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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,
Atlanta, Georgia 30341
Attention: Assisted Reproductive Technology Surveillance and Research Team

Subject: 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)

As nurses, we are concerned with the proposed modifications to data collection fields for reporting of pregnancy success rates from ART programs and to data validation procedures proposed in the notice "Reporting of Pregnancy Success Rates From Assisted Reproductive Technology (ART) Programs; Proposed Modifications to Data Collection Fields and Data Validation Procedures" from 11/28/2023.

The CDC is proposing to remove requirements for clinics to report dosage information on certain medications, some of which are established treatment options for ovulation induction. We ask, why? It is indicated in your proposal that dosage follows "established guidelines" but the public cannot readily find these "established guidelines" and it is unclear which "established guidelines" the proposal is referring to. Further, these medications are not only used on women that are undergoing ART for medical reasons (infertility), but also women who are egg 'donors' and surrogate mothers – a population that already lacks substantial research, data, and information on risks and harms to their health. As nurses we know that many outcomes and side-effects are dosage dependent. Dosing is relevant, especially with drugs being used often off-label on healthy women (egg 'donors' and surrogate mothers) who are not patients and have no medical need for taking such drugs.

The CDC is proposing to remove the requirement for clinics to report information on research cycle study type, applying to all data fields for research study. The reason given is because only a small number of research cycles are performed each year. Simply because something is irregularly done certainly doesn't mean we are uninterested in what studies are being done, who are the subjects of the research, and the outcomes of the research studies.

The CDC proposes to add the requirement for clinics to report the date of cryopreservation for fresh embryos to improve the reporting of factors that impact ART success rates. This is not unhelpful information, but more information needs to be provided to give a clear assessment on whether or not this is a beneficial addition. Further, we would add that, if the goal is to improve the reporting of factors that impact ART success rates, data collected from ART programs needs to drastically expand and become standardized across the nation. This expansion alone is certainly not sufficient. Additional data should be required, but not limited to, the following:

ART programs, and thereby the CDC, should report:

- The number of embryos from their clinic donated to research or discarded
- The number of embryos transferred in any given cycle (do clinics have a policy of only single embryo transfer)
- A clear distinction from pregnancies reporting a live birth from a surrogate mother vs a biological mother
- Improved, consistent data on embryo transfer(s), pregnancy, pregnancy outcome (miscarriage, abortion, selective-reduction, multiples, and live birth). It is well-known that not all clinics report equally, which makes reporting confusing and misguiding to the general public on success rates
- Outcomes of the child or children (NICU admission, complications, life beyond year one, how many live births died minutes, hours, or days after delivery)
- Fresh vs frozen embryo usage and the age of any frozen embryo from either an egg donor or the genetic mother
- Socioeconomic status/race of egg donors vs. those who use the donated egg
- Socioeconomic status/ race of surrogate mothers

The CDC proposes not to pursue targeted validation of clinics and identification of major data discrepancies because the identification of major data discrepancies would require review of a large number of clinic records at select clinics thereby increasing the data collection burden. This proposed change is unacceptable. ART programs are *required* to report their data, but we already know that many still do not and certainly not in any consistent way that the average American understands. Our stance is that reporting should be mandatory and standardized for all ART programs, no matter the volume of patients they treat or how they practice. Not only should reporting be mandatory, but those programs who fail to report data should be at risk of losing their ability to offer services. Similarly, poor reporting should be penalized not ignored. Finally, as outlined above, what is currently reported is not enough to better understand what constitutes success and reporting data points must be expanded. It is unacceptable that in a nation where our maternal mortality and morbidity rates fail to stand up next to other developed countries that we would not require our data reporting to have maternal/child health as our top priority.

The nation should be committed to women's health and that commitment requires accountability from fertility clinics (ART programs) and the tracking of all women who used or were used in ART (including surrogate mothers and egg 'donors') and the children born from such procedures or treatments. Americans should have access to reliable data, improving the little knowledge currently possessed on infertility care, fertility treatments, and the outcomes. Requiring less from ART programs is beneficial to no one, especially women considering utilizing the technology, those contemplating surrogate motherhood or egg 'donation', and the children born from such technologies.

Kallie Fell, R.N., B.S.N., M.S.
Executive Director, The Center for Bioethics and Culture Network

Jennifer Lahl, R.N., B.S.N, M.A.
Founder, The Center for Bioethics and Culture Network