statement on « Testing in health care settings following exposure to blood and without possible patient consent to a test » approved at the Council's plenary session of October 12th 2000.

[12] DGS Circular n° 09 of January 29th 1993 on the free and anonymous or free HIV testing programme, not published in the Official Journal.

[13] Confer the Statement on « Testing in health care settings following exposure to blood and without possible patient consent to a test » approved at the Council's plenary session of October 12th 2000.

[14] According to article 7 of Law n° 93-5 of January 4th 1993, « taking or attempting to take blood from a person without that person's consent » is punishable by five years prison sentence and considerable fines.

Encouraged to assess her own behaviours and that of her partner(s) through the physician's counselling, at a prenatal visit, the woman must first of all be clearly informed about the benefit of prenatal testing for reducing a vital risk to her baby. Ideally she will thus be able to circulate information and advice to her family and friends. In this manner, the prevention purpose of testing is closely linked to the the woman's free choice for testing. It also has to do with the will to promote best possible access to and follow up of, care. Understanding the test, understanding the implications of HIV infection and the way to cope, are imperative for medical care to be the most appropriate. Voluntary testing is therefore designed, in this case, to improve therapeutic care of women with HIV, prevention of MTCT and care for the infant in case of infection.

Any modification of the current policy must therefore be based on careful assessment of benefits and risks that might be generated by the change in modalities of access to prenatal testing in the sense of coercing pregnant women.

2.2 ASSESSING EXPECTED BENEFITS AND RISKS OF COMPULSORY TESTING OF PREGNANT WOMEN

One must never forget that compulsory HIV testing of pregnant women would only be designed to prevent some women from refusing the test or some physicians from supposedly forgetting to offer the test; in the case of voluntary testing, such refusals and omissions allegedly explain the unawareness of some women's HIV serostatus. Compulsory testing could not however respond to the very diversified and, to date, poorly documented situations in which appropriate care is lacking and which explain why unborn and newborn babies are still infected.

UNLIKELY BENEFITS

The alleged benefits of compulsory prenatal testing are related to two hypotheses considered separately as follows.

According to the first hypothesis, banning test refusal would cause a decrease in the number of women who, unaware of their positive HIV status, give birth to an HIV infected baby.

Given that 97 % of pregnant women with a positive HIV test and who give birth, accept preventive treatment[15], the hypothesis of a maximal gain through compulsory testing is based on the following assumptions :

- women with a negative result would not be infected during the rest of their pregnancy ;
- HIV positive women who refuse the test, in the current no coercive situation, would massively accept available treatments ;
- these women would have high quality pregnancy care ;
- they would agree not to breast-feed their babies.

Efficiency of compulsory testing also implies that it would have no adverse effect at all on women who at present accept the test, which would of course cancel the expected benefit.

The National AIDS Council must first and foremost point out[16] that it is strange to have to take a stand on the quantitative impact of a compulsory testing measure without knowing for sure exactly how many mothers give birth without having been informed about their seropositivity[17]. To date, only inconsistent estimates are available, owing to lack of ad hoc reporting on refusals and lack of a compulsory serostatus reporting system enabling to cross-check data provided by the French perinatal survey.

The potential quantitative benefit cannot therefore be evidenced, especially as almost all women accept the test offered at the first prenatal visit.

Beyond the issue as submitted, the Council considers that improving testing procedures and care for HIV positive women so as to prevent HIV mother-to-child transmission requires highly improved data collecting.

This applies both to estimates of the number of HIV infected infants through vertical transmission and the regular evaluation of prenatal testing procedures. For want of such data, it would remain terribly difficult to improve in every possible way the policy concerned.

[15] FPS data as quoted by Delfraissy, 2000.

[16] As did the High Committee for Public Health in its Statement and report on HIV testing, in March 1992 (page 20).

[17] The French perinatal Survey being based on identified HIV positive women, it does however enable to consider that women whose seropositivity was discovered too late following initial test refusal, would be concerned by the consequences of modified legislation.

The other hypothesis put to the Council is more unobtrusive than the first. It assumes that if patients are coerced, then physicians would be less likely to forget to offer testing and more tests would be carried out.

