

Negative Evidence: COVID-19 Vaccines and Fertility

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Introduction

Previous editorials have discussed the frequently overlooked significance of **negative evidence**.^{1,2} This term is used to denote situations in which there is a surprising absence of the anticipated data. Negative evidence does not reflect merely “the lack of proof,” but also provides an important clue that relevant information is being deliberately hidden. Therefore, a careful investigative process should include a meticulous search for any potential negative evidence.

This article scrutinizes the absence of expected data related to the potential impairment of fertility by COVID-19 vaccines. In addition, it describes investigative techniques that can be used by independent researchers in assessing the impact on fertility—and their pitfalls.

Biological, Cultural, and Political Relevance of Fertility

The biological relevance of fertility is self-explanatory. However, in addition to its biological aspect fertility has immense cultural significance.³ The societal reverence for fertility is reflected in religious beliefs, arts, traditions, and customs of all nations.⁴⁻⁶ Consequently, public interest in issues related to reproductive functions and their potential impairment by variety of external factors remains very high. Memories of the thalidomide debacle are still vivid.^{8,9} Mainstream media are full of articles about reproductive health. Some avidly watched television reality shows are dedicated exclusively to infertility.¹⁰ Plots of very popular works of fictions such as *The Handmaid's Tale*, *Children of Men*, and *Stargate: Ashen* revolve around horrors of global infertility.^{11,12}

In the U.S., societal concerns with fertility led to the establishment of the Center for the Evaluation of Risks to Human Reproduction (CERHR) by the National Toxicology Program (NTP) and the National Institute of Environmental Health Sciences (NIEHS).¹³ Since its inception in 1998, CERHR has provided diligent evaluations of potential adverse effects on fertility of virtually all substances to which humans might be exposed.

CERHR is just one of many governmental safety mechanisms guarding against mass fertility impairment. The impact of medications on reproductive health is vigorously studied. At least that is what the public is told. In theory, virtually every new medication (including vaccines) before being approved is supposed to pass a series of preclinical and clinical studies examining its impact on reproduction. This is to be followed by post-approval pharmacovigilance programs designed to detect possible safety signals related to reproductive dysfunctions.^{1,14-16} There are a variety of well-established reproductive safety protocols for drugs development called Developmental and Reproductive Toxicology (DART) Studies. The Food and Drug Administration (FDA) periodically issues detailed guidelines related to DART studies. The latest revision was published in 2021.¹⁷

The above describes what is supposed to happen in theory. In practice, one can notice the unusual discrepancy between the

dutiful diligence with which the reproductive safety of “classic drugs” is being investigated versus the rather nonchalant way in which the impact of vaccines on fertility is being addressed. This problem existed long before the COVID-19 vaccines. The 2012 monograph describing reproductive toxicity testing of vaccines contains a series of interesting observations.¹⁸ The author, Paul Barrow, commented that the preclinical developmental toxicology studies were carefully designed to assess the possible influences of each component of the vaccine and the antibodies it induced on the development of the conceptus, neonate, and suckling organism. However, preclinical pediatric investigations were not required for vaccines, even though most vaccines were given to adolescents and children. Furthermore, he opined that because of the limitations of the available animal models for reproductive toxicity testing, robust pharmacovigilance should be essential.¹⁸ In this context, the continuous reliance on less than perfect systems such as the Vaccine Adverse Event Reporting System (VAERS) or V-Safe Pregnancy Vaccine Registry is puzzling.¹⁹⁻²²

Authors of a more recent 2020 review, “The Effect of Vaccines on the Reproductive System,” concluded that further extensive and structured research is urgently needed to study the effect of vaccines on reproductive function.²³ This conclusion was based upon their discovery that currently there are no published prospective studies examining the effect of vaccines on human reproduction. The available information on the possible negative effects of vaccines is either conjectural or based on patient follow-up data without any prior survey of their reproductive status.

The public health authorities, politicians, and mainstream academicians are not as concerned with fertility as the public is. Therefore, they apparently do not worry about potential vaccine-induced infertility. A recent *Lancet Global Health* editorial aptly entitled: “Infertility—Why the Silence?” provides the following explanation for this situation: “*Key arguments for the lack of national and international policy interest in fertility care include more pressing concerns around **overpopulation** and the need for **population control**, and the **scarcity of resources** making it difficult to justify investment in expensive fertility treatment in settings with competing public health priorities, such as high burdens of infectious diseases and maternal mortality.* [emphasis added].”²⁴

COVID-19 Vaccines and Public Infertility Concerns

Because of the cultural and political relevance of fertility, the public has been primed to be especially concerned about the potential negative fertility impact of any novel medications including vaccines. Expectedly, such concerns began to appear on social media as soon as the public learned that the innovative mRNA COVID-19 vaccines had been developed.²⁵⁻²⁹ There were certainly many other concerns about those vaccines, but the fertility theme resonated highly with the public.²⁸ Those worries were legitimate, given the history of reproductive toxicity of the pharmaceutical products.³⁰ In the setting of health officials' disregard of public qualms about infertility, an

informational void was created.^{28,29} This vacuum started to be filled with the pervasive reports of variable quality.^{1,2,31} Medical officialdom, which was initially mute on the subject of vaccines and fertility, has lashed out against what it perceived as “the avalanche of misinformation,” seemingly oblivious to the fact that its own inaction contributed to that outcome.^{25-27, 29} After a period of shock, the medical establishment started to mount a counteroffensive against the tsunami of officially unapproved information about COVID-19 vaccines and fertility that flooded the internet.

