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KELLEY JEFFERSON

## Letter from the President



### Dear SART Members:

This has been a very busy and successful year for SART thus far. Our major accomplishment was the introduction of a new Clinic Summary Report (CSR). The Registry Committee is to be commended for its excellent work in making this happen. The new CSR is improved in many ways over the old report. We have placed increased emphasis on singleton delivery rates and on cumulative delivery rates. This is an answer to

**Bradley Van Voorhis, M.D.** criticism that prior clinic reports influenced practice and encouraged excessive numbers of embryos to be transferred. We recognize that the new CSR is complicated - it has to be in order to fully capture the complexities of modern IVF practice. However, we remain open to suggestions for improving the report and simplifying its format. We regard this report as a work in progress and are open to members' suggestions.

Another issue we continue to address is improper use of SART data. We are aware that insurance companies are designating some centers as "Centers of Excellence" (COE), which has implications for access to care and clinic reimbursement. In addition, internet ranking lists may influence patient decisions. In some cases, we believe that SART data is used in establishing COE designation or rankings on the internet. We know it is difficult, if not impossible, to directly compare clinics due to differences in patient selection and patient populations treated. In fact, we prohibit the use of our data in this manner.

We are taking several steps to try to protect our data and our members. Letters have been sent to insurance companies asking them to stop using SART data for COE designations and determinations. This letter is available to members on the "Professionals & Providers" section of the website. You can use this letter to appeal exclusion of your center by an

## MISSION STATEMENT OF THE SOCIETY FOR ASSISTED REPRODUCTIVE TECHNOLOGY

The Society for Assisted Reproductive Technology promotes and advances the standards for the practice of assisted reproductive technology to the benefit of our patients, members, and society at large.

## President letter continued...

insurance provider. We have recently added a disclaimer to our website which precludes improper use of our data. This must be acknowledged prior to access to SART data. Starting with the 2015 data, we can consider legal actions if we have evidence that our data is being used improperly. An important caveat is that similar data is available through the CDC. We reached out to the CDC to see if they would join us in prohibiting improper use of all ART outcomes to the detriment of patient access to care. It was explained to SART that this is not part of their mission at this time.

This year, SART will be conducting our own validation visits. We feel it is important, given the new data fields and CSR. We remain concerned that some cycles may be improperly designated as fertility preservation cycles when the intent was pregnancy in the near future for that patient. The indication for validation for this year will include a high rate of fertility preservation cycles and a high rate of conversion from fertility preservation to treatment cycles for immediate pregnancy.

At this time, we are soliciting the names of individuals who would be willing to be site visitors for validation purposes. We are also interested in a new list of individuals who would be willing to consult with SART member clinics that seek advice regarding improving outcomes. These efforts will be compensated. If you are interested in participating in these activities, [please fill out the application](#) form or contact Kelley Jefferson at (205) 978-5000, ext. 109, or [kjefferson@asrm.org](mailto:kjefferson@asrm.org).

We thank you for your continued membership in SART. We believe that we are finding meaningful ways to add value for member clinics and their patients. Thank you again for your support.

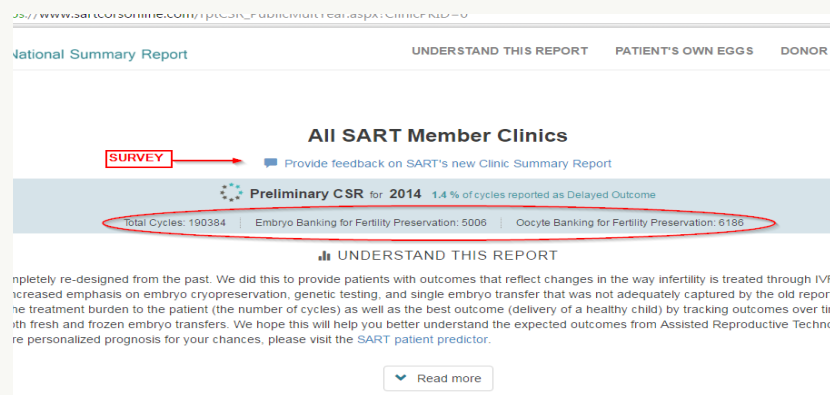
Sincerely,  
Brad Van Voorhis, M.D.  
President

## Registry Committee



Amy Sparks, Ph.D.