In this respect, available surveys, even if they are not recent, show that routine testing of pregnant women is already common practice. In the Paris area, HIV testing was carried out in all public settings for pregnant women who wished to have their babies, and in the private sector, 97% of interviewed physicians did the test during prenatal visits[18]. Unless one accepts that over the past few years medical practices have become slack – this would require raising duty awareness of all carers involved – the theory does not seem to be valid.

POTENTIAL RISKS THAT DO NOT JUSTIFY RULING OUT INFORMED AND CONSENTED-BASED TESTING

As regards overall HIV testing situations, the National AIDS Council must emphasize how important it is, especially in a context of less safe-sex, not to upgrade the systematic aspect of testing procedures detrimentally to their educational role. Making testing compulsory (just like testing without patients' knowing) could lead to neglecting counselling which must be ensured by the physician prior to test decision-making. The prevention effect of the procedure might well thus be lessened for the sole purpose of getting serological data on the patients concerned and subsequently demote the test.

The National AIDS Council must stress that HIV testing cannot be put on the same level as other, routine, prenatal tests, such as rubella or toxoplasmosis. Realizing that one is HIV positive makes for a period of extreme vulnerability and can have extremely serious consequences if the person has not been well prepared. Pregnancy is in itself a particularly important period of life. Disclosing to a woman who has not been well prepared that she is HIV positive during this period could lead her to have many doubts and queries on her private behaviours and her partner's, on her status as a mother-to-be and, in the long run, on her survival and that of her child. By anticipating moral reproof about her private life, her ability as a future mother, even advice on a possible abortion, that woman might prefer to shirk any offer of treatment.

The principle of voluntary and informed consent and the current organization of voluntary testing are designed to promote patients' empowerment and medical care ; this is why understanding seropositivity and treatments implied by HIV infection must be ensured. Accepting that all pregnant women be coercively tested at prenatal visits could amount to increased tests without their knowing, the serology test being included in a set of routine tests designed for prenatal care. Studies on patients' adherence to treatment do however show how important information is and how important it is for patients to be included in all therapeutic decision-making. Trust between patient and care provider plays an essential part in patients' adherence to successful care[19].

The Council expresses is concerned that coercing future mothers into testing, instead of promoting preventive treatment for the greataest possible number, might on the contrary be detrimental to access to care and overall compliance among HIV positive pregnant women.

Under the circumstances, the Council does not consider it advisable to revise the non coercive policy of HIV testing of pregnant women. Possible benefits of a coercive measure are doubtful and risks incurred seem high.

3 PERINATAL HIV MOTHER-TO-CHILD TRANSMISSION IN FRANCE : A WIDE RANGE OF SITUATIONS

Having carefully examined the actual situations involving an MTCT risk, the National AIDS Council suggests various improvements in several aspects of pregnancy care. They concern testing procedures, perinatal care, both medical and social, and the legal provisions on prenatal HIV testing.

3.1 REINFORCING RESPECT OF/ATTENTION TO GOOD TESTING PRACTICES

PRENATAL TESTING REFUSAL AND INFORMATION OF PREGNANT WOMEN

The various available studies show how unusual HIV testing refusals at the first prenatal visit are compared to the number of women testing is offered to.

When the refusal occurs whilst the patient is not yet aware of her HIV serostatus, it can to some extent reasonably be ascribed to the pregnant woman's negative representations. The meaning of the test may not have been correctly understood or the efficiency of

[18] Couturier et al, 1999.

[19] On adherence to HIV/AIDS treatment, see Bessette et al., 2001.

medical care for HIV and of MTCT prevention may have been underestimated. The issue is then to convince the patient, in a clear and comprehensible way, on the potential and effect of the various medical interventions.

Wanting to conceal HIV status that the person already knows about, can be the reason for some test refusals, as corroborated by as yet unpublished data from the FPS. This type of behaviour can be analysed as a « denial » of the infection. It is related to several types of explanation that are not exclusive of one another: an undue feeling of guilt or anxiety, the fear of serostatus being disclosed to family and friends, and subsequent stigma and rejection, and/or misinterpretation of the relation between risks and benefits of treatment.