The informational vacuum was indeed filled with speculations, misinformation, disinformation, and outright lies, which were mixed with relevant, sensible, and truthful observations. Under those circumstances it was becoming very difficult to separate the wheat from the chaff for the majority of lay public. However, determining the quality of the information was well within capability of the medical establishment. For reasons discussed below, officialdom decided to simply condemn any fertility-related vaccine information that did not originate within its own structures. There was no willingness to start any fair discussion on that matter. Instead, the mainstream reproductive medicine organizations started to issue individual and joint statements strongly condemning the “misinformation” about the infertility related to COVID-19 vaccine.³²⁻³⁶ To officialdom’s amazement, however, a large part of public remained unpersuaded by those statements.^{27,37} Instead, the public seemed to trust “random persons” on the internet more than the anointed “official experts” talking *ex cathedra*. Some of those “random internet persons” were actually nonconforming physicians and dissident scientists.³⁸⁻³⁹ Hence, the next step by officialdom’s reproductive experts was to join with other mainstream societies in threatening their unorthodox colleagues with disciplinary actions including revocation of their specialty board certifications.³⁶ That vindictive Orwellian move was supposed to solve the conundrum of the public mistrust in officialdom.

As was discussed in a previous editorial, we live in the Age of Narratives.¹ Hence, officialdom created its own narrative to explain the “cascade of undeserved public distrust” and the “anti-science aggression” stemming from it. According to this claim, the gullible public is constantly misled by hostile, anti-science influencers into not trusting the official experts. As shown in Figure 1, this narrative does not reflect reality. Simply put: one trusts a person who is trustworthy. Official experts did not earn the public’s trust, but steadily lost credibility over the past decades until reaching the point of no return.⁴⁰ By its own admission in its own prestigious journal, officialdom made it clear that it does not care about the fertility of the masses.²⁴ Yet it expects to be trusted

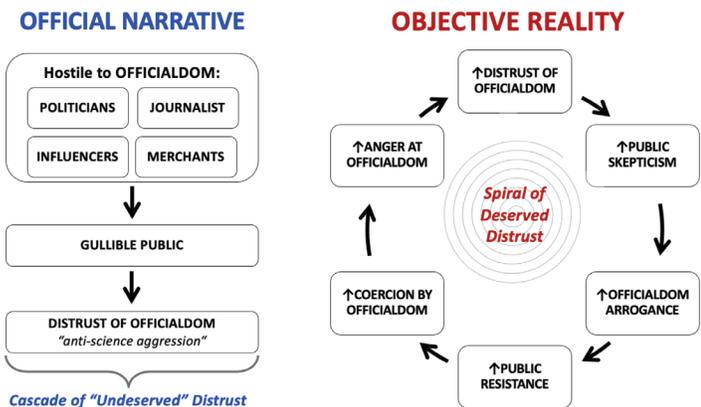


Figure 1. Officialdom’s Narrative versus Objective Reality of the Root Causes of Public Distrust

by the same masses on the matters of fertility. There is no “cascade of unjustified distrust”; there is a spiral of well-deserved distrust towards the medical establishment. The accelerating rotations of this spiral are powered by officialdom’s own arrogance, corruption, deception, and vindictiveness. To understand the root causes of this insane tailspin, one must comprehend the phenomenon of the politicization of medical science.

Politicization of Science and Medicine

Now, in 2022, discussing any medical or scientific matters without their political background benefits only the enemies of freedom. The detailed discussion of the politicization of science in the context of recent disturbing ideological and cultural shifts is beyond the scope of this editorial. Nevertheless, basic knowledge of this phenomenon is imperative for understanding of the current worrisome state of medicine.

The problem of potential reproductive toxicity of the COVID-19 vaccine is by its nature scientific. Its impartial examination requires the work of competent and politically unbiased scientists who have access to sophisticated scientific equipment and the support of a large collaborative team. That conclusion is obvious to anyone who was ever involved in any modern scientific project. The public and much of the medical community are not aware of that reality, as their understanding of how science works is rooted in the past.