As many of you know, the new Clinic Summary Report was released April 4, 2016. This new report is a dramatic departure from the former format, and the SART Registry Committee welcomes feedback. Please use the link to the survey on the CSR to voice your concerns.

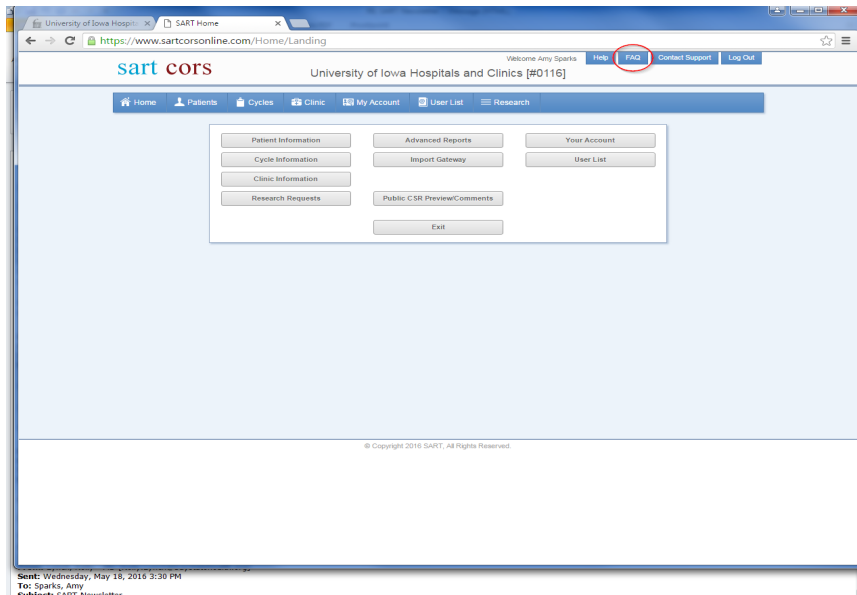


The screenshot shows the SART National Summary Report website. At the top, there are navigation links: "National Summary Report", "UNDERSTAND THIS REPORT", "PATIENT'S OWN EGGS", and "DONOR". Below this, a red box labeled "SURVEY" with an arrow points to a link: "Provide feedback on SART's new Clinic Summary Report". Underneath, a blue banner displays "Preliminary CSR for 2014" with a sub-header "1.4% of cycles reported as Delayed Outcome". Below the banner, three statistics are listed: "Total Cycles: 190384", "Embryo Banking for Fertility Preservation: 5006", and "Oocyte Banking for Fertility Preservation: 6186". A red circle highlights these three statistics. Below the statistics, there is a section titled "UNDERSTAND THIS REPORT" with a paragraph of text and a "Read more" button.

We are reviewing all responses and are taking your feedback into consideration as we continue to refine the report. Most recently, the total number of cycles and fertility preservation cycles were added to the report.

## Registry Committee continued...

Additional changes are being considered, and we are planning to publish the prospective cycle reporting rate in the 2015 CSR. Follow the step in the image below to gain access.



We hosted a webinar titled, "Navigating the new Clinic Specific Report" on March 8, 2016 in concert with the release of the national data in the new CSR format. The webinar was recorded and is available to members upon request. [Please click here to request access to the webinar.](#)

As the variety of procedures performed in our centers becomes more complicated, the Registry Committee members are committed to making the cycle data entry process as clear as possible for all users. For those entering cycle data into SARTCORS, please note that there is a tab labeled FAQ that provides a link to a list of frequently asked questions that were generated as 2014 cycles were being finalized.

