



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2020-0112]

**Assisted Reproductive Technology (ART) Success Rates
Reporting and Data Validation Procedures**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Request for comment.

SUMMARY: The Centers for Disease Control and Prevention,
within the Department of Health and Human Services,
announces the opening of a public docket to obtain public
comment on proposed changes in assisted reproductive
technology (ART) data validation selection process; data
validation approach; and data discrepancy reporting.

DATES: Written comments must be received on or before
**[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE
FEDERAL REGISTER]**.

ADDRESSES: You may submit comments identified by Docket No.
CDC-2020-0112 by any of the following methods:

- Federal eRulemaking Portal: <https://www.regulations.gov>.

Follow the instructions for submitting comments.

- Mail: 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 30341-3724. Attention: Assisted Reproduction Technology Surveillance and Research Team.

FOR FURTHER INFORMATION CONTACT:

Jeani Chang, 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 30341-3724. Telephone: (770) 488-5200. Email: ARTinfo@cdc.gov.

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data in response to the proposed changes described in this notice. CDC invites comments specifically on:

- Proposed changes in data validation selection process;
- Data validation approach; and
- Process for identifying discrepancies in reporting of pregnancy success rates from ART programs.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure.

Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact or withhold submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted.

Background

On May 31, 2018, CDC requested public comment on a plan to 1) revise the definition and characterization of Assisted Reproductive Technology (ART) success rates and 2) introduce clinic validation footnotes for the annual ART Fertility Clinic Success Rates Report (83 FR 25009). CDC received three public comments, of which one was non-substantive, one was supportive of CDC's planned approach for revising the definition of success rates and introducing clinic validation footnotes without further suggestions, and one contained concerns about CDC's planned

clinic validation footnotes for identified major data discrepancies and approach to clinic validation along with recommended changes.

This comment expressed concern that random selection of clinics during the current CDC validation system is unable to identify systematic reporting errors. It was suggested that targeted selection of clinics based on certain reporting characteristics that predict erroneously inflated ART success rates is a better approach to identify systematic reporting errors. There was also a concern that discrepancies identified during on-site data validation are not corrected prior to publication of the ART Fertility Clinic Success Rates Report. It was suggested that instead of including a footnote, identification of erroneous data should result in removing clinic success rates from ART Fertility Clinic Success Rates Report, and that erroneous data should not be included with data from other clinics. Finally, there was a concern that validation footnotes and an appendix will not be easily understood by the patients.

Pursuant to the Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. 263a-5, CDC publishes pregnancy success rates reported to the agency in accordance with section 263a-1(a)(1). The primary goal of public reporting of clinical outcomes of ART is to provide

accurate data to current or potential ART users. Therefore, multiple mechanisms ensuring data accuracy are employed by CDC: conducting data checks for logical errors and inconsistencies during data entry stage, verification of data accuracy by clinics' medical directors, additional data checks for logical errors and internal inconsistencies after submission. If any errors or inconsistencies are identified during these stages, clinics are contacted and data are immediately corrected. In addition, CDC conducts annual site visits by selecting 7-10% of all reporting clinics and about 70-80 cycles per clinic for data validation. This data validation process involves comparing information of key variables from patient's medical record with the data submitted to the National ART Surveillance System (NASS), the CDC data reporting system for ART procedures, to calculate discrepancy rates for these variables. Data validation is another step to ensure that clinics submit accurate data and to identify any systematic problems that could cause data collection to be inconsistent or incomplete.

CDC is currently conducting data validation using stratified random sampling of reporting clinics to assess discrepancy rates for key variables that are generalizable for all reporting clinics as described in "Reporting of

Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs” (80 FR 51811). CDC concurs with comments on proposed changes to data validation procedures (83 FR 25009) that targeted selection of clinics based on certain reporting characteristics is another mechanism to identify systematic reporting errors. CDC’s current targeted selection practice includes revisiting a small number of previously validated clinics to assess whether previously identified reporting errors have been corrected. Effective for calendar year 2022, CDC proposes to expand targeted selection of clinics to better capture systematic reporting errors by assessing certain reporting characteristics that may predict erroneously inflated ART success rates (e.g. number of cancelled cycles, inability to confirm reported live births, etc.). Information gained from targeted validation will not be used in calculating discrepancy rates since it cannot be generalizable for all reporting clinics.

