Screening for transmissible disease in ART patients not necessary at each donation

EurekAlert

Rome, Italy: European legislation that requires all couples undergoing assisted reproduction treatment (ART) to be screened for HIV and hepatitis at the time of every sperm or egg donation is unnecessary, expensive, and potentially distressing for patients, the 26th annual meeting of the European Society of Human Reproduction and Embryology heard today (Monday).

Ms Ciara Hughes, Senior Embryologist at Human Assisted Reproduction Ireland (HARI), Dublin, told the conference that, under the new Irish legislation, screens for HIV 1 and 2 and hepatitis B and C have to be carried out within 30 days of the start of each ART cycle. Prior to the transposition of the EU Tissues and Cells Directive into Irish law, these diseases were routinely screened for in patients at HARI and the clinic's policy was to have these screens performed within six months of the start of a couple's cycle of treatment.

"Most of these couples are in a stable relationship, and we believed that they were at minimal risk of contracting a communicable disease once the initial screen had showed them to be negative," said Ms Hughes. "However, we had no definitive proof of this and it is why we decided to carry out our study."

The researchers looked at screening results over a ten-year period from 1023 couples who had returned to the HARI clinic for testing after a 180 day quarantine of their surplus frozen embryos and gametes. These couples had been clear on their first screening. Following re-testing, the results were exactly the same no seroconversion (the development of specific antibodies in response to infection) had taken place in the intervening period. They also examined the screening results of 555 male oncology patients who were clear on first screening and returned for 180 days follow-up testing. Once again, all of them showed the same viral screen status and remained clear of infection.

"Since the introduction of the new testing requirement, we have carried out 17,494 viral screen tests either before therapy or within 30 days of egg collection and have not come across a single seroconversion," said Ms Hughes. "While I understand that safeguards are necessary to prevent the transmission of disease through the use of human tissue, assisted reproduction is not the same as organ donation or blood transfusion. The main difference is that in IVF the donation is to your cohabiting partner, whereas in tissue donation it is to an unknown person.

"Our research has proved what we already suspected; that there is negligible risk of seroconversion in this group of patients. Given the physical, financial, and emotional investment that each couple makes in undergoing a cycle of treatment, it is unjustifiable to request testing at the time of each donation in order to assess

such a minimal risk."

In requiring testing within 30 days of each cycle, Ireland has interpreted the Directive in a particularly restrictive way. Other countries such as Denmark have introduced more relaxed laws, which only require testing every two years. Since the introduction of the new law, all couples in Ireland have to pay, on average, an additional ?160 per cycle of IVF or ICSI. This could cost in the region of ?1.5 million per year, said Ms Hughes. At the clinic couples could have up to three cycles of treatment per year, and depending on the timing, this could mean each couple paying an additional ?480 per year on top of the treatment cost.

The legislation should be revised in order to factor in the unproven risks and to take into account individual patient needs, said Ms Hughes. "Our study is, to our knowledge, the first to carry out a risk assessment of the need for repeat viral screening in ART patients. Armed with this knowledge, a review of the European and Irish legislation in relation to assisted reproduction should be undertaken to avoid a lot of unnecessary costs, both financial and emotional, to couples undergoing ART," she concluded.

SOURCE [1]

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