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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2018-0054]

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

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

ACTION: Notice of availability.

SUMMARY: On May 31, 2018, the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) requested comments 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. In the plan, CDC proposed to include the footnotes to identify clinics selected by CDC to participate in the validation process of

the National ART Surveillance System (NASS) data and: (a) do participate, (b) do participate and have major data discrepancies identified through this process, or (c) decline to participate in the data validation process. This notice responds to the comments received in response to the notice published on May 31, 2018 and announces the availability of the revised process for ART Success Rates Reporting and plans for revising Data Validation Procedures.

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 N.E., Mailstop F-74, Atlanta, Georgia 30341. Telephone: (770) 488-5200; email: ARTinfo@cdc.gov.

Public Comment Summary and Responses

CDC received three public comments to the docket. One comment was considered nonsubstantive because it was outside the scope of the docket. A second comment was supportive of CDC's planned approach for revising the definition of success rates and introducing clinic validation footnotes. The third comment contained concerns

about CDC's planned clinic validation footnotes and the approach to clinic validation, and requested a clarification of the reporting requirements of embryo banking cycles. These suggestions, as well as CDC's responses, are included below:

1. ART success rates reporting: One commenter asked that CDC provide more details about reporting requirements of embryo banking cycles.

Response: CDC thanks the commenter for this request. Egg/embryo banking cycles intended for pregnancy in the short term include cycles initiated with the intent of cryopreserving all eggs/embryos for subsequent transfers within 12 months. Egg/embryo banking cycles intended for pregnancy in the long term (often referred to as fertility preservation) include cycles where the patient did not start any transfer cycles within the 12 month period following the date on which the intended retrieval cycle started and one of the following: 1) The cycle intent was long term (>12 months) banking for fertility preservation prior to gonadotoxic medical treatments; or 2) The cycle intent was long term (>12 months) banking for other reasons and (a) at least one egg was retrieved, and (b) at least

one egg or embryo was frozen. Specifics about the reporting process and requirements are described in "Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs" (80 FR 51811).

2. Clinic data validation and footnotes: A commenter expressed concern that discrepancies identified during on-site data validation would not be corrected prior to publication of the ART Fertility Clinic Success Rates Report. The commenter suggested that instead of including a footnote, identification of erroneous data (such as an incorrect number of reported cycles or pregnancy outcomes) 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. The commenter was also concerned that random selection of clinics under the current CDC validation system does not identify systematic reporting errors. The commenter suggested that targeted selection of clinics based on reporting characteristics that predict erroneously inflated ART success rates is a better approach to identify systematic reporting errors. Finally, the commenter was concerned that validation footnotes and the appendix may not be easily understood by the patients.

Response: CDC thanks the commenter for expressing these concerns and for providing suggestions to improve reporting. CDC is considering these concerns and reviewing options for future years' data validation. CDC is withdrawing its pending proposal for data validation footnotes (83 FR 25009). If CDC determines that changes in data validation selection processes and/or footnotes are advisable, proposed changes will be published in the *Federal Register* for public comment.

Appendix—Notice for Assisted Reproductive Technology (ART) Success Rates Reporting:

A. Background

Section 2(a) of Public Law 102-493 (42 U.S C.263a-1(a)), the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), requires that each assisted reproductive technology (ART) program report annually to the Secretary of the Department of Health and Human Services through the Centers for Disease Control and Prevention (CDC) pregnancy success rates achieved through assisted reproductive technology. The FCSRCA also requires CDC to annually publish and distribute to the public reported pregnancy success rates for each ART clinic.

According to the FCSRCA, the definitions of pregnancy success rates should be developed in consultation with appropriate consumer and professional organizations, should take into account the effect on success rates of age, diagnosis, and other significant factors, and should include the live birth rate per attempted ovarian stimulation procedure and the live birth rate per successful oocyte retrieval.

