# The Facts of Life: A Review of the Science and Ethics of IVF

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## OVERVIEW

IVF does not treat infertility; IVF is a technical workaround in attempts to have a baby.
IVF recognizes the biological fact that a human life begins at fertilization. But the IVF industry has been unregulated and unaccountable in providing a standard of medical care that recognizes and protects the lives involved.
Current IVF practice is seldom life-affirming and never life-sparing. Large numbers of embryos are created, graded for quality, and at least 90% do not survive, are destroyed, discarded, or frozen for storage.
IVF can pose distinct risks both to mothers and to babies.

## Introduction

Most people have heard of IVF (In Vitro Fertilization). A human life begins at fertilization, and since 1978, IVF has been used to produce millions of human embryos who have developed and been born. However, there is significant confusion and misunderstanding about the practices of the IVF industry, the details of IVF, the actual numbers of embryos created and destroyed along the path to gestation and birth, and IVF's risks and alternatives. This brief review will help readers make informed decisions about IVF and IVF-related policies.

## Few IVF laws and regulations, unaccountable industry

In the U.S., there are few laws regarding IVF and fertility medical practices other than requirements to report some statistics to the Centers for Disease Control and Prevention (CDC.) The lack of regulation leaves the IVF industry with very little oversight or accountability to the public or to their customers, and no standard of care, unlike the vast majority of medical practices. The American Society for Reproductive Medicine (ASRM) publishes guidance documents that set recommended practices for the industry, though practitioners are not obligated to follow these recommendations.[1]

*A recent report valued the global IVF market for 2023 at $25.34 billion, with an expected growth per annum of 5.57% in the coming years.*

As currently practiced, the IVF industry is a business practice, and a lucrative one. A recent report valued the global IVF market for 2023 at $25.34 billion, with an expected growth per annum of 5.57% in the coming years to reach $43.57 billion by 2033.[2] However, the industry is seldom life-affirming and in many ways falls short of respect for the patients who seek to have children – and certainly for the children created in the technological process.

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[1] American Society for Reproductive Medicine, "Practice Guidance," 2024; accessed at: https://www.asrm.org/practice-guidance/

[2] BioSpace, In Vitro Fertilization Market Experiencing Rapid Expansion, April 2, 2024; accessed at: https://www.biospace.com/in-vitro-fertilization-market-experiencing-rapid-expansion

The State of Louisiana has a statute in place since 1986 that protects all in vitro embryos.[3] The statute notes that "a viable in vitro fertilized human ovum is a juridical person" with legal status, "which shall not be intentionally destroyed by any natural or other juridical person or through the actions of any other such person." Yet with these standards of medical regulation, IVF is still successfully practiced in Louisiana.

*The State of Louisiana has a statute in place since 1986 that protects all in vitro embryos… with legal status.*

Some countries have laws that regulate IVF practices to varying degrees. In many cases, there are limits to the number of embryos that may be transferred per cycle; these limits were set in attempts to mitigate the risks of complications from multiple pregnancies. But in almost every case, the creation of multiple embryos is allowed (though recommended against in some countries) and the freezing and storage of excess embryos not transferred is also allowed.[4]

Germany has perhaps the most substantial laws regarding IVF. The German Embryo Protection Act, enacted in 1990, prohibits the destruction of a human embryo.[5] Limited numbers of embryos are allowed to be created at one time, preferably only the number that will be transferred to the womb that cycle. Embryo freezing, while allowed, is supposedly reserved for preservation of the lives of embryos not transferred to the womb at the time. In recent years, there has been a proposal termed the Deutscher Mittelweg (German Middleway). This interprets the law to allow the creation of multiple embryos and the culture of up to four to select the healthiest for single embryo transfer (SET), and the remaining embryos are frozen with the intent to transfer them in the near future.[6]

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[3] Louisiana Health Law, Chapter 3. LA-RS 9 §121-§133; accessed beginning, and following: https://legis.la.gov/legis/Law.aspx?d=108438

[4] McDermott O et al., A comparison of assisted human reproduction (AHR) regulation in Ireland with other developed countries, *Reprod Health* 19, 62, 2022; DOI: https://doi.org/10.1186/s12978-022-01359-0; AND Calhaz-Jorge C et al., Survey on ART and IUI: legislation, regulation, funding and registries in European countries: The European IVF-monitoring Consortium (EIM) for the European Society of Human Reproduction and Embryology (ESHRE), *Human Reproduction Open* 2020, 1-15, 2020; DOI: https://doi.org/10.1093/hropen/hoz044

[5] Federal Law Gazette, Part I, No. 69, issued in Bonn, 19th December 1990, page 2746
Act for Protection of Embryos, Gesetz zum Schutz von Embryonen (Embryonenschutzgesetz – ESchG) Of 13th December 1990; Accessed at:
https://www.rki.de/SharedDocs/Gesetzestexte/Embryonenschutzgesetz_englisch.pdf?__blob=publicationFile

[6] Deutsches IVF-Register e.V. (D·I·R) and Jahrbücher (German IVF Registry and Yearbooks); Accessed at : https://www.deutsches-ivf-register.de/; AND Kliebisch TK et al., The German Middleway as Precursor for Single Embryo Transfer. A Retrospective Data-analysis of the Düsseldorf University Hospital's Interdisciplinary Fertility Centre – UniKiD, *Geburtshilfe Frauenheilkd* 76, 690-698, 2016; DOI: 10.1055/s-0042-105747

**The well-established science on the beginning of a human being's life**

A recent Alabama Supreme Court decision recognized the basic biology of human reproduction (biological facts which are also recognized in the practice of IVF itself): a new human life begins at fertilization.[7] The result is an organism, a totipotent one-cell embryo, meaning a cell capable of generating a globally-coordinated developmental sequence.[8]

*"Prenatal age begins at fertilization, postnatal age at birth."*

Scientists have acknowledged the existence of this new human life for over a century. Formally, the Carnegie stages of human development[9] — which designate fertilization (in particular sperm-egg fusion) as the beginning of human life and organismal development — have been the accepted standard of human embryological development since 1942. These standards of human embryology were completed by the highly-respected embryologist Dr. Ronan O'Rahilly and have been reaffirmed by all leading embryologists ever since. O'Rahilly himself put it bluntly: "Prenatal age begins at fertilization, postnatal age at birth." [10]

Embryologists recognize this fact and rely on it for the production of human embryos for the IVF industry. In fact, while the first reported birth of a baby via IVF was in 1978,[11] the first reported production of in vitro human embryos was in the 1940's.[12] So science acknowledges the reality of a human being's beginnings. To take just one other example, the journal *Nature*, one of the leading scientific journals in the world, titled a story on human development "Your destiny, from day one."[13] As the details of this voyage of life continue to be illuminated, more and more details are being outlined about the development of a young human being.[14]

