The status of public reporting of clinical outcomes in assisted reproductive technology

Vitaly A. Kushnir, M.D.,[a] Andrea Vidali, M.D.,[b] David H. Barad, M.D., M.S.,[a,c] and Norbert Gleicher, M.D.[a,c]

[a] Center for Human Reproduction, [b] New York Reproductive Services, and [c] Foundation for Reproductive Medicine, New York, New York

Objective: To assess the transparency of assisted reproductive technology (ART) surveillance reports published by the Centers for Disease Control and Prevention (CDC) and by the Society for Assisted Reproductive Technologies (SART).
Design: Retrospective analysis.
Setting: Private clinical ART and research center.
Patient(s): We analyzed ART data for the years 2005–2010, which were reported under federal mandate to the CDC (818,927 completed cycles) and voluntarily to SART (812,400 initiated cycles).
Intervention(s): None.
Main Outcome Measure(s): Initiated cycles excluded from final outcome reporting were used to evaluate transparency.
Result(s): Only SART, but not CDC, reported initiated cycles, allowing analysis of excluded cycles. Excluded cycles increased significantly from 3.3% to 7.4% between 2005 and 2010. By 2010, 13/341 (3.8%) ART centers accounted for 50% of excluded cycles, representing an average of 37.3% of their cycles. These 13 clinics reported significantly better pregnancy and cancellations rates than national averages and collectively increased by 19.9% their share of U.S. ART cycles.
Conclusion(s): Our data indicate decreasing transparency in public ART reporting in the United States, likely due to changes in practice and reporting patterns. A few clinics accounted for the majority of excluded cycles, leading to improved reported clinical outcomes and increasing market share. CDC and SART should ensure that all ART clinics publicly report the outcomes of all initiated cycles including embryo-banking cycles. ART surveillance and quality of care may be improved by prospectively tracking the total reproductive potential of each initiated cycle. (Fertil Steril® 2013;100:736–41. ©2013 by American Society for Reproductive Medicine.)
Key Words: Assisted reproductive technology (ART), health care outcome reporting, in vitro fertilization (IVF), pregnancy rates

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Public reporting of health care outcomes is intended to provide transparency and is increasingly viewed as a promising strategy to improve health care outcomes (1). Concerns about such strategies have, however, also been expressed, likely the most prominent being that health care providers, as a consequence, may be risk averse and deny care to high-risk patients (2). Such reporting systems are also potentially subject to patient selection bias (3).

The Fertility Clinic Success Rate and Certification Act of Congress in 1992 (FCSRCA) mandated national public reporting of clinical outcomes of assisted reproductive technology (ART) programs, often also called IVF centers, via the Centers of Disease Control and Prevention (CDC) (4). The Society for Assisted Reproductive Technologies (SART), an affiliate of the American Society for Reproductive Medicine (ASRM), maintains a national voluntary reporting system and transfers some of its data to the CDC to

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V.A.K. is a consultant with the Centers for Disease Control and Prevention (CDC) to improve the National ART Surveillance System. The Center for Human Reproduction (CHR) annually routinely reports assisted reproductive technology outcome data to the CDC as well as to the Society for Assisted Reproductive Technologies and is represented in the data presented here among the nonoutlier clinics. The only financial contribution to this study came through salary support from CHR. A.V. has nothing to disclose. D.H.B. holds various patents for the use of androgens in ovulation induction and for the use of FMR1 analysis to predict potential changes in ovarian reserve; has received royalties from the sale of Fertinatal, a DHEA preparation used to promote better response to ovulation induction; and owns stock in Fertility Nutraceuticals LLC. N.G. is a board member of the Foundation for Reproductive Medicine; holds a patent and receives royalties on DHEA; owns stock in Fertility Nutraceuticals LLC; and owns the CHR, where this research was performed.
Reprint requests: Vitaly A. Kushnir, M.D., Center for Human Reproduction, 21 East 69th Street, New York, New York 10021 (E-mail: vkushnir@thechr.com).

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minimize duplicate reporting by its member ART clinics (5). Clinic-specific ART outcome reports are, therefore, currently publicly available from the websites of the CDC and SART (6, 7).

A principal architect of this federal reporting mandate recently described ART surveillance as a working model for other national efforts to publicly report the outcomes of medical and surgical procedures (8). We therefore investigated whether the model of ART outcome reporting, indeed, fulfilled the intent of offering transparent and unbiased outcome reporting for the public. We decided to investigate current reporting practices by concentrating on congruity between ART cycle starts and reported completed cycles.

