Opinion on present organisation of gamete donation and its consequences

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Opinion

The National Consultative Ethics Committee, after being informed of the implementation of decrees governing medically assisted reproduction (MAR) activities, considers that there are serious risks involved in the present situation because authorisation covers indiscriminately intra- or extra-marital gametes and in the absence of legislation, no such discrimination can be made.

The risks are

1. medical : risk of transmission of infectious diseases in particular the HIV virus since fresh donor sperm can be used; risk of transmission of hereditary conditions; risk of consanguinity;

2. ethical : risk of non compliance with the fundamental principle of non-commercial use of human organs and tissues.

The Committee is worried by the gravity of this newly created situation, and wishes to draw attention once more to the following points :

1. as regards gamete donation, a non payment rule should be observed;

2. fresh donor sperm should not be used;

3. the number of MAR centres authorised to collect, process, and store gametes from donors must be strictly limited. Numbers should be set taking into account the scantiness of indications on the one hand, and the requirement for a minimum size of population to be served by one single centre on the other;

4. only official centres should be authorised to undertake this kind of activity (i.e. public institutions or associated non-profit making private institutions) so that the principle of non-commercial use can be respected;

5. these centres must be made responsible for indications and distribution which must not preclude the possibility of use in both the public sector and private practice.

Legislation as a matter of urgency is essential so that the above can be achieved.

Report

The National Consultative Ethics Committee, in its opinion dated 23rd October, 1984, on the subject of ethical problems arising out of artificial reproductive techniques, stated that " activities and research resulting from the use of artificial reproductive techniques must no longer be undertaken by any but authorised non-profit making teams of researchers" . More

recently, (Update On Studies Undertaken By The Committee Regarding Gamete And Embryo Donation : December 1989), the Committee recalled that : " procreation by gamete or embryo donation is only imaginable in any case by medical prescription for stable heterosexual couples.It must only be practised within *public* authorised centres, under medical supervision and strict rules, and in very small numbers" .

The authorities had accepted the principle that the practice of medically assisted reproduction (MAR), particularly when gamete donation is involved, must be controlled in both quality and quantity.

In April 1988, two decrees (n°s 88327 and 88328) initiated regulations for MAR activities which in terms of their biology are defined as " sperm collection, processing of human gametes in view of fertilisation, their conservation, in vitro fertilisation and the conservation of fertilised human eggs with a view to transfer" . It is worthy of note that no difference is made between intra-marital MAR activities and those using gametes foreign to the couple. Any such difference would have had to be based on legislation which is still pending.

A commission for reproductive biology and medicine, in accordance with the decree, has been tasked to present to the Minister for approval, clinical centres on the one hand, and institutions authorised to practise MAR biological activities, on the other. Seventy-six clinical centres have been authorised and eighty-one institutions as described above. The latter are more or less equally divided between public health institutions (hospitals) and private clinical laboratories. Due to the impossibility of separating activities connected with gamete donation from other activities, each centre has received global authorisation.

Thus, strict application of the decree leads to a paradox. There used to be about twenty sperm banks in France. This number could be doubled or trebled tomorrow. Furthermore, quite a large number of clinical laboratories have been authorised to " prepare fresh sperm for insemination" . There is nothing to prevent them from interpreting the authorisation to include sperm foreign to the couple whereas implicitly only intra-marital sperm was intended.

This possible multiplication of the number of sperm banks leads to a high risk situation in terms of both public health and ethics. As far as public health is concerned, what certainty is there that technical methodology is sufficiently careful to exclude any risk of accidental transmission of infectious diseases (sexually transmitted diseases, HIV virus) or transmission of hereditary conditions and risk of consanguinity when no limitation is placed on the number of conceptions by the same donor ? There is also the fear that the very specific indications which this type of MAR should deal with (proven sterility or high risk of hereditary disorders) are no longer exclusive. Ethically, the situation is just as worrying.

Since 1973, existing structures which are part of the public health hospital system, have voluntarily applied principles based on blood donation practices which are regulated by law (articles L 666 to L 677 of the code of public health), i.e. free of charge donation, donor anonymity, non-profit preparation and conditioning. They also supervised indications and were responsible for the order of issue based exclusively on the date requests were registered. In this way it was possible both to allow sperm to be used through either the public or the private sector, and to totally guarantee that sperm donated by unpaid volunteers would not be sold. How can the licensing of institutions such as private clinical laboratories which are not non-profit organisations, be compatible with the fundamental principle of non commercial use of human organs and tissues ?