

DONOR SPERM

EVERYTHING YOU EVER WANTED TO KNOW BUT WERE AFRAID TO ASK

by HAIMANT BISSESSAR, BSc

The use of donor sperm for artificial insemination has been practiced for over a century. Worldwide policies on the use of donor sperm vary greatly: Italy, Tunisia and Turkey prohibit by law the use of donor sperm, while in Hong Kong and Slovenia the use is restricted to in-vitro fertilization procedures¹. In the United States, Canada and the United Kingdom, there are no restrictions on the use of donor sperm; however, the law regulates the screening of donors and the processing and distribution of samples.

Since 1996, semen for assisted conception has been classified by Health Canada in the same category as drugs, and therefore falls under the authority of the Food and Drugs Act (F&DA)² (it is common to refer to a sperm bank or sperm donor, but the proper term is semen bank or semen donor). Under this law it is necessary to adhere to the regulations governing the processing and distribution of semen samples, as outlined in the Processing and Distribution of Semen for Assisted Conception Regulations (Semen

Regulations) document³. These regulations have undergone many transformations since 1986, when the question of guidelines on donor insemination was raised at the Annual General Meeting of the Canadian Fertility and Andrology Society (CFAS), held in Toronto.

At that time, it was determined that the published guidelines of the American Fertility Society (now the American Society for Reproductive Medicine) were “in a number of ways, either inappropriate for

Canada, insufficient, or, in one or two specific matters, incorrect.”⁴ Consequently, Canadian guidelines were developed by the CFAS, and were approved by the Board of Directors and the general membership in October 1988.

The guidelines were revised several more times. The final guidelines expanded the donor selection criteria and the testing requirements for transmissible diseases. Conditions were specifically outlined that had to be met in order to distribute semen samples processed prior to March 14, 2000, when the guidelines became effective^{4,5}. The CFAS 2000 guidelines were then converted into the Health Canada directive entitled Technical Requirements for Therapeutic Donor Insemination, which became effective on July 27, 2000.

Over the past few years Health Canada has issued Guidance^{2,5}, Clarification⁷ and Inspection Strategy⁸ documents to assist semen processors and distributors in understanding the regulations.

Additional requirements were introduced in spring of 2004, with the passage into law of the Assisted Human Reproduction Act⁹. Under this Act, it is prohibited to pay a sperm donor for his donation. However, any actual expenditures associated with a donation can be reimbursed.

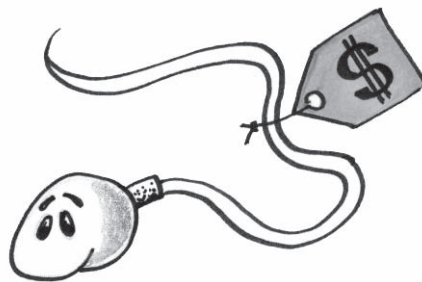
With these legal requirements, Canada now has the most stringent requirements worldwide for the screening and testing of semen donors.

The following are some of the questions that are typically asked by indi-

viduals who are considering using donor sperm to create their family:

Donor screening - What are the requirements to become a sperm donor? Can anyone be a donor?

All prospective donors must be between 18 and 39 years of age with no known hereditary or genetic disease or any serious disability and must have good quality sperm. They must all complete an extensive questionnaire, pass a physical examination, satisfy the rigorous standards for semen analysis, have a risk-free medical and family history, and undergo infectious disease and genetic testing⁶. Some sperm banks may impose other criteria such as a minimum educational background, height, height-to-weight ratio and overall attractive appearance. Only about 3-5% of prospective candidates eventually satisfy all these requirements and are accepted as sperm donors¹⁰.



Donor payment - How much are the donors paid?

Under the Assisted Human Reproduction Act of Canada (2004), it is prohibited to pay a donor for his sperm donation. Sperm samples that were in storage prior to the coming into force of the Act can still be used even if the donor was paid⁹.

Future availability - Would sperm for insemination be available in the future if donors are not paid?

Sperm banks are still able to import sperm from other countries where the donors are paid, until the importation of donor sperm regulation under the AHR act is developed and is in place. Once implemented, the importation regulations may affect the supply and availability of samples.

