ATTACHMENT H.

ART VALIDATION DESCRIPTION

2009 Validation Procedures

The 2009 procedure for selecting programs will use stratified sampling, with higher sampling rates among larger clinics. The purpose of this modification from earlier years is to provide better representation of the majority of cycles, 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, ART programs that had their 2008 data validated will not be subjected to sampling for validation of their 2009 data.

The following procedure will be used to select ART programs for the 2009 validation sample:

- Create an initial ART program sampling frame by including all programs that submitted ART data for 2009.
- Delete from the sampling frame those programs that were validated in 2008.
- Sort the sampling frame by (1) stratum and (2) annual number of ART cycles for 2009.
- Assign a MOS of 1.0 to each program in the sampling frame. Consequently, each ART program in the sampling frame will have the same probability of selection.
- Using systematic sampling to select 6 clinics from Stratum 1, 9 clinics from Stratum 2, 18 clinics from Stratum 3, and 2 clinics from Stratum 4. The sampling intervals will be 4.33, 6.22, 13.28, and 63.5, respectively for the four strata. The probability of an ART program being selected for validation will vary by stratum, with values of 0.23, 0.16, 0.075, and 0.016, respectively.

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

Each ART program selected for validation will be reviewed as follows:

- Validation of all up to 50 embryo-banking cycles;
- Full validation of up to 25 non-gestation cycles; and
- Full validation of up to 50 single or multiple-gestation cycles.

To calculate discrepancy rates, one must associate the collected validation data with the appropriate sample of cycles. There are three different samples of cycles:

- Sample of embryo banking cycles. This is a two-stage cluster sample, with the ART program as the first stage cluster, and the sample of up to 50 of embryo banking cycles as the second stage. Most clinics will have few (if any) embryo banking cycles. The data obtained from the review of embryo-banking cycles are associated with this sample.
- Sample of fully-validated treatment cycles resulting in no gestation. This is a two-stage sample—an ART clinic is the first-stage sample unit, and a treatment cycle is the second-stage sample unit.
- Sample of fully-validated treatment cycles resulting in single or multiple gestation. This is a two-stage sample—an ART clinic is the first-stage sample unit, and a treatment cycle is the second-stage sample unit.

Data from the latter two samples can be combined using sampling weights. Note that research cycles that are excluded from the Annual Clinic Tables are not included in any of the samples of cycles to be validated.

SELECTION OF ART PROGRAMS FOR VALIDATION OF 2009 DATA

Specifics of Selection Process

Of the 443 ART programs initially submitting Reporting Year (RY) 2009 data to NASS, 34 had been previously selected for 2008 data validation. These 34 clinics were removed from the sampling frame. The other ART program selected for 2008 validation did not report 2009 data to NASS. The remaining 409 ART programs were eligible for 2009 validation sampling, from which 35 were sampled.

After sample selection, one ART program that never submitted signed paperwork to Westat was moved from the reporters to non-reporters list per CDC guidance resulting in 442 reporting clinics in the 2009 preliminary delivery. This did not affect the 2009 validation sample as the clinic was not selected for validation.

ART Programs Selected for Validation of 2009 Data
(The names of the clinics have been concealed to protect their identity).

Clinic identifier	Cycles in NASS (N)	Full Validation (N)	Partial Validation

			(embryo banking) (N)
1	3272	75	30
2	2299	75	0
3	1917	75	7
4	1684	75	5
5	1242	75	13
6	1076	75	0
7	957	75	50
8	855	75	8
9	758	75	4
10	714	75	1
11	690	75	23
12	610	75	1
13	569	75	30
14	554	75	0
15	531	75	0
16	494	75	0
17	455	75	46
18	427	75	0
19	398	75	9
20	340	75	0
21	310	75	0
22	269	75	0
23	241	75	32
24	222	75	2
25	200	75	0
26	183	75	4
27	167	75	0
28	157	75	0
29	146	75	0
30	139	75	0
31	130	75	2
32	118	75	0
33	108	75	0
34	75	74	1
35	24	24	0

List of Variables for Full and Partial Validation

Full Validation Variables:

- Patient date of birth
- Cycle start date
- Any additional ART cycles for this patient started in 2006
- Patient diagnosis (i.e., reasons for ART)
- Transfer type (e.g., IVF, GIFT)
- Cancelled cycle notations if applicable
- Transfer date
- 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 live
- Number of infants stillborn

Partial Validation Variables:

- Patient date of birth
- Cycle start date
- Intent for embryo banking cycle
- Cancelled cycle notations if applicable
- Transfer date