

Policy Statement on Recontacting Artificially Inseminated Patients: Scientific and Ethical Foundations

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Sexually transmitted diseases can be passed not only through unprotected sexual intercourse, but also through artificial insemination with a contaminated semen sample. Taking into account the possibility of transmission of diseases from questionable semen samples, Health Canada decided in 1996 to regulate semen donor selection and the use of donated sperm samples. Regulations included a questionnaire to identify individuals at high risk for sexually transmitted diseases and serological and semen screenings for various pathogens before artificial insemination. Several sperm banks in Canada did not comply with the Health Canada regulatory requirements in certain procedures (Health Canada, 2000). Some did not screen for human T-lymphotropic virus (HTLV-I/II); others did not test semen samples for hepatitis B or C. To minimize the risk of transmission of infectious agents, these sperm banks have been prohibited from inseminating patients, and the embargo will be lifted only after the requirements of the Semen Regulations are satisfied.

Additionally, as a precautionary measure, Health Canada strongly recommended notification and testing of all patients who were artificially inseminated with untested or partially tested semen:

All recipients of donor semen should be tested as there are reasonable grounds to believe that they may have been at an increased risk of contracting one or more of

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the following: Hepatitis B and C, HTLV-I/II, Syphilis, Chlamydia and Neisseria gonorrhoea, CMV. . . . Your immediate response to the above recommendations is requested to identify patients who are at risk of undiagnosed infection (Health Canada, 1999).

The recontact of all patients artificially inseminated with semen that does not meet Health Canada's criteria may be beneficial to the physical health of the patient, but it may also have some adverse psychological effects on the patient, her family, and the donor. Taking into account the possibility of these risks, the Bioethics Committee of the University Hospital at Laval University considered the value of a broad recall, including evaluation of the scientific, medical, psychological, and ethical aspects of the problem.

Analysis

Scientific and Medical Aspects

Several pathogens, including hepatitis B and C and HTLV I and II, may be transmitted vertically and through non-protected sexual intercourse. Several diseases, often serious, may result from an in utero or a neonatal infection. The fetus, the infant, or even, after a long latency, the adult may be at risk. For example, an HTLV infection is followed in 25% of contaminated persons by a latency period of 20–30 years before leukemia occurs. The route of transmission of these pathogens and the consequences of an infection on health are summarized in Table 1.

Psychological Considerations

The decision to opt for artificial insemination often results after a long course leading to 1) the acceptance of the husband's infertility, and 2) the decision to procreate without the husband's semen. A recontact could therefore be psychologically harmful to the inseminated patient and her partner, as well as to her child and her family, in terms of the stress and anxiety associated with the announcement that she may be infected and that she may have infected her relatives (Chatel, 1983; Rouleau, 1989). It may also be stressful to the donor.

Consequences for the Inseminated Patient—The inseminated woman wanted to bear her own child and, in

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Table 1. Route of transmission and consequences on health after an infection with hepatitis B or C or with HTLV-I/II (Fauci et al, 1998)*

Pathogen	Route of Transmission	Consequences on Health
Hepatitis B	Infrequent in utero infection Sexual and perinatal transmission represent about 5% of all cases Unknown route of infection for most seropositive blood donors	A persistent infection results in progressive liver failure and even cirrhosis or carcinoma
Hepatitis C	Possible in utero and prenatal transmissions Prevalence in the United States: 5%–10% related to homosexuality in men; 25% related to heterosexuality; 30% related to intravenous drug uses; and suspected sexual transmission in all other cases (30%–40%)	
HTLV-I/II	Transmission associated with breast-feeding, sexual intercourse, blood transfusion, and intravenous drug use	Prevalence for leukemia and myelopathy are 25% and 2%–5%, respectively, in infected patients Latency for leukemia varies from 20 to 30 years, whereas it is 3.3 years for myelopathy

* HTLV-I/II indicates human T-lymphotropic virus.

agreement with her partner, decided to be treated by an infertility clinic and to be artificially inseminated with the donor semen. Recontact may remind her of the difficulties associated with the time she was trying to get pregnant. Recontact may create fears about her health and the health of the members of her family. She will think that she may have been infected during artificial insemination and that she may have transmitted the infectious agent to her partner and her children, and she may feel guilty and anxious.

Consequences for the Male Partner—A male partner's infertility may often be the impetus for using donor semen. In some individuals, this may be consciously or unconsciously distressing. Particularly for those individuals, a recontact may be harmful because it will remind them of a difficult period of their lives and because it will remind them of the reality that they are not the biological father. Such reactions may be severe in some individuals.

