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# Validation of birth outcomes from the SART CORS: Population-based analysis from the Massachusetts Outcome Study of Assisted Reproductive Technology (MOSART)

**Judy E Stern, PhD**[1], **Daksha Gopal, MPH**[2], **Rebecca F Liberman, MPH**[3], **Marlene Anderka, ScD, MPH**[3], **Milton Kotelchuck, PhD**[4], and **Barbara Luke, ScD, MPH**[5]

[1]Department of Obstetrics and Gynecology and Pathology, Geisel School of Medicine at Dartmouth, Lebanon, NH 03756

[2]Department of Community Health Sciences, Boston University, Boston MA, 02118

[3]Center for Birth Defects Research and Prevention, Massachusetts Department of Public Health, Boston, MA 02108

[4]Department of Pediatrics, Harvard Medical School Boston, MA, 02114

[5]Department of Obstetrics, Gynecology, and Reproductive Biology, Michigan State University, East Lansing, MI 48824

## Abstract

**Objective—**To assess the validity of outcome data reported to the Society for Assisted Reproductive Technology Clinic Outcome Reporting System (SART CORS) compared to data from vital records and the birth defects registry data in Massachusetts.

**Design—**Longitudinal cohort

**Setting—**Registry and vital records data

**Participants—**342,035 live births and fetal deaths to Massachusetts mothers giving birth in-state from July 1, 2004 to December 31, 2008; 9,092 births and fetal deaths were to mothers who had conceived with assisted reproductive technology (ART) and whose cycle data had been reported to the SART CORS.

**Interventions—**None

**Main Outcome Measures—**Percent agreement between maternal race and ethnicity, delivery outcome (live birth or fetal death), plurality (singleton, twin, or triplet+), delivery date, and singleton birthweight reported in the SART CORS versus vital records; sensitivity and specificity

Corresponding Author: Judy E. Stern, PhD, Department of Ob/Gyn, Geisel School of Medicine at Dartmouth, One Medical Center Drive, Lebanon, NH 03756, 603-653-9248, 603-650-0905-fax, judy.e.stern@dartmouth.edu.



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for birth defects among singletons as reported in the SART CORS versus the Massachusetts Birth Defects Monitoring Program (BDMP).

**Results—**There was >95% agreement between the SART CORS and vital records for fields of maternal race/ethnicity, live birth/fetal death, and plurality; birth outcome date was within 1 day with 94.9% agreement while birthweight was within 100 grams with 89.6% agreement. By contrast, sensitivity for report of any birth defect was 38.6% with range 18.4% to 50.0% for specific birth defect categories.

**Conclusions—**While most SART CORS outcome fields are accurately reported, birth defects variables showed poor sensitivity when compared with the gold standard data from the BDMP. We suggest that reporting of birth defects be discontinued.

### Keywords

birthweight; birth defects; validation; race; plurality; ART

Assisted reproductive technology (ART) conceived births now represent approximately 1.7% of all births in the US (1, 2). A growing concern, based on international research findings, has been that ART is associated with compromised birth outcomes, including greater risks of preterm birth and low birthweight, even in singletons (3). There have also been reports of an increased rate of birth defects in ART children (4, 5).

In recent years, numerous studies of the success rates and outcomes of ART in the US have been accomplished using two national databases, the Society for Assisted Reproductive Technology Clinic Outcome Reporting System (SART CORS) and the National ART Surveillance System (NASS) (6-11). Data for these national systems are entered by US ART clinics under the Fertility Clinic Success Rate and Certification Act of 1992 (Public Law 102-493). While the validity of some fields in these databases has been confirmed (http://www.cdc.gov/art/ART2011/NationalSummary_appixa.htm), no study thus far has fully evaluated the accuracy of the birth outcomes fields which are collected 8-9 months following treatment, and often self-reported by the patient or her obstetrical care provider. These fields include date of outcome, live birth and fetal death, plurality, birthweight and birth defects. Since researchers routinely use these fields it is important to confirm that they are accurate.

