Docket No. CDC–2023–0093

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Tiffany Brown
Executive Secretary, Centers for Disease Control and Prevention
Division of Reproductive Health
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
4770 Buford Highway NE,
Mailstop S107–2,
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Attention: Assisted Reproductive Technology Surveillance and Research Team

RE: ART NPRM Comment January 29, 11:59pm

NPRM: "Reporting of Pregnancy Success Rates From Assisted Reproductive Technology (ART) Programs; Proposed Modifications to Data Collection Fields and Data Validation Procedures; Request for Comment"
https://www.federalregister.gov/documents/2023/11/28/2023-26137/reporting-of-pregnancy-success-rates-from-assisted-reproductive-technology-art-programs-proposed

Submitted via Regulations.gov

Dear Executive Secretary Tiffany Brown,

We write to comment on the Notice of "Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs; Proposed Modifications to Data Collection Fields and Data Validation Procedures" (Docket No. CDC-2023-0093) pursuant to the notice and comment process outlined in and protected by the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA). We urge you to consider the following regarding the four proposed modifications:

Introduction

Established in The Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), the primary goal of public reporting of ART clinical outcomes is to "to provide accurate data to current or potential ART users" 42 U.S.C. 263a–5. Three of the departments' four proposed modifications undermine this goal. The first two modifications are unwarranted as they restrict access to pertinent information related to data

collection of fertility medication dosage amounts and research cycle study types. Standard practice within reproductive technology should aim to provide maximum transparency, even in minor details, with the public. The third modification requires clinics to report the date of cryopreservation for fresh embryos. This works toward achieving the CDC's greater goal of tracking and accountability. The fourth modification is a step in the wrong direction. The departments proposal to no longer pursue targeted validation of clinics and identification of major data discrepancies fails to protect potential clients and provide the necessary accountability consistent throughout medical practice.

In addition to specific concerns regarding each proposed change, we share broader concerns with how the reproductive industry in the United States functions. These concerns range from insufficient public transparency, inconsistent reasoning, the lack of available data to potential ART users and policy researchers, and the failure to consider the moral and ethical implications of widespread access to assisted reproductive technology.

Proposed Modifications

First Modification: Dosage Information for Fertility Medications

Under the current rule, clinics are obligated to report dosage information concerning Clomiphene, Letrozole, and other oral medications, prescribed to induce ovulation. The notice claims that clinics administer the same dosage according to the "established guidelines" for these medications (88 FR 83131). Thus, as the "established guidelines" prevent variability in the dosage of these medications, the department has determined the collection of dosage data to be unbeneficial. Consequently, the CDC proposes an adjustment to remove this requirement for the collection of data related to the dosage of these medications. Additionally, CDC aims to discontinue the collection of data associated with outdated medications like follicle stimulating hormone (FSH).

These deletions are problematic for several reasons. First, the notice assumes that the "established guidelines" for dosages is a minor and unchanging variable. The departments proposed rule does not specify what the general recommendations are for dosage amounts, nor does it account for the fact that clinics are legally allowed to give different dosages. If fertility clinics begin testing different dosage amounts, or new fertility medications that are not listed yet, how does the department intend to collect information on this? Since the department proposes to no longer need to report the dosage information, who is to stop CDC or another regulatory body from changing the established guidelines for dosage amounts? Does the department have a mechanism in place to ensure that women and egg donors, the latter of which is not a patient in this industry, are protected from dosage error or untracked changes? We strongly urge the department to continue requiring dosage amounts for these medications to maintain the precedent of tracking what and how much of a given drug is used to artificially simulate ovulation.

Secondly, CDC is incorrect in saying that FSH is "no longer used in ART practice" (88 FR 83131). Various health organizations and clinics, including the Mayo Clinic, freely admit that FSH is still used at ART practices, particularly in egg retrieval surgeries. The fact that the CDC is claiming that FSH is no longer in use without any evidence to support this claim is unacceptable. Per the CDC's own definition, assisted reproductive technology includes any procedures or treatments that deal with human eggs or embryos. The department must provide firm proof that FSH is no longer used in treatments to justify this decision.

