

ATTACHMENT H.

ART VALIDATION DESCRIPTION

2019 VALIDATION PROCEDURES

The validation sample for Reporting Year (RY) 2019 maintains the historical sample size of 35 ART clinics. Clinics are 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 are sampled with equal probability within strata. To avoid validating a program multiple years in a row, clinics that were selected for validation during the past three years¹ are removed from stratum for the current year. The stratum includes clinics that have been designated for a return validation visit based on previous validation results.

The following procedures are used to select clinics for the RY 2019 validation sample:

- Create an initial sampling frame by including all clinics submitting RY 2019 NASS data.
- Remove clinics validated during the last three reporting year from the sampling frame.
- Sort the sampling frame by: 1) stratum; and then by 2) number of RY 2019 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. Also, the average number of annual ART cycles per clinics for the selected sample should be close to the average number of annual ART cycles per clinics for the entire sampling frame.

RY 2019 cycles at each clinic selected for validation are 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:

¹ Validation was not performed for RY 2018 due to the COVID-19 pandemic. Therefore, no clinics are excluded as a result of validation of RY 2018 data.

- 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 2019 DATA

Clinic Stratification and Sample Allocation

There were 448 clinics that submitted RY 2019 data through NASS. Of those, 70 clinics were selected for validation of their RY 2016 or RY 2017 NASS data, and therefore are excluded from consideration for the present validation. The RY 2019 stratification and sample allocation for the remaining 378 clinics are used to select ART programs for validation.

List of Variables for Full and Partial Validation

□□ Patient date of birth

□□ Cycle start date

➤ Type of ART performed

□□ Additional ART cycles

□□ Patient diagnosis (i.e., reasons for ART)

□□ Egg retrieval date (for fresh, frozen, and banking cycles)

□□ Reasons for long term banking

□□ 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