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Letter from the President



Kevin Doody, M.D.

Dear Colleagues;

As you know, the SART Registry is an extremely valuable resource for our field. I want to offer some clarifications to protect the integrity and validity of our database. Based on the questions we have been getting and what the SART Validation Committee is seeing as it goes about its work, it has become apparent that many medical directors or assigned data entry personnel could benefit from clarification of the reporting rules. Most of the confusion seems

to center around the importance of prospective reporting and when and how to make determinations about reporting when cycles are to be categorized as fertility preservation or cancelled. Clinics and patients are better served if the outcomes reported are valid, based on clear criteria, and consistently applied across all SART members.

Validation Findings

The SART Validation Committee performs on-site visits to confirm the accuracy of ART cycle reporting. Reported data fields are compared to documentation in the medical and laboratory records in order to reduce reporting errors that may mislead the public and give undue advantage among member clinics.

Common reporting errors:

- 1) Lack of a formally documented, system-wide mechanism / standard operating procedure to capture all cycle starts. Cycles that were cancelled prior to egg retrieval were not reported by some clinics.
- 2) Systematic designation of cycles as fertility preservation when, in fact, the original intent of the cycle was to obtain pregnancy in the near term. Fertility preservation is correctly designated only for those cycles not intended for pregnancy immediately or in the near future (less than 12 months from cycle start).
- 3) Reporting cycles of predicted low responder patients only when their

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's letter, continued...

response justifies egg retrieval.

4) Failure to close out cycles with known negative outcomes. At some clinics, cycles of "freeze all" in which no euploid embryos were found were not reported as having a negative outcome. In addition, some "fertility preservation" cycles resulting in cancellation or lack of cryopreserved or euploid embryos were not reported as having known outcome.

Remedies:

- 1) Prospective reporting of all cycle starts. Fertility preservation will no longer be retrospectively designated.
- 2) Embryo accumulation / fertility preservation cycles will be systematically handled.
- 3) All cycle starts with the potential for proceeding to egg retrieval should be recorded as a cycle start and will be included in the denominator. Plans to undertake gonadotropin stimulation with possible attempt at retrieval based on "adequate gonadotropin response" require that the cycle be prospectively reported as an IVF cycle.
- 4) All ART cycles with outcomes known during the reporting time frame need to be incorporated into the success report calculations.

SART is making efforts to detect reporting errors in order to ensure that success reports are accurate and reporting methods are consistent between

clinics. A more detailed document has been sent to all medical directors, and I encourage you to review it. I want to thank all of you for your diligence in this area as we continue to improve the quality of service we provide to our patients.

Remember, as stated on our website, a primary goal of SART is to ensure accuracy of data collection so that we provide "...reliable information for patients to make informed decisions and understand the likelihood of success with different treatment options."

Sincerely,



Kevin Doody, M.D., H.C.L.D.
SART President

SART Advertising Committee



Paul C. Lin, M.D.

Dear Fellow SART Members and Colleagues:

Back in Summer 2016, we updated you on common SART advertising guidelines.

In response to the new clinic summary report (CSR) that recently made its debut on the SART website in the spring of 2016, this committee has been hard at work addressing the confusion regarding compliant presentations of SART members' advertising. In 2017, in response to your feedback, we have again

modified the SART advertising guidelines. The major changes are highlighted on the next page. The guidelines are also available on the SART.org website on the SART members' login page under "member resources." You will need to enter your ASRM username and password for access. Medical directors and marketing representatives familiarize themselves with the guidelines and make any appropriate changes as soon as possible.

Our field of medicine has become more complex, and the old CSR prior to 2014 was outdated and not reflective of current practice. It had to be changed, and the Registry Committee has been hard at work presenting a CSR that more accurately reflects what we do on a day-to-day basis. The challenge of the

Advertising Committee has been to oversee and advise our SART members to present their data (if they choose to) in a fair, transparent fashion that is reflective of that member's practice. At the same, we want to allow members to "put their best foot forward," be truthful and transparent, but also to not use comparative language, such as, "I am better than so and so", when we all know that we all treat different patient populations differently.

The best method is to just link to your individual CSR on the SART.org website and let your data speak for itself. That is, at minimum, required for any online, written, or oral presentation of your outcome data.

However, we acknowledge that each SART member practices differently and treats patient populations differently and may wish to present data either cumulatively (over several years) or specific to areas of assisted reproductive technology, i.e., minimal stimulation IVF. The section on the presentation of supplementation data addresses those SART members who elect to highlight or supplement what the current CSR is showing. This is allowable alongside a direct prominent link at the top of any online, oral or written presentation to the SART members' CSR so that patients can easily reference the complete data if they choose to. It is not SART's Advertising policy to omit data because we think it is too complex for our patients to understand. Our patients are quite saavy and well read. If there is confusion, as providers, we should consult with our patients individually and explain to them the subtleties of our practice patterns and what they are seeing on the CSR. There is an excellent micro-video by Amy Sparks on understanding the CSR. I highly encourage you to view it. The website address is: <http://www.sart.org/clinic-pages/video-understanding-the-sart-clinic-report/>

We are not a punitive committee (I will allow time for the laughter to subside), but are a committee of providers with busy academic and private practices just like you, volunteering our valuable time to help you present your data fairly and transparently without comparative language with your local esteemed colleagues in the field. Our success is not defined by our percentages, but by our empathy and compassion in taking care of our patients. We don't need to be ranked against each other.

