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Title:

THE PREVALENCE OF SEXUALLY TRANSMITTED INFECTIONS IN A LOW-RISK GAMETE DONOR POPULATION

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Objective:

The Federal Drug Administration (FDA) is tasked with preventing the transmission of sexually transmitted infections (STIs) from gamete donors to recipients. To ensure that we "first, do no harm," donors undergo an intensive screening process, including a medical interview, physical examination, and clinical evaluation for relevant communicable diseases. When considering predictive values of diagnostic or screening tests, it is important to first identify the disease prevalence in the population being tested. This study aimed to evaluate the prevalence of STIs in the largest cohort of US sperm and egg donors to date.

Design:

Retrospective, cohort study

Materials and Methods:

The study included infectious screening data from potential sperm and egg donors presenting to a gamete bank from 2016-2018. Infectious disease testing (Human Immunodeficiency Virus (HIV), Hepatitis B (HBV), Hepatitis (HCV), Treponema pallidum (syphilis), Neisseria gonorrhea/chlamydia trachomatis (GC/CT), and Human T-lymphotropic virus (HTLV)) was performed on all donors during initial screening, repeated for sperm donors at 3 month intervals (GC/CT repeated at one month intervals), and for egg donors within 30 days of oocyte retrieval. In addition to serologic testing, qualitative in vitro nucleic acid testing (NAT) for HIV, HBV, and HCV was performed using the Procleix Ultrio Assay. The prevalence of each disease was calculated.

Results:

A total of 1041 unique sperm donors and 355 unique egg donors were included in the study. Among sperm donors, 1.73% (N=18) tested positive for GC/CT, 0.19% (N=2) tested positive for HBV, 0.10% (N=1) tested positive for HIV, 0.38% (N= 4) tested positive for syphilis, and 0.29% (N=3) tested positive for HTLV. No sperm donors tested positive for HCV. Among egg donors, 2.54% (N=9) tested positive for Chlamydia/Gonorrhea. No egg donors were positive for HIV, HBV, HCV, syphilis, or HTLV. No sperm or egg donors tested positive for more than one disease.

Conclusions:

In the largest US study of gamete donors to date, we found that the incidence of STIs is reassuringly low. Analysis of covariates demonstrated that the presence of any one infection did not increase the likelihood of a second infection. Recipients of donor sperm and eggs should be reassured that with appropriate medical interviews, examinations, and screening for relevant communicable disease agents and diseases, the risk of STI transmission is minimal. By understanding disease prevalence, we can quantify risk of infectivity, counsel patients appropriately, and improve the safety and efficacy of third party reproduction.