In the past, breakthrough discoveries were made by individual brilliant scientists working in small labs, and science was largely apolitical. But today we do not have scientists who would meet all the required criteria for the impartial examination of our scientific problem. The researchers of today may be divided roughly into two categories as illustrated in Figure 2. Officialdom researchers possesses all the required resources, but they are politically biased since their primary audience is not the public, but politicians and industry. Hence they cannot be trusted. In contrast, most dissident researchers are less influenced by politics, but they lack the most basic resources. Nonetheless, the role of the dissident researchers is still significant. Their courageous criticism of the official “science” is at least slowing down the implementation of harmful policies that are endorsed by politically subservient researchers.

| | OFFICIALDOM RESEARCHERS | DISSIDENT RESEARCHERS |
|-----------------------|---------------------------------------|------------------------------------|
| FUNDING | PLENTIFUL | SCARCE |
| FUNDING SOURCES | GOVERNMENT INDUSTRY | CROWD FUNDED |
| RESOURCES | VAST: sophisticated equipment & staff | LIMITED: basic equipment if any |
| TRAINING | HIGHLY SPECIALIZED | VARIABLE |
| RESEARCH METHODS | COMPLEX ORIGINAL PROJECTS | ANALYSES OF PUBLISHED STUDIES/DATA |
| PUBLICATION PLATFORMS | PRESTIGIOUS JOURNALS | SOCIAL MEDIA |
| AUDIENCE | GOVERNMENT INDUSTRY PEERS PUBLIC | PUBLIC |

Figure 2. Differences between Officialdom and Dissident Researchers

How have we reached this dreadful stage? As unfathomable it may seem for many, our formerly healthy society has been transformed into the morbid one as it is illustrated in Figure 3. In a healthy free society, the power structures are not influenced by hidden agendas. They truly serve the public interest and are thus perceived by the public as very trustworthy. Misinformation of any sort is unable to proliferate in such circumstances. In contrast, the power structures of a morbid society are driven by hidden agendas that are contrary to the public interest. Sooner or later the public becomes aware that the centers of power are deceptive and not worthy of their trust. The corrupt power structures create their own forms of misinformation. Moreover, they withhold accurate information from the public for political reasons. This creates an informational void, which is being populated by information of variable quality.

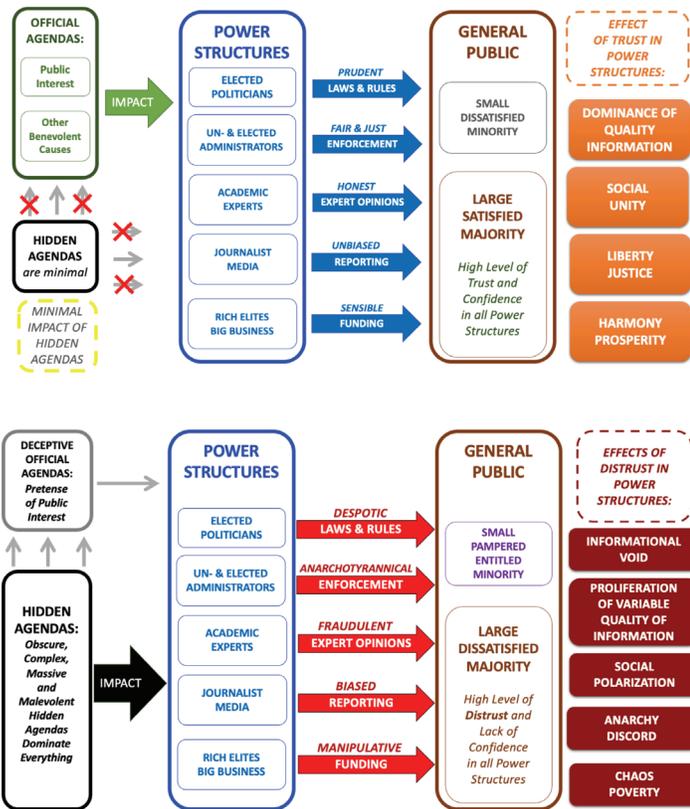


Figure 3. Power Structures in a Healthy vs. a Morbid Society

Rampant politicization is a hallmark of all morbid societies. Politization has been defined “as undue encroachment of (partisan) politics into seemingly neutral or non-political arenas, institutions, activities and realms, such as sport, religion, the arts, science, the civil service, etc.”⁴¹ Politicization of science and medicine is especially perilous, leading to the epistemologically precarious partiality of the fields that should be impartial.⁴²⁻⁴³ This perverts the role of medical and scientific experts. Instead of providing objective analysis of critical issues, the politicized “experts” assist their political masters in implementation of their hidden plans. Such “experts” misuse their scientific credentials to pursue their selfish political and financial interests. Their duplicity is ultimately discovered by the public, causing growing skepticism. The public turns away from the official science, seeking help from the alternative gurus who sometimes can be wonderful. Unfortunately, some of them can be also as unsavory and dangerous as the disgraced official “experts.” Interestingly, officialdom recognizes the concept of politicization of science.

However, in a typical Orwellian fashion it projects its own faults into the “other side,” as evidenced by the recent review entitled “Politicization and COVID-19 Vaccine Resistance in the U.S.”⁴⁴

Assessing the Impact of the COVID-19 Vaccine on Fertility in the Era of Politicization

Non-politicized, independent physicians face a very hard task when trying to assist their patients and the public in addressing their legitimate concerns about the potential negative impact of COVID-19 vaccine on fertility. Official “experts” cannot be trusted. Even the most reputable dissident researchers are severely limited in their ability to conduct the meaningful complex research studies that are necessary to thoroughly examine this matter. This situation is dismal, and it will not change until the morbid system is healed. In the meantime, for the sake of their patients and humanity, concerned physicians must do what they can using what is available to them. They must be keenly aware of the hardships and limitations imposed by the current circumstances.