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[7] Condic ML, When Does Human Life Begin? The Scientific Evidence and Terminology Revisited, *University of St. Thomas Journal of Law and Public Policy* 8, 44-81, 2013; accessed at: https://researchonline.stthomas.edu/esploro/outputs/991015131529403691

[8] Condic ML, Totipotency; What it is and what it is not. *Stem Cells and Development* 23, 796-812, 2014; doi: 10.1089/scd.2013.0364

[9] See, e.g., Carnegie Stages. Dr Mark Hill, 2024, UNSW Embryology ISBN: 978 0 7334 2609 4 - UNSW CRICOS Provider Code No. 00098G; accessed at: https://embryology.med.unsw.edu.au/embryology/index.php/Carnegie_Stages; AND Embryonic Ages & Stages, *The Virtual Human Embryo*, accessed at: https://www.ehd.org/virtual-human-embryo/ages.php

[10] O'Rahilly R, Müller F, Developmental Stages in Human Embryos: Revised and New Measurements, *Cells Tissues Organs* 192, 73–84, 2010; DOI: 10.1159/000289817

[11] Steptoe PC and Edwards RG, Birth After The Reimplantation Of A Human Embryo, *The Lancet* 312, 366, 12 August 1978; DOI: 10.1016/S0140-6736(78)92957-4

[12] Rock J, Menkin M, In vitro fertilization and cleavage of human ovarian eggs, *Science* 100, 105-107, 1944; DOI: 10.1126/science.100.2588.105; AND Menkin M, Rock J, In vitro fertilization and cleavage of human ovarian eggs, *Am J Obstet Gynecol.* 55, 3440-3452, 1948; DOI: 10.1016/S0002-9378(15)32963-X

[13] Pearson H, Your destiny, from day one, *Nature* 418, 14–15, 2002; https://doi.org/10.1038/418014a

[14] Voyage of Life, Charlotte Lozier Institute, last updated on January 15, 2024; accessed at: http://voyageoflife.com

## Current practices of IVF and other Assisted Reproductive Technologies

Most have a simplistic view of IVF and similar assisted reproductive technology (ART). The prevalent logic is: "IVF creates babies in the lab. We want babies, so IVF is pro-life and acceptable."

That incorrect logic ignores the actual numbers of embryos produced and destroyed, the risks to mothers and babies, and the fact that IVF is not even close to 100% efficient. These realities raise a plethora of medical and ethical concerns.

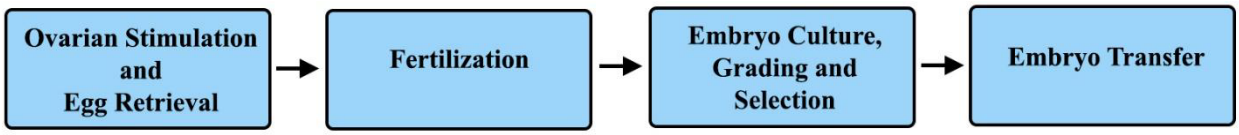
IVF has become the "quick fix" and popular high-tech answer to a diagnosis of infertility. The standard definition of infertility is failure of a male-female couple to achieve pregnancy after one year of unprotected intercourse.[15] Some practitioners use a time standard of only six months for women over age 35, since infertility rates increase with age. Initial treatment may involve surgery (e.g., opening blocked fallopian tubes) and/or attempts to hormonally stimulate the ovaries with various fertility drugs, as well as other means to increase the chances of fertilization (e.g., in utero insemination).[16] Others may skip all other treatment options and pressure couples to try IVF soon after diagnosis.

IVF is offered as a technological option to produce a baby. In an increasing number of cases, IVF is offered early in the treatment scheme, bypassing low-tech options. It has even been proposed that IVF be the sole method for human reproduction.[17]

Keep in mind that IVF does not treat the underlying causes of infertility; IVF is a workaround attempt to produce a baby without addressing the root causes of infertility.

## The Process of IVF

The normal steps for IVF are:

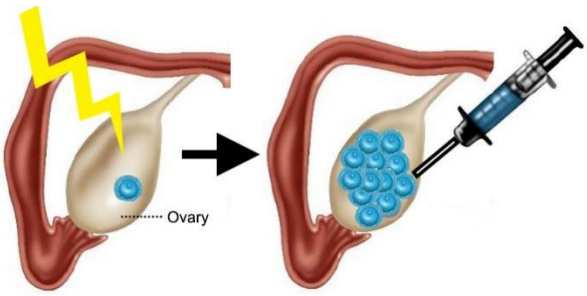



[15] Infertility FAQs, CDC, 2024; accessed at: https://www.cdc.gov/reproductivehealth/infertility/index.htm

[16] Carson AC, Kallen AN, Diagnosis and Management of Infertility A Review, *JAMA* 326, 65-76, 2021; doi:10.1001/jama.2021.4788

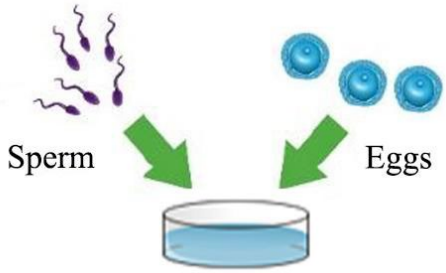
[17] Whelan J, Sex is for fun: IVF is for children, *New Scientist* 192, 42-45, 2006; DOI: 10.1016/s0262-4079(06)60791-4

Ovarian Stimulation and Egg Retrieval




The process of IVF begins with collection of eggs and sperm. Collection of eggs most often involves hormonal stimulation. Practitioners first put the menstrual cycle on hold to synchronize egg maturation, then apply high doses of hormones to stimulate the ovaries to produce multiple eggs at one time rather than the single egg usually matured per cycle. Laparoscopic surgery is used to harvest the eggs from the ovaries. In an increasing number of cases, "donor" eggs and/or sperm are used to create embryos. Once harvested, the eggs are fertilized to produce embryos.

Fertilization




At this stage, there are several variations on the procedure, with the differences depending on where fertilization takes place as well as the placement of embryos produced in the lab.

In *traditional IVF*, which makes up 99% of ART procedures, the eggs and sperm are combined in the lab dish, where fertilization takes place. Embryos are subsequently transferred to the uterus, where implantation into the uterine lining can take place.

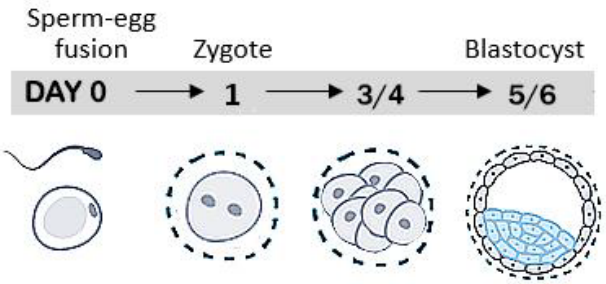
In *Gamete Intra-Fallopian Transfer (GIFT)*, eggs and sperm are transferred to the fallopian tube, which is the normal site of fertilization. Any embryos produced inside the body will develop as they move naturally down the fallopian tube until they reach the uterus, where implantation can take place. In this way, GIFT is an attempt to approximate the more natural environment for fertilization and the first days of human development.

