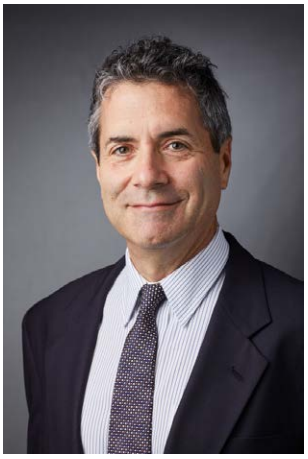
sart | Society For Assisted Reproductive Technology news



Dr. David Seifer

Moving Toward Improved Insurance Coverage

SART is encouraging access to care by assisting those who are working to expand insurance coverage for ART. The short term goal is coverage for vulnerable segments of the population with a long range goal of ART coverage for all. Long term, this means we are pursuing an incremental, pragmatic, and stepwise strategy. Step 1 was VA coverage for wounded veterans that ASRM was able to secure, at least preliminarily, in 2016. Step 2 is fertility preservation for patients with cancer and/or iatrogenic causes resulting from medical treatment for conditions such as lupus, sickle cell, and rheumatoid arthritis, which can result in infertility. More than 90% of members who participated in a recent SART survey regarding membership attitudes toward insurance coverage for ART support Step 2.

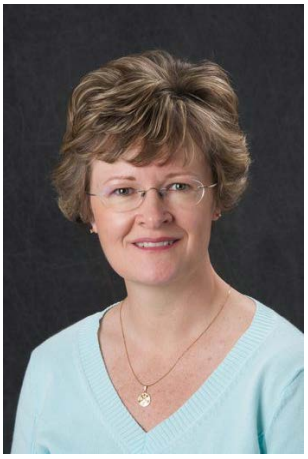
Patient advocacy groups are leading the way. A coalition of organizations have joined together to form the Coalition to Protect Parenthood After Cancer (CPPAC) to work collectively to share information and to strategize about how best to advance insurance coverage for fertility preservation services. CPPAC coalition partners consist of SART, ASRM, RESOLVE, the Alliance for Fertility Preservation, pharmaceutical companies Ferring and EMD Serono, and several national cancer organizations.

Policy arguments being put forth by advocacy groups include several principles. 1) Fertility preservation is not elective, but is instead a medical necessity to facilitate conception of an individual's similar genetic child following treatment of cancer. 2) Fertility preservation is an established treatment, and is standard of care as recognized by the AMA, WHO, ASCO, ASRM and AAP. 3) Fertility preservation may promote better medical outcomes and treatment (less recurrence) by lessening reluctance to undergo treatment for cancer because of concerns of becoming infertile. 4) Such coverage has relatively low expense and provides potential cost offsets by increasing coverage by a few cents per member, per month. This

represents a fraction of overall cancer care costs while helping to avoid costly poor cancer outcomes due to non-compliance. 5) There is an ethical basis for coverage by providing equitable access to reproductive preservation for women as a fundamental life activity equivalent to men who freeze their gametes (sperm) for a fraction of the cost.

No one, single strategic approach is being employed. Several different strategic approaches are being explored in different states. One strategy that gained traction and met with success in 2017 was updating existing state insurance mandates. This "modernization" of current mandates included fertility preservation, marital status, gender and age limitations, as was the case with Connecticut and Rhode Island. At the federal level, CPPAC partners are arguing that coverage for fertility preservation should be part of comprehensive cancer care per the Women's Health and Cancer Rights Act passed in 1998. Just as current medical insurance covers breast reconstruction following mastectomy for treatment of breast cancer, such should be the case with fertility preservation. Other possible approaches also are being considered, but remain untested. Whatever approaches are ultimately successful, the hope is that once enough states have fertility preservation coverage, we will be able to obtain population-based data to engage additional insurance gatekeepers by demonstrating cost effectiveness and the beneficial social impact of providing such coverage to those who are in need.

David Seifer, M.D.
SART President



Dr. Amy Sparks

SART CORS

As most of you are aware, there are several new or modified fields for each cycle in SART CORS. These modifications were made in response to changes in clinical practice and recommendations from ASRM Affiliated Societies including SART and patient advocacy groups. The majority of the new changes are required by law for the National ART Surveillance System (NASS) and apply to non-SART clinics as well. We've heard from many members since the new fields were added last year about the burden of adjusting to these changes. The current challenge for SART is to help ease the data reporting obligation by providing a data collection system equipped with tools for efficient

and accurate data reporting and allow clinics to utilize the data.

How did we get here?

The proposed changes to the reporting requirements were published in the Federal Register on July 21, 2014 and February 18, 2015. At that time, the SART Executive Council alerted members to the announcement and encouraged members to provide comments directly to the Office of Management and Budget (OMB) during the comment periods. SART and ASRM objected formally in writing to the expansion of the NASS, arguing that many of the proposed additional fields were not required to fulfill the CDC's mission to calculate pregnancy success rates for ART cycles as required by the Fertility Clinic Success Rate and Certification Act (FCSRCA). The comments opposing the CDC's plan to expand the NASS failed to have an impact and a final notice of the additional reporting requirements was posted in the Federal Register on August 26, 2015, requiring the new data fields for 2016 cycles.