The Committee is currently reviewing and developing reporting instructions for additional data fields and revisions to existing data fields required by the CDC. These changes will be deployed in SARTCORS in July 2016. The changes will impact 2016 cycles that will be finalized in the fall of 2017. Once these changes are deployed, we will focus our attention on developing educational material that may be used for orienting members of your staff who are new to data entry in SARTCORS.

Sincerely,

**Committee Members:**

Amy Sparks, Ph.D., Chair

Peter McGovern, M.D.

John Norian, M.D.

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## SART Advertising Committee



**Paul C. Lin, M.D.**

Dear Fellow SART Members and Colleagues:

Back in January 2015, we updated you on common SART Advertising Guidelines violations so that corrective action on your part could be undertaken.

Behind the scenes, the SART Advertising Committee has been constantly reviewing the websites and any and all written or electronic communications to patients and referring physicians of all SART member clinics. We understand that ours is a competitive field, and everybody is searching for an edge, but as SART members who value SART membership and the quality of care it represents, the Advertising Committee works to make sure all clinics comply with the same guidelines. After all, the chief goal of our practice is to provide the best quality of care to our patients while maintaining a respectable reputation.

In response to the new clinic summary format, the Committee has been hard at work modifying the SART Advertising Guidelines to accommodate the increasing complexity of our field and the data presented in the CSR. The 2016 SART Advertising Guidelines have been modified to allow SART members to communicate their practice to their patients in a fair and unbiased fashion, but also prohibit negative campaigning and unnecessary comparison with local colleagues. The major changes are highlighted. The guidelines are also available on the SART.org website on the SART members' login page under "policies." The medical director and any marketing representatives should make themselves familiar with the guidelines and make any appropriate changes as soon as possible.

Current members of the Committee are Tim Hickman, M.D., Matt Retzloff, M.D., Beth Malizia, M.D., Eli Reshef, M.D., Tien Arthur Chang, Ph.D., Jani Jensen, M.D., Laurel Stadtmauer, M.D., Ph.D., Russell Foulks, Peter McGovern, M.D., and Ricardo Loret de Mola, M.D. All are busy practitioners with patients, as well as academic departments and divisions to run. They volunteer their valuable time toward this endeavor because, if we don't police ourselves, someone else less knowledgeable about our field, will. I would like to thank them personally for all of the hard work and the weekly harassing I dole out to keep up with their reviews.

Currently, the Committee spends much of its time passively reviewing our SART members' current advertising; providing valuable feedback; addressing any and all complaints about advertising by another practice; and constantly discussing any and all issues that come up in order to protect the SART members and their communication to their patients in a fair, transparent, and honest fashion.

If you know of advertising that you are not sure is in compliance, we also can provide feedback regarding that advertising. Please contact the SART office.

Sincerely,

Paul C. Lin, Chair  
SART Advertising Committee

## ***SART Policy for Advertising by ART Programs***

*Effective June 2016*

Reporting assisted reproductive technology (ART) outcomes is mandated by the 1992 Fertility Clinic Success Rate and Certification Act (1). The general public, including patients and referring physicians, has the right to know pregnancy and multiple pregnancy rates from ART procedures such as *in vitro* fertilization (IVF). These statistics are displayed on the public web sites, [www.sart.org](http://www.sart.org) and [www.cdc.gov](http://www.cdc.gov), and are updated annually. Accurate data reporting assists in forming realistic expectations and promotes patient confidence in the integrity of the ART field. Patient education about these complex techniques and their outcomes is an important component of the doctor-patient relationship. SART has implemented this advertising policy in order to preserve the integrity of the ART field and promote public awareness of and confidence in its services. Adherence to this advertising policy is a requirement for membership in SART.

SART and its member clinics should minimize the appearance of commercialization of reproductive services and maximize the profession's sensitivity to its patients' needs. Advertising is the act of attracting public attention to a product or business, whether by print (e.g., newspapers, magazines, flyers), broadcast (e.g., radio, television, podcast), verbal (e.g., lectures, seminars), or via the electronic media (e.g., websites, blogs, email, chat rooms and social media such as Twitter, Instagram, etc.)