Designated or directed donors - Can I have a personal donor who will direct his donations for my use only?

A prospective donor can request that his donation be used only to inseminate a particular individual. The prospective donor will have to meet all of the requirements of the semen regulations to become a donor. Men who are rejected from becoming donors based on the exclusion criteria of the semen regulations may appeal to Health Canada for consideration under the provisions of the donor semen special access programme^{11,12}. Under this program, Health Canada may grant special access to individuals who wish to build their families using semen from donors who are excluded from donating semen for normal distribution on the basis of the exclusion criteria. These criteria would exclude men in the following categories from becoming sperm donors: men older than 40 years of age; men who have a history of alcoholism; men who have engaged in sex in exchange for money or for drugs at anytime since 1977; men who are homosexuals; or who are employed or have a family member employed by the sperm bank⁶.

The \$2500 to \$3500 cost of screening the donor and freezing and storing the samples would have to be paid by the prospective donor or recipient of the samples.

Regular inspection - Has the semen establishment (clinic, physician's office, semen bank) undergone regular inspection by Health Canada and are the semen samples compliant with the semen regulations?

Health Canada schedules inspections on a yearly basis or once every 2 to 4 years, depending on the activity of the semen establishment⁸. Semen samples must be checked to ensure that they are in accordance with the regulations prior to their distribution for use in the treatment of women undergoing donor insemination.



Disease testing - What are some of the tests the donors must undergo?

Donors must have blood tests for HIV1 & 2, Human T-cell leukemia-lymphoma virus (HTLV) 1 & 2, Hepatitis B & C, Syphilis, blood type and Rh factor, and every ejaculate must be tested for Chlamydia, Gonorrhea and general microbiological organisms. All semen samples must be placed in quarantine – this is achieved by freezing them for a mini-

mum of 180 days to allow for repeat screening and testing before they can be released for distribution^{6,12,13}.

Additional tests - Are other tests performed in addition to those specified in the semen regulations?

Additional tests that are performed include chromosomal analysis (karyotype), testing for Cystic Fibrosis carrier status, Alpha-1 antitrypsin deficiency carrier status (S & Z mutations), Human Papilloma (HPV) virus, and Herpes simplex virus types 1 & 2. However, these tests are not required under the semen regulations and are not performed by all sperm banks.

Testing methods - How effective are testing methods to detect infectious diseases?

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Test kits used for screening or detecting infectious diseases must be approved or licensed under the Canadian Medical Devices Regulations, or must meet the technical requirements specified by Health Canada in the Technical Requirements for Therapeutic Donor Insemination document⁶.

Ethnic donor testing - Are ethnic donors (e.g. Jewish, African, Chinese, Mediterranean) tested for conditions specific to their ancestry?

Although not a requirement under the semen regulations, donors of French-Canadian ancestry may be tested for carrier status of Tay Sachs, while donors of Jewish descent may be tested for Tay Sachs, Canavan, Gaucher, Bloom syndrome, Fanconi-Anemia Type C, Breast & Ovarian Cancer (BRCA-1) gene mutations, Niemann-Pick carrier status and Familial Dysautonomia. Donors of African descent may be tested for sickle cell anemia and other hemoglobinopathies while Asian, Middle Eastern and Mediterranean donors may be tested for Thalassemia.

Register of available donors - What information about the donor does it contain?

Information about the donor's ethnicity, height, weight, hair and eye colour, blood type, education, occupation and interests should be available¹³. Most semen banks will have a donor register or catalogue with this information available on their website for easy viewing and downloading.



Donor information - Beyond the basic information, is additional information available about the donors and their families?

Most donors have extensive profiles with medical and personal information, in addition to childhood, adult and lifetime (series of photos from infant to adulthood) photos, videos, audio CDs, donor essay, photo donor likeness and personality profiles. This additional information is usually available at a cost ranging from \$10 - \$150.

Photo matching may be an option if there is a person you want the donor to resemble. In this process, the sperm bank personnel will provide at least three donors who closely resemble the individual in the photograph you provide.

Anonymous versus ID consent or ID disclosure donors - What is the difference?

Anonymous donors are men who have donated sperm with the understanding that the sperm bank will not compromise their or the recipient's identities. Anonymous donors will always remain anonymous; they will never become ID consent donors.