SART informed members to the pending changes through emails and during the annual members' meetings in 2015 and 2016. Despite these efforts to communicate the upcoming changes, it was difficult for centers to fully appreciate the impact until the new fields were released.

How did we get relief from 2016 reporting requirements?

In response to a number of complaints from members and a number of meetings with the CDC, SART was able to petition the CDC to postpone an absolute requirement for some of the fields for 2016 cycles. Several changes have been made in SART CORS to reduce the burden of direct data entry and the gateway is available for programs that wish to upload their data directly from their EMR or internal database as this will preclude double entry.
While the comment period for the expansion of the NASS has long passed, comments regarding the estimate for the reporting burden and suggestions for reducing this burden may be sent to:
The NASS team at the CDC: artinfo@cdc.gov
The General Services Administration at risc@gsa.gov and refer to OMB No. 0920-0556 for ART Program Reporting System. Please cc: artinfo@cdc.gov.

When life gives you lemons…

SART CORS continues to be a superior vehicle for reporting. Non-SART clinics that report through NASS describe a much less intuitive and convenient interface; a few such clinics have applied for SART

membership as a consequence. Additionally, SART provides an import gateway that allows clinics using EMRs to directly upload their data into SART CORS, avoiding the time and hazard of double entry. NASS does not provide such a gateway.
As the number and complexity of ART cycles grow, so does the effort required for accurate data reporting. SART is working to find ways centers can use their ART cycle data. Within the next year, members will be able to create queries in SART CORS to use their cycle-specific data for a variety of functions such as data analysis for their own quality management program and sharing outcome data with their PGT reference laboratories. We all spend a lot of time collecting and entering data. SART's goal is that member centers reap more benefits from their efforts.

How do SART members currently benefit from SART CORS?

Data that are submitted to SART CORS are used for a variety of functions that benefit both SART members and their patients. The current benefits include:

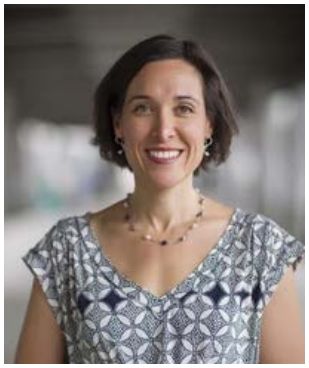
Comprehensive clinic report: SART CORS generates clinic reports that provide outcomes for all cycles initiated for egg retrieval without intended long term fertility preservation.
• Patient education: Use of the clinic specific report that provides filters to display outcomes that are relevant to a patient's diagnosis and treatment plan.
• SART patient predictor: The SART patient predictor utilizes cycles from all clinics to generate a predicted outcome for individuals.
• Quality Assurance: The original mission of SART was to monitor the safety and efficacy of ART treatments. Very quickly, SART transitioned into a role of providing an external Quality Assurance for members. As you know, SART programs are held to the highest standards of personnel experience and laboratory certification. An active QA committee identifies and assists in clinical and laboratory improvement. This important QA role is clear to third party payors. Currently most employers and insurance companies insist that ART services are provided by SART members.
• Advertising: The SART advertising committee reviews all members' advertising to assure compliance with the SART advertising guidelines .
• Accurate Data Reporting: SART's validation committee reviews center reporting trends and conducts center visits to assure that all cycles are reported and reported accurately. In the event errors are discovered, data correction may be required.
• Research: Members of SART centers may submit proposals and request for data from SART CORS through the research portal.
• Compliance with the FCSRCA: SART CORS exports the

cycle data to the NASS annually. In the event that reporting errors are discovered and corrected in SART after the data export, the corrected data will only be reflected in the SART clinic and national report. The NASS is unable to revise any of the data after finalization.

Keep calm and enter on…

I want to thank all of you for your commitment to report ART cycles accurately. The SART Registry Committee is developing new resources for guiding users and orienting new members of your team to SART CORS. The primary goal of SART's ART outcomes reporting is to ensure accuracy of data collection to provide reliable information for patients to make informed decisions and understand the likelihood of success with different treatment options. Your commitment to excellent patient care and accurate data reporting are essential for achieving this goal.

Amy Sparks, Ph.D.
SART President Elect


Dr. Jennifer Mersereau

SART Practice Committee

The Society for Assisted Reproductive Technology (SART) Practice Committee (PC) is tasked with working with the ASRM Practice Committee to improve the quality of practice in reproductive medicine by promoting quality reproductive health care through the implementation of evidence-based approaches to practice.