*Zygote Intra-Fallopian Transfer (ZIFT)* combines eggs and sperm outside the body in the lab dish to form the single-cell embryo, termed a zygote, as is done with traditional IVF. But the embryo is then transferred to the fallopian tube, approximating the site and environment where she would have been produced normally by fertilization. This again is an attempt to approximate the natural environment for early embryo development, moving down the fallopian tube and reaching the uterus, where implantation can take place.

*Intra-Cytoplasmic Sperm Injection (ICSI)* is a variation of IVF used when the sperm fails to fertilize the egg naturally, when there is poor sperm motility, and for other reasons related to sperm quality or problems with egg or sperm in achieving fertilization. The lab technician literally does the fertilization, injecting one sperm into each egg under a microscope. After a further period of growth in the lab dish, the embryo is transferred to the uterus as in traditional IVF. There is some increased concern with this procedure since more parts of the sperm enter the

egg than in natural sperm-induced fertilization, as well as due to the significant manipulation of the egg involved.[18]

Embryo Culture, Grading, and Selection




Once created, the embryos are grown in laboratory culture dishes with liquid nutrient growth media for several days. This is done to observe embryo health. Some embryos do not survive and grow but instead die in the dish. After 2-5 days' culture, surviving embryos are evaluated by various methods and are "graded" by subjective microscope inspection to indicate a judgment of their potential for implantation and development.[19] There has even been a movement to incorporate AI into the grading of embryo quality.[20] Theoretically, those judged as "high-quality" embryos have a better chance of implantation and gestation to birth, but studies show that even so-called "low-quality" embryos can develop into normal babies.[21]

Genetic testing has also been used to evaluate embryo quality and specifically to select for or against embryos with various genetic traits. Preimplantation genetic testing (PGT, sometimes termed PGD for preimplantation genetic diagnosis or PGS for preimplantation genetic screening) involves pulling off one or two cells from the early embryo. The cell(s) undergoes genetic analysis while most often the embryo is frozen in the meantime, awaiting a decision on genetic fitness.[22] Screening may be for aneuploidies (different chromosome numbers, e.g., trisomies such as Down syndrome, trisomy 13, trisomy 18) or for specific genetic compositions and traits, including for sex selection, and even potential adult-

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[18] Henningsen A-KA et al., Risk of congenital malformations in live-born singletons conceived after intracytoplasmic sperm injection: a Nordic study from the CoNARTaS group, *Fertility and Sterility* 120, 1033-1041, 2023; DOI: https://doi.org/10.1016/j.fertnstert.2023.07.003; AND Esteves S et al., Intracytoplasmic sperm injection for male infertility and consequences for offspring, *Nature Reviews Urology* 15, 535-562, 2018; DOI: https://doi.org/10.1038/s41585-018-0051-8; AND The Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technology, Genetic considerations related to intracytoplasmic sperm injection (ICSI), *Fertility and Sterility* 86, Issue 5, Supplement, S103-S105, 2006; DOI: https://doi.org/10.1016/j.fertnstert.2006.07.1489; AND Sanchez-Calabuig MJ et al., Potential health risks associated to ICSI: insights from animal models and strategies for a safe procedure, *Frontiers of Public Health* 2, 2014; DOI: https://doi.org/10.3389/fpubh.2014.00241

[19] Racowsky C et al., Standardization of grading embryo morphology, *Fertility and Sterility* 94, 1152-1153, 2010; DOI: https://doi.org/10.1016/j.fertnstert.2010.05.042; AND Nasiri N, Eftekhari-Yazdi P, An Overview of The Available Methods for Morphological Scoring of Pre-Implantation Embryos in In Vitro Fertilization, *Cell J.* 16, 392–405, 2015; DOI: 10.22074/cellj.2015.486

[20] Gilboa D et al., Implementing an artificial intelligence (AI)-enabled embryo analysis algorithm (AiVF Score) improves data-driven decision-making in the IVF clinic, *Reproductive Biomedicine Online* 45, SUPPLEMENT 1, e32-e33, 2022; DOI: https://doi.org/10.1016/j.rbmo.2022.08.055

[21] Lai I et al., Transfers of lower quality embryos based on morphological appearance result in appreciable live birth rates: a Canadian center's experience, *F S Rep*. 1, 264–269, 2020; DOI: 10.1016/j.xfre.2020.09.003

[22] Baruch S et al., Genetic testing of embryos: practices and perspectives of US in vitro fertilization clinics, *Fertility and Sterility* 89, 1053-1058, 2008; DOI: https://doi.org/10.1016/j.fertnstert.2007.05.048

onset disorders (e.g., breast cancer). While some early studies showed increased success at live birth using genetic selection of the desired embryos, other studies indicate PGT actually lowers the live birth rate,[23] does not improve pregnancy, implantation, or live birth rates,[24] and should not be used except perhaps for research studies.[25] As with visual grading, many embryos labeled "low quality" or "abnormal" by PGT produce normal, healthy babies.[26] As one might expect, not all embryos survive having some of their cells pulled off.

Despite the eugenic nature of PGT, more comprehensive genetic screening of IVF embryos, called polygenic embryo selection/screening (PES), has become commercially available. This involves genetic screening of many embryos for multiple genes, followed by estimates of the embryos' "polygenic risk score" for likelihood of various diseases or traits. An embryo is then selected for transfer on the basis of this score. This practice raises additional ethical concerns due to the unproven predictive value of the scores and the eugenic utility of PES.[27]

Clinics may offer PGT or other "add-ons" as incentives, claiming they improve the efficiency and survival of embryos to live birth. The Cochrane reviews, considered of highest quality in academic literature, "found that none of the IVF add-ons are supported by high-quality evidence that the add-on is effective and safe."[28]


Embryo Transfer

If embryos survive and develop for a few days and are graded positively, they can then be transferred to the womb. The number of embryos and their age in days, when transferred, are important considerations for subsequent gestation. In the past, anywhere from two to six embryos were transferred to give a better chance for at least one to implant in the uterine lining and continue development and gestation. However, this led to increased multiple pregnancies (twins, triplets, and more), which is a health risk to both the mother and the babies. Some practitioners use "selective reduction" to destroy some gestating fetuses among multiples, but, as the literature notes, this can endanger all of the developing fetuses,

[23] Mastenbroek S et al., Preimplantation genetic screening: a systematic review and meta-analysis of RCTs, *Human Reproduction Update* 17, 454–466, 2011; DOI: https://doi.org/10.1093/humupd/dmr003