Specifics about the reporting process and requirements are described in "Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs" (August 26, 2015; 80 FR (51811-51819)). Specifics about the definition and characterization of ART success rates were last described in "Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs" (February 5, 2004; 69 FR (5548-5550)). Success rates for fresh, nondonor cycles were defined as: 1. the rate of pregnancy after completion of ART according to the number of all ovarian stimulation or monitoring procedures; 2. the rate of live birth after completion of ART according to the number of all ovarian stimulation or monitoring procedures, the number of oocyte retrieval processes, and the number of embryo (or zygote or oocyte) transfer procedures; 3. the rate of singleton live birth after completion of ART

according to the number of all ovarian stimulation or monitoring procedures and the number of embryo (or zygote or oocyte) transfer procedures. Success rates for cycles using thawed embryos and cycles using donor oocytes or embryos were defined as: 4. the rate of live birth after completion of ART according to the number of embryo (or zygote or oocyte) transfer procedures; 5. the rate of singleton live birth after completion of ART according to the number of embryo (or zygote or oocyte) transfer procedures.

Effective for reporting year 2017, CDC is implementing substantial changes to the definition and characterization of ART success rates due to changes in clinical practice and more variation in treatment options, including improvements in cryopreservation resulting in more segmentation of typical treatment cycles. The field of ART is moving toward the calculation and reporting of cumulative success rates where data collection systems can collect successes over all embryo transfers from a single oocyte retrieval or across several oocyte retrievals and embryo transfers. After consultation with consumer and professional organizations with expertise in ART, CDC will begin cumulative ART success rates reporting in reporting year 2017. The ART success rates described in this Federal

Register notice shall replace those previously described in 2004.

B. ART Procedures among Patients Using Their Own Oocytes

ART success rates for ART procedures among all patients using their own eggs are defined as:

1. The rate of live birth or singleton live birth resulting from the transfer of oocytes retrieved from the patient in the year prior to the reporting year or from the transfer of embryos created from oocytes retrieved from the patient in the year prior to the reporting year. For the purpose of this definition, transfer procedures must have started within 12 months of the start of the retrieval procedure. Oocytes must have been retrieved in the year prior to the reporting year in order to allow a full year to perform transfers of the retrieved oocytes (either in the prior reporting year or in the current reporting year). The live birth rate and singleton live birth rate will be presented according to the number of:
    a. All ovarian stimulation or monitoring procedures started from the year prior to the

reporting year with the intent to retrieve oocytes from the patient.

b. All ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient in which at least one oocyte was retrieved.

c. All transfer procedures of at least one oocyte retrieved from the patient in the year prior to the reporting year, or of at least one embryo created from an oocyte retrieved from the patient in the year prior to the reporting year. For the purpose of this definition, egg or embryo transfer procedures must have started within 12 months of the start of the retrieval procedure.

2. The number of ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient presented according to the number of:

a. Live births resulting from all transfers of at least one oocyte retrieved from the patient in the year prior to the reporting year, or

transfers of at least one embryo created from an oocyte retrieved from the patient in the year prior to the reporting year. For the purpose of this definition, egg or embryo transfer procedures must have started within 12 months of the start of the retrieval procedure.

Other rates for ART procedures among all patients using their own eggs are defined as follows (and may be provided publically at the ART program's discretion)-

3. The rate of cancellation, implantation, pregnancy, live birth, singleton live birth, multiple live birth, twin live birth, triplet or higher order live birth, preterm live birth, low birthweight live birth or term, normal birthweight and singleton live birth resulting from the transfer of oocytes retrieved from the patient in the year prior to the reporting year or the transfer of embryos created from oocytes retrieved from the patient in the year prior to the reporting year. For the purpose of this definition, transfer procedures must have started within 12 months of the start of the retrieval procedure. These other rates may be presented according to the number of:

a. All ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient.
b. All ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient in which at least one oocyte was retrieved.
c. All transfer procedures of at least one oocyte retrieved from the patient in the year prior to the reporting year, or of at least one embryo created from an oocyte retrieved from the patient in the year prior to the reporting year. For the purpose of this definition, egg or embryo transfer procedures must have started within 12 months of the start of the retrieval procedure.
d. All first, second, third, or more transfer procedures after retrieval of at least one oocyte from the patient in the year prior to the reporting year, or of at least one embryo created from an oocyte retrieved from the patient in the year prior to the reporting

year. For the purpose of this definition, egg or embryo transfer procedures must have started within 12 months of the start of the retrieval procedure.

