Attachment B2. Program Response to Comments to 60 Day FRN

Comments in response to the Federal Register Notice

A 60-day Notice was published in the Federal Register on April 5, 2024, Vol. 89, No. 67, pp. 24005-24007 with the title Proposed Data Collection Submitted for Public Comment and Recommendations (**Attachment B1**). CDC received two comments related to this notice (**Attachment B2**). CDC did not provide a response to one comment because it fell outside the scope of this information collection. The other comment was supportive of the data collection and provided feedback on enhancing the quality, utility, and clarity of the information to be collected.

Comments	Date Received by CDC	CDC's Response
A comment submitted by Jean Publie. The commenter suggested that data collection was not necessary and a waste of federal funds	04/06/2024	No reply (outside scope of project).
Comment submitted jointly by Dr. Tierney, Dr. Jacobsen, and Dr. Leyser-Whalen. The commenters suggested improvements in race and ethnicity data collection for both patients and gestational carriers, and also suggested additional data collection elements related to social determinants of health such as educational attainment, income, and insurance or payment type to capture inequalities in utilization and outcomes of ART treatments. Additionally, the commenters suggested that percentages be replaced with numbers in the reports for fertility preservation by patient age, and also requested that clinic data tables in excel spreadsheets are archived as was done previously.	06/04/2024	CDC thanks the commenters for their comments. CDC currently collects race and ethnicity data for both intended parents as well as for oocyte sources and pregnancy carriers to ensure consistency in demographic data collection. CDC agrees that improvements can be made in the collection of other demographic variables such as educational attainment, income, and insurance or payment type. However, additional data collection by CDC is undertaken after careful estimations of extra burden on clinics. CDC thanks the commenters for their comments and notes the commenters' feedback regarding these reporting improvements. CDC will consider measures that improve the practical utility of the information collected and disseminated, while protecting confidentiality of patients.

The commenters expressed appreciation of the ART Fertility Clinic and National Summary Report.		

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PUBLIC SUBMISSION

Docket: CDC-2024-0025
Assisted Reproductive Technology (ART) Program Reporting System

Comment On: CDC-2024-0025-0001
Assisted Reproductive Technology (ART) Program Reporting System

Document: CDC-2024-0025-0002
Comment from publie, jean

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General Comment

i totally oppose billions of dollars going to this sneaky operation with its closed meetings and failure to report to the us public via foia,this regulatgory agency is a sneaky closed shop that has been causing fertility problems with bad vaccineis and drugs for years and we need to stop their regulatory authority. all of them bounce back and forth between bigpharma and the govt jobs for more and more money and they seem to have no real connection to doing right by ghe public. they have taken actions which have been negative for the us public imo i do not think this close connection with this field isnecessary art all and believe itis a waste of our total tax dollars. it needs to be shut down. this collection is not necessary and tells us noting valuable that we need. this agency has been out of control for the last 25 years always asking for more and more money with zero accountability for results. resutls dont count. just more money for these useless mostly animal abusers. we shoudl shut down all animal research by these sadists imo. the grade i wuold give this group is f minus or zero for its work.

June 4, 2024

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RE: CDC, Assisted Reproductive Technology (ART) Program Reporting System

Dear CDC:

Thank you for the opportunity to comment on the Assisted Reproductive Technology (ART) Program Reporting System. This comment responds to the identified issue of “enhanc[ing] the quality, utility, and clarity of the information to be collected.”

As professors and social scientists researching assisted reproduction, we utilize the Centers for Disease Control and Prevention’s *Assisted Reproductive Technology Fertility Clinic and National Summary Report* that is generated via the ART Program Reporting System in our research. This report and the available datasets are a primary data source for statistics to understand the scope and practice of ART in the U.S. We write to express our support for this vitally important continued data collection. Specifically, these are the only high-quality, publicly available data on ART success rates and births in the U.S. Although information on ART use is collected on the U.S. birth certificate, several studies have shown that birth certificate data underreport ART births (e.g., Cohen et al. 2014; Moaddab et al. 2016; Thoma et al. 2014; Tierney & Cai 2019). Further, the vital statistics datasets are often difficult for the general public to access due to the size of the data files, which necessitates the use of specialized software. In addition, based on historical studies (Stephen et al. 2016), demographic projections (Tierney 2022), and ongoing delays to first births (e.g., Osterman et al. 2024), we believe demand for ART will only increase.