Our goal in this study was to evaluate the accuracy of the data fields in the SART CORS of maternal race and ethnicity, delivery outcome (live birth/fetal death, plurality, birth date, and singleton birthweight), and birth defects using Massachusetts ART outcome data linked to the reference gold standards of vital records (live birth and fetal death certificates) and the Massachusetts Birth Defects Monitoring Program (BDMP). The study extends the preliminary estimates on several parameters performed by us previously (12).

## Methods

### Study design and setting

This retrospective study included 9,092 ART deliveries of which 6,509 were singleton ART births that occurred between July 1, 2004 and Dec 31, 2008 in Massachusetts. The births from these ART cycles in SART CORS were linked to Massachusetts live birth and fetal

death certificates and to the BDMP. Human subjects approvals were obtained from Boston University and from the Massachusetts Department of Public Health.

## Data Sources

**The Society for Assisted Reproductive Technology Clinic Outcome Reporting System (SART CORS):** The SART CORS database collects national ART data under the Fertility Clinic Success Rate and Certification Act of 1992 (Public Law 102-493) and reports these data to the Centers for Disease Control and Prevention (CDC). SART CORS data includes patient demographic information, cycle-specific treatment parameters and outcomes. Data are validated annually through review by SART and CDC. Information on birth defects field and other outcomes is collected by the clinics through a combination of medical record information, provider report, and patient self-report. The data are collected before the next reporting year, which occurs in November of the year after the ART cycle. There is no consistent time frame after delivery for acquisition of these data.

**Massachusetts Birth Defects Monitoring Program (BDMP):** Since 1999, the BDMP has conducted statewide, population-based active surveillance of birth defects among Massachusetts residents under state mandate. Information is collected from birthing hospitals, hospital nurseries, tertiary care hospitals, and birth and fetal death certificates on deliveries as well as early fetal losses. The BDMP identifies cases with structural birth defects diagnosed through one year of age from multiple sources, including delivery and specialty care hospitals, birthing centers, and vital records. Potential birth defect cases are assigned to trained abstractors who review maternal and infant medical records. All cases are coded according to the International Classification of Diseases, Ninth Revision, Clinical Modification, modified British Pediatric Association (ICD-9-CM/BPA) system. Complex cases, cases with syndromes, and cases in which the infant died are reviewed by a clinical geneticist. BDMP collects data on birth defects and identifies related trends, searches for potential causative factors associated with birth defects, addresses community concerns about birth defects, and collects information on related screening and prevention efforts.

**Data Linkage: The Massachusetts Outcome Study of Assisted Reproductive Technology (MOSART):** We linked ART cycles reported in SART CORS among Massachusetts residents with identified live birth or fetal death outcomes to Massachusetts live birth and fetal death certificates for in-state deliveries to create the Massachusetts Outcome Study of Assisted Reproductive Technology (MOSART) database. The linkage methods involved a deterministic multistep procedure that primarily used mothers' names, dates of birth, infant dates of birth (70.8% of matches), and secondarily, fathers' last names and plurality to obtain an overall linkage rate of 89.7% as reported previously (12). The starting date was chosen based on the availability of SART CORS data (January 1, 2004) to allow us to capture any deliveries associated with ART and the end date (December 31, 2008) reflected the latest available data from both SART and vital records when we began the MOSART study.

## Participants

Live birth and stillbirth deliveries of ≥ 20 weeks gestation or birthweights ≥ 350 grams were included. Both singleton and multiple deliveries were included in comparisons of maternal race and ethnicity, birth outcome (live birth/fetal death), plurality, and delivery date. For analysis of birthweight and birth defects, we limited our population to singleton linked deliveries (N=6,503) in order to avoid the problems related to consistently distinguishing one infant from another in multiple deliveries.