MATERIALS AND METHODS

The integrity of any outcome reporting system is based on the completeness and accuracy of reported data. We have no ability to assess the accuracy of data reported to either the CDC or SART, but risk of random validation site visits would suggest at least reasonable compliance (5).

To assess the transparency of national ART outcome reporting, we therefore decided to concentrate on the completeness of the reported data by evaluating congruity between reported cycle starts and reported cycle outcomes. For ART cycles, this means that every started treatment cycle has to have a defined, reported outcome conclusion. Cycles without outcomes would be defined as "missing" cycles, which are viewed as not interpretable and therefore contributing to the lack of transparency.

Investigated Registry Data

Data publicly available via the CDC and SART websites were analyzed (6, 7). Table 1 summarizes the two investigated registries. Between 2005 and 2010, the number of clinics known to provide ART in the United States remained fairly constant, ranging between 469 and 484. Of the 474 ART clinics in 2010, 443 (93.5%) reported to the CDC and 31 (6.5%) did not. The identity of these nonreporting clinics is published in the Annual Report of the CDC (http://www.cdc.gov/art/artreports.htm; accessed 10/1/2012).

TABLE 1

Investigated registries.

	CDC	SART
Reporting clinics (%)	422–443 (88.2–93.5)	341 (71.9)[a]
Not reporting (%)	31–57 (6.5–11.8)	133 (28.1)
No. of completed ART cycles	818,927	772,855
No. of started ART cycles 2005–2010	–	812,400
No. of started ART cycles 2005	–	123,200
No. of started ART cycles 2010	–	146,693
Excluded cycles 2005–2010 (%)	–	39,545 (4.9)
Excluded cycles 2005 (%)	–	4,102 (3.3)[b]
Excluded cycles 2010 (%)	–	10,821 (7.4)[b]

Note: The total number of ART clinics was 469–484. The study period was 2005–2010.
[a] Clinics with a complete data set available from SART for analysis in 2010.
[b] $P \leq .001$.

Kushnir. Public ART outcome reporting. Fertil Steril 2013.

However, only 341 (71.9%) of 474 of these clinics reported a complete data set to SART, while 133 (28.1%) did not report a complete data set to SART; 74 clinics reported their data directly to the CDC.

CDC data do not offer cycle start information. They only offer cycle outcome statistics for so-called completed cycles. To determine missing cycles, the analysis presented here had to rely exclusively on available SART data. The data presented here are therefore, in 2010, based on reported cycle starts from only 71.9% of U.S. ART centers and in preceding years on the respective numbers of centers reporting to SART (Table 1).

Current reporting rules for SART allow exclusion of cycles from the general cycle outcome reporting mandate if cycles are designated by the reporting clinic as either experimental or are prospectively determined to have no immediate expected cycle outcomes, as in cases of fertility preservation and/or embryo banking (7).

Table 1 lists initiated cycles in years 2005–2010. By 2010, the SART report lists 146,693 such cycles. To calculate the total number of excluded cycles from outcome reporting (n = 10,821), we subtracted for each reporting clinic, in each age category, the number of fresh and thawed nondonor and donor oocyte ET cycles from total initiated cycles and then calculated, based on reported outcomes, the number (and %) of excluded and, therefore, unreported cycles.

Definition of Outlier Centers

To define outliers among reporting clinics with excessive numbers of missing (i.e., excluded) cycles, we established the 95th percentile for unreported cycles among clinics at 16.0%. Only 13 (3.8%) of 341 clinics were in this way defined as outliers. Cycle characteristics for these 13 clinics (outliers) were then compared with the remaining 328 clinics reporting to SART and, where possible, with clinics reporting their data directly to the CDC.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics version 21. A χ^2 analysis was performed to compare cycle exclusions. Comparison of cycle outcomes used logistic regression with a bivariate outcome variable coded 1 for live birth and 0 for no live birth. The statistical significance levels for all tests were set at .05. Data from 328 clinics reporting to SART with less than 16% unreported cycles were used as the reference group for all statistical comparisons with the 13 outlier clinics and with 74 clinics that reported their outcomes directly to the CDC .

RESULTS

As Supplemental Table 1 demonstrates, the age of female patient populations significantly differed between the 13 outlier and remaining 328 clinics reporting to SART. The 74 clinics reporting directly to the CDC demonstrated a similar age distribution to the 328 clinics reporting to SART. Specifically, at cycle start, outlier clinics reported only 31.2% of patients under age 38 (remaining SART clinics,