Therefore, continued collection and reporting on these data is necessary to both inform patient-clients and enhance population level research on ART.

We would like to communicate our appreciation for the improvements made over the years to data collection efforts and the presentation of the generated data in the *ART Fertility Clinic and National Summary Report*. This includes the change begun with the 2021 report of including numbers of patients receiving ART treatments, in addition to the number of ART cycles. We appreciate the attention to this data collection and would like to make four specific suggestions for continued improvement.

1) While demographic data are collected, expanding the patient demographic data that are made available and easily accessible in the national summary report and dataset would not only assist social scientists studying ART but would also help provide more transparent data to patient-clients about ART accessibility. We make the following specific recommendations related to demographic data collection/reporting:
    a. *Improvements to Race/Ethnicity Reporting*– given the well documented disparities in ART access and outcomes by racial/ethnic groups, efforts to address the known quality issues in the reporting of race/ethnicity (as reported by Wellons et al. 2012) is needed both for patient-clients searching for care and to improve population-level research on these inequalities. Furthermore, reporting easily accessible demographic information on gestational carriers would provide much-needed data for researchers.
    b. *Improvements to Age Reporting*—first, in the reports, most data charts are displayed only by age groups, which obscures the overall rates. Thus, we believe adding a summary of aggregated data in the consumer-facing reports would be useful. At the same time, datasets provided to researchers, or geared toward clinicians, should include more detailed information of outcomes by age. More detailed age reporting would also be valuable to consumers as they seek to make informed medical decisions, and to clinicians counseling patients. Therefore, reporting of these data by single year of age or with more clearly bounded age groups would enhance their utility. For example, many outcomes are reported for individuals under 35 and over 40. However, for quantitative research, such "unbounded" numbers require researchers to make assumptions about the population at-risk. Therefore, specifying the lower and upper bounds of these ranges would enable more accurate inferences. Importantly, we believe that such detailed age data should only be reported at the national level to help safeguard individuals' privacy.
    c. *Addition of Indicators of Socioeconomic Status (SES)*—another area of inequality in ART utilization and outcomes is related to SES. As policy contexts for mandated coverage continue to change, information on social class (such as income, educational attainment, or insurance or payment type) would represent a critical expansion in the ability of researchers to understand access to ART care and inequalities in ART by SES.
2) Certain language choices could be updated and/or modified:

   a. The term “gender” is used in reports when referring to “sex.”
   b. The term “people” could replace “women” to be more gender inclusive.
   c. While an explanation for the use of the term “cycle” is provided, referring to procedures as cycles may prove confusing for readers of the national reports, especially for patient-clients.

3) The percentages provided in the tables in the National and Clinic reports (e.g., the percentage of cycles for fertility preservation by patient age in the “Characteristics of ART Cycles” section) are easily interpretable and of use for patient-clients. However, for the research-oriented dataset, we would strongly advise directly reporting the underlying numbers (e.g., number of cycles for fertility preservation in each age group). Such an adjustment would allow researchers to transparently create their own measures without the need for “back-calculations,” which introduces error.

4) Starting with the 2019 data on the Archived ART website (https://www.cdc.gov/art/reports/archive.html), the presentation of clinic data on the EXCEL spreadsheet for each year changed, such as the “Clinic Table Data Records” no longer being available. The consistency of those data from 1995 forward is helpful for researchers studying changes and trends in ART-providing clinics. We suggest reintroducing the Clinic Table Data Records in the archived data and making efforts to harmonize the national data reporting across years to the extent possible.

In summary, the ART data collection and high-quality reports made available via the CDC are vital for researchers studying assisted reproduction in the U.S. and useful for patient-clients and those providing services and support to them. Our comments here reflect suggestions for improvement based on our experiences using the data. Thank you for the opportunity to make comments.