Consequences for the Semen Donor—For several reasons, including altruism, generosity, and financial interest, the donor decided to participate in a program of artificial insemination. At the time of the gift, he was younger. Today, he may be married and does not necessarily wish to think about his previous paternity. His wife does not necessarily know about his semen donation. Recontact may remind him of a previous phase of his life that he may not necessarily wish to think about.

Consequences for the Child—The child does not necessarily know about his conception. A recontact may distress the whole family and indirectly affect the child himself. The intrafamilial relationships may be disturbed depending on the parents' reaction. A child's reaction will depend on his age, personality, and the information he has or has not received.

It is therefore likely that the announcement of a possible infection resulting from the use of an untested semen

sample in artificial insemination will result in both conscious and unconscious disturbance and anxiety for all members of the family and even for the semen donor. The level of harm is difficult to quantify, however, as it is dependent on individual reaction.

Dilemma

Recontact of all patients inseminated with untested semen samples is medically justified because of the risk of sexually transmitted diseases. On the other hand, informing patients of a possible contamination may result in psychological disturbance and anxiety for the woman, her partner, the child, and even the semen donor. Although contamination of a semen sample used for artificial insemination is hypothetical, a decision not to recontact at-risk artificially inseminated women might result in more distrust than notification.

The dilemma between psychological harm and the possibility of infection raises 2 fundamental questions that we addressed: 1) Is it scientifically feasible to screen either these men or the blood of a donor to retroactively declare safe semen samples used earlier for artificial insemination?, and 2) If the answer is yes, then would it be ethically justifiable not to recontact all the patients inseminated with untested semen but to recontact only patients inseminated with contaminated semen?

Retroactive Screening of Semen Donors and Artificially Inseminated Patients

The first question has been answered by the Committee for Prevention of Infectious Diseases at the University Hospital: when serological testing is negative for pathogens, a donor whose semen had previously been used in

Table 2. Most important recommendations from the Committee for Prevention of Infectious Diseases

Recontact all donors of semen and proceed with serological testing as recommended by the Canadian Fertility and Andrology Society (Health Canada, 2000).

Store semen from all donors including previous, actual, and eventual donors of semen.

For any positive results:

Recontact all exposed patients and proceed with the appropriate follow-up; and

Destroy unused frozen semen, except for a few samples that could be used for future analysis.

When serological testing is negative for all pathogens:

It is not necessary to recontact the inseminated patients for a follow-up.

In the impossibility of locating donor of semen:

Recontact all exposed recipients as if they had been inseminated with a contaminated sample; and

Destroy unused frozen samples, except for a few samples that could be used for future analysis.

Concerning the recruitment of semen donors, the Canadian Fertility and Andrology Society exclusion criteria must be applied with the following addition:

"Any individual having resided more than a month in a country with endemic prior disease must be excluded as a potential semen donor."

artificial insemination can be declared safe. On the other hand, a positive serological testing, or in the impossibility of locating a donor of semen, the Committee for Prevention of Infectious Diseases, recommends recontact of all exposed recipients.

Since it is feasible to validate *retroactively* the semen of a donor used in artificial insemination, and taking into account the psychological risks of recontact, a recontact policy for all recipients of donor semen must be rejected. The most important recommendations of this committee are presented in Table 2.

Ethical Considerations

Since the answer to the first question was affirmative, the second question was then addressed by the Bioethics Committee at Laval University Hospital.

The ethical discussion requires that the following aspects be considered: informed consent, the requirements of the therapeutic relationship, the basis of follow-up, the reason for follow-up, and justice.

Requirements of the Therapeutic Relationship (Beauchamp and Childress, 1994d)—Professionals involved in counseling must base their intervention on the well-being of those counseled. This beneficence is fundamental to the relationship. The well-being of the patient sought after by the professional is not limited to any particular dimension of the individual. The professional must be con-

scious that the person being treated is multidimensional: physical, psychological, intellectual, and spiritual.

The health professional has the competency and technique that places him in a position of power with those whom he helps. Furthermore, the nature of the relationship affords the professional an access to the privacy and the intimacy of those who place their confidence in him. He must strive for the welfare of those with whom he has a therapeutic relationship. Nonconformity with accepted procedures and regulated requirements does not meet the duties of the relationship and does not respect either beneficence or patient welfare.