[24] Meyer LR et al., A prospective randomized controlled trial of preimplantation genetic screening in the "good prognosis" patient, *Fertility and Sterility* 91, 1731-1738, 2009; DOI: https://doi.org/10.1016/j.fertnstert.2008.02.162

[25] Gleicher N, Orvieto R, Is the hypothesis of preimplantation genetic screening (PGS) still supportable? A review, *J Ovarian Res.* 10, 21, 2017; DOI: 10.1186/s13048-017-0318-3

[26] E.g., Gleicher N *et al.,* Previously reported and here added cases demonstrate euploid pregnancies followed by PGT-A as "mosaic" as well as "aneuploid" designated embryos, *Reprod Biol Endocrinol* 21, 25 2023; DOI: https://doi.org/10.1186/s12958-023-01077-7; AND Klein, Alice, 'Abnormal' IVF embryos can actually become healthy babies, *New Scientist* 251, No. 3357, Pg. 12, October 20, 2021

[27] Lázaro-Muñoz G et al., Screening embryos for polygenic conditions and traits: ethical considerations for an emerging technology, *Genetics Medicine* 23, 432-434, 2021; DOI: https://doi.org/10.1038/s41436-020-01019-3; AND Siermann M et al., A review of normative documents on preimplantation genetic testing: Recommendations for PGT-P, *Genetics in Medicine* 24, 1165-1175, 2022; DOI: https://doi.org/10.1016/j.gim.2022.03.001

[28] Lensen S, Uphoff N. "IVF add-ons: the latest Cochrane evidence". Evidently Cochrane blog, 16 October 2020. https://www.evidentlycochrane.net/ivf-add-ons-the-latest-cochrane-evidence/

does not completely eliminate risks associated with multiple pregnancies, and can have adverse psychological consequences for the mother.[29]

Current guidelines in the U.S., as well as laws in many other countries, limit the number of embryos to be transferred. In the U.S., the recommendation is for only one older embryo (single embryo transfer, SET) to be transferred in healthy young women, with two or at most three older embryos as a limit in older women. Numbers of younger embryos transferred are sometimes increased up to a limit of four in older women.[30] While some references report low- to moderate-quality evidence for slightly higher success rates in transfer of older (blastocyst stage, 5-6 day) embryos than younger (cleavage stage, 2-3 day) embryos, other studies show no significant advantage of using older embryos.[31]

## Embryo Disposition: Numbers created, destroyed, frozen, transferred, born

The latest estimate is that at least 12 million babies were born via IVF between 1978 and 2022.[32] Less well-known are estimates of the number of embryos created that resulted in the 12 million births: Conservative estimates are that at least 90% of embryos created in IVF do not survive, are destroyed, discarded, or are frozen and stored.

*Conservative estimates are that at least 90% of embryos created in IVF do not survive, are destroyed, discarded, or are frozen and stored.*

Numbers of pregnancies and births are usually reported, as well as numbers of cycles (embryo transfer attempts), primarily to determine the efficiency of the IVF procedure at producing

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[29] Stone J et al., A single center experience with 1000 consecutive cases of multifetal pregnancy reduction, *American Journal of Obstetrics and Gynecology* 187, 1163-1167, 2002; DOI: https://doi.org/10.1067/mob.2002.126988; AND Ughade PA, Shrivastava D, Successful Fetal Reduction in Early Second Trimester: Series of Three Cases Conceived With Infertility Treatment, *Cureus* 16(2): e54753, 2024; DOI: 10.7759/cureus.54753

[30] Practice Committee of the American Society for Reproductive Medicine and the Practice Committee for the Society for Assisted Reproductive Technologies, Guidance on the limits to the number of embryos to transfer: a committee opinion, *Fertility and Sterility* 116, 651-654, 2021; DOI: https://doi.org/10.1016/j.fertnstert.2021.06.050; AND Kissin DM et al., Number of Embryos Transferred After In Vitro Fertilization and Good Perinatal Outcome, *Obstet Gynecol*. 123, 239–247, 2014; DOI: 10.1097/AOG.0000000000000106; AND Practice Committee of the American Society for Reproductive Medicine and Practice Committee of the Society for Assisted Reproductive Technology, Blastocyst culture and transfer in clinically assisted reproduction: a committee opinion, *Fertility and Sterility* 110, 1246–1252, 2018; DOI: https://doi.org/10.1016/j.fertnstert.2018.09.011

[31] Glujovsky D et al., Cleavage-stage versus blastocyst-stage embryo transfer in assisted reproductive technology, *Cochrane Database of Systematic Reviews* 2022, Issue 5. Art. No.: CD002118. DOI: https://doi.org/10.1002/14651858.CD002118.pub6; AND Neblett MF et al., Is there still a role for a cleavage-stage embryo transfer, *F&S Reports* 2, 269-274, 2021; DOI: https://doi.org/10.1016/j.xfre.2021.06.004; AND Awadalla MS, Cleavage-stage embryo transfer: we'll never let it go, *F&S Reports* 2, 261-262, September 2021; DOI: https://doi.org/10.1016/j.xfre.2021.06.009; AND Fauque P et al., Comparisons of cumulative live birth rates after embryo transfers at day 2/3 versus day 5/6: a French national study, *Reproductive BioMedicine Online* 49, 104384, 2024; DOI: 10.1016/j.rbmo.2024.104384

[32] ICMART, 2023 Annual Meeting, 'At least 12 million babies' since the first IVF birth in 1978; accessed at: https://www.focusonreproduction.eu/article/ESHRE-News-COP23_adamson

babies. For example, the most recent complete data (for 2021) from the Society for Assisted Reproductive Technology (SART) show a range of live births from all embryo transfers in the U.S. of 54.0% for younger women to only 4.0% for women over 42 years old, with approximately 14-17% of these births as pre-term or very pre-term.[33] The U.S. Centers for Disease Control and Prevention (CDC) in its most recent data (2021) documents 413,776 cycles performed, resulting in 97,128 live-born infants.[34] The numbers represent an average success rate of only 25-30% live births achieved per embryo transfer. Obviously, not all embryos survive transfer and gestation, just as not all embryos survive lab culture.

But clinics do not report numbers of embryos created, nor do the reports reference numbers of embryos destroyed, discarded, or cryopreserved. As noted above, ovarian stimulation and egg harvesting often involve collecting multiple eggs for embryo production. How many eggs are collected at one time? Often, as many as possible. One reference notes that one fresh cycle with a high yield of eggs is an optimal business plan for IVF, and that studies show the optimal number of eggs to retrieve in one cycle is 15. Since the usual practice is to fertilize all eggs at once, then, as the reference points out, "supernumerary embryos are expected."[35] The terms "supernumerary", "extra", or "leftover" are often applied to the human embryos created but not selected for transfer to the womb. The high-quality embryos are sometimes frozen, perhaps for use in future transfers, but if their screening delegates them to a grade of low quality or genetically undesirable, the embryos are discarded. In many cases, a family will not go back to the freezer for more embryos, regardless of their graded quality, once a desired number of children is reached.