Whatever the case may be, it seems that part of the problems can be solved by talking to the clinician and getting his/her advice on the issue of testing for HIV and him/her being able to answer in an appropriate way to questions asked by pregnant women. Counselling prior to consent to the test must therefore be carefully provided as it concerns all at the same time: offering information on how and why the test; presenting opportunities of medical prevention of MTCT and the possibilities of care for the patient's possible own infection; clearly guaranteeing total confidentiality about the test.

From this angle, it would seem that procedures actually applied in prenatal visits, ought to be considerably perfected. The proportion of physicians who test women without their consent

(i.e. without the patients' knowing or against the patients' will) is high : for the Paris region in 1997, an estimated 11% in public settings and 29% in the private sector[20]. The fact that a low proportion of settings routinely provide information on the risks of HIV infection may well mean that pre-test counselling for pregnant women is sometimes nonexistent and often very far from perfect. A number of reasons can explain this state of things; it must however be stressed that this is a breach of regulations on testing and of good practice recommendations.

Prior to the prenatal visit, it is the duty of all support settings, welfare and medico-social settings (MCH centres, planned parenthood centres, shelters…) who care for women of child bearing age or pregnant women, to provide complete information on the benefits of testing, on the issues of early HIV care and on possibilities of reducing MTCT, so as to promote voluntary testing.

THE IMPORTANCE OF ROUTINE MEDICAL COUNSELLING WHEN RESULTS ARE COMMUNICATED

Even when a pregnant woman is diagnosed with HIV at the beginning of pregnancy, she can still refuse preventive treatment for mother-to-child transmission of the virus. This is a circumstance that occurs even more rarely than the previous one, indeed among the 3 % of identified untreated HIV positive pregnant women[21], only some refuse this treatment[22]. The number seems to have decreased since the implementation of antiretroviral combination therapy. Here again, reasons for such refusals can vary: fear of serostatus being disclosed to family and friends, adverse and sometimes serious effects of some treatments, misperception of benefits and efficiency of treatments…

The talk between a physician and a pregnant woman, both before the test and when HIV positive results are communicated, is from this standpoint the crucial time for setting a compliant behaviour. This is when the various aspects of care can be talked through and (as the case may be) the woman referred to specialized teams for her own treatment if such is not yet the case.

It must moreover be emphasized just how important this talk is for providing clear recommendations designed to avoid breast feeding once the child is born; it appears that a few infants have been infected in this way over the last few years. Considering the possibility that some women overrule the contraindication or were not warned, the Council suggests that an effort be made to raise awareness among physicians, specially pediatricians, on the risk of HIV transmission through breast feeding. HIV infection is an absolute contraindication for breast feeding and therefore requires pediatricians to make sure no breast feeding mother is HIV positive.

As regards medical counselling during the prenatal stage, the National AIDS Council has already stated its astonishment that a number of tests are done without pregnant women's consent. The aforementioned survey on testing procedures also shows that there is no standard communication of test results, which means that regulations and recommendations are overruled.

Thus[23], information on HIV infection was only routinely supplied to pregnant women in public settings in 60% of Parisian settings in 1997. A mere 17% of private physicians provided such information routinely and 50% were alleged never to do so.

[20] Couturier et al., 1999.

[21] Delfraissy, 2000.

[22] The rareness of such refusals is evidenced in unpublished FPS data. At local level, some medical investigators of the French Perintatal survey reported a relative frequency among the women in their wards.

[23] Couturier et al., 1999.

Other findings from the survey show that results of the test were communicated to the patient by the prescribing physician in 70% of public settings (while the private sector seems to have haphazard practices as the result can be directly communicated by the laboratory that actually tested the sample). Inasmuch as 90% of public sector physicians who prescribe a test to a pregnant woman tested HIV positive, ensure pregnancy care till delivery, this discontinued therapeutic relationship can be detrimental to optimized treatment follow up. Lastly, in some private settings, HIV positive mothers-to-be are not routinely advised against breastfeeding.

The assumption that such practices can lead to distrust towards medical care, to treatment refusal and to poor information of HIV positive women, must seriously be considered.