Absence of Informed Consent—Informed consent has a long history (Faden and Beauchamp, 1986) and became one of the fundamental principles in biomedical ethics (Reich, 1995a,b). A fundamental ethical principle is that of physical and personal integrity. There must be no intervention without the free and informed consent of the person concerned. Free consent exists when a person acts on his own without fear, threat, or any sort of pressure. Consent is informed when the person has knowledge of and understands the information required for him to make a decision. The person must particularly be informed concerning any risks or complications specifically related to the planned intervention. As with other forms of health care, consent to a procedure is based on the legitimate presumption that any professionals involved would follow standard procedures within the legal limits. Since screenings on semen samples as Health Canada required were not performed, there was risk of transmission of infectious diseases. It would therefore seem doubtful that informed consent existed in these cases.

Reason for Follow-up—The possibility of follow-up must be examined after considering the benefits and disadvantages involved (Pellegrino and Thomasma, 1988). Three advantages of advising potentially at-risk individuals can be identified: 1) a person who is conscious of his clinical situation is able to benefit from available medical measures to cure a sickness and to diminish or delay its effects, and the concerned individual may also benefit from any new therapy; 2) changes in the person's lifestyle may affect the evolution of illness or disease, arguing in support of informing the person of her serological status; and 3) preventive measures can be adopted to prevent infection of the recipient's contacts.

Psychological and familial risks associated with the recontact and follow-up of individuals are discussed above. In spite of these risks, it would seem that the lack of follow-up involves greater risks for the recipient and her contacts. Consideration of the benefits and risks related to follow-up leads us to conclude that follow-up is reasonable.

The possibility of the recontact and follow-up of all recipients must be examined according to principles of

Table 3. Recommended procedure *

- 1) Each andrology laboratory must inform at-risk recipients as soon as they have any knowledge of possible contamination. In light of the health risks, this must be undertaken rapidly.
- 2) Health professionals should use state-of-the-art procedures in these interventions.
- 3) Even though a cause-and-effect link may be impossible to establish between semen of a CMV-seropositive donor and the contamination of a woman who was inseminated with the donor's semen, those persons responsible for the sperm bank are responsible for informing the patient of the risk.
- 4) Any procedure aiming to inform at-risk recipients must strive to incur the least risk possible, especially with regard to the psychological and familial dimensions. If it is feasible and scientifically valid to retroactively guarantee the safety of the semen used in artificial insemination, then a recontact of all recipients is unnecessary. In light of the considerable psychological and familial impacts that it is possible to avoid, this approach should be favored when donor testing proves negative.

* CMV indicates cytomegalovirus.

beneficence and not maleficence. The scientific and medical considerations highlighted in the present document point clearly to 2 conclusions: 1) there is no additional benefit to the recipient group to be gained through universal follow-up vs follow-up of at-risk recipients, and 2) universal follow-up would cause unnecessary and considerable harm of both a psychological and familial nature.

Recommended Procedure—Ethics demands that sperm banks act if certain interventions could favor the health and welfare of recipients. These interventions must be conducted in a manner likely to produce the least risk possible. In light of the gravity of the consequences to their health, recipients who were inseminated with seropositive semen ought to be rapidly recontacted. Furthermore, in light of the health risks related to insemination with untested semen, whether the intervention occurred before or after the 1996 guidelines, recontact of donors or at-risk recipients must be undertaken without regard to any date or timeline (Table 3).

Conclusion

When it is possible to proceed with serological testing and to retroactively declare safe semen samples used in artificial insemination, recontact of all women inseminated with untested semen is not justified scientifically and ethically and must not be undertaken. Only those women who have been inseminated by a seropositive or an unidentified donor need to be notified.

Consequently, any andrology laboratory has the obligation to rapidly recontact all donors of semen and to proceed to serological screening, as required by Canadian Fertility and Andrology Society, as follows: 1) for any

positive results, recipients exposed to these semen samples should be rapidly recontacted, and an appropriate follow-up should be initiated; 2) for a negative result, semen from the donor may be considered as if they were not contaminated—it is not necessary to recontact recipients; 3) in the impossibility of recalling a donor whose semen had not been screened as required, the semen samples should be treated as if they were infected, and recipients exposed to these semen samples should be rapidly recontacted, and an appropriate follow-up should be initiated; and 4) recipients at risk should be informed rapidly, and state-of-the-art procedures should be applied in those situations; moreover, psychological assistance should be offered to these recipients and their family.

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