

ATTACHMENT H.

ART VALIDATION DESCRIPTION

2021 VALIDATION PROCEDURES

The validation sample for Reporting Year (RY) 2021 will maintain the historical sample size of 35 ART clinics. Clinics will be stratified by number of cycles reported in NASS, with larger clinics having greater chance of selection. The purpose of sampling larger clinics at a higher rate is to provide better representation of the majority of cycles, most of which are found in larger clinics.

Clinics will be sampled with equal probability within strata. To avoid validating a program two years in a row, clinics that were selected for validation during the past three years will be removed from stratum for the current year. The stratum will include clinics that have been designated for a return validation visit based on previous validation results.

The following procedures will be used to select clinics for the RY 2021 validation sample:

- Create an initial sampling frame by including all clinics submitting RY 2021 NASS data.
- Remove clinics validated during the last three reporting years from the sampling frame.
- Sort the sampling frame by: 1) stratum; and then by 2) number of RY 2021 ART cycles.
- Use systematic sampling to select the number of clinics from each stratum.

Sorting the sampling frame by clinic size (within strata) and selecting systematic samples of clinics will have the effect of further stabilizing the size of clinics, in addition to the effect of stratification. That is, this approach eliminates the chance of selecting only the largest or smallest clinics within a given stratum. Moreover, the average number of annual ART cycles per clinic for the selected sample should be close to the average number of annual ART cycles per clinic for the entire sampling frame.

RY 2021 cycles at each clinic selected for validation will be reviewed as follows:

- Full validation of up to 10 donor cycles;
- Full validation of up to 50-60 nondonor cycles;
- Partial validation of up to 10 long term banking cycles; and
- Partial validation of up to 10 unreported cycles (i.e., ART cycles that were not reported in NASS)

To calculate validation discrepancy rates, the collected validation data must be associated with the appropriate sample of cycles. There are five different samples of cycles:

- Sample of fully-validated donor cycles without gestation. This is a two-stage sample—a clinic is the first-stage sample unit, and an ART cycle is the second-stage sample unit.
- Sample of fully-validated donor cycles with gestation. This is a two-stage sample—a clinic is the first-stage sample unit, and an ART cycle is the second-stage sample unit.
- Sample of fully-validated nondonor cycles without gestation. This is a two-stage sample—a clinic is the first-stage sample unit, and an ART cycle is the second-stage sample unit.
- Sample of fully-validated nondonor cycles resulting in single or multiple gestation. This is a two-stage sample—a clinic is the first-stage sample unit, and an ART cycle is the second-stage sample unit.
- Sample of long term banking cycles. This is a two-stage cluster sample, with the clinic as the first stage cluster, and the sample of up to 10 long term banking cycles as the second stage.

SELECTION OF ART PROGRAMS FOR VALIDATION OF 2021 DATA

Clinic Stratification and Sample Allocation

There were 453 clinics that submitted RY 2021 data through NASS. Of those, 64 clinics were selected for validation of their RY 2018, RY 2019, or RY 2020 NASS data, and therefore were excluded from consideration for the present validation. The RY 2021 stratification and sample allocation for the remaining 389 clinics are used to select ART programs for validation.

List of Variables for Full and Partial Validation

- Patient date of birth
- Cycle start date
- Cycle intention
- Additional ART cycles
- Patient diagnosis (i.e., reasons for ART)
- Transfer type (e.g., IVF, GIFT)
- Egg retrieval date
- Donor date of birth or donor age
- Reasons for long term banking
- Cancelled cycle notations if applicable
- Total number of embryos or oocytes transferred
- Outcome of treatment (e.g., biochemical only, clinical uterine gestation, ectopic)
- Outcome of pregnancy (e.g., live birth, spontaneous abortion)
- Date of pregnancy outcome
- Number of infants born