For the National AIDS Council, testing procedures within the framework of prenatal visits in early pregnancy, are very far from perfect; test refusals both among women who are unaware of their serostatus and among those who know they are HIV positive, treatment refusals, poor compliance or breasfeeding with HIV infection can be avoided by improving routine test offers and disclosure circumstances. Regulations (laws and circulars) should be carefully respected by prescribing physicians and should be regularly evaluated by the Health Authorities[24].

The Council stresses that informed consent for testing is part of recommendations endorsed at international level. This endorsement is echoed by a set of national legal, administrative and ethical[25] standards including the recent Law on Patients' Rights and Health Care System Quality which instates a right to patients' information « on the various investigations, treatments or preventive actions that are offered »[26]. Law n° 93-121 of January 27th 1993 clearly establishes that at the first prenatal visit a test is « offered ». To the information on infection risks (whatever these may be, therefore including infection of the unborn baby), the pursuant circular of January 29th 1993 mentioned above, adds physicians' duty to counsel and refer, before and after the test, whether or not the woman is HIV positive. During the visit, guarantees must be expressed on the total confidentiaity of information on possible Hiv infection.

Beyond the issue of respecting rules and regulations, the National AIDS Council acknowledges that there are pregnant women with problems related to follow up and communication with health care settings. Such difficulties probably have something to do with test or care refusals. They may however generate other situations that can cause infection of the unborn baby.

3.2 REINFORCING INTERDISCIPLINARY CARE AND FOLLOW UP OF HIV POSITIVE PREGNANT WOMEN

Various occurrences contribute to the inadequacies of the MTCT prevention programme that were reported to the National AIDS Council. As regards initial pregnancy care, problems affect :

- women never having been tested for HIV and receiving no prenatal care;
- women no longer in touch who are unaware of their positive result because after they agreed to have a test, either it was not done or the results could not be communicated;
- women who are aware of their seropositivity but are no longer in touch after having just started pregnancy care.

Such occurrences are likely to lead to delayed pregnancy care. There can even be unawareness of a woman's HIV status at the time of delivery or an HIV test that is too late (right at the end of pregnancy, just before delivery) to enable satisfactory prevention of MTCT in case of HIV positivity.

The impact of poor pregnancy care is not only detrimental in terms of HIV infection. Late or too irregular, it can have consequences on the child's overall health. Surveys[27] carried out in the general population on pregnancies with poor care or none at all can therefore provide information on reasons and associated risk factors.

When questioned about reasons for poor follow up, the pregnant women concerned gave the following reasons :

-unintended pregnancy or late discovery[28] ;

- wanting to conceal pregnancy in an adverse family context;

[24] The latest surveys deserve to be updated.

[25] Medical Ethics Code, article 36 : « (…) the patient's consent must be sought in every case. When the patient, able to express his or her will, refuses examinations or treatment as offered, the physician must respect that refusal after having informed the patient of the consequences (…) ».

[26] Article 6 formulating new article L 1111-2 of the Public Health Code.

[27] See in particular Blondel and Marshall, 1996 and Badeyan et al., 2000.

[28] The high rate of abortions before seropositivity is known, in the European cohort of HIV positive women, shows that they tend to plan pregnancies less than the general population. See Van Benthem et al., 2000 ; Heard, 2001.

- distance from or access problems to, health care facilities;
- financial problems.

Nationality is a controversial risk marker. Women who are nationals of Sub-Saharan African countries are considerably over-represented in the population receiving poor pregnancy care but nationality in itself is not a risk factor. Its effect is cancelled out when the impact of lack of health insurance among these African women is taken into account. According to some studies[29], lack of health insurance multiplies by 22 the risk of having poor pregnancy care whatever the woman's nationality. Irregular residence in France, unawareness of mother-and-child health services, as well as pregnancy initiated in a country with inadequate health care settings, also have a significant impact. Lastly, secondary risk factors can also adversely affect the women concerned: coping with a foreign language, apprehension of physicians' judgmental attitudes on their choosing to have a baby despite difficult family circumstances, child-minding problems affecting hospital appointments and fear of being examined by a man.

Specifically concerning HIV positive women, one cannot disregard possible fear of having their serostatus disclosed to family and friends judged to be hostile; this could explain their going to other health care facilities so as to partly avoid care (this problem is similar to treatment refusal).