Rates for ART procedures among new ART patients (i.e. patients that have never had a prior ART cycle ever) using their own oocytes are defined as-

4. The rate of live birth resulting from the transfer of oocytes or embryos from all first intended oocyte retrievals presented according to the number of:
    a. ART patients who reported at the start of the retrieval procedure that they had no prior ART stimulations and no prior frozen ART procedures. For the purpose of this definition, the retrieval procedure must have started in the year prior to the reporting year.

5. The rate of live birth resulting from the transfer of oocytes or embryos from all first or second intended oocyte retrievals presented according to the number of:

a. ART patients who reported at the start of the retrieval procedure that they had no prior ART stimulations and no prior frozen ART procedures. For the purpose of this definition, the retrieval procedure must have started in the year prior to the reporting year.

6. The rate of live birth resulting from the transfer of oocytes or embryos from all intended oocyte retrievals presented according to the number of:
   a. ART patients who reported at the start of the retrieval procedure that they had no prior ART stimulations and no prior frozen ART procedures. For the purpose of this definition, the retrieval procedure must have started in the year prior to the reporting year.

7. The number of ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient presented according to the number of:

a. ART patients who reported at the start of the retrieval procedure that they had no prior ART stimulations and no prior frozen ART procedures.

8. The number of transfer procedures of at least one oocyte retrieved from the patient in the year prior to the reporting year, or of at least one embryo created from an oocyte retrieved from the patient in the year prior to the reporting year presented according to the number of:

   a. Ovarian stimulation or monitoring procedures started in the year prior to the reporting year with the intent to retrieve oocytes from the patient. For the purpose of this definition, egg or embryo transfer procedures must have started within 12 months of the start of the retrieval procedure. Also, ART patients must have reported at the start of the retrieval procedure that they had no prior ART stimulations and no prior frozen ART procedures.

C. ART Procedures among Patients Using Oocytes or Embryos from a Donor

Success rates for ART procedures among patients using oocytes or embryos from a donor are defined as-

9. The rate of live birth or singleton live birth presented according to the number of:
    a. Transfer procedures of at least one donor egg, embryo created from a donor egg, or donated embryo started in the current reporting year.

Other rates for ART procedures among patients using oocytes or embryos from a donor are defined as follows (and may be provided publically at the ART program's discretion):

10. The rate of cancellation, implantation, pregnancy, live birth, singleton live birth, multiple live birth, twin live birth, triplet or higher order live birth, preterm live birth, low birthweight live birth, or term, normal birthweight and singleton live birth presented according to the number of:
    a. ART procedures to prepare a patient (recipient) for the transfer of at least one donor egg,

embryo created from a donor egg, or donated embryo, started in the current reporting year.

b. Transfer procedures of at least one donor egg, embryo created from a donor egg, or donated embryo started in the current reporting year.

D. ART Procedures among All Patients and All Cycle Types

At the discretion of the ART program, ART reporting also may include:

11. The number, average number or percentage of ART procedures or ART patients with certain characteristics, such as:

a. Patient characteristics (e.g. patient age or reason for ART).

b. ART procedure characteristics (e.g. type of treatment (fertility preservation, short term banking, in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer), stimulation protocol, source of the oocytes or embryos (patient or donor), the state of the oocytes or embryos (fresh or frozen), the intent of the procedure, the use of prenatal genetic diagnosis or screening, the use of intracytoplasmic sperm injection, the

use of assisted hatching, the use of a gestational carrier, the stage of the embryo at transfer, or the number of embryos transferred).

All ART patient and procedure characteristics, ART success rates, and other rates for patients using their own oocytes as well as for patients using oocytes or embryos from a donor may be stratified by CDC by factors thought to influence the outcome of an ART procedure.

12. Factors for stratification may include:
    a. Characteristics of the ART patient such as patient age or reason for ART.
    b. Characteristics of the ART procedure such as type of treatment (fertility preservation, short term banking, in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer), stimulation protocol, the source of the oocytes or embryos (patient or donor), the state of the oocytes or embryos (fresh or frozen), the intent of the procedure, the use of prenatal genetic diagnosis or screening, the use of intracytoplasmic sperm

injection, the use of assisted hatching, the use of a gestational carrier, the stage of the embryo at transfer, or the number of embryos transferred.

Dated: October 17, 2018.

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Sandra Cashman,

Executive Secretary,

Centers for Disease Control and Prevention.

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