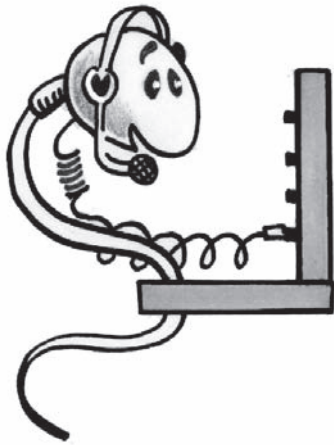
ID Consent donors agree to a limited release of identifying information

(name, address, phone number, date of birth) when the offspring from their donated sperm reach 18 years of age or older. Adult offspring will be the only individuals with the authority to request identifying information and to have access to the identifying information.

Recipient patients are required to sign a consent form, which may have to be notarized before purchasing ID Consent donors. When a child is born, the child must be registered with the sperm bank. At age 18, the registered child can contact the sperm bank and be provided with the information that the donor has agreed to release. In most cases, there is no commitment beyond releasing the donor information. It will be up to the child to locate the donor if he or she chooses, but there is no guarantee that the donor will be found, or that he will be able to accommodate the wishes of the offspring.

Sample availability - Does the semen bank have an adequate inventory of samples for the donors listed in the register?

Nothing can be more frustrating than spending hours selecting a particular donor only to find that his samples are unavailable. To avoid this situation, sperm banks try to maintain up-to-date inventory records. It is important to acquire samples in advance, especially if you are planning another pregnancy using the same donor. Samples can be purchased and stored at the sperm bank for future use. If these samples are no longer required, in most cases the sperm bank will refund a portion of the purchase price, usually 50%.



Placing an order - How do I order samples?

Depending on the setup at your physician's office or clinic, orders can be submitted by fax, by e-mail, by phone, or in person, by you or the clinic staff. In all cases, please verify the donor number with your health care provider prior to being inseminated.

Shipment of samples - How are samples shipped and what is the delivery time?

Samples are maintained in a frozen state in a specialized shipping tank. Delivery is usually by overnight courier service; however, your clinic may have pre-arranged a set day of the week for samples to be delivered. Delivery outside of metropolitan areas can take two to three days.



Washed and unwashed samples - What is the difference between washed and unwashed samples?

Seminal plasma contains prostaglandin hormones, which can cause uterine cramping. In washed samples, the prostaglandins are removed prior to cryopreservation (freezing). When thawed, these samples can be used for either intrauterine insemination (IUI) or intracervical insemination (ICI). Unwashed samples do not have the seminal plasma removed prior to freezing, and if samples are not washed after thawing, they can only be used for intracervical insemination.

Intracervical and intrauterine insemination - What is the difference between intracervical and intrauterine insemination?

In an intracervical insemination, the thawed semen sample is drawn up into a catheter and deposited around the cervix (opening to the uterus). In an intrauterine insemination, the washed sperm sample is transferred into the uterus by means of a catheter directly through the cervix.

Sample quality warranty - Is sperm quality guaranteed?

Most semen banks will warranty that the sperm samples have a minimum of 25% to 35% motility and at least 10 million motile sperm when thawed. This is more than adequate to achieve pregnancy.

Cost of samples and shipping - What are the sample and shipping costs?

The cost for each unwashed sample ranges from \$350 - \$500; the cost for each washed sample ranges from

\$435 - \$650. Shipping costs are between \$50 and \$200, depending on where the samples are to be shipped.

Other costs - How much more can I expect to pay?

Sperm banks may have handling charges which are typically \$25 - \$35 per order, a rush order fee for samples ordered for delivery within 24 hours (\$75 - \$125); a fee for cancellation of a processed order (\$75); a storage fee (\$25/month); a retrieval fee for removing units in storage for shipment (\$25), an application completion fee for donor special access program (\$125) and a tank rental fee (\$25 - \$35/day).

Goods and services tax (GST) is applicable for all charges, except for donor sperm, which is not taxable. Fertility clinics or physicians receiving donor sperm may levy a receiving fee on a per-sample or per-order basis. This fee can be as high as \$250 and is typically charged to cover the cost of assessing compliance of the samples to the Health Canada Semen Regulations.

