This recommendation is a follow-up to the previous recommendations adopted by the National AIDS Council1 on intended pregnancy in serodiscordant couples where the man is HIV positive. First it concerns intended pregnancy in serodiscordant couples where the woman is HIV positive. Addressing the issue was suggested mainly by the Aides-Fédération nationale association; the Council asked its Medical Aspects Commission to examine the ethical issues of access to fertility assistance for such couples and of the attention they might need. Second, the recommendation considers the ethical issues raised by intended pregnancy in couples at viral risk: couples where both partners are HIV positive; couples where one or both partners have one or several viral infections. The National AIDS Council can only express satisfaction at the regulations decided last May by the Minister of Health (2) on fertility assistance for patients at viral risk. The reappraisal of the rules of good clinical and biological practice is for the most part consistent with the recommendations published by the National AIDS Council over a year ago in favour of fertility assistance to serodiscordant couples where the man is HIV positive. Furthermore new regulations now make fertility assistance possible for couples where the woman is HIV positive and in cases where one or both partners are HCV or HBV infected.

The Council approves the end of the formal ban on access to fertility assistance which was discriminatory to certain couples, but it does however regret that regulation does not define a precise framework for fertility assistance to couples where both partners are HIV positive and that it does not specifically authorize fertility assistance for couples with several viral risks.

The Council also considers that registered fertility centres willing to attend to patients with a viral risk, should apply stricter biological and clinical procedures. Fertility centres authorized to deal with such patients should include a multi-disciplinary team with not only biological and clinical specialists in reproduction, but also on a continuous collaboration basis, specialists in biological, virological and clinical management of HIV infection and, more generally, of any viral infection. Centres with former experience of cooperation with Cishiis (Centres for Human Immunodeficiency Information and Care) seem best prepared to assist couples at viral risk.

Moreover, the new legal procedures will in no way solve all the problems of couples at viral risk, if only because fertility assistance is not necessary for all couples at viral risk – especially serodiscordant couples where the woman is HIV-positive and that have no fertility problems.

1 SERODISCORDANT COUPLES WHERE THE WOMAN IS HIV POSITIVE.

1.1 GENERAL MEDICAL-MANAGEMENT PRINCIPLES

INFORMING THE PATIENTS

If progress achieved in the medical management of HIV infection justifies the increasing expression of a desire for children, couples involved must be totally aware that there are still medical risks for the baby (3).

More and more serodiscordant couples where the woman is HIV positive strongly express fertility desires. This is motivated by two main developments. First, antiretroviral (ARV) therapy has improved the health status of a great many people living with HIV and has thus considerably increased their life prospects and enabled them to return to a "normal" life, especially job and family wise.

1 Recommendation on the ethical issues raised by intended pregnancy in couples where the man is HIV positive and the woman is HIV negative. National AIDS Council, National Advisory Ethics Committee, February 10th 1998 ; Recommendation on fertility assistance for serodiscordant couples where the man is HIV positive. National AIDS Council, April 4th 2000.
Second, careful monitoring of pregnancy and pregnant women’s health, current therapeutic regimens with ARV medication given to mother and child and possibly combined with a scheduled caesarian section, have reduced the risk of HIV mother-to-infant transmission. This breakthrough has caused a decrease in mother-to-infant transmission rates, now estimated at 1% to 2% of births.

Nevertheless, even when an HIV positive woman receives such care during pregnancy and delivery, there are still potential, more or less proven risks for the baby.

The risk of vertical transmission is nowadays very low but it does still exist. It must therefore be thoroughly and concisely explained and regularly up-dated to the couples involved.

Another possible risk for a baby born from an HIV positive mother is potential ARV toxicity. Toxicity has been discussed at international level and remains partly unknown. However the mitochondrial toxicity of nucleoside analogue reverse transcriptase inhibitors (NRTI) which can cause serious or even lethal neurological disorders, has been sufficiently shown by several French studies, for that risk to be acknowledged. However low that risk may be, its assessment must be continued and must also be extensively explained to couples who desire a child. They must also be informed on the possible occurrence of various drug-related anomalies, yet to be known and occurring at a later stage in the child.

Fertility desires concern first and foremost the would-be parents and fertility decision-making is their responsibility; but their physician (whether gynaecologist, general practitioner, infectiologist, etc.) must provide, or ensure they are provided with, information as detailed and objective as possible on the types, levels, determinants and implications of the risks to the infant of vertical HIV transmission and drug toxicity.

Obviously, providing such information must also be an opportunity for the physician to emphasize basic precautionary principles on HIV transmission (through sex and blood), even if these couples generally have appropriate prevention behaviour. Furthermore it is essential to provide the mother-to-be with a prognosis of the evolution of her infection, or else refer her to a physician who can do so. Also, the physician consulted for an intended pregnancy by a couple where only the woman is HIV positive, must make sure she receives regular and high quality gynaecological attention and if not, do his utmost to improve the health care she does get.

Whatever the case may be, any information and advice provided must respect the couples’ free-will and give them all the necessary elements for their own decision-making. This is a matter of communication as much as information. It must be stressed just how important it is to check that both partners understand the information and are able to put it in their own words.

**PROVIDING MEDICAL ATTENTION**

Once information is handed over and understood, if the couple confirms its decision, the physician must medically support the project. Medically supporting a reproductive decision means explaining to the couple self-insemination modalities and essential measures to prevent HIV transmission to the man. It may also entail suggesting a fertility assessment; when this is prescribed, and if infertility is diagnosed, the physician must facilitate access to an appropriate form of fertility assistance – intra-uterine insemination, in vitro fertilisation (IVF) or micro-injection of a single sperm. Once pregnancy occurs the physician must furthermore ensure that the best possible ARV therapy is initiated.

