2012

# Appendix A

## Validation

# APPENDIX A: VALIDATION

## Findings from Validation Visits for 2012 ART Data

Site visits to assisted reproductive technology (ART) clinics for validation of 2012 ART data were conducted during April through June 2014. For validation of 2012 data, 35 of the 456 reporting clinics were randomly selected after taking into consideration the number of ART procedures performed at each clinic, some cycle and clinic characteristics, and whether the clinic had been selected before. During each validation visit, ART data reported by the clinic to the Centers for Disease Control and Prevention were compared with information documented in medical records.

For each clinic, the fully validated sample included up to 40 ART cycles resulting in pregnancy and up to 20 ART cycles not resulting in pregnancy. Up to 10 cycles using donor eggs were included among the fully validated sample at each clinic. In total, 2,045 ART cycles performed in 2012 across the 35 clinics were randomly selected for full validation, along with 238 egg/embryo banking cycles. The full validation included review of 1,318 cycles for which a pregnancy was reported. Among the nondonor cycles, 331 were multiple-fetus pregnancies. In addition, among patients whose cycles were validated, we verified the number of ART cycles performed during 2012. For each of these patients, we compared the total number of ART cycles reported with the total number of ART cycles included in the medical record. If unreported cycles were identified in selected medical records, up to 10 of these cycles were also selected for partial validation.

Discrepancy rates are listed on the next pages for validated items of interest. Overall, validation of 2012 ART cycle data indicated that most discrepancy rates were low (<5%).

## Discrepancy Rates by Data Fields Selected for Validation

| Data Field Name | Discrepancy Rate* (Confidence Interval†) | Comments |
|---|---|---|
| Patient date of birth | 1.7% (1.0–2.4) | For approximately two out of three discrepancies, the difference did not result in changing the age category (age of woman). |
| Cycle intention | 4.1% (0.0–8.2) | For approximately 90% of the discrepancies, an ART procedure cycle was misreported as an egg/embryo banking cycle. |
| Cycle cancellation | 1.4% (0.3–2.5) | For approximately half of the discrepancies, a cycle was misreported as canceled. |
| Number of eggs/ embryos transferred | <1% | |
| Outcome of ART treatment (i.e., pregnant vs. not pregnant) | 1.8% (0.2–3.3) | For approximately one out of three discrepancies, the ART treatment outcome was misreported as clinical intrauterine gestation. |
| Number of fetal hearts on ultrasound | 2.0% (1.0–3.0) | For 10% of the discrepancies, multiple-fetus pregnancies were misreported as single-fetus pregnancies, whereas for 15%, one or more fetal hearts were misreported when the medical records actually showed zero (0) fetal hearts. For approximately 50% of the discrepancies, the maximum number of fetal hearts could not be confirmed in the medical records. |
| Pregnancy outcome (e.g., miscarriage, live birth, and stillbirth) | 2.3% (0.7–3.9) | For about 50% of the discrepancies, pregnancy outcome was misreported as a live birth when there was no information on pregnancy outcome in the medical records to confirm the birth. |
| Date of pregnancy outcome | 4.7% (2.8–6.5) | For about 40% of the discrepancies, there was no information on pregnancy outcome date in the medical records. For another 25% of the discrepancies, the date in the medical records was within 7 days of the reported date. |
| Number of infants born | 1.6% (0.6–2.7) | For approximately 80% of the discrepancies, there was no information on the number of infants born in the medical records. |

## Discrepancy Rates by Data Fields Selected for Validation (Cont'd)

| Data Field Name | Discrepancy Rate* (Confidence Interval†) | Comments |
|---|---|---|
| Cycle count | 2.3% (0.7–3.9) | For approximately 80% of the discrepancies, fewer cycles were reported by clinics than were found in the medical records. The majority of these discrepancies were due to reporting one less cycle. A further analysis of the unreported cycles revealed that approximately one in three were canceled cycles and an overwhelming majority (around 95%) did not result in a live birth (i.e. success). |
| **Patient Diagnosis—Reason for ART** | | |
| Male factor | 4.0% (1.9–6.1) | The following reasons for ART were underreported: male factor, endometriosis, tubal factor, ovulatory dysfunction, diminished ovarian reserve, and uterine factor. Other factor, as a reason for ART, was equally under- and overreported. Unknown factor, as a reason for ART, was overreported. |
| Endometriosis | 2.2% (1.2–3.2) | |
| Tubal factor | 2.2% (0.9–3.5) | |
| Ovulatory dysfunction | 3.3% (1.2–5.5) | |
| Diminished ovarian reserve | 6.5% (4.2–8.8) | |
| Uterine factor | 1.7% (0.7–2.7) | |
| Other factor | 5.5% (3.1–7.9) | |
| Unknown factor | 4.0% (1.8–6.2) | |

Note: ART = assisted reproductive technology.

* Discrepancy rates estimate the proportion of all ART cycles with differences for a particular data item. The discrepancy rate calculations weight the data from validated cycles to reflect the overall number of cycles performed at each clinic. Thus, findings from larger clinical practices were weighted more heavily than those from smaller practices.

† This table shows a range, called the 95% confidence interval, that conveys the reliability of the discrepancy rate. For a general explanation of confidence intervals, see page 68.

# How to Interpret a Confidence Interval for Findings from Validation Visits

## What is a confidence interval?

Simply speaking, confidence intervals are a useful way to consider margin of error, a statistic often used in voter polls to indicate the range within which a value is likely to be correct (e.g., 30% of the voters favor a particular candidate with a margin of error of plus or minus 3.5%). Similarly, in this report, confidence intervals are presented to provide a discrepancy rate range that we can be confident is an estimate of the proportion of all ART cycles, performed in a given reporting year, with differences for a particular data item.

## Why do we need to consider confidence intervals if we already know the exact discrepancy rates for each clinic?

No discrepancy rate or statistic is absolute. Suppose that during validation, 100 cycles were reviewed, and a discrepancy rate of 15% was determined for a particular data item with a confidence interval of 10%–20%. The 15% discrepancy rate tells us that the average chance that a discrepancy occurred for the selected data field among all reported cycles was 15%. But because only a certain percentage of ART cycles were reviewed during the validation visits at a select number of clinics, how likely is it that this would be the discrepancy rate if we repeated validation? For example, if another 100 cycles were reviewed using similar validation parameters, would the discrepancy rate again be 15%? The confidence interval tells us that the discrepancy rate would likely fall between 10% and 20%.