Social Implications of Non-Invasive Blood Tests to Determine the Sex of Fetuses[1]

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By 2011, researchers in the US had established that non-invasive blood tests can accurately determine the gender of a human fetus[4] as early as seven weeks after fertilization[5]. Experts predicted that this ability may encourage the use of prenatal sex screening tests by women interested to know the gender of their fetuses. As more people begin to use non-invasive blood tests that accurately determine the sex of the fetus[4] at 7 weeks, many ethical questions pertaining to regulation[6], the consequences of gender-imbalanced societies, and altered meanings of the parent-child relationship.

Physicians have used technology to detect the sex of the fetus[4] in gestation[7] since the invention of the prenatal ultrasound[8] in 1957. A prenatal ultrasound[8], also known as a sonogram, is a procedure in which doctors or nurses use a machine that emits and receives high-frequency sound waves to create images on a monitor of a fetus[4] in a woman’s uterus[9]. With ultrasounds, doctors or nurses can observe the anatomy of a fetus[4] and thus detect its sex around eighteen weeks of gestation[7], but depending on the position of the fetus[4], they do not always make accurate predictions.

For decades, other technologies like amniocentesis and choronic villus sampling have helped researchers obtain genetic information about the fetus[4], including its sex during gestation[7]. However, because these tests increase the risk of miscarriage[10], they are usually offered only to women who are at an elevated risk for carrying a child with a genetic disease. Amniocentesis[11] involves the surgical insertion of a needle into the uterus[9] of a pregnant woman to obtain fluid from the amniotic sac[12] for analysis. Doctors have used amniocentesis since 1956, but it cannot be used until at least the fifteenth week of pregnancy[13]. Additionally, amniocentesis carries a one in two hundred risk of miscarriage[10]. Choronic villus sampling is a test in which a technician inserts a needle into a pregnant woman’s uterus[9] and removes a sample of chorionic villi from the placenta[14] for testing. Choronic villi are branching outgrowths of the outer membrane that encloses the fetus[4] that increase surface area for absorption of nutrients in the womb[15]. Choronic villus sampling is performed between the ninth and twelfth week of pregnancy[13] and carries a one to three percent risk of fetal loss. Less than two percent of all US pregnancies undergo amniocentesis or choronic villus.

Many prenatal testing technologies were created, in part, as a means to avoid the birth of children with genetic diseases ranging from substantial to lethal. For example, in Europe, blood tests for detecting the sex of a fetus[4] have been used to screen for sex-related genetic disorders, such as Duchenne muscular dystrophy[16], which affects boys. However, if the fetus[4] is not at risk for those disorders, doctor's don't conduct the tests. Researchers have shown that some people use this technology merely to detect the genetic sex of a fetus[4] or embryo. Pre-implantation[17] genetic diagnosis is a test to determine if an embryo has genetic or chromosomal disorders; but for embryos conceived through in-vitro fertilization[5] (IVF).

In 1997, Yuk-Ming Dennis Lo, at Oxford University in Oxford, UK, and the Chinese University of Hong Kong[18] in Shatin, Hong Kong and his colleagues discovered fetal DNA in the blood plasma of pregnant women. The DNA was not in cells. In the fifteen years following this discovery, techniques to isolate the fetal DNA from the maternal blood and test it for diagnostic purposes became available. In 2011, researchers published the results of an assessment to measure the analytic validity of non-invasive fetal sex detection tests. The research team of this study included representation from several institutions, such as the Genetics and Public Policy Center for Johns Hopkins University[19], in Washington, DC, the US Department of Health and Human Services[20], at the US National Institutes of Health[21] (NIH), Bethesda, Maryland, and the Women and Infants Hospital, at Brown University[22], in Providence, Rhode Island. They performed a review and meta-analysis of studies in which researchers worked to detect fetal DNA in the blood of pregnant women, the results of which demonstrated that blood tests in a clinical setting can detect the genetic sex of fetuses after seven weeks of gestation[7] with ninety-five to ninety-nine percent accuracy.