Nevertheless, I would like to thank the members

of my hard-working committee who have targets on their chests so to speak: Eli Reshef, Russell Foulk, Peter McGovern, Timothy Hickman, Matthew Retzloff, Laurel Stadtmauer, Arthur Chang, Serene Srouji, Diana Wu, and Jani Jensen. These individuals volunteer their valuable time to this endeavor because, if we don't police ourselves, someone else, less knowledgeable about our field, will. If you have any questions about your own advertising or that of your local colleagues, please do not hesitate to interact with me or any member of my committee regarding those concerns. If you receive an email and/or a phone call regarding feedback about current advertising, do not be afraid, we are here to help you.

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 other practices, and constantly discussing any and all issues that arise in order to protect SART members and their communication to their patients in a fair, transparent and honest fashion. If you are aware of advertising that you are not sure is in compliance, by yours or others, we also can provide feedback regarding that advertising. Please contact Kelley Jefferson at the SART office.

Find the newest SART Advertising Guidelines by clicking here <http://bit.ly/2qXwWhP>, or visit the SART Members Only section at www.sart.org under Professionals and Providers.

Respectfully,
Paul C. Lin, Chair

Research Committee Projects

SART is fortunate to have the services of an exceptional epidemiologist in Barbara Luke, Sc.D., M.P.H. Last year, her group published 17 original manuscripts, currently has two more in press and an additional three in preparation. The data for these publications typically involves SART CORS information, and may be cross indexed with other health related databases. Additionally, 14 abstracts were presented last year and eight more were presented at the end of January, 2017. Four funded grants are in process through 2021. They include:

- Massachusetts Outcomes Study of Assisted Reproductive Technology Collaborative (MOSART) (6/2016-5/2021) *Subfertility and Assisted Conception Study of Parents and Their Children*
- Assisted Reproduction and the Risks for Childhood Cancer (3/2011-2/2017)
- (NOT-CA-12-001) *Administrative Supplements to NCI-funded Research Projects: Funding to Advance Research on Cancers in Women* (7/2012-2/17)
- (PAR-14-272): *Assisted Reproductive Technology and Child Health: Risk of Birth Defects, Mortality, and Effect on Grade School Performance* (7/2016-6/2021).

An important contribution of the group is the prediction model, known as the Patient Predictor. It can be found on the home page of the SART website (PREDICT MY SUCCESS). It is a useful tool for counseling patients about the chances of success with ART. A physician treatment model. Descriptions of these two models are provided below:

The prediction model of live birth based on the first three cycles, using SART CORS 2004-11 cycles, was published in *Fertility and Sterility* in September, 2014. The prediction models based on the morphologic measures in fresh cycles in the SART CORS for 2007-11 were published in *Fertility and Sterility*, in September, 2015. During the summer of 2014, we revised the original analyses to include the 2012 cycles, and these are the coefficients currently in use on the website. The application of the prediction model was presented at the Society for Maternal-Fetal Medicine annual meeting in San Diego, California in February, 2015, and published in May, 2015 in the *American Journal of Obstetrics and Gynecology*. These analyses showed that the live birth rate with one embryo transferred over two cycles was comparable to two embryos transferred in one cycle, and resulted in a 20-fold reduction in the multiple birth rate. The 2013 cycles were received in September, 2015, and the coefficients for the original patient predictor model have been updated. The first version of the patient predictor (implemented in 2014 and based on 2004-12 cycles) included three models showing the chance for live birth after 1, 2 and 3 fresh IVF cycles based on age, BMI, prior gravidity and infertility diagnosis, as well as first cycle using donor oocytes. It also compares multiple pregnancy rates when one embryo is transferred over two cycles versus two embryos transferred in one cycle. The revised version (based on 2006-13 cycles standardized to 2013) includes day of transfer, and expanded the donor model to include the chance of a live birth and a multiple birth with one or two embryos transferred.

Physician Treatment Model: As an extension of the Patient Predictor models, we also have developed physician treatment models to predict the chances of live birth and multiple birth. These models are planned as a series of five models. All models will include year of treatment, maternal age, gravidity and reproductive history, infertility diagnoses, body mass index, and day of transfer. The first cycle models will be based on the use of autologous oocytes and fresh embryos, number of oocytes retrieved, and embryos transferred and cryopreserved. A second model also will include embryo morphology. A second cycle model will be based on factors in the prior cycle, which did not result in a live birth. Two additional models for any cycle will include factors in all prior cycles, and the use of either fresh or thawed embryos, as well as other factors in the current cycle.