Additionally, the department should affirm the approved purpose for each of these drugs by the Food and Drug Administration. Are these drugs approved on an off-label basis? For example, if these drugs are used without direct approval for egg retrievals of donor women who are not formally involved in this medical treatment, then such a use is off-label and warrants a closer study of the FSH drug use.

Given these reasons, we urge the department not to remove the requirement to track dosage amounts.

Second Modification: Research Cycle Study Type

The CDC's second proposed change to remove the requirement for clinics to report research cycle study types' is short-sighted and based on poor reasoning. Per the proposed rule, the removal of this requirement will apply to all data fields for research study types including device study, protocol study, pharmaceutical study, and laboratory technique. The department's justification for this removal is that "only a small number of research cycles are performed each year" (88 FR 83131).

The department's claim that a small number of reported research cycles justifies the removal this reporting mechanism is insufficient.

First, the CDC should clarify what goes into creating and implementing a new research cycle type. What is required for clinics to do this? Is this something that requires the approval of a medical board or other body? Since there are no state laws governing the practice of assisted reproductive technology, and few federal laws, we know very little about the research study types that are conducted within reproductive technology, such as IVF.

Notably, just because few research cycle types have been submitted in recent years does not, by any means, suggest that this will continue. This proposed change suggests that the CDC does not expect research cycle types to increase in the next 1,2,3,5, or 10 years and yet the department does not provide any justification for why this is the case. As assisted reproductive technology rapidly increases and new types of cycles are studied in university research clinic settings, should clinics begin trying new research cycle types, the department will have no way of tracking or ensuring that proper mechanisms are in place. With three-parent embryo research, pre-implantation genetic testing, and other forms of genetic testing rapidly increasing as common practices, this is not the time that the CDC should require fewer reporting mechanisms, but more.

We strongly urge the department to reconsider this proposed change. Without providing proper justification, the CDC risks playing fast and loose with research cycle types that deal with the creation and modification of human life itself. Without proper reporting mechanisms in place, the CDC will open itself up to lawsuits, negligence, and harm to the men, women, and children they claim to serve. The CDC must continue to require clinic reporting of the research cycle study types that they use.

Third Modification: Cryopreservation Date for Fresh Embryos

The CDC's proposed modification to require clinics to report the cryopreservation date for fresh embryos is a step in the right direction. We commend the department for this decision to increase transparency and reporting for assisted reproductive technology treatments. This additional modification establishes the CDC's ability to collect thorough data. Because of this, we urge the CDC to remain consistent in their efforts to require detailed data collection. The CDC's reluctance to gather sufficient data in the other areas of this proposed rule stands out even more in contrast.

We commend Tiffany Brown, the CDC Executive Secretary, in her call for an uptake in cryopreservation data collection to ultimately achieve the greater goal of "improv[ing] the reporting of factors that impact ART success rates" (88 FR 8313). We urge the department to embrace this same attitude in *all* areas of ART data collection, particularly in ones that may impact ART failure rates such as the percentage of live births, success rates for IVF, and more.

We ask CDC to implement even *more* data requirements surrounding cryopreservation. The department should require clinics to report the exact number of embryos that clinics create, destroy, experiment with, or donate per each assisted reproductive technology cycle. It is imperative for potential ART users to have access to this information because there are great ethical implications of handling embryos outside of the womb.

Fourth Modification: Targeted Validation of Clinics and Identification of Major Data Discrepancies

The department's final modification to remove the requirement that the CDC identify major data discrepancies within clinic success rate reporting is unacceptable. This proposed rule undermines the very basis of the initial reason for the Fertility Clinic Success Rate and Certification Act of 1992. This act is the only federal law that holds clinics to an external standard of reporting and accountability. While the enforcement mechanism was already weak, this proposed change to remove the targeted validation of clinics and the identification of major data discrepancies undermines the CDC's own stated goals. Further, this decision hinders the CDC's primary goal to provide potential parents with accurate data.

The CDC's justification for this change is weak and lacks good reasons as to why they have made this change. Specifically, the CDC's claim that this requirement would place an undue burden on clinics is an insufficient, unproved, and farcical claim.