1. Advertising by SART members must comply with guidelines of the Federal Trade Commission (FTC)
2. Use of the ASRM logo on clinic websites and elsewhere is not permitted. Use of the SART logo is permitted. It must be requested annually and date stamped.
3. The advertisement must not lead patients or the public to believe that the chances of success are greater than they really are. In order to avoid misleading information, clinics are to report live birth data per cycle, per egg retrieval, and per embryo transfer along with the number of cycles per category (the denominator).

Any presentation of success rates or pregnancy rates must include AT MINIMUM a direct link to the practice's clinic summary report on the SART.org website. If presentation is written or in paper form, such documentation should include the website address of the practice's clinic summary report. Such a link should be PROMINENTLY DISPLAYED at the top of the presentation or website page.

4. Claims made in advertising must be supported by verifiable published data. Because practice patterns and patient demographics differ among practices, claims of superiority are not verifiable and are prohibited. See Addendum A for examples.
5. Ranking programs is prohibited as it implies superiority of one program over another program. Specific data used in advertising/marketing that ranks or compares clinics or practices is not permitted. See Addendum B for examples.
6. Comparisons between programs' statistics with SART data for national averages are permitted with the following stipulations:
  - a. All initiated cycles must be included.

- b. Categories must conform to published SART format consistent with the clinic summary report.
- c. Comparisons to SART national data must be within the same reporting year.
- d. Data is consistent with that reported to SART.

7. The following statement **MUST** be included when quoting program statistics on the website or in written literature:

“A comparison of clinic success rates may not be meaningful because patient medical characteristics, treatment approaches, and entry criteria for ART may vary from clinic to clinic”.

8. Format of reporting results:

- a. If a SART member clinic website chooses to display its success rates, it must include a direct hyperlink to its own data (clinic summary report or CSR) on the SART website ([www.SART.org](http://www.SART.org)) first and prominently displayed at the top of the website or document presentation. Any additional supplemental data that is in agreement with section D below can then follow if a practice so chooses.
- b. If a specific data point is comprised of less than 20 cycles, the numerator and denominator must be reported.
- c. If the data point is comprised of 20 or more cycles, the denominator (number of cycles) and percent success may be reported. See addendum C for examples of appropriate reporting.
- d. Supplemental success data format:

If the clinic chooses to display more current data than what is on the SART website or cumulative data of several prior years, it must be displayed in SART format (live births per cycle start when possible, retrieval, and transfer) with the number of cycle starts per category (numerator) clearly displayed, and the numerator displayed when the number of cases per category is less than 20. If no live birth data is available to the program yet, clinical pregnancy rates as defined by SART must be displayed.

WHEN POSSIBLE, THE PRESENTATION MUST BE IN SART FORMAT AND REPRESENT A PARTIAL REPLICATION OF THE CURRENT CSR THAT THE PRACTICE WISHES TO HIGHLIGHT ABOUT THEIR PRACTICE, I.E., PRIMARY CYCLE, SUBSEQUENT CYCLES, CUMULATIVE PREGNANCY RATES, LIVE BIRTH PER PATIENT WITH THE ALLOWABLE FILTERS THAT CAN BE CHOSEN IN “CLICK TO VIEW” FORMAT, I.E., FIRST IVF CYCLE, eSET, PGS, DAY 5/6 TRANSFER, FROZEN OR FRESH DONOR EGGS, DONOR EMBRYOS, GESTATIONAL CARRIER AND ICSI.

- a. The standard SART definition of pregnancy must be used in the presentation, i.e., clinical or ongoing pregnancy is defined as evidence of pregnancy by ultrasound visualization of a gestational sac<sup>3</sup>. It includes ectopic pregnancies. Multiple gestational sacs in one patient are counted as ONE clinical pregnancy.
- b. This applies to all forms of presentations including video, website, printed media and/or social media postings.
- c. Supplemental success statistics on the website must be updated annually within 30 days of the official release of that year’s SART data to the public (e.g., if 2014 data is released February 15th all website supplemental information must be updated by March 15th at the latest).
- d. Supplemental data **CANNOT** include the most recent SART data. Such data must stand alone as suggested in Part A of this section.

