The Eeva™ Test

Infertility and the Role of In Vitro Fertilization

The Center for Disease Control reports that, in the United States, one out of eight couples is impacted by infertility.[1]

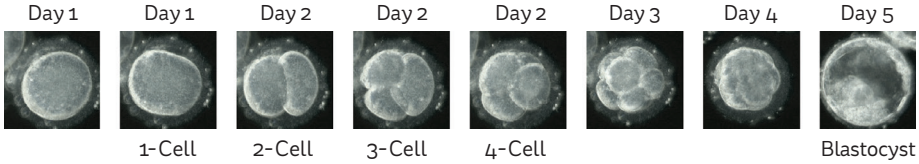
INFERTILITY

Infertility can be caused by a range of issues, including abnormal sperm production, function or delivery, cancer, ovulation disorders, abnormalities or damage to the uterus, cervix or fallopian tubes, pelvic adhesions, or advanced maternal age.

IN VITRO FERTILIZATION (IVF)

The Center for Disease Control reports that approximately 40% of couples with infertility seek treatment, many through *in vitro* fertilization (IVF). In fact, worldwide, the demand for assisted reproduction diagnostic tools and procedures has grown by 5% to 10% each year for the last few years with 1.5 million IVF procedures performed worldwide annually and an estimated 350,000 babies being born.[2]

The IVF process begins when egg(s) are retrieved from a woman's ovaries through ultrasound guided needle aspiration and then inseminated with sperm in a petri dish in an embryology laboratory (Day 0). Once fertilization of the egg(s) is confirmed on Day 1, culture of the embryo begins. By Day 3, a normally developing embryo will contain approximately 6 to 10 cells. By Day 5, a fluid cavity forms in the embryo and the placenta and fetal tissues begin to separate –this stage is called Blastocyst. Reaching the Blastocyst phase is a key indicator of a viable embryo. Blastocyst(s) is then transferred back into the mother.



Studies have shown that Day 5 transfers have a 50-70% relative improvement in live-birth rates versus Day 3 transfers.[3,4] However, some IVF clinicians and patients decide not to pursue Day 5 transfer because of the potential risks for cancelled transfer, high rate of multiples, monozygotic twinning, altered sex ratio or neonatal and long term outcome issues.[5]

EMBRYO SELECTION DURING IVF

Only about one-third of IVF cycles result in live births, with the success rate decreasing as maternal age increases.[6] In attempt to improve success rates, clinicians often transfer multiple embryos for each IVF cycle, particularly for women over the age of 35. As a result, more than 30% of IVF transfers in the U.S. result in twins or higher multiples, the highest multiples rate in the world.[7] Multiples dramatically increase the health risks for the mother and her babies, often with long-term developmental consequences.[2]

For this reason, many IVF clinicians use advanced technologies to help increase their accuracy of predicting embryo developmental potential and aid in selecting only the best embryos for transfer to reduce the multiples rate.

During the standard embryo selection process, embryos are removed from the incubator at fixed times, viewed manually under a microscope, graded by an embryologist based on several visual characteristics and then selected for transfer—this process is known as "morphology grading."

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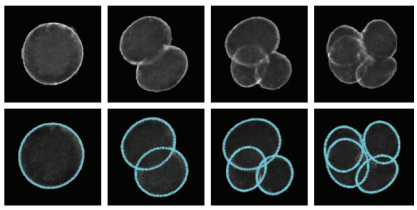
To enhance this process, breakthrough technologies like the FDA-cleared Eeva™ Test take time-lapse images of the embryos every five minutes inside of the incubator, decreasing the time the embryos are exposed to external elements during the incubation period while also collecting valuable embryo developmental information. The images are then analyzed by proprietary and automated image analysis software against cell division timing parameters to predict the embryo's developmental potential.



ECONOMIC IMPACT OF IVF

The average cost of an IVF cycle in the U.S. is estimated at $12,400 per cycle, according to the American Association of Reproductive Medicine. Medication usually costs between $3,000 to 5,000.[8] A 2012 study by RESOLVE, a patient advocacy organization, found that cost is the number one barrier to medical treatment for people with infertility.

Additionally, according to the *American Journal of Obstetrics & Gynecology*, twins cost approximately 5 times as much as singleton pregnancies; pregnancies with delivery of triplets or more are nearly 20 times as high. On average, heath care costs for singletons is $21,458 compared to $104,831 with twins and $407,199 with triplets or more.[9]

In many countries, the majority of patients pay out of pocket for IVF cycles, while payors bear the health care costs associated with multiples. In a 2013 survey by RESOLVE, more than 1600 women and men diagnosed with infertility revealed that nearly 50% of people have insurance but infertility treatments are not covered, while an additional 15% have plans that cover less than 25% of infertility treatment costs. Even in countries where IVF cycles may be partially or fully funded, many couples endure physical and emotional stress associated with repeat cycles to achieve live birth.

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1. *National Survey of Family Growth, 2010: http://www.cdc.gov/nchs/data/nhsr/nhsr073.pdf*
2. *ESHRE ART Fact Sheet: http://www.eshre.eu/Guidelines-and-Legal/ART-fact-sheet.aspx*
3. *Papanikolaou et al. New England Journal of Medicine. 1139-1146. 2006*
4. *Papanikolaou et al. Human Reproduction. 20(11): 3198–3203. 2005*
5. *ASRM Guidelines: Blastocyst culture and transfer in clinical-assisted reproduction: a committee opinion. Fertil Steril 2013; 99:667-72*
6. *SART Clinical Summary Report: https://www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?ClinicPKID=0*
7. *CDC website http://www.cdc.gov/art/*
8. *ASRM: http://www.reproductivefacts.org/detail.aspx?id=3023*
9. *Lemos, et al, American Journal of Obstetrics, December 2013*

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