*Current estimates for numbers of embryos destroyed, discarded, or frozen under usual IVF practices range from 90-98%.*

"Embryo wastage" is a term used by some IVF practitioners for embryo loss and death. One study found that rates of embryo loss in the U.S. had decreased from 90% to 76.5% but still remained high, and these numbers didn't necessarily include embryos discarded.[36] Another study calculated embryo loss as 85% but did not include embryos discarded or lost from thawing after cryopreservation, , stating that the 85% rate of loss "greatly under-estimates the overall loss."[37] Adjustments for these additional losses would raise the rate of loss over 90%. Gleicher et al. note regarding genetic testing that "Because of the high false-positivity rate, a large number of perfectly normal embryos are now routinely discarded which, if transferred, in surprisingly high

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[33] SART, Final National Summary Report for 2021, accessed at: https://sartcorsonline.com/Csr/Public?ClinicPKID=0&reportingYear=2021&newReport=True

[34] Centers for Disease Control and Prevention. 2021 Assisted Reproductive Technology Fertility Clinic and National Summary Report. US Dept of Health and Human Services; 2023. Accessed at: https://www.cdc.gov/art/reports/2021/index.html

[35] Vaughan DA et al., How many oocytes are optimal to achieve multiple live births with one stimulation cycle? The one-and-done approach, *Fertil Steril* 107:397-404.e3, 2017. Accessed at: https://www.fertstert.org/article/S0015-0282(16)62960-6/abstract

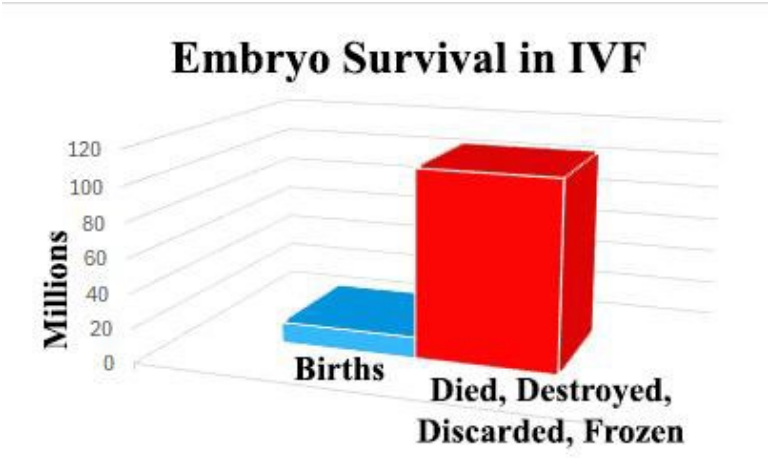
[36] Ghazal S, Patrizio P, Embryo wastage rates remain high in assisted reproductive technology (ART): a look at the trends from 2004–2013 in the USA, *J Assist Reprod Genet* 34, 159–166, 2017; DOI: 10.1007/s10815-016-0858-2

[37] Kovalevsky G, Patrizio P, High rates of embryo wastage with use of assisted reproductive technology: a look at the trends between 1995 and 2001 in the United States, *Fertility and Sterility* 84, 325-330, August 2005; DOI: https://doi.org/10.1016/j.fertnstert.2005.04.020

percentages still would result in normal births."[38] Other references find that a large number of embryos arrest their growth early in development, often due to life-limiting genetic conditions but also possibly due to effects of the in vitro growth environment, but again, many of these embryos that are normally discarded can be induced to resume growth.[39] Current estimates for actual numbers of embryos destroyed, discarded, or frozen under current usual IVF practices range from 90-98%.

*...those 12 million live-born IVF babies are the lone survivors of at least 120 million embryos originally created... at least 108 million human embryos met their demise.*

Even using the conservative estimate of 90% who do not survive, this means those 12 million live-born IVF babies are the lone survivors of at least 120 million embryos originally created, and that at least 108 million human embryos met their demise. At the higher end of the estimates, this would mean over half a billion human embryos perished.




Cryopreservation is sometimes considered a life-sparing practice to preserve live embryos for future transfer. As with embryo discarding, most clinics do not report the number of embryos they freeze. In 2003, the first survey of clinics found 400,000 embryos in freezers in the U.S.[40] A 2020 study indicated at that time over 1.2 million embryos in storage freezers.[41] Some estimate that there are now 1.5 million embryos in freezers in the U.S. alone.[42]

Survival of embryos after freezing is a significant concern. The process of cryopreservation involves protecting the embryo by infusing cryopreservative solutions (cellular antifreeze) into the cells of the embryo, followed by either a slow freezing process or flash freezing

[38] Gleicher N et al., Worldwide decline of IVF birth rates and its probable causes, *Human Reproduction Open* Volume 2019, Issue 3, 2019, hoz017, DOI: https://doi.org/10.1093/hropen/hoz017

[39] Yang Y et al. Metabolic and epigenetic dysfunctions underlie the arrest of in vitro fertilized human embryos in a senescent-like state, *PLOS Biology* 20, e3001682, 2022; DOI: 10.1371/journal.pbio.3001682; AND McCoy RC et al., Meiotic and mitotic aneuploidies drive arrest of in vitro fertilized human preimplantation embryos, *Genome Med* 15, 77, 2023; DOI: https://doi.org/10.1186/s13073-023-01231-1

[40] Hoffman DI et al., How Many Frozen Human Embryos Are Available for Research? Santa Monica, CA: RAND Corporation, 2003. https://www.rand.org/pubs/research_briefs/RB9038.html

[41] Christianson MS et al., Embryo cryopreservation and utilization in the United States from 2004–2013, *Fertility & Sterility Reports* 1, 71-77, 2020; https://doi.org/10.1016/j.xfre.2020.05.010

[42] Keenan J, National Embryo Donation Center; accessed March 2024 at: https://www.embryodonation.org/

(vitrification).[43] The process works because there are few cells in the young embryo, allowing the cryopreservative to penetrate most cells and prevent damaging ice crystal formation. Theoretically, freezing at liquid nitrogen temperatures (-320ºF/-196 ºC) can preserve embryos without cell degradation over long periods, though some recent studies indicate that older embryos may suffer some damage from freezing, as well as from genetic testing.[44] However, the greatest danger is from ice crystals that form upon thawing, which destroys many embryos. Previously, a 50% survival rate after freezing and thawing was considered standard. More recently, for some clinics using good technique and care, rates of survival in some cases can be up to 96%.[45] Most survival rates are lower, however, pointing out the fact that freezing and thawing lead to the deaths of many embryos.