The reasoning provided by the department for the removal of the identification process of major discrepancies is that requiring a "larger" number of clinic records would increase the "data collection burden for clinics" (88 FR 83131). We have many concerns with this rationale. The CDC should provide additional reasons and clarify what their goal is in proposing this change. Does this goal align with the CDC's responsibility to provide potential parents and researchers with reliable data? Is the CDC still committed to their primary responsibility to provide accurate data to potential parents who are spending countless hours, dollars, and risking their health to create a child? We are deeply concerned that the CDC is reneging on their responsibility and further encouraging the fertility industry to self-regulate without any accountability from federal or state governing agencies.

Moreover, the CDC must show by what standard that this current requirement is an undue burden for clinics? How many more records would need to be reviewed? We urge the CDC to reconsider. It is a basic expectation for clinics to submit accurate reporting information and be held accountable in their submission of accurate data. Moreover, we would like to underscore that countless potential parents are relying on the CDC to ensure that clinics are reporting accurate information and not allowed to fly under the radar on their ethical standards and practices. The CDC's failure to require accurate reporting from clinics is an encouragement to clinics to practice false advertising, misrepresent their own success rates, or otherwise mislead potential parents. The CDC must answer as to why they think that this clinic reporting requirement is not worth the value of potential parents receiving the most thorough and accurate data possible?

Considering the dangers and unethical practices within assisted reproductive technology, the CDC should strive to limit the potential harms imposed on women, not the potential burden of clinics.

Statistical evidence to support this proposal must be provided by CDC before this potentially harmful modification is implemented, and CDC must establish how this modification **helps** to achieve its stated goal. As it currently stands, this proposed change seems like a move to undermine the CDC's goal and the purpose of this act.

Further, we ask the CDC to clarify if it is the case that these "major discrepancies" would not, in fact, inflate ART success rates? The CDC must provide proof of such a change in reporting requirements would not increase misleading reports. The department must provide evidence that the data validation practices it intends to implement can sufficiently deliver excellent data to women.

Moreover, has CDC studied the level of influence that access to accurate data has on the decision-making habits of potential parents? This information is important because if there is a positive relationship between access to reliable data and a potential parent's decision to use certain treatments, then any amount of inflated or inaccurate data will likely mislead potential parents. It is irresponsible and unethical for the department to intentionally soften reporting requirements to benefit financially motivated clinics at the expense of potential parents.

Additional Considerations

As we stated above, our concerns range from insufficient public transparency, inconsistent reasoning, the lack of available data to potential ART users and policy researchers, and the failure to consider the moral and ethical implications of widespread access to assisted reproductive technology.

Public Transparency

We urge the department to remain firm in its commitment to provide transparent and reliable data to the public. The safety, reliability, or viability of a given medical treatment or procedure should not be left to individual clinics or the financially motivated fertility industry to determine. We ask the CDC to maintain and improve its commitment to uphold the best standards for public transparency in assisted reproductive treatments.

Call for Consistency

It is important to note the inconsistency in the CDC's reasoning for various modifications across this notice. Specifically, we would like to highlight the inconsistent reasoning in the third proposed modification and the second and fourth proposed modification. In the third modification, the department commits to collect the date of cryopreservation and states that it "is an important predictor of ART success rates" (88 FR 83131).

Contrary to this, the department does not apply the same line of reasoning to the second proposal to remove the requirement that clinics track the research cycle study type used. The reasoning provided is that "only a small number of research cycles are performed each year" and therefore, it is not relevant. Is the relevancy of a certain data defined by its impact on ART success rates or by its numerical prevalence? If relevancy is defined by the former, then it must be confirmed by CDC that research cycle study type data has no impact on ART success rates or safety before its official removal.

If the justification for whether or collect data is determined by its prevalence, then the CDC must confirm that they do not expect and can reasonably guarantee that different or new research cycle types will not increase. As it currently stands, it seems unlikely that the CDC could make this claim in good faith, and therefore must provide a stronger justification or drop this proposal altogether.