Considering how critical pregnancy follow up is for the prevention of MTCT, the Council considers that any obstetrical team caring for a pregnant woman must attempt as soon as possible to diagnose any possible HIV infection; if that woman does not have recent test results, a test must be offered as required at the first prenatal visit. If care is only accessed at the time of delivery and if serostatus is not known, using rapid tests could, as a last resort, be useful for initiating emergency prophylaxis.

The Council considers that gynecologic and obstetrical teams should receive training in HIV care and pre- and post test counselling. Links with specialized HIV care providers, ideally CISIH physicians, must systematically be initiated.

It moreover appears that referral to and coordination with, psychological and social care should be strengthened. Each pregnant woman having tested positive for HIV, and especially when specific risk factors affecting pregnancy follow up so require, should be offered support[30] ; support should address access to social and administrative rights for underprivileged persons with HIV; this demand mostly concerns women of foreign nationalities who do not yet have those rights. Gynecological and obstetrical teams who care for HIV pregnant women should thereby work in close contact with welfare workers and MCH centres.

Outside the scope of health care departments, all medico-social and social support facilities should offer any possible contribution to an improved follow up of pregnancy.

It is the Public Authorities' duty to evaluate and provide adequate human and financial resources, including in mother and child health centres[31] that are not answerable to the Health Authorities.

3.3 PREVENTING MOTHER-TO-CHILD HIV TRANSMISSION IN THE CASE OF CONTAMINATION DURING PREGNANCY OR AFTER DELIVERY

It may happen that the pregnant woman or her clinician take at face value during the first prenatal visit, a previous negative HIV test result. For the woman, refusing a new test can be motivated by the certainty that she has not been infected; on the physician's part, not to routinely offer a test would be seriously unprofessional conduct. Some cases of seropositivity could thus remain undiagnosed whereas if requirements had been met, such late disclosure might well have been avoided.

But even when the woman has been tested after her first prenatal visit, the policy implemented in 1993 is inadequate for cases of mother to child transmission due to the woman's serconversion during pregnancy. Like seroconversions occurring during breast feeding, seroconversions during pregnancy can cause a substantial proportion of mother-to¬child transmissions.

Late infection of the pregnant woman, undetected at the first test, is not unusual, as reported to the National AIDS Council by the French perinatal survey investigators. The frequency of STDs in the European cohort of HIV positive women[32] also shows evidence of repeated unprotected sex.

[29] Blondel and Marshall, op. cit.

[30] As stipulated by the aforementioned circular of January 29th 1993.

[31] Accountable to the local Authorities

[32] This concerns SDTs contracted prior to HIV testing. See Van Benthem et al., 2000 and Heard, 2001.

A retrospective study[33] carried out between 1992 and 1996 in the Robert Debré and Bichat Hospitals in Paris, shows that out of 18 cases of MTCT, 5 were women tested HIV negative at the outstart of pregnancy, i.e. 28%. In 4 cases out of 5, further examination showed that mothers were infected at the end of pregnancy or while breast feeding (the 4 children were breast fed). All the fathers were HIV positive. A proportion of fathers were injecting drug users. Such situations are all the more prejudicial as the child is only diagnosed when clinical signs, which show an advanced stage of infection, appear.

Inasmuch as the main route of infection of the women under consideration is unprotected sex, the policy proves unsuccessful on three counts :

- the Law requires that a test be offered to the woman but not to her sexual partner who is however likely to be HIV positive and the potential cause of infection before and at the outstart of, pregnancy;

- the test is required at the first prenatal visit, whereas the woman can be infected at a later stage and is all the more likely to infect her baby as no preventive MTCT treatment will have been initiated;

- actual infections during pregnancy show that prevention counselling was not provided with sufficient clarity or was not fully understood, as regards protected sex. The same applies to ruling out breast feeding for an HIV positive mother.

Given the number of women infected during pregnancy, the frequent lack of counselling when negative results are communicated is particularly unfortunate. In 1997, 14 % of public settings in Paris did not provide any personalized communication of negative results.

