Who's the daddy? US sperm banks must be better regulated

- 09 August 2007
- NewScientist.com news service
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CAREFUL, exacting, high-tech - that's the image US sperm banks like to project to their customers. They run limited genetic tests on their donors and trace medical records back three generations. They also screen for chemical exposure, drug use and even do complex psychological profiling.

Equally interesting is what sperm banks don't do - and are not required to do by law. They don't verify that all the medical or personal information that donors give them is correct. They don't routinely test for the majority of known genetic diseases. They do not confirm that the sperm the woman requested is the sperm that ends up in her body. And they don't always know where to find donors or recipient families should a concern crop up.
Now a small, not-for-profit company is beginning to fill in these gaps. In doing so, it threatens to expose just how common errors in the American fertility industry might be, and how little oversight exists to stop these problems from happening or to deal with them if they do occur.

In January this year, the Donor Semen Archive (DSA) was quietly launched in Ann Arbor, Michigan, to store donor-related DNA samples - from donor offspring, viable frozen samples of semen, used donor semen vials and syringes, and donors themselves - each filed against the donor's number. Its purpose is to keep a record of as many donors as possible, to make it much easier to answer any concerns that may arise about donors' health or identity, and identify whether any other children born to that donor might be at risk of genetic disease, for example. Run by a non-profit arm of Ann Arbor-based biotech company Cayman Chemical, the DSA's director, Kirk Maxey, hopes the archive will help keep tabs on an industry that he feels has been under-regulated.
Each year about 50,000 American women undergo donor insemination, which involves inserting living sperm into the body. Unlike IVF, in which all live births are recorded by the Centers for Disease Control, there is no dedicated record of babies conceived

through donor sperm in the US. There are around 20 sperm banks in the country.
Since 2005 the Food and Drug Administration has regulated the screening and testing of donors for infectious diseases, including HIV and hepatitis B and C, and the collection and storage of semen, but from that point on there is no supervision.

This is in stark contrast to the UK, where the Human Fertilisation and Embryology Authority (HFEA) collects data on live births, ensures that each donor helps create no more than 10 families, and holds a register of data on donors that offspring can access when they reach 18 or are seeking a marriage license.

In the US, errors are often detected only when the recipient family notices something amiss, such as a baby whose skin colour doesn't tally with the purported donor. Maxey himself was a sperm donor for 16 years, but quit when a lab technician told him she had stolen a vial of his sperm and inseminated herself. "I'm convinced that every conceivable misstep and perversion has happened," he says. "Many, many women with blue eyes have picked blue-eyed donors and ended up with brown-eyed kids."

Charles Sims, founder and medical director of California Cryobank, a sperm bank in Los Angeles, admits that such mistakes do happen. At his bank, he says there have been just two known cases of a woman getting the wrong sperm, and both were discovered by the clients. However, such errors are rare, and extraordinary steps are taken to avoid them, he says.

The American Society for Reproductive Medicine in Birmingham, Alabama, agrees that few complaints are made about donor insemination. "The record of problems is quite thin," says spokesman Sean Tipton. However, in its short life, the DSA has already begun investigating a number of irregularities. In one case, two women with the same donor who met through the Donor Sibling Registry - a service enabling people conceived through artificial insemination to contact genetic relatives - noticed something odd: one profile of the donor said that he had straight hair, while another said it was curly. DNA testing revealed that they had been fathered by two different men.

In another case, four children were born to different mothers who used the same donor, but the mothers now think that one child has a different father. As with any product, sperm banks do have some responsibility to give their buyer the item that they paid for, but so far these are untested waters. In March this year, a couple who had undergone IVF filed a lawsuit claiming emotional distress after their clinic used the wrong sperm. The clinic says it has no legal responsibility for the mix-up, however.
While these cases may be worrying enough, medical concerns loom larger. Last year, doctors in Ann Arbor published a report of five children in Michigan, born to four different mothers, who had all inherited an identical mutation for a rare genetic disease called severe congenital neutropenia. All five were the offspring of a single sperm donor. The sperm bank did not know how many children the man had fathered in total nor whether he was still donating elsewhere (New Scientist, 23 May 2006).

Maxey argues that if the semen had been independently archived, it could have been taken out of circulation after the first child was diagnosed. Instead, it was used for at least two more years.
The DSA is also investigating a similar case in which a child was born with a severe cranio-facial abnormality. The mother wants to purchase a new vial of the sperm to test if the mutation came from the father, but the sperm bank is refusing. It is under no legal obligation to test the sperm, nor is the donor required to be tested. These cases highlight the fact that there is little guidance on what to do if a donor is suspected of having a harmful mutation. The American Association of Tissue Banks issues voluntary guidelines encouraging traceability, but only six sperm banks are accredited by it. One of them is California Cryobank, which in a separate case is trying to track down all families who may have had children by one of their donors, who they now suspect carries a recessive gene for a metabolic disorder. Tracking down the families is a laborious task, admits Sims, "but we have an ethical obligation". All sperm banks ask mothers or their doctors to report live births and mention any problems, but few recipients bother, and there is no legal obligation to register these details. In the UK, fertility clinics are obliged to report live births to a central registry.

Maxey believes all used vials should be sent for sequencing as a matter of course, with the DNA profile then filed against donor number. "Somebody should be doing it," agrees Laura Shanner, a bioethicist at the University of Alberta in Edmonton, though she thinks it should be the government's responsibility rather than the DSA's.

Both Shanner and Arthur Caplan, a bioethicist at the University of Pennsylvania in Philadelphia, are worried that the DSA is violating the principle of informed consent – donors give sperm on the understanding that it will only be used for conception, not genetic testing. "Surreptitiously keeping samples in a biobank without explicit consent is unethical," says Caplan.
Meanwhile, the DSA continues to compile detailed genetic and personal profiles. Maxey says that like many people, he assumed that sperm banks kept records of all the resulting children. In fact, when he asked, the clinic had no idea how many offspring had been born to him, where they lived and whether or not they were healthy. "It dawned on me that we were missing a piece of the needed quality control in donor insemination," he says.

Eggs and embryos too

It's not just sperm banks that make mistakes. An audit of a bankrupt Californian egg donor registry has revealed that thousands of donated eggs have mysteriously gone missing.
Melinda Lansford, the former medical records supervisor at the Options National Fertility Registry, decided to go public last month after she was diagnosed with aggressive thyroid cancer.
Options was one of the biggest egg donor registries in the US, matching egg donors with recipients across the country. It filed for bankruptcy in 2005 following a damaging court case in which an egg donor referred to as "Elizabeth" discovered that a doctor had given some of her eggs to a second infertile couple without her consent or knowledge.

An audit of 12 years of records, detailing how many eggs each donor produced and what happened to them, suggests that Elizabeth's eggs were not the only ones to be "shared". Records indicate that 596 embryos and 2189 eggs remain unaccounted for. In total, 80 separate medical facilities and 102 doctors have been implicated in the mistakes, involving 229 donors. "It has happened once, and appears to have happened several more times," Lansford told The Orange County Register, which broke the story.

The scandal follows a similar incident at the University of California, Irvine, in which doctors gave away embryos belonging to infertile couples. At least a dozen babies were born as a result.