Contrary to conventional wisdom, fertility, especially female fertility, is a very complex trait. It is determined by a variety of physiological, behavioral, and external factors.⁴⁵ Even the assessment of baseline fertility is very difficult. The persuasive demonstration of a change in fertility in response to a harmful substance is even more challenging.

Theoretically, there are numerous ways in which fertility change in response to vaccine can be assessed. Unfortunately, many of those paradigms are not available to independent researchers. Some of the available approaches have many pitfalls. Those methodological drawbacks may prompt unexperienced but enthusiastic researchers to draw patently wrong conclusions, which will be used by officialdom to discredit those dissident scientists. Helpful methods are discussed below. These indirect methods cannot provide a firm response to the question of whether COVID-19 vaccine causes infertility. However, they can inform us about the potential presence of a safety signal.

Examination of the Negative Evidence

Despite the pivotal biological and cultural relevance of fertility, the potential detrimental impact of the novel COVID-19 vaccines on reproductive health was disregarded by the manufacturers during vaccine development. This negligence occurred with the explicit permission of the scientific establishment. The legitimate public concerns were initially ignored by officialdom, but eventually, the public discontent with such a carelessness reached the boiling point. Only then did the vaccine makers and academia start to reluctantly pay attention to the purported negative impact of COVID-19 vaccines on fertility. However, those efforts are clearly contrived and insincere. Their main goal is damage control, rather than the honest desire to investigate those issues objectively. The strongly worded reassuring statements issued by officialdom about fertility and COVID-19 vaccinations are yet to be backed by the solid data. The lack of the expected quantity and quality of the studies in this area demonstrates that the negative evidence in this field remains dominant.

The staggering scarcity of studies examining the potential link between the COVID-19 vaccine and infertility is illustrated by Figure 4. That figure contains the results of the National Library of Medicine timeline tool, which was programed to show the number of publications retrieved using the search term “COVID vaccine and fertility” since the beginning of the COVID-19 pandemic in 2020. There were only 106 papers

retrieved. Six were published in 2020 (a vaccine became available in the U.S. in December 2020). There were 54 such papers in 2021, and 57 between January and July of 2022. For comparison, 10,245 papers dealing with COVID-19 infection in patients with diabetes were published between the years 2020-2022. This shocking discrepancy occurred despite the fact that diabetes, while an important disease, is not as relevant for the public as fertility.

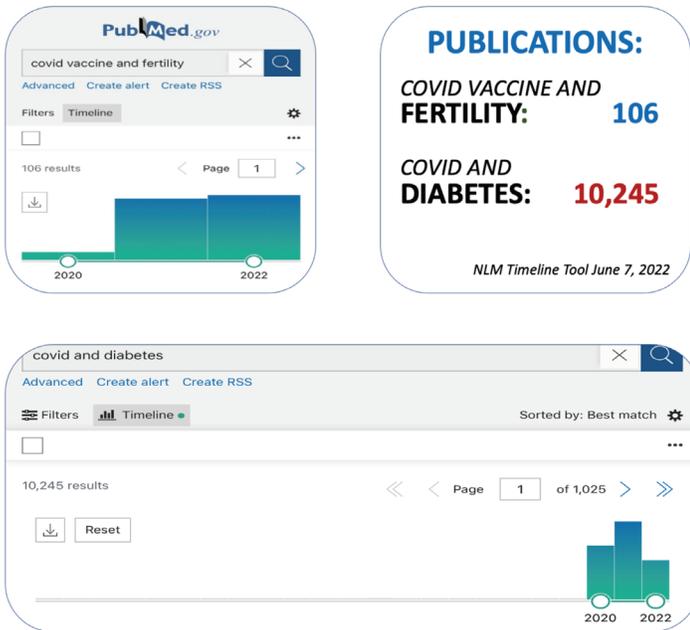


Figure 4. Number of Publications Related to “COVID Vaccine and Fertility” Compared to “COVID and Diabetes”

The disappointingly low quantity of the research studies is not compensated for by quality. In fact, the quality of the available studies is overall very low. As discussed previously, the male and female fertility studies should be done pre-clinically and prospectively.²³ Instead, we have a cluster of weak post-clinical observational studies. A brief review of the most representative papers shows the following:

For males, the findings were contradictory. There are a few rather weak studies claiming that both Pfizer and Moderna COVID-19 vaccines had no effect on sperm parameters, including sperm concentration, semen volume, sperm motility, sperm volume, and total number of motile sperm.^{46,47} This was contradicted by the recent Israeli research paper by Gat et al. This study made quite a stir in the circles of vaccine skeptics,⁴⁸ and it has been shared on social media as a long-awaited “proof” of COVID-19 induced male infertility.⁴⁹ However, that enthusiasm was unwarranted. This rather modest research study simply demonstrated a temporal reduction in sperm count occurring three months after a second dose of COVID-19 vaccine. However, the authors concluded that this impact was irrelevant since it was fully reversible and was caused by fever, a common cause of self-limited sperm count decrease. Thus, they fully endorsed the use of this vaccine.⁴⁸