## Outcome Variables

We compared reported maternal race and ethnicity (when present), birth outcome (live birth/fetal death), plurality, outcome or delivery date, and singleton birthweight in the SART CORS and vital records. For analysis of birth defects we used the Birth Defects field in SART CORS which contains the following options which may be entered for either live births or fetal deaths: none (if selected, no other options may be selected); unknown (if selected, no other options may be selected); cleft palate; genetic defect; limb defect; cardiac defect; other. No instructions are given on which diagnoses are to be entered into each of these classifications. There is also a field for Neonatal Death with instructions to enter a death if it occurred up to 28 days post-delivery. The BDMP collects information on cases with ICD-9/BPA codes codes ranging from 740.0 to 759.9 and several other selected codes outside this range for defects such as DiGeorge syndrome, Pierre Robin sequence and amniotic bands. For analysis, we grouped the BDMP fields to correspond with the SART CORS classifications including ICD-9-CM/BPA codes ranging from 740.0 to 759.9 and several other selected codes outside this range for defects such as DiGeorge syndrome, Pierre Robin sequence and amniotic bands. For analysis, we grouped the BDMP fields to correspond with the SART CORS classifications including ICD-9-CM/BPA codes for the categories of cleft palate (749.00-09); genetic (chromosomal) defect (758 code series along with selected additional codes); limb reduction defects (755.20-.39) ; and cardiac defects (selected codes in the range of 745-747, with the exception of patient ductus arteriosis, patent foramen ovale, and muscular ventricular septal defect). (See Supplementary Table 1 for details of codes used for these categories). We did a further analysis in which we expanded the definition of cleft palate to include cleft lip (749.10-.29) to determine whether this improved sensitivity of SART CORS data, with the assumption that some clinics may have included cleft lip in the cleft palate category.

## Statistical Methods

Information reported in SART CORS was compared with information in vital records and the BDMP. Maternal race and ethnicity, delivery, and birth parameters were reported as percent agreement, with a calculated kappa correlation statistic for overall agreement in each category. For birth defects we reported the total number of defects from each source overall and within each SART CORS defect category. Sensitivity and specificity were then calculated using the BDMP data as the gold standard. We also calculated 95% confidence intervals (CI) for sensitivity. The data were analyzed using SAS software version 9.3 (SAS Institute Inc., Cary, NC, USA).

## Results

There were 9,092 ART deliveries, including 6,509 singletons (6,503 singleton deliveries had a SART CORS entry for birth defects) during the study period. As shown in Table 1, maternal race and ethnicity was missing in 69% of the SART CORS records, but there was a high level of agreement (95.3%) when it was recorded. There were also high levels of concordance between the SART CORS and the vital record report of: delivery outcome (live birth/fetal death) (99.9% agreement) and plurality (99.5% agreement). Neonatal deaths were reported for 13 infants in both systems, but 11 infant deaths were reported in SART CORS that did not appear in the vital record system.

Outcome date and birthweight comparisons are shown in Table 2. Date of delivery in SART CORS matched the exact date of delivery from the live birth /fetal death certificate in 92.6% of cases, and 94.9% were within one day with no bias in discrepant cases. Birthweight difference in the two data sources was subdivided into groups ranging from 0-49 grams to ≥1,500 grams difference. There were 89.6% of deliveries with less than 100 grams difference in birthweight.

Rates of all birth defects and those in each category are shown in Table 3. Among the 6,503 singleton ART births in which an entry was made in the SART CORS birth defects field, there were 135 birth defects reported for 132 infants in SART CORS and 184 birth defects in 132 infants in BDMP, however there were only 51 infants with defects reported in both sources. There was a general lack of agreement between SART CORS and BDMP by defect category. Of the defects reported, the sensitivity ranged from 18.4% to 50.0%, although the specificity was 98.7% for all defects and >99% for each defect group examined. However, the absolute number of defects in each group was small. When we used an expanded definition of cleft palate that included cleft lip we found that the number of defects in BDMP increased from 5 to 12 (sensitivity 41.7%) with 5 reported in both sources (data not shown). Because the numbers were coincidently similar for the total number of infants with birth defects in SART CORS and BDMP even though the number of specific defects differed, we re-evaluated the SART CORS to vital records linkages for the 81 children with birth defects in each group who did not match. We found 91.3% of the links to be among those that agreed on the gender of the infant and were within 100gms in birthweight. Neonatal deaths were reported for 13 infants in both systems, but 11 infant deaths were reported in SART CORS that did not appear in the vital record system.