9. Reporting of statistics must include ALL initiated cycles and their outcomes within that specified

category and cannot selectively omit some treatment cycles. Cycles under research protocols must be presented either as included within the statistics or separately, at the discretion of the practice.

10. It should be clear to patients when advertised procedures or treatments are still considered investigational or experimental. Such advertisements for investigational or experimental procedures must proceed only with the approval of a properly constituted institutional review board (IRB).

11. The practice and medical director are held responsible for the content of all advertisements. If advertising and media releases are outsourced, it is ultimately the responsibility of the medical director to educate such personnel of the SART Advertising Guidelines.

#### ACTION FOR SART ADVERTISING VIOLATIONS (MAJOR VIOLATIONS REQUIRING CORRECTIVE ACTION)

The SART Advertising Committee will review all advertising complaints and address any potential violations with individual programs. If violations of SART advertising policy are substantial, the program will be given 30 days to correct the offense and provide proof of such corrective action to the Committee. Failure to comply will trigger further interaction by the Committee on the timeline as described below. After reasonable due process and communication between the violating practice and the SART Advertising Committee, further review of the uncorrected violations will be reviewed by the full SART Executive Council (EC). The SART EC has the right to rescind the SART membership of any program failing to comply with the advertising policy.

##### 1. First violation(s):

- a. A WARNING letter or e-mail from the SART Advertising Committee informing a member clinic of advertising violations (C-letter)
- b. A request from SART for response from the member clinic in writing of proposed corrective action for these violations within 30 days
- c. An offer from the Committee to discuss violations by phone or in person (not mandatory)
- d. Evidence of corrective action to be provided by member program in written format

##### 2. Second violation(s) – clinic ignoring SART’s letter for first violation(s) and/or violating guidelines for three MONTHS from the first documented date of communication of the First violation

- a. A letter or e-mail from SART informing a member clinic of advertising violation(s) and a PROBATION status.

Violating practice’s clinic summary report on SART.org will be altered as follows:

Leave data in place and state, “The following program is not in compliance with the SART Advertising Guidelines. Please interpret any and all data presented by this practice beyond the data below with caution.”

- b. In addition, no further validation with insurances by SART when requested.
- c. Mandatory discussion with the SART Advertising Committee by phone and/or email about the violation(s) and proposed corrective action.
- d. Probation status of a clinic will be posted in SART communications to other SART clinics, either as an e-mail from the Advertising Committee or in periodic SART publications.
- e. Evidence of corrective action to be provided by member program in writing by email/letter to SART office

3. Third violation(s)- a clinic ignoring warning and probation letters and violating guidelines for SIX successive MONTHS:

- a. A registered/certified letter from SART informing a member clinic of advertising violation(s) and that the possibility of EXPULSION from SART (AT-RISK status) will be discussed at the next SART Executive Council meeting unless the violation(s) are addressed immediately IN WRITTEN FORM BY THE PROGRAM ITSELF AND VISIBLE ACTION, I.E. WEBSITE CHANGES.
- b. A mandatory discussion with SART presidential chain, either by phone and email and posted certified letter.
- c. At-risk status of a clinic will be posted in SART communications to other SART clinics via periodic SART publications and to the public on [www.sart.org](http://www.sart.org), where access to the clinic's website on the Clinic Contact Information page will be blocked, replaced by the following statement, "This clinic is in violation of SART advertising guidelines and access to its website on this page is blocked until these issues are resolved."
- d. Evidence of corrective action to be provided by member program
- e. Every effort will be made by SART Advertising Committee to resolve the issues amicably. Expulsion and blocked access to the clinic's website are last resorts.
- f. If a good-faith effort of the violating practice to rectify the violations as determined by the SART Advertising Committee, the above timeline may be extended.