While researchers verified the accuracy of non-invasive prenatal genetic blood tests in 2011, private biotech companies had produced and sold these tests to consumers online and in US drugstore chains for years beforehand. An at-home test put on the market in 2005 by Acu-Gen, headquarter in Lowell, Massachusetts, who claimed that it could detect fetal gender five weeks into pregnancy[13] with only a pinprick of the pregnant woman’s blood, but the company soon faced many lawsuits and filed for bankruptcy. In 2009, the company Sequenom, headquartered in San Diego, California, claimed to have an at-home prenatal blood test that detected Down syndrome[23] with 99 percent specificity, but later research showed that the company’s claim was not
based on evidence. A variety of other brands existed on the market in the years that followed, some of which didn't incite lawsuits or product recalls, but independently verified only to varying degrees.

Up to at least 2014, the US Food and Drug Administration (FDA) didn't regulate non-invasive prenatal blood tests and the US federal government didn't certify medical labs to use them, which discouraged US physicians from prescribing such tests. The FDA did not regulate tests that detect the sex of the fetus because the tests are not officially categorized as a medical device. FDA approval is not needed for direct-to-consumer genetic screening tests as long as the blood samples are sent to a private lab and the test is sold as a service. In February 2012 the US National Society of Genetic Counselors, in Chicago, Illinois, recommended that non-invasive prenatal tests should be offered in a clinical setting only, and administered by a qualified health care provider.

Researchers have documented the occurrence and consequences of sex selection at a nationwide levels since the early 1990s. Brought about by social norms and the increased accessibility of the ultrasound, decades of sex selective practices in China and India have resulted in imbalanced gender ratios, which predominantly favor males. Researchers cite China's One Child Policy for accelerating the gender imbalance in China, as the nation incentivizes families to have only one child, and those families often choose to have male offspring. In the early twenty-first century, India and China restricted abortions as a means of sex selection, and other nations adopted similar stances against sex selection.

After reports indicated that people in several former soviet states selectively aborted female fetuses, in September 2011 the EU Council Committee adopted a resolution prohibiting doctors from informing parents of the sex of their fetus. Many countries, such as the UK, Canada, Australia, Japan, France, and Germany, prohibit the use of pre-implantation genetic diagnosis for sex selection. In contrast to these countries, the US had no federal restrictions on sex selection, before or after implantation. In the US, the market treated the option of choosing whether or not to procreate, and in what manners, to be individuals' rights.

In the US, many discouraged the selection of sex via abortion, but in to the early twenty-first century, no regulations enforced such views. For example, a California company called Consumer Genetics sold a test called Pink or Blue that indicated fetal sex at eight weeks of pregnancy, however, Consumer Genetics stated that it does not want its test used for sex selection. Consumer Genetics sold approximately 1,000 Pink or Blue tests online per year, and the company stated that it would not test the blood samples unless the person submitting the sample signed a contract stating that they would not use the results for abortive sex selection. Critics noted that these contracts were largely symbolic because there was no mechanism in place to verify that customers who signed the contracts adhered to them. Consumer Genetics also said that it would not sell Pink or Blue tests to consumers living in China or India.

Some people defended their desires to select for gender on the basis of the concept of family balancing, especially when using pre-implantation genetic diagnosis technology. Family balancing is the practice of choosing sex based on the sex of children the family already had. Some countries adopted partial regulatory measures to accommodate for family balancing. For example, parents in Israel can use sex selection if a family has four children of one gender and wants to select for a child of the opposite gender. In the US, the 1973 Supreme Court decision Roe v. Wade legalized all abortions up through the first trimester on the basis of US constitutional right of privacy.

Some argue that choosing a fetus based upon such characteristics as sex treats the value of the child as conditional, and creates a parent-child relationship where value is measured by properties found desirable by the parent. Harvard professor Michael Sandel at Harvard University in Cambridge, Massachusetts, articulated these sentiments in his 2004 article, "The Case Against Perfection," maintaining that the quest to engineer the perfect child undermines human dignity. Thomas Murray, who was president of the bioethics institution the Hastings Center in Garrison, New York, from 1999 through 2012, cautioned that when children's characteristics are regarded as products of choice, a potential harm ensues, as they are born with expectations of fulfilling a defined gender role.

**Sources**


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