Refund policy and procedure - Is there a refund/replacement policy and under what conditions would a refund or replacement sample be issued?

Most sperm banks have a sample quality guarantee and would offer a credit, refund the cost, or replace a sperm sample that falls below this quality level, providing the thawing and semen assessment instructions were followed by the physician's office or clinic. The refund procedure may require a written request from the physician or clinic as well as information about the quality of the thawed sample. Other conditions,

such as the length of time the samples are in storage at your physician's office, may affect the warranty. Please check the refund policy of each of the sperm banks used.

Access to information - How easily can information on the donor be accessed?

Most semen processors and distributors have web sites and brochures that contain information about their company and their donors. Updated donor registry information (catalogue) can be viewed and downloaded in the privacy of your home. Toll-free phone and fax lines make it easier to fax orders or contact the distributor without having to incur additional costs.

Donor fecundity - What is the typical pregnancy rate with donor sperm?

Pregnancy rates using cryopreserved donor sperm are in the range of 9 – 20% per cycle^{14,15}, and are not only dependent on the individual fertility diagnosis, but also on the clinic's rate of success. The clinic's statistics should be evaluated before proceeding with treatment.

Factors that affect pregnancy rates include maternal age or other infertility factors, timing of ovulation, sperm source (sperm bank) and semen quality^{16,17}.

Pregnancy limits - Is there a limit to the number of babies that can be conceived from one donor within a geographical area?

Sperm banks rely on the physician or clinic and the patients using the sperm samples to provide pregnancy outcome information. While limitations of donor use are not addressed in the Semen Regulations, it is difficult to provide a precise number of donor offspring in a given population without first considering the population base from which the donor was recruited, as well as the geographical area served by the donor¹³.

The American Association for Reproductive Medicine guidelines suggest that limiting a single donor to no more than 25 births in a population of 800,000 would avoid an increased risk of inadvertent consanguineous conception (i.e. offspring from the same donor producing children)¹³.



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Reserving samples - Can I reserve samples for future sibling pregnancies?

Sperm bank inventory changes on a daily basis, so if you are considering future pregnancies with the same donor it is prudent that you purchase units and have them stored either at the sperm bank or your doctor's office or clinic.

If the samples are stored at the sperm bank and are no longer needed, you may be eligible for a credit or partial refund of the purchase price. However, in most cases, once the samples have left the sperm bank, they cannot be returned for a refund, as there is no way of guaranteeing that the samples were properly stored.

Future testing - Are there provisions in place to test the donors for diseases that may be identified in the future?

Sperm banks may store serum, semen and DNA from the donor for future testing if required.

Customer service - Is a qualified and knowledgeable person available to answer questions? Sperm banks should

have a knowledgeable staff to assist patients in making their final selection, and should be able to respond to questions within 24 to 48 hours.

As the regulations change governing the procurement, processing and distribution of donor semen for assisted conception, there will be new factors to consider when selecting a sperm donor to be the biological father of your child.

There should not be any questions that you are afraid to ask when making this important and emotional decision. Feeling comfortable with the sperm bank you have chosen, understanding the process you are undertaking, having available all the necessary information and dealing with knowledgeable sperm bank staff can make a seemingly overwhelming decision much easier.

Patient resources

<http://www.iaac.ca>
<http://www.donorsiblingregistry.com>
<http://www.infertilitynetwork.org>
<http://www.members.shaw.ca/edmontoninfertility>

Institutional resources

<http://www.donorspermohs.com> - Canadian distributor for Xytex

Corporation

<http://www.repromedltd.com> - Repromed Ltd, a Canadian sperm bank.

<http://www.canamcryo.com> - Canadian distributor for Fairfax Cryobank

<http://www.hc-sc.gc.ca> - Health Canada's web site

http://www.hc-sc.gc.ca/hl-vs/reprod/index_e.html - Assisted Human Reproduction of Canada

<http://www.cfas.ca> - Canadian Fertility and Andrology Society

<http://www.asrm.com> - American Society for Reproductive Medicine



About the Author

Haimant Bissessar is vice-president of CAN-AM Cryoservices, a leading Canadian sperm distributor, located in Hamilton, Ontario.

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