For females, the simplistic assessment of follicular steroidogenesis and oocyte quality did not show any measurable difference between vaccinated unvaccinated women.⁵⁰ In another study, researchers reported that many in-vitro fertilization (IVF) treatment parameters, such as the number of oocytes and mature oocytes retrieved, fertilization rate, and the ratio of top-quality embryos (TQEs) per fertilized

oocyte, did not significantly differ between the pre- and post-BNT162b2 vaccination groups. However, these researchers had also found that COVID-19 infection could lead to a significantly lower proportion of TQEs.⁵¹

One of the largest and most interesting studies of the negative impact of COVID-19 vaccine on the menstrual cycle was performed in response to the “rash of anecdotes about menstrual irregularities after a COVID-19 vaccine, and resulting misinformation that the vaccines could disrupt fertility.”⁵² It is a large cohort (n=35,000) study providing the most comprehensive-to-date assessment of the menstrual pattern changes occurring within two weeks after receiving the COVID-19 vaccine,⁵³ reported by women from various socioeconomic strata including the study’s own authors. This study is the exception to the rule of mediocrity typical for officialdom. It does not, however, investigate effects on fertility, but simply asserts that “menstrual bleeding changes of this nature are generally not indicative of changes to fertility.”⁵³ The authors’ stated belief in the “the vaccines’ overall established safety generally and in relation to fertility and pregnancy” influenced their choice of methodology: “we opted for an observational and retrospective study design of vaccinated people rather than a prospective design with a control or crossover group of unvaccinated individuals.”⁵³ The authors write that such studies are needed “to address questions that matter to those historically excluded from reproductive and menstruation science” and to “provide adequate and culturally and physically relevant care to these populations.”⁵³ Evidently, they assume that fertility is not of concern to these populations.

Theory-Driven Conclusions

This is one of the methods most frequently used by vaccine skeptics. It is understood that the dissident researchers who lack the vast research resources of academia or industry will be tempted to use this easily available method, but it yields variable results due to its purely speculative nature.

The **syncytin-1 cross-reactivity theory** is a good example of the problems with this approach. According to the viral report by *Health and Money News*, a former Pfizer scientist, Dr. Michael Yeadon, and a pulmonologist, Dr. Wolfgang Wodarg, raised concern about the apparent homology between the COVID-19 viral spike glycoprotein and syncytin-1, a cell-cell fusion protein that is critical for placental development.³⁹ They theorized that antibodies against the COVID-19 spike protein may cross-react with syncytin-1, causing a persistent autoimmune reaction with production of anti-placental antibodies.

Yale immunologist Akiko Iwasaki reported that after examining the reactivity of 3,000 proteins in humans to the antibodies induced by SARS-CoV-2 infection or COVID-19 vaccination she has not observed any reactivity to syncytin-1. Oddly, she has published those findings not in a research journal but in *The New York Times* as an opinion piece.⁵⁴ Then, subsequent diligent research by other mainstream scientists demonstrated that SARS-CoV-2 spike protein and syncytin-1 protein do not share a significant sequence homology that would be sufficient to mediate a robust cross-reactivity, and no evidence of anti-syncytin-1 antibody induction has been demonstrated following COVID-19 mRNA vaccination.⁵⁵⁻⁵⁹

Dr. Yeadon later clarified that his claim was based on a minuscule sequence of five amino acids, four of which are reportedly shared between the 538-amino acid syncytin-1 protein and the 1,273-amino acid SARS-CoV-2 spike protein.⁶⁰ He maintained that this homology, while limited, is still concerning.

Clearly, this is a difficult situation in which a plausible

theory-driven conclusion was made by a dissident researcher, only to be subjected to scrutiny by officialdom scientists. Whom should we believe? Officialdom scientists who lost their public credibility, or the dissident scientist who sticks to his original theory? Wouldn't it be prudent to conclude that the issue remains unresolved; hence we shall err on the side of safety and recommend avoidance of the potentially unsafe vaccine?

Review of the Vaccine Manufacturers' Documentation Filed with Regulatory Agencies

The documents filed with regulatory agencies by vaccine manufactures should contain a description of the animal and human safety studies. Therefore, they can constitute a potentially valuable resource for independent researchers. Regulatory agencies including FDA and the Centers for Disease Control and Prevention (CDC) have established very strict requirements and protocols for the development, testing, and approval of vaccines. Those standards are available on-line.^{61,62} Moreover, the FDA maintains a summary page of its authorized COVID-19 vaccines, which contains links to the pertinent documentation.⁶³ The FDA briefing documents containing the summaries of the safety studies for the Pfizer and Moderna COVID-19 vaccines are available on that agency's Website.^{64,65} In 2022 a U.S. District Court ordered the FDA to produce all its data on the Pfizer COVID-19 vaccine after it was sued by the nonprofit organization Public Health and Medical Professionals for Transparency (PHMPT).⁶⁶⁻⁶⁸ Those documents are available on PHMPT's website.⁶⁹ This court order has been described by officialdom as "a risky move" because it is enabling the vaccine skeptics "to cherry pick and take things out of context."⁶⁸