To improve gynaecological follow-up of HIV positive women as regards both HIV infection and pregnancy, and to ensure good medical support of intended pregnancy in couples where only the woman is HIV positive, the Council considers that the contribution of Cishis' specialized teams is indispensable. The Council therefore recommends that when no prior forms of collaboration exist, regular cooperation be set up between biologists, reproduction specialists, perinatal paediatricians and HIV specialists, all usually amalgamated within a Cish.

Any physician, (whether general practitioner, gynaecologist, infectiologist, etc.) must be granted the right to refuse to provide such medical support. But then it is that physician’s duty to refer the couple to other physicians who will; ideally Cish teams. No refusal on principle should be tolerated without the referral counterpart.

At legal level, the physician’s liability as regards the infant must be clarified. The Council considers that, except for proven malpractice, medical attention to couples who desire a child and where only the woman is HIV positive, should not involve the physician’s liability insofar as that physician has facilitated the couple’s informed fertility decision-making, has complied with good practice procedures as set by the competent authorities and has provided information on the risks to the child.

**TRAINING AND INFORMATION : RAISING HEALTH CARE PROVIDERS’ AWARENESS**

It is the public authorities’ responsibility to make not only physicians (Cish teams, GPs, gynaecologists, etc.) but all those who deal with HIV patients and their problems, aware of the duty to inform. Considerable awareness and training efforts must be made as regards reproduction possibilities and the related risks for serodiscordant couples where the woman is HIV positive. These efforts must also apply to teams in fertility centres.

2/S - CONSEIL NATIONAL DU SIDA – Opinion from 2001 December 1st - english
1.2 MANAGING FERTILITY ASSISTANCE

ADOPTING REAPPRAISABLE CRITERIA

The previously mentioned regulation of May 10th 2001 sets the rules applicable to fertility assistance for couples where the woman is HIV positive. It particularly specifies that clinical, immunological and virological criteria for access to fertility assistance for serodiscordant couples where the man is HIV positive also apply to couples where the woman is HIV positive.

Understandable in terms of equal treatment for couples, the principle of identical rules whatever the serodiscordant couple, should however be applied with great caution. It does seem necessary, in cases where the woman is HIV positive, that criteria – and especially virological criteria – take into account the severity of the mother's infection and the risks of HIV transmission to the infant.

More generally, the criteria which set the levels of access to fertility assistance must be regularly reappraised, according to progress in knowledge on the medical parameters for HIV progression and the effects of ARVs on the unborn baby.

Defining such criteria and reappraising them regularly must be completed with the effective continuation of epidemiological surveillance of children born to HIV positive mothers (e.g. French perinatal survey) with the assistance of the French Agency for the Safety of Health and Health Products (Afssaps). This also implies creating a watch-dog system for, and any necessary research on, possible drug toxicity to the children.

CLARIFYING THE TERMS OF THERAPEUTIC PARTNERSHIP

Deciding to provide couples with fertility assistance implies mutual consent between the multi-disciplinary team and the couple as regards criteria for access to such care. Consent should be obtained in a clear way and based on precise, up-dated and correctly understood information on the risks incurred.

2 MANAGING FERTILITY ASSISTANCE FOR COUPLES WHERE THE MAN AND THE WOMAN ARE BOTH HIV POSITIVE.

2.1 ACKNOWLEDGING POSSIBLE FERTILITY ASSISTANCE

Couples where both partners are HIV positive, regardless of possible infertility of either partner, may need fertility assistance so as to reduce the risk of infection from another strain. Furthermore, techniques such as IVF or micro-injections are necessary for reproduction if the couple suffers from infertility.

Technically, fertility assistance for these couples is similar to that available for serodiscordant couples where the man is HIV positive.

It therefore seems necessary to complete the above mentioned regulation of May 10th 2001 so as to specifically authorize fertility assistance for couples where both partners are infected and to define procedures.

2.2 ESTABLISHING CRITERIA FOR ACCESS TO FERTILITY ASSISTANCE.

At ethical level, most of the principles stated above apply to these couples :
- duty of the medical team to inform on parents’ health prospects and on possible risks to the infant ; assurance of parents’ total understanding of such information ;
- possibility for the team, in case of internal disagreement, not to get involved, providing the couple is referred to another team;
- clear agreement on the couple’s and the medical team’s respective responsibilities, based on clear and complete knowledge of risks incurred and medical criteria applied for decision-making.

The Council considers that respecting these principles is particularly important, as access to fertility assistance for couples where both partners are HIV positive raises in an acute and complex way the issue of the parents’ life prospects.

Likewise, as in serodiscordant couples where the woman is HIV positive, the clinical, immunological and virological criteria which determine access to fertility assistance, must be established and reappraised according to progress in knowledge on their relative effects on the unborn baby.
3 ATTENDING TO COUPLES WHERE ONE IS OR BOTH PARTNERS ARE AT RISK FOR SEVERAL VIRAL INFECTIONS.

The Council must draw the Authorities’ attention to the fact that the regulation of May 10th 2001 does not mention the issues raised by assistance to couples where one or both partners are at high risk for several viral infections, such as co-infection by HIV and HVC and/or HVB.

Such issues, and especially the medical criteria of eligibility for fertility assistance, drug toxicity and interactions, make complete and clear information, couples’ choices and medical decision-making all the more difficult.

Here again, whatever the reservations expressed by some physicians, the information must respect the couple’s free-will and at the same time provide all the necessary available data for careful decision-making.
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This document was approved by the majority of NAC councilors at the plenary assembly of December 4th 2001.

13 members voted in favour of it, 3 abstained. None voted against it.