Some parents of frozen embryos may offer their embryos for adoption or donation to other infertile couples. This has led to a growing trend of more frozen embryos being born in the U.S.[46] In other cases, couples may designate that their frozen embryos be thawed and discarded. Frozen embryos that are abandoned and unclaimed are also discarded.[47] In other cases, embryos are given to research projects, where they are destroyed in experiments.

One other trend with a darker side for IVF involves the creation of sometimes hundreds of embryos as savior siblings. Embryos are created by parents of a born child who has a lethal diagnosis, with the idea that a healthy, genetically-matched embryo can be gestated and this savior sibling, once born, can be an adult stem cell donor or even a tissue donor.[48] All of the other embryos either remain in frozen storage or are discarded.

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[43] Pomeroy KO et al., The ART of cryopreservation and its changing landscape, *Fertility and Sterility* 117, 469-476, 2022; DOI:https://doi.org/10.1016/j.fertnstert.2022.01.018

[44] Wang X et al., The impact of blastocyst freezing and biopsy on the association of blastocyst morphological parameters with live birth and singleton birthweight, *Fertil Steril* 119, 56–66, 2023; https://doi.org/10.1016/j.fertnstert.2022.09.030

[45] Liebermann J, Vitrification of human blastocysts: an update, *Reproductive BioMedicine Online* 19, Supplement 4, 105-114, 2009; DOI: https://doi.org/10.1016/S1472-6483(10)61073-5

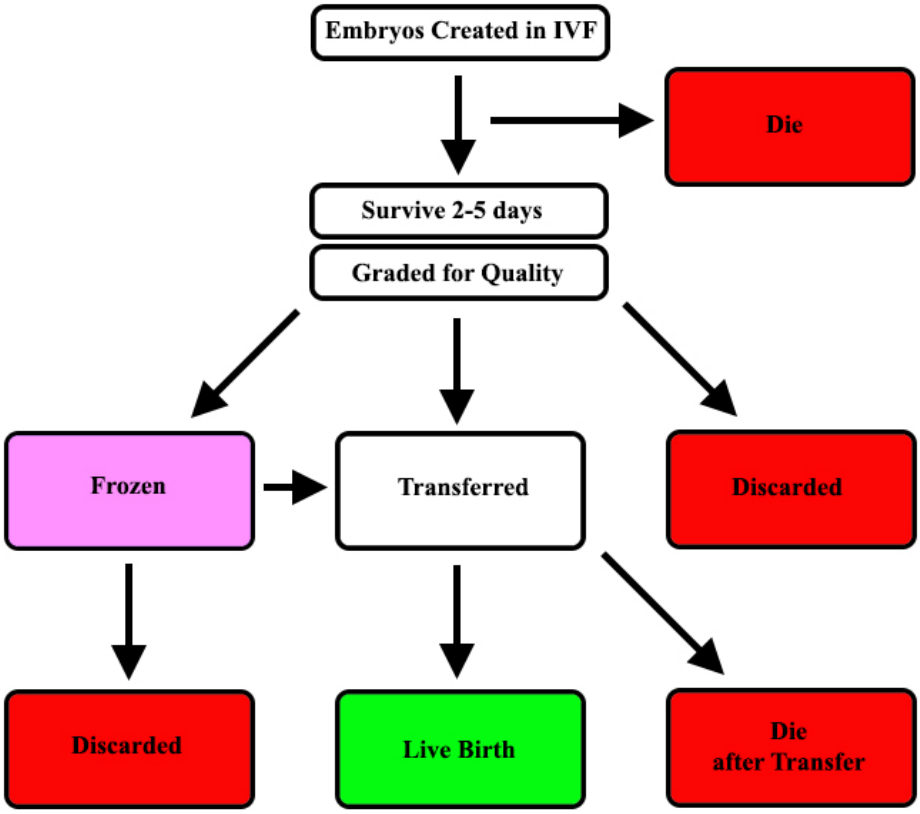
[46] Lee JC et al., Embryo donation: national trends and outcomes, 2004–2019, Am J Obstet Gynecol, 228:318.e1-7, 2023; DOI: https://doi.org/10.1016/j.ajog.2022.10.045

[47] Ethics Committee of the American Society for Reproductive Medicine, Disposition of unclaimed embryos: an Ethics Committee opinion, *Fertility and Sterility* 116, 48-52, 2021; DOI: https://doi.org/10.1016/j.fertnstert.2021.02.020

[48] Allen Goldberg, "IVF bans like Alabama's could cost the lives of children already born", Feb. 27, 2024; accessed at: https://www.statnews.com/2024/02/27/alabama-ivf-ban-pre-implantation-diagnosis-pgd-fanconi-anemia-donor-siblings/

The following figure graphically summarizes the flow of the stages of IVF and potential outcomes for embryos created in the process, as well as the numerous points at which embryos can die or be destroyed.

**Flow Chart and Outcomes for IVF Embryos**




**Risks and harms to mothers and embryos/babies of ART practices**

*IVF can pose distinct risks both to mothers and to babies.*

IVF can pose distinct risks both to mothers and to babies. The possibility of Ovarian Hyperstimulation Syndrome (OHSS) is a significant concern. The high doses of hormones used to over-stimulate ovarian production to collect multiple eggs in one cycle can lead to fluid accumulation in the abdomen as well as the chest cavity, and can cause pain, require hospitalization, and result in renal failure, potential future infertility, and even death. OHSS has been termed "a non-vital treatment with a potential fatal outcome," and occurs at a usual rate of 0.3-10%, with an incidence of up to 20% in high-risk women.[49] Risks to egg donors have not

[49] Palomba S, Caserta D, Chapter 23 - Ovarian hyperstimulation syndrome, *in*: Management of Infertility, 223-239, 2023; DOI: https://doi.org/10.1016/B978-0-323-89907-9.00009-0; AND Delvigne A, Rozenberg S, Epidemiology and prevention of ovarian hyperstimulation syndrome (OHSS): a review *Human Reproduction Update* 8, 559–577,

been well studied, since these are supposedly young, healthy women who are not considered patients, but there is concern that ovarian hyperstimulation may increase the risk of other adverse outcomes, including an increased risk for breast cancer.[50] There are also reports of women being hospitalized with a rare form of pneumonia caused by an allergic reaction to the sesame oil in the progesterone shots given during IVF.[51]

*Ovarian hyperstimulation may increase the risk of other adverse outcomes, including an increased risk for breast cancer.*

Egg retrieval via laparoscopy is itself a non-trivial concern, as complications can include the need for reparative surgery, especially if large numbers of eggs are collected.[52]

Multiple pregnancies (twins, triplets, and more) from IVF increase the risk of complications for both mother and babies, including premature birth, low birth weight, pre-eclampsia, anemia, postpartum hemorrhage, and intrauterine growth restriction.[53] Twin pregnancies conceived via IVF show higher absolute obstetric risks compared with IVF-conceived singleton pregnancies or naturally conceived twin pregnancies.[54]