Sincerely,

Dr. Tierney, Dr. Jacobson, Dr. Leyser-Whalen

References

Cohen, Bruce, Dana Bernson, William Sappenfield, Russell S. Kirby, Dmitry Kissin, Yujia Zhang, Glenn Copeland, Zi Zhang, and Maurizio Macaluso. 2014. “Accuracy of Assisted Reproductive Technology Information on Birth Certificates: Florida and Massachusetts, 2004–06.” *Paediatric and Perinatal Epidemiology* 28(3):181–90. doi: 10.1111/ppe.12110.

Humphries, Leigh A., Olivia Chang, Kathryn Humm, Denny Sakkas, and Michele R. Hacker. 2016. “Influence of Race and Ethnicity on in Vitro Fertilization Outcomes: Systematic Review.” *American Journal of Obstetrics and Gynecology* 214(2):212.e1-212.e17. doi: 10.1016/j.ajog.2015.09.002.

Imrie, Rachel, Srirupa Ghosh, Nitish Narvekar, Kugajeevan Vigneswaran, Yanzhong Wang, and Mike Savvas. 2023. “Socioeconomic Status and Fertility Treatment Outcomes in High-Income Countries: A Review of the Current Literature.” *Human Fertility* 26(1):27–37. doi: 10.1080/14647273.2021.1957503.

Moaddab, Amirhossein, Zhoobin H. Bateni, Gary A. Dildy, and Steven L. Clark. 2016. “Poor Compliance and Lack of Improvement in Birth Certificate Reporting of Assisted Reproductive Technology Pregnancies in the United States.” *American Journal of Obstetrics & Gynecology* 215(4):528–30. doi: 10.1016/j.ajog.2016.06.041.

Osterman, Michelle J. K., Brady E. Hamilton, Joyce A. Martin, Anne K. Driscoll, and Claudia P. Valenzuela. 2024. “Births: Final Data for 2022.” 73(2):1–56.

Stephen, Elizabeth Hervey, Anjani Chandra, and Rosalind Berkowitz King. 2016. “Supply of and Demand for Assisted Reproductive Technologies in the United States: Clinic- and Population-Based Data, 1995–2010.” *Fertility and Sterility* 105(2):451–58. doi: 10.1016/j.fertnstert.2015.10.007.

Smith, James F., Michael L. Eisenberg, David Glidden, Susan G. Millstein, Marcelle Cedars, Thomas J. Walsh, Jonathan Showstack, Lauri A. Pasch, Nancy Adler, and Patricia P. Katz. 2011. “Socioeconomic Disparities in the Use and Success of Fertility Treatments: Analysis of Data from a Prospective Cohort in the United States.” *Fertility and Sterility* 96(1):95–101. doi: 10.1016/j.fertnstert.2011.04.054.

Thoma, M. E., S. Boulet, J. A. Martin, and D. Kissin. 2014. “Births Resulting from Assisted Reproductive Technology: Comparing Birth Certificate and National ART Surveillance System Data, 2011.” *National Vital Statistics Reports: From the Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System* 63(8):1–11.

Tierney, Katherine. 2022. “The Future of Assisted Reproductive Technology Live Births in the United States.” *Population Research and Policy Review* 1–21. doi: 10.1007/s11113-022-09731-5.

Tierney, Katherine, and Yong Cai. 2019. “Assisted Reproductive Technology Use in the United States: A Population Assessment.” *Fertility and Sterility* 112(6):1136-1143.e4. doi: 10.1016/j.fertnstert.2019.07.1323.

Wellons, Melissa F., Victor Y. Fujimoto, Valerie L. Baker, Debbie S. Barrington, Diana Broomfield, William H. Catherino, Gloria Richard-Davis, Mary Ryan, Kim Thornton, and Alicia Y. Armstrong. 2012. “Race Matters: A Systematic Review of Racial/Ethnic Disparity in Society for Assisted Reproductive Technology Reported Outcomes.” *Fertility and Sterility* 98(2):406–9. doi: 10.1016/j.fertnstert.2012.05.012.