

ATTACHMENT H.

ART VALIDATION DESCRIPTION

2015 VALIDATION PROCEDURES

The validation sample for Reporting Year (RY) 2015 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 2015 validation sample:

- Create an initial ART clinic sampling frame by including all clinics that submitted ART data in NASS for RY 2015.
- 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 2015 ART cycles.
- Use systematic sampling to select the number of clinics indicated in Table 1 from each stratum.
- As noted earlier, one clinic has been pre-designated for validation and will be included in the sample, resulting in a total of 35 clinics.

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 2015 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 embryo-banking cycles; and
- Partial validation of up to 10 unreported cycles.

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 banking cycles. This is a two-stage cluster sample, with the clinic as the first stage cluster, and the sample of up to 10 banking cycles as the second stage.

SELECTION OF ART PROGRAMS FOR VALIDATION OF 2012 DATA

Clinic Stratification and Sample Allocation

There were 464 clinics that submitted RY 2015 data through NASS. Of those, 101 clinics were selected for validation of their RY 2012, RY 2013, or RY 2014 NASS data, and therefore were excluded from consideration for the present validation. The RY 2015 stratification and sample allocation for the remaining 363 eligible 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

□□Any additional ART cycles for this patient started in 2015

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

□□Transfer type (e.g., IVF, GIFT)

□□Cancelled cycle notations if applicable

□□Total number of embryos or oocytes transferred

□□Outcome of treatment (e.g., biochemical only, clinical uterine gestation, ectopic)

□□Ultrasound with maximum number of fetal hearts detected

□□Outcome of pregnancy (e.g., live birth, spontaneous abortion)

□□Date of pregnancy outcome

□□Number of infants born

□□Donor date of birth or donor age