## Discussion

In this paper we have evaluated the accuracy of the SART CORS fields of maternal race and ethnicity, delivery outcomes, and birth defects in Massachusetts by comparing them with vital records and statewide birth defects registry data. Maternal race and ethnicity, live birth/ fetal death, plurality, singleton birthweight and outcome data agreed well with these records. For birth defects we used the BDMP, the reference gold standard for birth defect information in this state, and demonstrated very poor agreement. Our study suggests that while most birth outcome fields in SART CORS can be used with confidence for research studies, the birth defects field is inaccurate and should not be used.

A number of publications have demonstrated compromised outcomes for ART deliveries (13-16) and this has prompted increasing interest in the use of SART CORS data for the study of ART outcomes on a national level (6, 17, 18). Our study suggests that the data used for these studies on outcomes other than birth defects are accurate and that these studies can be interpreted with confidence.

Although an occasional report has shown no increase in risk of birth defects in ART deliveries (19), many others have reported a small but significant risk (20-23). Recent data suggest that this risk could be decreasing in more recent years (24). Whether specific ART treatments are associated with increased birth defect rates is still under debate (25). Belva et al (4) reported rates of major malformations to be highest in children born from cryopreserved embryos with ICSI (6.4%) compared to children born from cryopreserved embryos with IVF (3.1%), and fresh embryos with ICSI (3.4%). Other studies have reported malformation rates in frozen cycles ranging from 1.0% (26) to 8.7% (5). In a recent study, we used our linkage of SART CORS to the BDMP to also show that births to women treated with ART have increases in specific birth defects even in singletons (27). Although SART CORS birth defects data have been requested for research (personal communication from SART), we are unaware of any publications that have yet used these data.

Our data also demonstrate that SART CORS birth defects data are not accurate. The poor sensitivity of the SART CORS birth defects field may be related to lack of adequate instructions on how to collect and classify these data, choices are limited to only four specific birth defect categories, the high frequency of maternal self-report, and the absence of quality control. An additional cause of the difference between SART CORS and BDMP might be that BDMP collects data through the first year of life while SART CORS is more likely collecting only those defects reported around the time of birth. Although under-reporting of some birth defects may be explained by this time factor, the reason for over-reporting of other defects is unclear. Nevertheless, recent data suggest that even the birth certificates do not accurately report birth defect information (28). With regard to specific birth defect categories, there is the possibility that clinics may have categorized birth defects differently from one another and from BDMP. We specifically looked at this possibility for cleft palate, which we assumed could have been reported as being present with or without cleft lip. We found that neither classification provided accurate results. Other differences in classification could have affected results as well. Since there are no instructions given for collection of this data field, clinics are likely to interpret information they obtain differently, and with so few categories, it is highly likely that clinics might classify any reported defects in the “other category” or to fail to report any defect that doesn’t fall within one of the specified categories.

The major strength of this study is the use of linked data between SART CORS, vital records, and the BDMP to obtain an accurate measure of outcomes. However, the study has some limitations. The data are from only one state, Massachusetts, and may not accurately reflect how these fields are reported nationally. For birth defects, time to collection of data could differ significantly between SART CORS and BDMP and could have led to a reduced rate of reported cases in SART CORS. However, while this may account for a lower rate of defects in the SART CORS data, it doesn’t account for the 81 situations where a birth defect

was reported in SART CORS that never appeared in BDMP. It is more likely, that extra cases in SART CORS result from incomplete or incorrect information being conveyed to the clinic or assumptions made at birth which are later modified or reversed. For example, patent ductus arteriosus (a cardiac code) is not coded in premature infants if it doesn't persist. It could also result from stricter definitions for birth defects used by the BDMP than may be assumed by clinicians entering information at birth. For example, defining the defect of polydactyly requires bone or cartilage involvement which may not be known at birth, and the defect of clubfoot requires casting.

In summary we have demonstrated the accuracy of most outcome fields in SART CORS, but the birth defects field has poor sensitivity. We strongly suggest that this field be removed from the national reporting requirement both to reduce the reporting burden on clinics and to ensure that research and surveillance studies are not done in the future using incorrect data.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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**Capsule**

Although most birth outcomes in the SART CORS are accurate, birth defects are not and should be removed from the national reporting requirement.