IVF itself can increase risks to mothers for adverse obstetric outcomes and vascular problems, including severe outcomes.[55] Use of donated eggs, frozen embryos, and donated frozen embryos has also been reported to increase risks for hypertensive disease in pregnancy, post-partum hemorrhage, pre-term delivery, and other complications.[56] A recent study found that women

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2002; DOI: https://doi.org/10.1093/humupd/8.6.559; AND Magnus D, Cho M, Issues in Oocyte Donation for Stem Cell Research, *Science* 308, 1747-1748, 2005; DOI: 10.1126/science.11144; AND Practice Committee of the American Society for Reproductive Medicine, Prevention of moderate and severe ovarian hyperstimulation syndrome: a guideline, *Fertility and Sterility* 121, 230-245, 2024; DOI: https://doi.org/10.1016/j.fertnstert.2023.11.013

[50] Schneider J et al., Long-term breast cancer risk following ovarian stimulation in young egg donors: a call for follow-up, research and informed consent, *Reprod Biomed Online* 34, 480-485, 2017; DOI: 10.1016/j.rbmo.2017.02.003

[51] Ahuja A and Ikladios O, Progesterone as a cause of eosinophilic pneumonia after in vitro fertilization, *J Community Hosp Intern Med Perspect.* 7, 366–368, 2017; doi: 10.1080/20009666.2017.1404418

[52] Levi-Setti PE et al., Appraisal of clinical complications after 23,827 oocyte retrievals in a large assisted reproductive technology program, *Fertility and Sterility* 109, 1038-1043.e1, 2018; DOI: 10.1016/j.fertnstert.2018.02.002

[53] Santana DS et al., Multiple gestation pregnancy, *Human Reproduction* 15, 1856-1864, 2000; DOI: https://doi.org/10.1093/humrep/15.8.1856

[54] Wang Y et al., Absolute Risk of Adverse Obstetric Outcomes Among Twin Pregnancies After In Vitro Fertilization by Maternal Age, *JAMA Network Open* 4, e2123634, 2021; DOI: 10.1001/jamanetworkopen.2021.23634

[55] Dayan N et al., Infertility treatment and risk of severe maternal morbidity: a propensity score–matched cohort study, *CMAJ* 2019 February 4;191:E118-27. doi: 10.1503/cmaj.181124; AND Wu R et al., In-Hospital Complications in Pregnancies Conceived by Assisted Reproductive Technology, *J Am Heart Assoc.* 11:e022658, 2022; DOI: 10.1161/JAHA.121.022658

[56] Shah A et al., Obstetric Complications of Donor Egg Conception Pregnancies, *J Obstet Gynaecol India*, 69, 395–398, 2019; DOI: 10.1007/s13224-019-01211-9; AND Luke B et al., Risk of severe maternal morbidity by maternal fertility status: a US study in 8 states, *Am J Obstet Gynecol* 220, 195.e1-195.e12, 2019; DOI: 10.1016/j.ajog.2018.10.012; AND Peigné M et al., Donated-embryo pregnancies are associated with increased risk

who have an IVF pregnancy have a doubled risk for preterm birth, and a 42% increased risk of placental abruption, a serious complication.[57,58]

*Reports have been appearing that show concern for increased risks of various kinds to children created via the IVF process.*

Risks to embryos do not disappear even if they have survived to the point of transfer to the womb. Reports have been appearing that show concern for increased risks of various kinds to children created via the IVF process. These increased risks, not studied in the early years of IVF, include congenital anomalies, neurodevelopmental disorders, certain cancers, and other long-term complications.[59] One recent study found a significantly increased risk of congenital heart defects in IVF babies.[60,61]

Several reports now indicate that IVF procedures themselves can negatively affect embryo health and quality. Embryo laboratory culture, i.e., being grown for a few days in vitro, can induce long-lasting changes that may be associated with altered risks for health and aging across the lifespan of IVF children.[62]

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of hypertensive disorders even for young recipients: a retrospective matched-cohort study, *Fertility and Sterility* 119, 69-77, 2023; DOI: https://doi.org/10.1016/j.fertnstert.2022.09.024

[57] Andrew Smith, "Study Reveals Doubled Risk of Preterm Birth for IVF Pregnancies," *Rutgers Today* August 21, 2024; accessed at: https://www.rutgers.edu/news/study-reveals-doubled-risk-preterm-birth-ivf-pregnancies-complicated-placental-abruption

[58] Zhang JT et al., Risks of Placental Abruption and Preterm Delivery in Patients Undergoing Assisted Reproduction, *JAMA Network Open*. 7(7):e2420970, 2024; doi:10.1001/jamanetworkopen.2024.20970

[59] Sullivan-Pyke CS et al., In Vitro fertilization and adverse obstetric and perinatal outcomes, Seminars in Perinatology 41, 345-353, 2017; DOI: https://doi.org/10.1053/j.semperi.2017.07.001; AND Pinborg A et al., Long-term outcomes for children conceived by assisted reproductive technology, *Fertility and Sterility* 120, 449-456, 2023; DOI: https://doi.org/10.1016/j.fertnstert.2023.04.022; AND Venetis C et al., Risk for Congenital Anomalies in Children Conceived With Medically Assisted Fertility Treatment : A Population-Based Cohort Study, *Annals of Internal Medicine* 176, 1308-1320, 2023; https://doi.org/10.7326/M23-0872; AND Sargisian N et al., Cancer in children born after frozen-thawed embryo transfer: A cohort study, *PLoS Med*. 19, e1004078; 2022; DOI: 10.1371/journal.pmed.1004078

[60] "Babies born after fertility treatment have higher risk of heart defects," European Society for Cardiology Press Office, Sept 27, 2024; accessed at: https://www.escardio.org/The-ESC/Press-Office/Press-releases/babies-born-after-fertility-treatment-have-higher-risk-of-heart-defects

[61] Sargisian N et al., Congenital heart defects in children born after assisted reproductive technology: a CoNARTaS study, *European Heart Journal*, ehae572, Sept 26, 2024; doi: 10.1093/eurheartj/ehae572

[62] Grace KS, Sinclair KD, Assisted Reproductive Technology, Epigenetics, and Long-Term Health: A Developmental Time Bomb Still Ticking, *Semin Reprod Med* 27, 409-416, 2009; DOI: 10.1055/s-0029-1237429; AND Brison, D.R. IVF children and healthy aging, *Nat Med* **28**, 2476–2477 (2022). https://doi.org/10.1038/s41591-022-02098-2; AND Woo I *et al.*, Perinatal outcomes after natural conception versus in vitro fertilization (IVF) in gestational surrogates: a model to evaluate IVF treatment versus maternal effects, *Fertility and Sterility* 108, 993-998, 2017; DOI: https://doi.org/10.1016/j.fertnstert.2017.09.014; AND Kleijkers SHM *et al.,* Influence of embryo culture medium (G5 and HTF) on pregnancy and perinatal outcome after IVF: a multicenter RCT, *Human Reproduction* 31, 2219-2230, 2016; DOI: https://doi.org/10.1093/humrep/dew156

**Possible Paths Forward for Fertility Treatment**

*IVF embryos are human beings and should be regarded as such and not as commercial products.*

Human beings conceived in vitro by scientific bioengineering are no less human than those conceived in vivo by natural processes. Therefore, they have the same moral significance and require the same bioethical considerations. IVF embryos are human beings and should be regarded as such and not as commercial products.

