Understanding IVF Success Rates and Legal Recourses for Misrepresentation

By John Phelps, M.D., J.D., LL.M. Candidate
JYPhelps@aol.com

Infertile couples seeking in vitro fertilization (IVF) in order to conceive a child oftentimes lack a basic understanding of the various methods of calculating IVF success rates. Without a basic understanding of various methods used to calculate IVF success rates, interpretation of IVF success rates can be bewildering and confusing. Also, infertile couples in their desperation to have a child are extremely vulnerable to unscrupulous and misleading success rate advertising. Although the majority of fertility clinics make good faith efforts to present their IVF success rates to potential patients in a manner that is accurate and understandable, some fertility clinics may take advantage of the naiveté of infertile couples who lack an understanding of the various methods used to calculate IVF success rates. Also, fertility clinics have a financial incentive to exaggerate their IVF success rates or present their rates in a misleading manner.

One of the principle determinative factors for infertile couples in choosing a particular fertility clinic over another is the clinic’s reported IVF success rate.1 It is a powerful lure to attract infertile couples for a fertility clinic to claim higher IVF success rates than its competitors; even if only by a few percentage points. This is one of the few areas of medicine – if not the only area – where potential patients are subjected to success rate advertising. Moreover, the accuracy of success rate reporting is rarely reviewed or questioned and is generally dependent on the self-imposed integrity of the individual fertility clinic.

An understanding of the steps of an IVF cycle is necessary to appreciate why IVF success rates vary depending on the stage of the IVF cycle. An IVF cycle entails a progression of multiple steps including ovulation induction, transvaginal oocyte retrieval, in vitro fertilization and embryo transfer. The first step of an IVF cycle is ovulation induction. In this first step of an IVF cycle, a woman is given injections of fertility drugs to induce the ovaries to produce follicles from which eggs will later be harvested. Usually ovulation induction will require between nine to 14 days of injections of fertility drugs. The second step of an IVF cycle is called transvaginal oocyte retrieval, which involves a surgical procedure to harvest the eggs from the ovaries. In this step a needle is passed through the vagina into the ovaries under ultrasound guidance. The eggs are aspirated from the ovarian follicles and immediately handed off to an embryologist. In the third step of an IVF cycle, the embryologist places the eggs in a Petri dish along with the husband’s sperm. Fertilization will take place in the Petri dish. This step is the actual in vitro fertilization process.

The fertilized eggs now are called embryos and will be grown in a Petri dish over the next three to five days before being transferred into the uterine cavity. The fourth step of an IVF

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1 For IVF success rates that were reported to the Center for Disease Control by fertility clinics in different areas, see http://www.cdc.gov/reproductivehealth/ART02/index.htm (last visited Dec. 5, 2005).
cycle is called the embryo transfer. This is done by placing the embryos into a catheter and from a vaginal approach inserting the catheter through the cervix into the uterine cavity. Upon inserting the catheter containing the embryos into the uterus, the embryos are injected into the uterine cavity. A pregnancy test is performed approximately two weeks after the embryo transfer, and, if positive, a woman is said to have a “chemical pregnancy.” Once a gestational sac is visualized with the uterus by ultrasound, it is considered a “clinical pregnancy.” Finally, once the infant is born, it is considered a live birth.

Because IVF is a multi-step process with multiple outcome variables, IVF success rates can be calculated in any of the following manners:

1. \((\text{Number of patients with a positive pregnancy test / number of patients starting ovulation induction}) \times 100\).
2. \((\text{Number of patients with ultrasound confirmed pregnancy / number of patients starting ovulation induction}) \times 100\).
3. \((\text{Number of patients with a live birth / number of patients starting ovulation induction}) \times 100\).
4. \((\text{Number of patients with a positive pregnancy test / number of patients who underwent transvaginal oocyte retrieval}) \times 100\).
5. \((\text{Number of patients with ultrasound confirmed pregnancy / number of patients who underwent transvaginal oocyte retrieval}) \times 100\).
6. \((\text{Number of patients with a live birth / number of patients who underwent transvaginal oocyte retrieval}) \times 100\).
7. \((\text{Number of patients with a positive pregnancy test / number of patients who underwent embryo transfer}) \times 100\).
8. \((\text{Number of patients with ultrasound confirmed pregnancy / number of patients who underwent embryo transfer}) \times 100\).
9. \((\text{Number of patients with a live birth / number of patients who underwent embryo transfer}) \times 100\).

