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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs; Clarifications and Corrections

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

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces clarifications for and correction to certain data collection fields, terminology, and definitions used 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: These clarifications and corrections will be implemented January 1, 2020.

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: On August 26, 2015, HHS/CDC published a notice in the *Federal Register* (80 FR 51811) 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. This current notice, published [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], includes clarifications for some variables and definitions to improve quality of data. Corrections were made to align with current terminology. These clarifications and corrections will be helpful by clarifying reporting requirements in certain unique situations and updating terminology to align with current practice. This notice includes the current guidance and

definitions that will be implemented starting January 1, 2020.

CLARIFICATIONS AND CORRECTIONS:

Section II. When and How to Report

Section A. Reporting Activities

Current: All cycle data must be reported prospectively, *i.e.*, reporting of initial cycle intent and select patient details is required within four days of cycle initiation.

Clarification (to improve the quality of data by clarifying prospective reporting requirements for natural cycles and frozen cycles; effective January 1, 2020): All cycle data must be reported prospectively, *i.e.*, reporting of initial cycle intent and select patient details is required: a) at least one day prior to oocyte retrieval for all natural cycles using fresh embryos created from fresh eggs; b) at least one day prior to thaw for all frozen oocyte or frozen embryo cycles; and c) within four days of cycle initiation for all other cycles.

Section B. Cycle Information

Current: Intended banking type (Embryo banking, autologous oocyte banking, donor oocyte banking)

Clarification (to differentiate oocyte source for banking cycles; effective January 1, 2020): Intended banking type (Embryo banking from autologous oocytes, embryo banking from donor oocytes, autologous oocyte, donor oocyte)

Section C. Patient History

Current: Number of Prior ART cycles (Fresh & Frozen)

Clarification (to clarify question applicability; effective January 1, 2020): Number of Prior ART cycles started with the intent to transfer oocytes or embryos

Section F. Stimulation and Retrieval

Current: Date of retrieval

Clarification (to clarify the definition for different treatment protocols; effective January 1, 2020): In general, each retrieval should be reported as its own cycle. This includes egg retrievals for fertility preservation cycles (e.g., for cancer patients). In the case of continuous stimulation or dual stimulation to maximize the number of eggs retrieved in the shortest possible time, the cycle start date for the subsequent retrieval will be the day that stimulation medication was restarted after the trigger was administered for the previous egg retrieval; if the

stimulation medication was never stopped, stimulation start will be the day after the previous egg retrieval.
If a patient is having a second egg retrieval due to a "failed trigger" (i.e., patient medication administration error or poor response to the trigger that results in unexpectedly low number of eggs), the second trigger and retrieval date would be used for reporting as part of the first cycle. In this case, the interval between the first and second retrieval should not exceed 2 days. If the interval exceeds 2 days, each retrieval should be entered as its own cycle.

Section G. Laboratory Information

Current:

Indication for ICSI (Prior failed fertilization, Poor fertilization, PGD or PGS, Abnormal semen parameters, Low oocyte yield, Laboratory routine, Frozen cycle, Rescue ICSI, Other)

PGD (Pre-implantation genetic diagnosis) or screening (PGS)

Reasons for PGD or PGS

Technique used for PGD or PGS

Correction (to update the terminology for preimplantation genetic testing; effective January 1, 2020):

Indication for ICSI (Prior failed fertilization, Poor fertilization, PGT, Abnormal semen parameters, Low oocyte yield, Laboratory routine, Frozen cycle, Rescue ICSI, Other)

PGT (Pre-implantation genetic testing)

Reasons for PGT

Technique used for PGT

Section H. Transfer Information

Current: Endometrial Thickness Prior to Embryo Transfer

Clarification (to clarify the timing of measurement; *effective January 1, 2020):* Most Recent Endometrial Thickness

Section J. Definitions:

Current: Cycle start date (cycle initiation date)—

(1) For fresh embryo (both donor and nondonor):

The first day that medication to stimulate follicular development is given in a stimulated cycle or the first day of menses in an unstimulated cycle. For example:

a. The first day of gonadotropins in a gonadotropin only cycle or in a long suppression GnRH agonist-gonadotropin cycle;

b. The first day of GnRH agonist in a GnRH agonist flare-gonadotropin cycle;

c. The first day of clomiphene or letrozole in a clomiphene/gonadotropin cycle or a clomiphene only cycle;

d. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

(2) For fresh embryo donor cycles:

a. The first day exogenous sex steroids are given to patient to prepare the endometrium;

b. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

(3) For frozen embryo cycles (both donor and non-donor):

a. The first day exogenous sex steroids are given to prepare the endometrium;

b. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

(4) For oocyte/embryo banking cycles:

a. The first day of gonadotropins in a gonadotropin only cycle or in a long suppression GnRH agonist-gonadotropin cycle;

b. The first day of GnRH agonist in a GnRH agonist flare-gonadotropin cycle;

c. The first day of clomiphene or letrozole in a clomiphene/gonadotropin cycle or a clomiphene only cycle;

d. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

Clarification (to clarify the definition for different types of cycles; effective January 1, 2020): Cycle start date (cycle initiation date)—

(1) For cycles using fresh embryos created from fresh nondonor eggs: The first day that medication to stimulate follicular development is given in a stimulated cycle or the first day of menses in an unstimulated cycle. For example:

a. The first day of gonadotropins in a gonadotropin only cycle or in a long suppression GnRH agonist-gonadotropin cycle;

b. The first day of GnRH agonist in a GnRH agonist flare-gonadotropin cycle;

c. The first day of clomiphene or letrozole in a clomiphene/gonadotropin cycle or a clomiphene only cycle;

d. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

(2) For cycles using fresh embryos created from fresh donor eggs:

a. The first day exogenous sex steroids are given to patient to prepare the endometrium;

b. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

(3) For cycles using frozen eggs or frozen embryos (both donor and non-donor):

a. The first day exogenous sex steroids are given to prepare the endometrium;

b. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

(4) For oocyte/embryo banking cycles:

a. The first day of gonadotropins in a gonadotropin only cycle or in a long suppression GnRH agonist-gonadotropin cycle;

b. The first day of GnRH agonist in a GnRH agonist flare-gonadotropin cycle;

c. The first day of clomiphene or letrozole in a clomiphene/gonadotropin cycle or a clomiphene only cycle;

d. The first day of natural menses or withdrawal bleeding in an unstimulated cycle.

Current: Preimplantation genetic diagnosis (PGD)— Characterization of a cell or cells from preimplanted embryos from IVF cycles to determine the presence or absence of a specific genetic defect.

Preimplantation genetic screening (PGS)—Characterization of a cell or cells from preimplanted embryos from IVF cycles to identify genetic abnormalities.

Correction (to update the terminology; effective January 1, 2020): Preimplantation genetic testing (PGT)-Testing performed to analyze DNA from oocytes or embryos for determining genetic abnormalities, including aneuploidies (PGT-A), monogenic/single gene defects (PGT-M), and chromosomal structural rearrangements (PGT-SR).

Dated: October 30, 2019

Sandra Cashman,

Executive Secretary,

Centers for Disease Control and Prevention.

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