Since information on potential data errors is not available from non-validated clinics and CDC’s annual data validation only represents a very small proportion of clinics (7-10%) and cycles (1% of total reported cycles), correcting identified discrepancies in the final dataset for a small subset of cycles will not have any significant

effect on data quality or published success rates. However, CDC took into account comments that publishing inaccurate data with known *major* discrepancies can be misleading, even in the presence of a footnote describing data quality concerns. Therefore, if a clinic is selected to participate in the NASS data validation process (either through stratified random sampling or through targeted selection), does participate, and major data discrepancies are identified (e.g., lack of supporting information for a significant proportion of reported pregnancy outcomes, inability to confirm a significant proportion of reported live births, underreporting a significant proportion of cycles, etc.), a message will be displayed in the ART Fertility Clinic Success Rates Report for the clinic as:

CDC conducts data validation of a sample of reporting clinics to assess discrepancy rates for key variables helping, in part, to ensure clinics submit accurate data and to identify any systematic problems. This clinic was visited for validation of (insert: reporting year) data and major data discrepancies were identified. This clinic's reported success rates data are therefore not published in this report and not included in aggregate national data reports.

CDC may re-select this ART program for data validation during the following reporting year(s) to assess corrections of identified data errors.

In addition, CDC will publish information in the annual ART Fertility Clinic Success Rates Report to identify clinics that are selected by CDC to participate in the NASS data validation but decline to participate. (See 80 FR 51811 for further information concerning external validation of clinic data). If a clinic is selected to participate in the NASS data validation process and declines to participate, the following message will be displayed in the ART Fertility Clinic Success Rates Report for the clinic as:

CDC conducts data validation of a sample of reporting clinics to assess discrepancy rates for key variables helping, in part, to ensure clinics submit accurate data and to identify any systematic problems. This clinic was selected for validation of (insert: reporting year) data, but declined to participate. This clinic's reported data are therefore not published in this report and not included in aggregate national data reports.

CDC may re-select this ART program for data validation during the following reporting year(s). Participation in

data validation is integral to helping ensure the accuracy of the required pregnancy success rates reported to have been achieved by clinics. Therefore, displaying this message, as well as the other messages outlined herein, is important in providing the public with the most accurate information.

For consistency, for all other clinics that are selected to participate in the NASS data validation and do participate, the following footnote will be added:

CDC conducts data validation of a sample of reporting clinics to assess discrepancy rates for key variables helping, in part, to ensure clinics submit accurate data and to identify any systematic problems. This clinic was visited for validation of (insert: reporting year) data and no systematic problems were identified.

Any messages added to a clinic's success rates page in the ART Fertility Clinic Success Rates Report will appear only for the reporting year that the clinic was selected for validation. These enhanced processes and messages in the annual ART Fertility Clinic Success Rates Report will help to inform the public if there are issues with data quality, thereby increasing the transparency and help ensure the accuracy of the NASS data reporting.

For 2017 reporting year, CDC started reporting cumulative success rates which take into account successes over all embryo transfers within 12-month period from a single oocyte retrieval and, therefore, span two reporting years (83 FR 53253). Effective for data validation conducted in calendar year 2021, data validation approach will be aligned with ART reporting approach and will also span two reporting years. Data validation conducted in 2021 will cover oocyte retrievals conducted in reporting year 2018 and associated embryo transfers that took place within 12-month period from oocyte retrievals (reporting years 2018 and 2019). As a result of this transition to a cumulative approach in data validation and due to impacts of the COVID-19 pandemic (i.e., travel restrictions), no data validations will be conducted in calendar year 2020.

Dated: October 15, 2020

Sandra Cashman,

Executive Secretary,

Centers for Disease Control and Prevention.

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