The pregnancy loss rate between four to 20 weeks gestation is estimated to be 15% and may be as high as 50% in the first two to four weeks following conception.\(^2\) Because the chances of pregnancy loss are higher in the earlier stages of pregnancy, IVF success rates calculated using positive pregnancy tests as the numerator will be higher than IVF success rates calculated based on the visualization of a gestational sac within the uterine cavity, i.e., a clinical pregnancy. Similarly, IVF success rates using identification of a gestational sac within the uterine cavity as the numerator will be higher than IVF success rates using live births as the numerator. Thus it is not uncommon for fertility clinics to report their rates to potential patients using positive pregnancy tests or clinical pregnancies as the numerator instead of live births. In addition to understanding how the use of positive pregnancy tests instead of live births in the numerator can impact IVF success rates, it is also important to understand that the denominator used to calculate IVF success rates will vary greatly depending on the stage of the IVF cycles. There is a decrease in the number of patients at each stage of IVF cycles as the cycle stage progresses from ovulation induction, to

transvaginal oocyte retrieval and to embryo transfer. Just because a patient starts ovulation induction with fertility drugs does not mean that she will adequately respond or produce enough ovarian follicles to proceed with the next step of an IVF cycle. Some patients are “poor responders” and are unable to produce follicles despite fertility drugs. These “poor responders” are frequently dropped from the IVF cycle and never proceed to the next stage, which is the transvaginal oocyte retrieval. Also patients who respond too well may be dropped due to ovarian hyperstimulation. Approximately 13% of patients who start the fertility drugs are dropped before the transvaginal oocyte retrieval stage, and approximately 19% are dropped before the embryo transfer stage. Thus, the denominator of the number of patients undergoing transvaginal oocyte retrieval is lower than the number of patient who initially started ovulation induction. In addition to these methods, fertility clinics may use other methods to boost their IVF success rates, such as counting multiple births (e.g., twins, triplets or quadruplets) as more than one live birth.

Fertility clinics should report their IVF success rates based on what a reasonable person considering IVF would want to know about a clinic’s success rates. Because infertile couples seeking infertility services are most interested in knowing what the “take home baby rate” is, this is the most meaningful outcome variable and should be the one that is used. Accordingly, the outcome variable used to calculate IVF success rates in the numerator should be the live birth rate and not a positive pregnancy test or a gestational sac visualized within the uterine cavity. Similarly, the denominator used in calculation of IVF success rates should be the number of patients who start an IVF cycle because the majority of patients inquiring into an IVF program are most interested in knowing what their chances are of taking home a live baby after paying money and starting the fertility drugs.

Fertility clinics should also explain the impact poor responders and age have on IVF success rates, as well as the importance of looking at other measures such as IVF success rates based on transvaginal oocyte retrieval and embryo transfer. However, so as to keep the reporting of IVF success rates uniform and lessen the likelihood of confusion for infertile couples, success rate advertising based on transvaginal oocyte retrieval or embryo transfer should not be the primary method of statistical reporting, but rather only a means to provide additional information to infertile couples. It is inherently confusing to patients for IVF programs to report their success rates using methods to calculate IVF success rates other than live births as the numerator and starting of the IVF cycle with fertility drugs as the denominator. This confusion is further compounded when fertility clinics are overly optimistic in their reporting of IVF success rates to potential patients.

Fertility clinics that intentionally or negligently make material misrepresentations of their IVF success rates may be subject to liability. Infertile couples who detrimentally relied on a clinic’s misrepresentation of IVF success rates may be able to recover the cost of the IVF cycle including medication costs, physician, ultrasound, and laboratory fees. Also, infertile couples may be able to recover the cost from time missed from work, attorney fees, and

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noneconomic damages for mental anguish, pain and suffering. In addition, if the misrepresentation was intentional and made with a reckless disregard for the truth, infertile couples may be able to recover punitive damages. In States that have deceptive trade practice and consumer protection laws such as Texas, infertile couples who detrimentally relied on a fertility clinic’s inaccurate or misleading representation of IVF success rates may be able to recover treble damages (three times actual economic damages). Also, the Federal Trade Commission and a State’s Office of Attorney General may intervene on behalf of consumers. Previously the FTC has won cease and desist orders against fertility clinics for deceptive advertising in states such as Arizona, California, Colorado, Massachusetts and New York.4 Similarly, various Offices of the Attorney General have filed motions against fertility clinics for deceptive advertising of IVF success rates.5 Just like any other business, fertility clinics are also subject to the legal consequences of false and misleading advertising.

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