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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2019-0103]

Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs; Proposed Additional Data Collection Fields; Request for Comment

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 (CDC), located within the Department of Health and Human Services (HHS), announces the opening of a public docket to obtain comment and review of proposed additional data collection fields and reporting requirement modification for reporting of pregnancy success rates from assisted reproductive technology (ART) programs. This reporting is required by the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA).

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

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0103 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, Mailstop S107-2, 4770 Buford Hwy, N.E., 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, MS-C107-2, Atlanta, Georgia 30341. Phone: (770) 488-6355. E-mail: ARTinfo@cdc.gov.

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. In addition, CDC invites comments specifically on proposed additional data collection fields and reporting requirement modification for reporting of pregnancy success

rates from assisted reproductive technology (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 August 26, 2015, HHS/CDC published a notice in the *Federal Register* (80 FR 51811) (Current Notice) announcing the overall reporting requirements of the National ART Surveillance System (NASS). The notice described who shall report to HHS/CDC; the process for reporting by each ART

program; the data to be reported; and the contents of the published reports. CDC has already obtained approval from the Office of Management and Budget under the Paperwork Reduction Act to collect this information, which is needed to determine the annual pregnancy success rates for each clinic that provides ART services. This data collection is approved under OMB Control Number 0920-0556, expiration date: 08/31/2021. This information includes clinical information pertaining to the ART procedure, outcome information on resultant pregnancies and births, and information on factors that may affect outcomes, such as patient demographics, medical history, and infertility diagnosis. The purpose of this notice published [current date] is to apply consistent data collection requirements to various treatment options, including certain rare situations to improve quality of data. This notice provides opportunity for public review and comment for the proposed additional data collection fields.

PROPOSED ADDITIONAL DATA COLLECTION FIELDS:

Section III. What to Report

Section A. Patient Demographic Information

CDC is currently collecting information on race/ethnicity for oocyte source and pregnancy carrier. In the rare

situation when a patient is not using her own oocytes (uses donor eggs) and does not carry the pregnancy (uses gestational carrier), the current data collection system will not capture patient race/ethnicity. CDC proposes adding these questions to the patient profile in the beginning of the questionnaire to help better understand the demographic profile of all ART users and accurately assess ART success rates in this rare situation. To reduce the reporting burden, the system will then pre-fill race/ethnicity of oocyte source, sperm source, or gestational carrier, if applicable.

Addition (for patients who are not oocyte source or pregnancy carrier):

Ethnicity (Hispanic, non-Hispanic, Refused, Unknown); Race (White, Black, Asian, Native Hawaiian/Pacific Islander, American Indian or Alaska Native, Refused, Unknown).

Section D. Oocyte Source and Carrier Information

CDC is currently collecting information on height, weight, smoking history, prior ART cycles, diagnostic tests, and the pregnancy history of a patient. However, this information is important regardless of oocyte source to better understand the role of these factors on ART success

rates. CDC proposes adding these questions to the donor oocyte source profile.

Addition (for oocyte donors):

Height; Weight; History of Smoking; History of Prior Pregnancies and Births (Number of prior pregnancies [ectopic, spontaneous abortions], number of prior births [full term, preterm, live births, stillbirths]; History of Prior ART cycles (fresh, frozen); Maximum FSH Level (value in mIU/mL); Most Recent AMH Level (value in ng/mL, date).

Section H. Transfer Information

CDC is currently collecting the date of any previous oocyte retrieval that contributed to a reported embryo transfer cycle to allow for details of previous retrievals to be linked to current transfers. However, this information is only collected if egg retrieval and transfer occur in the same clinic. It is important to link retrievals and transfers whether the retrieval and transfer occurred in the same clinic or when oocytes were retrieved in an ART clinic that is different from the ART clinic where the current transfer is taking place. Collection of the clinic name in which the previous retrieval took place (if different from the clinic performing the transfer) will allow for more complete linkage of embryo transfers to egg

retrievals. This information will allow for a better understanding of the cumulative success rates over multiple ART treatment cycles. CDC therefore proposes adding this information for current fresh embryo transfers or thawed embryo transfers if the retrieval and transfer did not occur in the same clinic.

Addition (if oocyte retrieval was not conducted at the same clinic as transfer):

1. Fresh Embryo Transfer

Name of clinic if different from where oocyte retrieval took place.

2. Thawed Embryo Transfer

Name of clinic if different from where oocyte retrieval took place.

PROPOSED REPORTING REQUIREMENT MODIFICATIONS*:*

Section I. Who Reports

Sub-section C. Reporting Responsibilities of ART Program

CDC currently requires that, when multiple programs are involved in one cycle, the requirement to report cycles lies with the ART program that accepts responsibility for the embryo culture or thawing the oocytes or embryos. However, when clinics are contracting with external embryo

laboratories, these laboratories may not be recognizable to the consumer. Therefore, we are proposing to change the requirement to report cycles to the ART program that directs the clinical management of the cycle. Both current and modified guidelines are provided below.

Current: Multiple ART programs involved in one cycle—Different ART programs responsible for ovarian stimulation, oocyte retrieval, and/or embryo transfer.

The following guidelines should be used:

a. The requirement to report cycles lies with the ART program that accepts responsibility for the embryo culture. The ART programs involved must have a method in place to ensure that these cycles can be prospectively reported by the ART program required to report them. In addition, all canceled cycles must be reported by the ART program accepting responsibility for the embryo culture.

b. Cycles involving previously cryopreserved oocytes/embryos are to be reported by the ART program that accepts responsibility for thawing the oocytes/embryos.

Modification (to ensure more accurate reporting by modifying reporting responsibilities when more than one program is involved in one cycle): Multiple ART programs

involved in one cycle—Different ART programs responsible for ovarian stimulation, oocyte retrieval, and/or embryo transfer.

The following guidelines should be used:

a. The requirement to report cycles lies with the ART program that directs the clinical management of the cycle, which would include (but is not limited to) multiple aspects of the treatment such as patient selection, pre-treatment counseling and selection of the specific treatment protocol. The ART programs involved must have a method in place to ensure that these cycles can be prospectively reported by the ART program required to report them. In addition, all canceled cycles must be reported by the same ART program.

b. Cycles involving previously cryopreserved oocytes/embryos are to be reported by the ART program that accepts responsibility for thawing the oocytes/embryos.

Dated: October 31, 2019.

Sandra Cashman,

Executive Secretary,

Centers for Disease Control and Prevention.

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