The same confusion occurs in the fourth modification. Again, the CDC deviates from its commitment to provide strong reporting data in the third modification by claiming that clinic success rate reporting accuracy is somehow incidental to this act or to the practice of assisted reproductive technology.

Overall, it is unclear what the departments general criteria is for adding or removing data reporting requirements is. The CDC should declare its criteria so that the public can ensure it is being objective in its decision making.

Available Data for Researchers and Policymakers

Currently, researchers and policymakers must dig deeply within the CDC's website to find data on success rates, side effects, or other factors in assisted reproductive technology treatments. Moreover much information regarding the total number of IVF cycles, implantations, and "live births" remains obscured in weak reporting requirements by clinics.

For the sake of research, we ask the CDC to begin tracking more outcomes. For example, the CDC should implement a longitudinal study of children born from IVF and other assisted reproductive technologies to track their long term health outcomes and their long term emotional, psychological, educational, financial, and family structure decision-making outcomes. Are children born from such treatments more likely to pursue similar treatments? Less likely? What are the reasons why potential parents select such treatments now? Are they motivated by factors outside of fertility or other health reasons? These questions are imperative to understanding the fertility industry. We urge the CDC to implement sufficient reporting requirements to track decision making and long term outcomes associated with assisted reproductive technology.

Moral and Ethical Concerns with Assisted Reproductive Technology

While we applaud the CDC's commitment to track birth rate, term, multiples, and other health related outcomes associated with the birth of a child from assisted reproductive technology, we ask the CDC to implement additional regulations, reporting requirements, and features to address the deeper moral and ethical concerns.

Unlike other medical treatments, assisted reproductive technologies deal with the creation and preservation of human life itself. While many people may debate when a human life becomes a "person" (a misguided question to begin with), all biologists and scientists recognize that a life begins at the point of sustained growth. Based on this medical and biological definition, a human embryo created via assisted reproductive technology *is* a living human being, no matter how small.

Because of this, we urge the CDC to consider the moral and ethical implications of being able to create a child for profit. Even with the best intentions, the ability for a clinic to purchase or ascertain egg, sperm, or an embryo to create, genetically test or modify, and destroy human life must be held in the highest scrutiny.

Children are not products to be bought, sold, or designed. The fertility industry—unlike organ donation or adoption—is a highly lucrative business. Big Fertility is rife with flagrant human rights violations. Few regulations govern the use of IVF and surrogate motherhood in the United States; notably, this is at odds with the laws in most developed nations. As many activists and legal rulings have noted, the industry functions as a form of commercialized and contractual baby selling.

For example, if a man purchases the egg, the womb, and the necessary paperwork, the line between a legitimate commercial surrogacy agreement, driven by unfortunate health circumstances, and outright baby selling dissolves. As Matthew Lee Anderson put it in his preface to Oliver O'Donovan's *Begotten or Made?*, "to describe reproductive medicine and research as the industrialization of human fertility is not to invoke a metaphor, but to name a reality."

Of course, it's not wrong to pay for medical services that aim to heal or restore the human body. There is a big difference between paying for legitimate medical treatments and using medical technology to artificially create and birth human life outside of the bonds of marriage, sex, and procreation. In part, the fight against gender ideology has revealed a similar situation when doctors use medical treatments to transmogrify the human person.

The CDC should think carefully about the message that assisted reproductive technology sends future generations. Children, who are first and foremost a gift, ought to be loved and accepted as they are, not because they fit the mold of a given parent's desirable child.

Children are not an act of the will, nor is reproductive technology a means of wish fulfillment. A culture that values and protects life is one where parents submit their own wishes to the wellbeing of children. That includes children who do not exist yet.

Conclusion

We urge CDC to reflect on its "primary goal" of providing accurate data to current or potential ART users 42 U.S.C. 263a–5. The proposed modifications in this note bring to question whether that goal was simply a statement of good intention, or a commitment to good *action*. These modifications to data collection have great implications for the health of women and future generations, and therefore warrant the utmost level of transparency. If the goal of data collection and validation by CDC truly is to provide accurate data to women, then these modifications must be reformed, and the broader concerns outlined in this comment must be addressed.

Respectfully submitted,

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