Here again, the National AIDS Council can only strongly advise improvement of counselling and guidance for women at the visits prior to HIV testing and when results are disclosed. Prevention counselling must be repeated throughout pregnancy. Counselling of pregnant women during these visits to the physician must clearly stress that condoms are the only safe barrier to sexual transmission of HIV. Any test offer to pregnant women should be provided with information on the benefit of testing for sexual partners.

This suggestion is not easy to implement and must in no way be seen as a change in the principle of confidentiality of HIV test results. It is nonetheless obvious that infections may have occurred while the allegedly HIV negative woman's partner was not aware of his positive serostatus.

The National AIDS Council also considers it unfortunate that delays in treatment for both mother and child, owing to undiagnosed HIV infections in women with clinical signs of infection during pregnancy, have in some cases have got worse. The Council therefore repeats its recommendation on the training of gynecologic and obstetrical teams as regards diagnosis of and care for, HIV infection, as well as the implementation of interdisciplinary follow up including the continuation of or access to, care by a physician (or a ward) experienced in the clinical and biological monitoring of HIV infected patients.

Lastly, it would be advisable to change the Law of January 27th 1993 so as to provide as many opportunities as possible of preventing MTCT in women initially diagnosed as HIV negative. The test offer must be repeated at the end of the second trimester of pregnancy and again just before delivery.

This last recommendation implies that consent to testing be clearly emphasized when the test is offered. The recommendation is designed to repeat sexual prevention counselling; the woman must in no way be coerced into another test which might be useless. On the assumption of seroconversion since the first test, repeating the test might also provide an opportunity for preventing mother-to-child transmission.

Implemented as a whole, the National AIDS Council's proposals will not prevent all HIV mother-to-child transmissions. They could however enable to provide a certain number of extra guarantees against the few, avoidable to date, infections of the unborn baby. The following recommendations retrace the elements of improvement of HIV testing procedures and care of pregnant women which should, in the Council's opinion, prove efficient. They show how closely related treatment and prevention of HIV infection are in the perspective of a decrease in the number of cases of perinatal HIV transmission.

RECOMMENDATIONS

Ideally, mother-to-child transmission of HIV could affect less than 2 % of children born from HIV positive mothers. In actual fact, the overall transmission rate in France is higher.

[33] Duval et al., 1999.

Consulted on the advisability of changing current HIV testing frameworks applied to pregnant women, the National AIDS Council reviewed all infection risks for the unborn baby and the infant.

The recommendations issued by the Council are based on the inseparability of prevention and medical management of HIV infection, whether of the mother or the unborn baby.

- **The Council found that data are still too fragmented to take into account the different barriers to a minimal level of mother-to-child transmission.**

The National AIDS Council regrets this lack of information and wishes that all necessary steps be taken to provide necessary data for the analysis of mother-to-child transmission cases.

- **Test refusal only concerns a very small proportion of pregnant women to whom it is offered. In the current system where physicians must offer a test at the first prenatal visit, nearly all the women urged to do so, accept.**

Consequently, the National AIDS Council considers that maintaining the non coercive policy, with the possibility of pregnant women refusing the test, is preferable to policies which go against the principle and objectives of voluntary and informed consent.

But, in order to avoid test refusals as much as possible, the Council wishes that all administrative, medical, social and medico-social settings dealing with pregnant women supply them with information on the benefits of HIV testing during pregnancy and on the prevention of infection risks.

The Council stresses that voluntary consent to testing, when indispensable information is added, has several advantages :

- it is quantitatively efficient, as almost all pregnant women are tested for HIV and as a considerable number of infected women discover their seropositivity during pregnancy ;

- it protects the person's free will and therefore helps ensure a trust relationship with the care provider which will contribute to the possible initation of treatment ;

- it plays a role in prevention by offering an opportunity of personalized counselling on the risks of infection, whatever these may be. Correctly carried out, it promotes the circulation of good practice recommendations throughout society.

So as to fully meet these objectives, the test must necessarily be preceded by a consultation during which a physician explains the test's significance, provides information on HIV and its monitoring and delineates the basic rules of prevention so as to avoid infection of the woman, her sexual partner and the unborn baby.

The test result must be communicated during a medical visit. The clinician must, whatever the result, repeat information and counselling advice, and make quite sure these elements are clearly understood. In the instance of a positive result, the physician considers, jointly with the pregnant woman, the appropriate medical response which takes into account all the available means of reducing the infection risk for the unborn baby.