Review of Performed Pre-Clinical And Post-Marketing DART Animal Studies

Animal Developmental and Reproductive Toxicology (DART) studies are traditionally done for medications and occasionally for vaccines. However, the role of those studies should be limited to severe toxicity studies. Any attempts to translate the physiological findings from animal studies, especially regarding reproduction, to humans are purely conjectural. Rodents' reproduction is very different from that of humans, and even primates are not that close. The human reproductive system is unique. Yet, due to the contentious nature of the novel COVID-19 vaccines, meticulous DART studies in animals should be done and made available to the public. It appears that while some such studies were done, they are not of the expected quality and quantity.^{64,65} The explanation for this is that the vaccine manufactures were rushing to save the world and they had no time for "minutiae." The public, however, does not consider fertility matters to be of "minute" significance.

Review of Performed Human Fertility Safety Studies

Review of the vaccine manufacturers' documentation of human safety studies pertinent to fertility should be a straightforward task. However, manufacturers are allowing access to their data very slowly, sparingly, and in a convoluted way. Both Pfizer and Moderna FDA briefing documents are hard to study since they are quite disorganized.^{64,65} Moreover, they contain only summaries of performed research and not actual data. Additional documents are both hard to find and to navigate.⁶⁹ Under such circumstances, inaccurate and easily contested impressions can result. For instance, based upon the cursory review of the manufacturer's documentation, the following contestable impressions were made:

First, it has been said that "*mRNA vaccine technology is brand*

new therefore it hasn't been tested long enough to know if it can cause infertility." In fact, mRNA technology did not originate with those vaccines. The results of first phase I/II clinical vaccination trial with direct injection of mRNA were reported in 2008.⁷⁰ This does not mean that the peculiar mRNA vaccines used for COVID-19 are safe in terms of fertility, but the technology itself is not new. Still, a prudent approach would be to not use a product on a mass scale in pregnant patients and their babies without gathering enough data related to the specific COVID-19 vaccines.

Second, it is said that "*the vaccines haven't been tested for pregnant people or those trying to conceive. Hence dramatic complications such as miscarriages cannot be excluded.*" This claim has been contested by Male in her review paper.⁵⁵ She acknowledges that in the early stages of vaccine trials, pregnant women and those trying to conceive were excluded due to safety concerns, but that accidental pregnancies occurred in those trials. This unplanned fertility safety study showed no significant difference in the rate of accidental pregnancies or miscarriages in the vaccinated group (n=29) versus the control groups (n=28). However, Male's conclusion that the vaccines are perfectly safe for pregnant women is reckless. The stakes are too high to push for the mass vaccination of pregnant women just because the results of a very low-powered, accidental study were reassuring.

Review of Pharmacovigilance Data

Theoretically, the data collected by well-designed public pharmacovigilance systems could be used by anyone to search for possible safety signals. VAERS or the V-Safe Pregnancy Vaccine Registry are flawed,¹⁹⁻²² but better than nothing. Interestingly, officialdom considers the VAERS and V-Safe vaccine registry to be reliable only when their data show results consistent with its narrative, but absolute trash when data contained there contradict it. First, officialdom publishes the scolding reports about how the very imperfect VAERS system is being misused by antivaccine activists to scare the public,⁷¹ only to follow with its own studies "proving that the COVID-19 vaccines are safe in pregnancy," which are entirely based upon VAERS and V-Safe registries.^{72,73}

Clinical Assessment of Male and Female Fertility

The clinical assessment of male and female fertility is complex and can be especially laborious in females. None of the tests used in this process are routine or easy to perform, particularly outside of fertility clinics.

Male Fertility

Formal clinical evaluation of male fertility is quite complex, but semen analysis can be used as the main assessment tool.⁷⁴ The standard semen analysis includes semen volume and pH and microscopy for sperm concentration, count, motility, and morphology; debris and agglutination; leukocyte count; and immature germ cells. The semen sample should be collected after two to seven days of ejaculatory abstinence. At least two samples should be collected at least one week apart. The semen analysis should be performed using standardized methods.⁷⁵

Female Fertility

As summarized in Figure 5, assessment of female fertility requires assessment of history, hormone levels, and anatomy.

It is said that women with normal and regular menses approximately every four weeks with molimina symptoms are almost always ovulatory. Women whose menstrual pattern

differs from this standard should be suspected of having abnormal ovulatory cycles. They should undergo hormonal evaluation with at least the measurement of the mid-luteal phase serum progesterone level.⁷⁶

Ovarian reserve is determined by measuring anti-Müllerian hormone (AMH) level and a day-3 follicle-stimulating hormone (FSH) and estradiol levels.⁷⁷ Other tests such as the clomiphene citrate challenge test (CCCT) and antral follicle count are also used in special circumstances. These tests have good specificity for predicting a poor response in IVF cycles, but have more limited value for predicting “fertility success” (e.g., ultimately successful IVF outcome).