## Table 1

Agreement in Mother's Race and Ethnicity, Delivery Outcome, and Plurality in Vital Records versus the SART CORS

| | | Massachusetts Vital Statistics | | | | |
|---|---|---|---|---|---|---|
| Society for Assisted Reproductive Technology Clinic Outcome Reporting System (SART CORS) | **Maternal** | | Non-Hispanic | Non-Hispanic | | |
| | **Race/Ethnicity** | Hispanic | White | Black | Asian | Overall |
| | Hispanic | **75.0** | 1.0 | 2.3 | 0.4 | |
| | Non-Hispanic White | 19.3 | **97.5** | 4.5 | 5.7 | |
| | Non-Hispanic Black | 3.4 | 0.4 | **90.9** | 0.9 | |
| | Asian | 2.3 | 1.1 | 2.3 | **93.0** | |
| | Overall | | | | | **95.3** |
| | Kappa = 0.86 (0.83, 0.88) | | | | | |
| | | | | | | |
| | **Delivery Outcome** | Live Birth | Fetal Death | | | Overall |
| | Live Birth | **99.9** | 11.8 | | | |
| | Fetal Death | 0.1 | **88.2** | | | |
| | Overall | | | | | **99.9** |
| | Kappa = 0.88 (0.87-0.89) | | | | | |
| | | | | | | |
| | **Plurality at Birth** | Singleton | Twins | Triplets+ | | Overall |
| | Singleton | **99.8** | 1.4 | 0.0 | | |
| | Twins | 0.1 | **98.6** | 3.0 | | |
| | Triplets + | 0.1 | 0.0 | **97.0** | | |
| | Overall | | | | | **99.5** |
| | Kappa = 0.99 (0.98, 0.99) | | | | | |

**Table 2**

Comparison of the SART CORS and Vital Statistics Outcome/Delivery Date and Birthweight

| | Agreement (N) | Agreement (%) | Cumulative (%) |
|---|---|---|---|
| Outcome/Delivery Date (N) | 9,092 | | |
| Difference (days) | | | |
| 0 | 8,385 | 92.6 | 92.6 |
| 1 | 205 | 2.3 | 94.9 |
| 2-7 | 261 | 2.9 | 97.8 |
| 8-14 | 117 | 1.3 | 99.1 |
| 15-21 | 55 | 0.5 | 99.6 |
| 22-30 | 32 | 0.3 | 99.9 |
| Missing | 37 | 0.3 | 100.0 |
| | | | |
| Birthweight of Singletons (N) | 6,509 | | |
| Difference (grams) | | | |
| 0-49 | 5,645 | 86.7 | 86.7 |
| 50-99 | 189 | 2.9 | 89.6 |
| 100-149 | 92 | 1.4 | 91.0 |
| 150-299 | 193 | 3.0 | 94.0 |
| 300-499 | 114 | 1.8 | 95.8 |
| 500-999 | 105 | 1.6 | 97.4 |
| 1,000-1,499 | 37 | 0.6 | 98.0 |
| ≥1,500 | 30 | 0.5 | 98.5 |
| Missing | 104 | 1.5 | 100.0 |
| | | | |

## Table 3

Comparison of Recorded Birth Defects in SART CORS and BDMP

| | SART CORS (N) | BDMP (N) | Reported in Both (N) | Sensitivity[2] (%) | 95% CI for Sensitivity[2] (%) |
|---|---|---|---|---|---|
| | 6,503 | 6,503 | | | |
| All birth defects[1] | 135 | 184 | | | |
| Infants with a birth defect | 132 | 132 | 51 | 38.6 | 30.3-47.5 |
| Cleft palate | 6 | 5 | 2 | 40.0 | 5.3-85.3 |
| Genetic | 18 | 23 | 10 | 43.5 | 23.2-65.5 |
| Cardiac | 25 | 40 | 11 | 27.5 | 14.6-43.9 |
| Limb | 7 | 2 | 1 | 50.0 | 1.3-98.7 |
| Other[3] | 54 | 114 | 21 | 18.4 | 11.8-26.8 |
| Unknown | 25 | -- | - | -- | |

[1] Some infants have more than one birth defect.

[2] Sensitivity of 80% or greater is considered acceptable (29).

[3] The category of Other in BDMP includes all defect codes not classified as cleft palate, genetic, cardiac, chromosomal, or limb.