*IVF does not treat infertility.*

IVF does not treat infertility, it provides a technical workaround in hopes of producing babies. Current IVF practice is seldom life-affirming and never life-sparing. Large numbers of embryos are created, graded for quality, and at least 90% do not survive, are destroyed, discarded, or frozen for storage. Moreover, IVF can pose distinct risks both to mothers and to babies.

There are people of good conscience who reject IVF because of its in vitro manipulation of young human life. Some reject IVF due to the unnatural separation of embryo creation from the normal procreative act. Some are concerned about laboratory experimentation with nascent human beings. Other people of good conscience could potentially accept a form of IVF that is life-sparing, but are nonetheless appalled at the overwhelmingly life-destroying nature of current practices. As a society that has pledged to protect the weak and vulnerable, we must take a serious look at the facts about IVF, and renew our commitment to protect every human being.

Recognizing this range of serious concerns with IVF and other ARTs, what follows are potential recommendations toward making IVF unnecessary, or at a minimum, reforming the practice to make IVF life sparing.

Recommendations

Before any attempts at IVF, every effort should be made to utilize restorative reproductive medicine as an authentic treatment for infertility.[63] Restorative reproductive medicine has been documented to restore fertility even after IVF failure.[64] Treatment and resolution of the underlying causes of the infertility address the real needs of the patients.

Before any attempts at IVF, there should be thorough counseling to provide complete informed consent regarding the facts of IVF, including efficiencies, risks and ethical considerations.

Accountability through transparency and mandatory, comprehensive data reporting.

Long-term health follow-up and data collection for mothers, babies, egg donors.

No destruction or discarding of any human embryos.

No freezing of embryos, except perhaps as a last resort in attempts to preserve the embryo's life.

No-stimulation (natural cycle) or minimal-stimulation IVF. Such procedures decrease risks both to mothers and to children. The assumption that more oocytes lead to better success has been contradicted by several studies, and the advantages of decreased risk to women from ovarian hyperstimulation are significant. These techniques, which utilize no, or minimal, added hormonal boost, also are less costly than traditional IVF. Natural cycle IVF in particular brings the industry back to its historical roots of utilizing only a single egg naturally matured during a cycle, and single-embryo transfer (SET), decreasing health risks both for mother and child.[65]

Creation of only the number of embryos intended for transfer at any one time.

Limit numbers of embryos transferred each cycle, preferably using single-embryo transfer (SET) of blastocyst stage embryos, limit of two cleavage stage embryos.

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[63] Duane M *et al.,* Fertility Awareness-Based Methods for Women's Health and Family Planning, *Frontiers in Medicine* Volume 9, 2022; DOI: https://doi.org/10.3389/fmed.2022.858977; AND Stanford JB *et al*., Restorative reproductive medicine for infertility in two family medicine clinics in New England, an observational study, *BMC Pregnancy Childbirth*. 21, 495, 2021; DOI: 10.1186/s12884-021-03946-8

[64] Boyle PC *et al*., Successful pregnancy with restorative reproductive medicine after 16 years of infertility, three recurrent miscarriages, and eight unsuccessful embryo transfers with in vitro fertilization/intracytoplasmic sperm injection: a case report, *J Med Case Reports* 16, 246, 2022; DOI: https://doi.org/10.1186/s13256-022-03465-w; AND Boyle PC *et al*., Healthy Singleton Pregnancies From Restorative Reproductive Medicine (RRM) After Failed IVF, *Front. Med*. 5:210, 2018; DOI: 10.3389/fmed.2018.00210

[65] Hammoud, A.O., Gibson, M. (2011). Minimal Stimulation IVF. In: Racowsky, C., Schlegel, P., Fauser, B., Carrell, D. (eds) Biennial Review of Infertility. Springer, Boston, MA. https://doi.org/10.1007/978-1-4419-8456-2_2; AND Magaton IM et al., Oocyte maturity, oocyte fertilization and cleavage-stage embryo morphology are better in natural compared with high-dose gonadotrophin stimulated IVF cycles, *Reproductive BioMedicine Online* 46, 705-712, April 2023; DOI: https://doi.org/10.1016/j.rbmo.2022.11.008; AND Datta AK et al., Mild versus conventional ovarian stimulation for IVF in poor, normal and hyper-responders: a systematic review and meta-analysis, *Human Reproduction Update* 27, 229-253, 2020; DOI: https://doi.org/10.1093/humupd/dmaa035

Freeze eggs rather than embryos. Freezing eggs does not obviate all ethical concerns, but poses fewer potential problems than embryo-freezing.[66]

Prohibit all forms of PGT as this is a eugenic technique.

Prohibit use of donor eggs or sperm.

Embryo adoption should be an encouraged practice.

## *The well-being of children is of paramount importance.*

Parents must retain legal oversight and responsibility for their children, even when those children are still tiny, vulnerable embryos. Parents themselves deserve legal protections as the guardians of their children. Parents deserve full informed consent. The well-being of children is of paramount importance, and parents should retain legal recourse for negligent injury or loss of their embryos.

Embryos deserve some recognition of status, e.g., as a juridical person.

Embryos should not be exposed to any conditions that risk injury or death beyond risks normally experienced by embryos in the natural in vivo environment. Only procedures that hold out the prospect of direct benefit to the embryo or pose minimal risk allowed.

## *There should be a standard of medical care for IVF.*

There should be a published standard of medical care for IVF and other ART procedures, similar to that for virtually every other clinical procedure and medical field. Regulatory oversight is sorely needed, including certification or other licensing models, to provide accountability.

Prohibit surrogacy.

Prohibit creation of embryos for research.

Prohibit any research on embryos that does not provide some benefit to the embryo, or at least poses no additional risk of injury or death.

Prohibit creation of embryos other than by use of a single human sperm with a single human egg.

Prohibit any manipulation where a human embryo is intentionally created or modified to include a heritable genetic modification.

Prohibit gestation in an animal or man-made uterus or an artificial gestational container.

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[66] Cascante, SD *et al*., Planned oocyte cryopreservation: the state of the ART, *RBMO* 47, 1-11, 2023; doi: https://doi.org/10.1016/j.rbmo.2023.103367