- **It appears that an important proportion of babies' infections are due to mothers' infection during pregnancy, or even after birth when infants have been breast fed.**

So as to avoid infections in unborn babies and infants by mothers whose first test was negative, communication must also provide very clear prevention counselling.

Any communication of a positive result to a pregnant woman must also clearly rule out breast feeding.

It is the physician's duty to inform the patient, whatever that person's serostatus, on the benefits for both partners to be tested. Moreover, during this visit, the Hiv negative pregnant woman must be warned about infection risks during pregnancy, through unprotected sex.

- **Prevention counselling must be repeated throughout pregnancy, as safe behaviours can never be taken for granted.**

- **The National AIDS Council advises the Public Authorities to change article L 2122-1 of the Public Health Code pursuant to Law n° 93-121 of January 27th 1993. That article, which defines the frameworks of HIV prenatal testing for pregnant women, establishes that a test is offered to pregnant women at the first prenatal visit, following information on infection risks.**

But, for uninfected women, there is a gap of several months between that first prenatal visit and the time when preventive treatments should be initiated to prevent HIV transmission from the mother to the child. During that period of time, certain high risk behaviours may have caused HIV infection in a woman who was initially seronegative. The Council suggests that the Law provide for two new test offers. One at the end of the second trimester of pregnancy so as to be able to initiate treatment if need be at the beginning of the seventh month of pregnancy ; another at the final prenatal visit, when a short preventive regimen for the mother and care for the neonate can still be decided.

- **The legal text should also mention the necessity of explicit consent from the woman, before the HIV test. This is designed to stress that there is no automatic aspect to testing and also to avoid testing without consent.**

It did indeed appear to the Council that part of the alleged failures of the current policy may be generated by all too frequent coercive testing practices (tests carried out without patients knowing and/or without their explicit consent) or without complete prior information and post-test counselling.

- **The National AIDS Council considers that breaches of the Law, of ethical rules and standards are not acceptable as regards information and consent of the pregnant woman to being tested. Anxious to improve overall testing and prevention policies, the Council wishes that the application of legal requirements on prenatal testing be regularly evaluated. Evaluation could be carried out through regular surveys on perinatal testing practices and on monitoring of HIV positive women. The national perinatal surveys carried out on all pregnant women having given birth can fulfill this request.**

- **The difficulty in implementing the legal provisions can partly be ascribed to some clinicians' unawareness and lack of know-how. Improvements in the training and awareness of obstetrical teams therefore seem advisable.**

- **Monitoring certain aspects related to HIV can indeed be tricky whether diagnosis, treatment or prevention counselling. The Public Authorities and physicians must also promote interdisciplinary coordination between obstetrical teams and physicians caring for patients with HIV/AIDS (mainly within Cisihs) who have the required competencies for the follow up of HIV positive women.**

Pre- and post-test counselling, coordination with teams specialized in HIV care can represent an important investment in the departments concerned. It is therefore necessary to ensure that adequate human resources be allocated, so as to carry out such tasks in the best possible way.

- **Referring HIV positive pregnant women to psychological and social support services is often indispensable for optimal pregnancy conditions. They offer solutions to the many associated social difficulties of poor pregnancy care and therapeutic indications on HIV infection ; they contribute to ensuring access to necessary rights, particularly for certain foreign women ; they can provide indispensable support in case of emotional or psychological problems.**

The National AIDS Council suggests that the Health Authorities' policy guidelines be repeated and detailed, as regards the systematic coordination between :

- medical teams ;
- mother-and-child health services ;
- assistance, support and social support professionals.

In the same way as medical coordination, the Council requests that the various Public Authorities involved allocate the necessary human and financial resources for such collaboration.

- **However advanced pregnancy may be at the woman's first visit, gynecologists and obstetricians must offer an HIV test, unless they have the written result of a recent test (for that patient). The offer must respect the rule of informed consent of the person to testing.**

- **So as to reduce the risk of infection after delivery, the Council suggests that all physicians, and particularly pediatricians, be made aware of risks incurred by breast feeding by HIV positive women.**

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