Assessing the female genital tract requires tests to rule out tubal occlusion and evaluate the uterine cavity. Most reproductive endocrinologists usually perform a hysterosalpingogram (HSG), or hysterosalpingo-contrast sonography (HyCoSy), which evaluates both the uterus and tubes, but laparoscopy with chromotubation combined with hysteroscopy may be more appropriate in women suspected of having endometriosis.

Assessment of Female Fertility Requires Examination of:

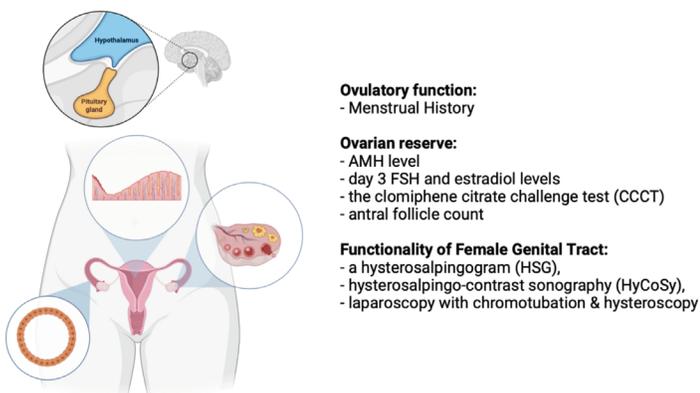


Figure 5. Assessment of Female Fertility

Review of Anecdotal Clinical Data

Official dogma states that “the plural of the anecdote is not evidence.”⁷⁹ However, practicing clinicians appreciate the immense value of accidental observations. Those random tacit experiences have led to many major scientific discoveries.⁸⁰ Thus, independent researchers should pay attention to anecdotal data provided to them by colleagues, families, and strangers.

Anecdotal data appear to play a significant role in detection of the signal indicating that COVID-19 vaccination affects the reproductive system. Soon after introduction of these vaccines it became apparent that many women started to experience numerous disturbing gynecological symptoms after receiving their injections. Those complaints included excruciating menstrual cramps, ovarian pain, abnormal menstrual cycles, and various types of dysfunctional uterine bleeding. There seemed to be not a single person in any community who did not either experience those symptoms or know someone who did. Social media were flooded by posts from women from different walks of life complaining about those symptoms. Even the women who were physicians or scientists and enthusiastic supporters of vaccinations were not spared.⁵³ Ultimately, officialdom was compelled by its own members who were affected by those symptoms to perform the previously described large study examining the link between the COVID-19 vaccination and menstrual abnormalities,⁵² which did not explore a possible connection to impairment of fertility.

In addition to omnipresent menstrual problems, much less prevalent informal reports became visible online and in real life. Those reports were typically made confidentially by the staff of fertility clinics. They implied that the COVID-19 vaccination impairs the effectiveness of fertility treatments including IVF methods. Unlike with menstrual problems, those anecdotes were not confirmed by official elegantly performed studies examining impact of the COVID-19 vaccine on fresh and frozen embryo transfer IVF.⁸¹⁻⁸³ The question remains: Who can be trusted?

Analysis of Demographic Data Related to Fertility

Like a theory-driven conclusion, this method has a lot of appeal to independent researchers due to its outwardly simple logic and the availability of the data, but it can also be very treacherous. It was recently used by dissident researchers in attempts to demonstrate the potential reproductive side effects of the COVID-19 vaccine, but the results were much less persuasive than expected.

In the summer of 2022, an impressive-looking chart emerged on social media and went viral very fast. This chart purportedly showed that the birth rate in Germany during the first quarter of 2022 had fallen by 15 percent as compared with the same period in 2021. Those data were immediately interpreted by many vaccine skeptics as a reflection of COVID-19 vaccine-induced infertility. As in many similar instances, the excitement was unfounded. cursory examination showed that the chart contained a trivial error, but more importantly its interpretation was naïve and deeply flawed, since it overlooked numerous factors influencing the birth rate. The approach had already been criticized and invalidated in 2021.⁸⁴ More harsh and valid criticism soon followed.⁸⁵ The alleged “six-sigma event” (the extremely rare event that is beyond the sixth standard deviation in a normal distribution) has been shown to be a non-issue.

However, this embarrassment should not be discouraging for the diligent independent researcher. Finding the truth is never easy, especially when the truth is hidden by a much more powerful and resourceful opponent. Persistence, resilience, and learning from one’s own errors are key factors for achieving ultimate success.

