Comité consultatif national d'éthique pour les sciences de la vie et de la santé

Medically assisted reproduction for couples presenting a risk of viral transmission - Reflections on responsibilities

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Medical responsibilities sometimes seem rather contradictory. This is so when a couple of which one member carries a serious communicable disease, wishes to have a child, and calls on the medical profession for help. This may be needed either because the couple is infertile, or because they wish to reduce the risk of transmitting the viral infection to the child or to the other partner. Doctors in such cases are sometimes torn between their duty to respond to the legitimate wish of a couple to bear a child, and the risks to that child because of the parents' condition.

Such a situation has already been the subject of Opinions, previously adopted by the National AIDS Council and the National Consultative Ethics Committee (CCNE) on care for HIV-discordant couples, where the man is HIV-positive[1]. In its Opinion of April 19, 2001, in response to a referral from Madame Gillot, Secretary of State for Health and the Handicapped, CCNE had stated that ethical issues raised by an HIV-discordant couple's wish to bear children when the woman is HIV positive, would be the subject of a separate opinion. In this situation, the aim of a request for medically assisted reproduction (MAR) may be, as is the case in the general population, treating infertility, or, if the male partner is not infected, his protection. However, the need to do everything possible to avoid infecting the unborn child is always paramount. As it happens, whereas protection of the child can nowadays be almost entirely secured in the case of an HIV-positive man and HIV-negative woman, the opposite case is much more uncertain. In fact, in this latter case, assisted reproduction techniques (ART) are not, in themselves, able to reduce the risks run by the child.

This Opinion also refers to the problem of the wish to conceive on the part of couples in which both man and woman are HIV-positive, or when another viral infection affects one (or both) partners.

CCNE welcomes recent rules regarding assisted reproduction techniques for patients at viral risk, adopted on May 10, 2001 by the Minister for Health[2]. Modification of rules of good clinical and biological practices in this respect respond, to a large degree, to the recommendations made by CCNE in favour of MAR management for sero-discordant couples in which the male partner is HIV-positive. Furthermore, these new practices make it possible to provide assistance to couples in which the female partner is HIV-positive, and those in which one or both partners are infected by hepatitis type C (VHC) or B (VHB).

The new ruling thereby eliminates denial of access to MAR on principle which certain couples experienced as discriminatory. It creates strict rules to govern clinical and biological practices of approved MAR centres who may wish to institute special treatment for viral risk patients. The adoption of new rules does not however solve all of the problems encountered by the couples concerned. In particular, although recourse to MAR seems essential for sero-discordant couples in which the male partner is HIV-positive, it does not necessarily appear

as crucial to all sero-discordant couples in which the female partner is sero-positive. This Opinion is also concerned with all virus-infected couples wishing to start a family.

1) Sero-discordant couples in which the woman is HIV-positive

a) Present epidemiological and scientific data

Although in the early years - the 80s and early 90s, HIV transmission from mother to child involved 25 to 35% of deliveries, since 1996, recent antiretroviral treatment strategies have radically modified this situation. Firstly, couples under adequate treatment are in remission; they know that their life expectancy has increased and more frequently than before, they want to live an ordinary life, particularly as regards starting a family. The mother's lower viral load, treatment for the child, and recourse to caesarean section, have lowered the risk of HIV transmission from mother to child to less than 2%. This is of course an average, and should be modulated according to viral load. The possibility of contaminating the unborn child is therefore low, but not non-existent. However, there are also other risks, such as mitochondrial toxicity of nucleoside analogs, which may lead to serious neurologic damage. An exact evaluation of the importance of that risk is not completed, although it does seem to be very low (about 5%). Although pregnancy does not seem to have an effect on the evolution of HIV infection, long term evolution of the mother's health, despite treatment, is still a major anxiety, in particular as regards the child, insofar as the disease is still incurable. In this difficult situation, the physician must inform, advise, and attend

b) Duty to inform couples

Physicians have a duty to fully inform couples about risks incurred by the child : contamination by the HIV virus, drug toxicity. Furthermore, these couples must be reminded of the precautions to be taken to avoid transmission of the infection, even though most of them will have already adopted appropriate preventive measures. Finally, their attention must be drawn to uncertainties regarding the mother's future health due to development of the disease, although in the long term prognosis will obviously depend on medical breakthroughs, which are hoped for but not yet a reality. Whatever personal reservations may be expressed by doctors, who may be reluctant to engage in action which could lead to the birth of an infected child, the aim is to provide full, clear and loyal information enabling the couple to make an enlightened and autonomous decision.

c) Medical attention

If a physician feels that, in view of residual risk to the child, and the mother's uncertain future, he does not wish to take the responsibility of being involved in medically assisted reproduction for these couples, he is duty bound to direct them to another practitioner who may be able to help them. In any event, the physician who does assist, must do everything possible to minimise the risk of viral transmission : evaluation of the mother's viral load before fertilisation, and appropriate treatment to reduce it as far as possible. When pregnancy occurs, the most adequate antiviral treatment should be administered. Intra-uterine insemination with the partner's sperm is one way of avoiding the latter's infection. Some gynaecologists deem it preferable that the couple should take care of the insemination themselves (self-insemination) so as to enhance appropriation by both man and woman of the parental project, and their autonomy. However, any preference given to self-insemination should not be a way for the physician to elude responsibility and gain protection in case of litigation. The ruling of May 10, 2001 states the conditions in which pluridisciplinary assistance is provided to a sero-discordant couple wishing to start a family and must of course be observed in the initial stages and throughout the pregnancy.