#### References:

1. <https://www.govtrack.us/congress/bills/102/hr4773>
2. <https://www.ftc.gov/news-events/media-resources/truth-advertising>
3. [http://www.fda.gov/ohrms/dockets/ac/03/briefing/3985B1\\_03\\_Definitions.htm](http://www.fda.gov/ohrms/dockets/ac/03/briefing/3985B1_03_Definitions.htm)

#### ADDENDUM A

Examples of inappropriate claims suggesting superiority over others:

- "Our clinic offers best care in the state of Michigan"
- "Our clinic has the best doctors in the United States"
- "Our clinic has consistently achieved superior success to other clinics in the state" (when actual SART data does not support such claim)
- "More babies have been born in Reproductive Science center than Reproductive Medical Associate"
- "More patients choose Reproductive Science Center than any other practice"
- "RMA is the best practice in the Midwest"
- "Dr. Smith is the best doctor in the Silicon Valley, the nation, the city, the world, etc."

#### ADDENDUM B

Examples of inappropriate claims suggesting rank status:

- "Our clinic has been consistently ranked by SART in the top 10th percentile"
- "Our success places us as the number one clinic in California"
- "Our program has been ranked by \_\_\_\_\_ as one of the top programs in the nation"
- Active paid advertising by the practice with vendors that rank practices based on success rate criteria. Passive participation on such websites is allowable. No website link to such vendors that rank practices with others is allowed.

#### ADDENDUM C

Examples of appropriate data reporting of success:

- Program A initiated 17 fresh IVF cycles in women <35 that resulted in 8 live births. Their advertising for live births must include the numerator (8) and denominator (17).
- Program B initiated 320 fresh IVF cycles in women <35 that resulted in 151 live births. Its advertising could include the numerator (151) or a live birth rate per cycle start (47%) but either choice must be accompanied by the denominator (320).
- Program C initiated 151 fresh autologous IVF cycles in women ages 35-37, resulting in 47 live births. 15 of the cycles were cancelled and 7 retrievals did not result in an embryo transfer. The correct reporting is 31% live births per cycle; 35% live births per retrieval; and 36% live births per transfer.



## SART Advertising Survey

Your opinion matters to SART. Please click on the link below to answer two questions about SART Advertising Policy.

Please follow this [link](#).

## Quality Assurance Committee



**Eric Levens, M.D.**

clinics through this QA initiative.

The Society for Assisted Reproductive Technology (SART) Quality Assurance Committee is tasked with carrying out multiple quality assurance initiatives in order to maintain high performance standards for the care of infertile patients undergoing assisted reproductive technology (ART) procedures in the United States. While reporting assisted reproductive technology outcomes is mandated by the 1992 Fertility Clinic Success Rate and Certification Act, SART has proactively taken steps over the years to ensure compliance with current ART guidelines, and has included outcome parameters to the oversight process since 2011. It is the SART Quality Assurance (QA) Committee that has the responsibility to monitor SART member

For each reporting year, SART publishes QA parameters on the Professionals & Providers page of the SART website under the member login. These criteria are those that are to be evaluated in the reporting year. SART QA performance measures are intended not only to identify areas where quality can be improved, but to also provide a mechanism for clinics needing improvement to do so. In recent years, the focus has been on improving upon lower pregnancy rates and reducing multi-fetal gestation.

In addition to pursuing SART specific initiatives, the QA Committee has participated in performance improvement initiatives with the Center for Disease Control and Prevention (CDC). CDC launched an initiative to monitor multi-fetal gestation rates throughout the country. In an effort to better serve SART member clinics, the SART Executive Committee has called on the QA Committee to coordinate educational site visits aimed at lowering the multi fetal gestation rate. Recent evidence has demonstrated that this cooperation between SART member clinics and the CDC has led to a reduction in the multifetal gestation rate, thus improving reproductive outcomes.

In conclusion, the aim of the SART QA Committee and the SART QA initiatives is to improve reproductive outcomes through ART for those requiring treatment in the U.S. Moreover, the Committee is committed to assisting those member clinics that may need assistance to improve outcomes. Should member clinics have questions or concerns regarding the activities of the QA Committee, please feel free to contact me. Concerns are thoughtfully adjudicated.

Respectfully Submitted,

**Eric Levens, M.D.**  
**SART QA Chair**