From this debacle we can learn the important lesson that demographic assessment of female fertility is treacherous. As depicted in Figure 6, the birth rate is a mere crude signal. Many confounders, effect modifiers, and biases affect it. We need to know much more than mere birth rate. There are other useful measures of fertility, including total fertility rate (TFR), age-specific fertility rate (ASFR), gross reproduction rate (GRR), and net reproduction rate (NRR).⁸⁶

From those measures, the TFR is a better index of fertility than the crude birth rate. TFR is the total number of children a woman would bear during her lifetime if she were to experience the prevailing age-specific fertility rates of women and survive until the end of her reproductive life. TFR is therefore a synthetic rate, which is not based on the fertility of any real group of women and is a better index of fertility than the crude birth rate because of its independence of the age structure of the population. The main drawback of TFR is that it does not necessarily predict how many children young women now will eventually have, as their fertility rates in years to come may change from those of older women now.⁸⁶

The ultimate lesson here is that independent researchers who like to use the demographic data paradigm should invest

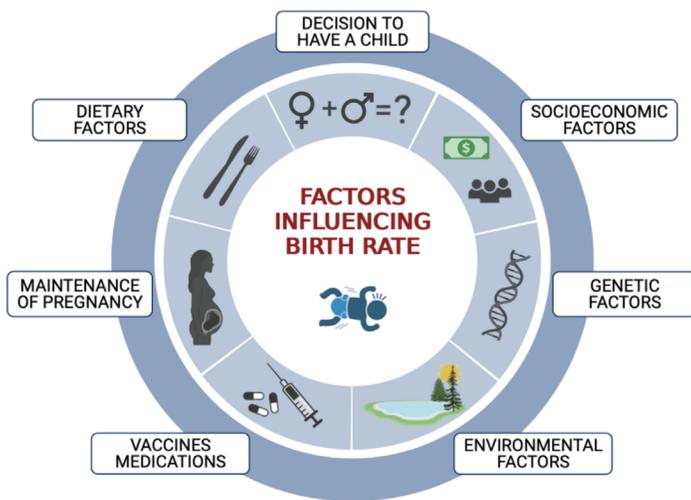


Figure 6. Main Factors Influencing Birth Rate

their time in thorough study of the statistical methods used in demography.

Conclusions

Public concerns about fertility disruption in males and females by COVID-19 vaccines are legitimate given the long history of the reproductive toxicity of pharmaceutical preparations. There are numerous safety signals suggesting that COVID-19 vaccines maybe indeed causing male and female infertility. Yet the coercion to administer those potentially dangerous vaccines on a massive scale continues unabated. Officialdom attempts to silence criticism of the official narrative by oppressive and vindictive actions.

Dissident researchers who are genuinely concerned with public welfare do not have the means to conduct the serious research needed to address the extremely complex issues involving fertility. Therefore, their main effort has to be focused on exposing the deceptions and fallacies of officialdom.

Official experts have the ethical responsibility to *rule out* this devastating potential consequence to current and all potential future generations before *permitting*, much less mandating use of these products in persons who have the ability to reproduce. They have betrayed the public's trust.

In this perilous environment, concerned physicians must do the best they can to protect the life and health of their patients, using the limited and imperfect information available to them. In the long term, we must purge the politicization and corruption in our once-great institutions, or replace them.

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AAPS PRINCIPLES OF MEDICAL POLICY

Medical care is a professional service, not a right. Rights (as to life, liberty, and property) may be defended by force, if necessary. Professional services are subject to economic laws, such as supply and demand, and are not properly procured by force.

Physicians are professionals. Professionals are agents of their patients or clients, not of corporations, government, insurers, or other entities. Professionals act according to their own best judgment, not government "guidelines," which soon become mandates. Physicians' decisions and procedures cannot be dictated by overseers without destroying their professionalism.

Third-party payment introduces conflicts of interest. Physicians are best paid directly by the recipients of their services. The insurer's contract should be only with subscribers, not with physicians. Patients should pay their physician a mutually agreed-upon fee; the insurer should reimburse the subscriber according to the terms of the contract.

Government regulations reduce access to care. Barriers to market entry, and regulations that impose costs and burdens on the provision of care need to be greatly reduced. Examples include insurance mandates, certificate of need, translation requirements, CLIA regulation of physician office laboratories, HIPAA requirements, FDA restrictions on freedom of speech and physicians' judgment, etc.

Honest, publicly accessible pricing and accounting ("transparency") is essential to controlling costs and optimizing access. Government and other third-party payment or price-

fixing obscures the true value of a service, which can only be determined by a buyer's willingness to pay. The resulting misallocation of resources creates both waste and unavailability of services.

Confidentiality is essential to good medical care. Trust is the foundation of the patient-physician relationship. Patient confidences should be preserved; information should be released only upon patient informed consent, with rare exceptions determined by law and related to credible immediate threats to the safety or health of others.

Physicians should be treated fairly in licensure, peer review, and other proceedings. Physicians should not fear loss of their livelihood or burdensome legal expenses because of baseless accusations, competitors' malice, hospitals' attempts to silence dissent, or refusal to violate their consciences. They should be accorded both procedural and substantive due process. They do not lose the basic rights enjoyed by Americans simply because of their vocation.

Medical insurance should be voluntary. While everyone has the responsibility to pay for goods and services he uses, insurance is not the only or best way to finance medical care. It greatly increases costs and expenditures. The right to decline to buy a product is the ultimate and necessary protection against low quality, overpriced offerings by monopolistic providers.

Coverage is not care. Health plans deny payment and ration care. Their promises are often broken. The only reliable protection against serious shortages and deterioration of quality is the right of patients to use their own money to buy the care of their choice.