d) Improving recognition by members of the medical profession of their duty to instruct and inform

It is the responsibility of authorities to make this duty plain to healthcare providers, and to all those who play a role in serving the needs of HIV positive individuals. Considerable efforts should be made to train those concerned on the subject of reproductive possibilities and risks for sero-discordant couples in which the woman is HIV-positive. Such efforts should also be aimed at workers in MAR centres.

e) Initiating medically assisted reproduction

Indications for possible MAR readily arise after self-insemination failure or at the time when a sero-positive condition is discovered during infertility treatment for one or the other partner. The ruling dated May 10,2001, defines the rules governing MAR for couples in which the woman is HIV-positive. In particular, it states that the clinical, immunological, and viral criteria for access to MAR for sero-discordant couples in which the man is HIV-positive also apply to couples in which the woman is HIV-positive. It should be emphasised in this connection that the criteria for MAR access thresholds will need to be revised as and when advances are made on knowledge about HIV transmission to children, and on the medical parameters of the progress of HIV infection. As CCNE pointed out in its opinion dated April 19, 2001, on the subject of sero-discordant couples in which the male partner is HIV-positive, treatment must be "truly pluridisciplinary and provided by a medical team in which the gynaecologist/obstetrician and the biologist specialising in MAR, must enlist the services of an HIV specialised clinician, a virologist, and of a psychologist or a psychiatrist".

Regular and meticulous short and long term follow-up, of children born to sero-positive mothers is essential. Centres should be committed to offering these mothers the chance of participating in a cohort-type epidemiological study.

It seems necessary to underline that initiating MAR for these couples implies a sharing of the burden of responsibility between the pluridisciplinary team and the couple themselves, based on clear and full information regarding risks incurred and the criteria (particularly viral) involved when the decision to treat was taken.

2) Initiating MAR for couples in which both partners are HIV-positive

a) Recognising the possibility of initiating MAR

When both partners are HIV-positive, they may wish, irrespective of their fertility status, to use assisted reproductive technology (ART) with the aim of reducing cross-contamination within the couple. Technically, there is a similarity with sero-discordant couples in which the man is sero-positive, and recourse to ART methods such as IVF or ICSI may be justified. The May 10, 2001 ruling should be modified so as to include couples in which both partners are HIV-positive for access to MAR, if the case arises

b) Establishing access criteria for MAR

On an ethical level, most of the principles mentioned above remain applicable to these couples:

- the medical team is duty bound to inform parents of the uncertain status of their long term prognosis, in the present state of medical knowledge, and of the risks incurred by the child;

- the fundamental importance o and of an assessment of the parents' state of health;

- possibility for the team of rejecting initiation of MAR, with directions to the couple for treatment elsewhere. CCNE considers that respecting such principles is all the more important because access to MAR by couples in which both partners are HIV-positive puts an even sharper and critical emphasis on the issue of the prognosis for the health of future parents, and therefore on the risk that a young child may find itself in a dramatic situation, with both parents seriously ill, or even be orphaned.

3)Treatment of couples in which either or both partners are at risk for several viruses

CCNE draws the attention of the authorities to the fact that the May 10, 2001 ruling does not refer to the problems arising out of the management of couples in which either or both partners have several viral risks, for example in the case of co-infection with HIV and VHC and/or VHB. These problems concern inter alia medical admission criteria for MAR, known toxicity of certain treatments and their interaction; they considerably increase the complexity of providing full and clear information, and of selecting the members of the medical team, and the couple itself. The existence of teratogenic treatment (in particular for hepatitis C) should encourage particular circumspection when dealing with such couples. Sexual transmission of VHC is rare. The risk of hepf meticulous viral parametersatitis C transmission to the child is also low, but has not been the subject of therapeutic protocols. The complexity of such situations is such that information, although it must respect the freedom of decision of the couple, has to be particularly prudent. Changes brought about by medical advances will constantly lead to revising indications upwards or downwards.

In conclusion, CCNE considers that when a seropositive woman or couple wishing to have a child, approaches the medical profession, the latter are faced with a dual obligation : **to help the couple, without discrimination, whilst preserving to a maximum degree the future and the best interests of the child**.

Such situations are never simple. Facing up to them, the medical team needs to be open-minded regarding the couple's parental project, but also be mindful of their responsibility as regards a possible future child. This tension can only be dispelled if information given to both man and woman is plentiful and benevolent, without any concessions, highlighting in particular all the uncertainties and anxieties about the child's future, and providing all information that may help the couple in their decision.
Physicians must pursue two aims simultaneously: reasonable assistance for the success of a couple's parental project, and due regard for the child's best interest.

REFERENCES

[1] Opinion on ethical questions raised when a couple, in which the man is HIV-positive and the woman is HIV-negative, wish to bear a child. National AIDS Council (Conseil National du SIDA, CNS), and National Consultative Ethics Committee, February 10 1998 Opinion on medically assisted reproduction for HIV-discordant couples, in which the man is HIV-positive, National AIDS Council, April 4, 2000. By letter addressed to the Minister for Health on April 19, 2001, CCNE agreed with the CNS opinion quoted above.

[2] Ruling of May, 10, 2001, modifying ruling of January 12, 1999, regarding rules of good clinical and biological practice in medically assisted reproduction, Journal Officiel, May 15, 2001, p. 7735-7737.