



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

**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: Final Notice.

SUMMARY: The Centers for Disease Control and Prevention, within the Department of Health and Human Services, announces the changes in assisted reproductive technology (ART) data validation selection process; data validation approach; and data discrepancy reporting. The proposed changes to ART data validation were published in the *Federal Register* on October 20, 2020 (85 FR. 66566); public comments and recommendations were requested, and no comments were received. This notice describes changes to the data validation process that will be implemented effective for calendar year 2022.

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: 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 helps ensure that clinics submit accurate data and to identify any systematic problems that could cause data collection to be inconsistent or incomplete.

Data Validation

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). Effective for calendar year 2022, CDC also will conduct targeted validation 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 be used to identify and address systematic reporting errors, but will not be used in calculating discrepancy rates since it cannot be generalized to all reporting clinics.

If a clinic is selected to participate in the NASS data validation process (either through stratified random

sampling or through targeted selection), participates in validation, 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, to identify any systematic problems, and to help ensure clinics submit accurate data. 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 during the following reporting year(s) to assess corrections of identified data errors.

In addition, CDC will publish a statement 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, to identify any systematic problems, and to help ensure clinics submit accurate data. 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 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, to identify any systematic problems, and to help

ensure clinics submit accurate data. 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.

Dated: April 15, 2021.

Sandra Cashman,
Executive Secretary,
Centers for Disease Control and Prevention.

[FR Doc. 2021-08117 Filed: 4/19/2021 8:45 am; Publication Date: 4/20/2021]