As chair of the SART Practice Committee, I am the representative from SART for the ASRM Practice Committee (PC). The ASRM Practice Committee is comprised of representatives from ASRM affiliate societies (SART, SREI, SRS, SRBT and SMRU), ACOG, the ASRM The Patient Education Committee; the ASRM Vice-President, three members-at-large, a consulting epidemiologist, the ASRM Chief Executive Officer, the ASRM Chief Scientific Officer and two members of the ASRM staff. We meet in person two times per year, and consider all clinical aspects of the medical, surgical, and laboratory practice of reproductive medicine and making appropriate recommendations regarding needs in the areas of education and research, as well as development in the area of reproductive health care. The ASRM PC develops state-of-the-art opinions on new techniques and their appropriateness for clinical application and

on subjects related to clinical management, as necessary. The ASRM PC has formal, reciprocal representation with the American Congress of Obstetricians and Gynecologists.

The ASRM PC develops documents such as guidelines, committee opinions, and guidance documents. See below for an explanation of ASRM documents and how you can contribute.

The SART Practice Committee members include myself, Barry Behr, Ph.D.. Matthew (Tex) VerMilyea Ph.D., Jennifer Hirshfeld-Cytron M.D.,MSCI and Kathryn Calhoun, M.D. Our committee communicates by phone or email, and these members contribute to committee opinions and guidance documents.

Should SART members have questions or concerns regarding the activities of the Practice Committee, please feel free to contact me.

Jennifer Mersereau, M.D., MSCI
SART Practice Committee Chair

ASRM Practice Committee Documents

ASRM Practice documents have changed over time and this explains how and why. Also contained herein is how you as an SART member can get involved by volunteering to join a committee or task force.

What's the difference between Guidelines and everything else that the ASRM publishes?

In 2013, the ASRM responded to a call for improved stringency in its production of evidence-based guidelines. They chose to adopt a structured, standardized approach as outlined by the National Guidelines Clearinghouse (NGC). The NGC is a database of evidence-based clinical practice guidelines and related documents. It is maintained as a public resource by the Agency for Healthcare Research and Quality (AHRQ) of the U.S. Department of Health and Human Services (free online access to guidelines http://www.guideline.gov

The NGC mission "is to provide physicians, nurses, and other health professionals, health care providers, health plans, integrated delivery systems, purchasers and others an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to further their dissemination, implementation and use."

All new documents that the ASRM publishes using the term "Guideline" and all existing guidelines that are reviewed must meet the criteria for consideration by the NGC. The criteria are:

• The guideline must contain systematically developed recommendations, strategies, or other information to assist health care decision-making in specific

clinical circumstances.
• The guideline development process must have included a verifiable, systematic literature search and review of existing evidence published in peer-reviewed journals.
• The guideline must be current and the most recent version (i.e., developed, reviewed, or revised within the last 5 years).

To date, eight ASRM guidelines have been accepted and published by the NGC and a ninth is under consideration.

What is an ASRM Guideline?
• Developed to help guide medical practice in the field of reproductive medicine
• Based on a documented, structured, comprehensive, reproducible systematic literature review
• Answers predetermined scientific questions (NOT a book chapter, structured in Q&A format to answer specific scientific questions)
• Guidelines are very labor intensive. Each guideline takes between 12-18 months to conceive, develop, review, and publish.

Where do ideas for new guidelines come from?
Ideas for new guidelines come from ASRM affiliate societies, special interest groups (SIGs), and individual members. If you would like to submit an idea, please send a note to Kelley Jefferson at sart@asrm.org to be forwarded to the SART Practice Committee. Suggestions for guidelines are reviewed by the ASRM Practice Committee.

How is a guideline written?
Once a guideline topic is chosen, a task force is empaneled. Each guideline has its own unique writing task force.

Who is on a task force?
• Chair (a sitting member of the ASRM Practice Committee)
• Consulting epidemiologist
• Members (3-4 clinicians at various levels of practice)
• Clinician 10+ years in practice
• Clinician 5-10 years in practice
• Clinician 0-5 years in practice (may be a fellow)
• An International member of ASRM (non-USA based)
• Past CREST scholar
• Other experts (mental health, genetics, laboratory, etc.)
• ASRM staff:
• Carla Stec, M.A., Practice Initiatives and Guidelines Specialist
• Jessica Goldstein, R.N., Education Program Coordinator
• Richard Reindollar, M.D., Chief Executive Officer (CEO)
• Susan Gitlin, Ph.D., Chief Scientific Officer (CSO)

How can I volunteer to be on an ASRM Task Force or Committee?
ASRM leadership encourages all members to be active participants in their society. Simply fill out the volunteer form and indicate your areas of expertise and interest. Please click here .

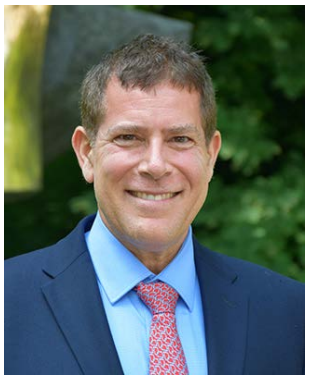
What are Committee Opinions and Guidance Documents and will ASRM still publish them?
CO's and Guidance documents are and will continue to be written on topics that

don't lend themselves well to becoming a formal guideline. They are referenced analyses and like guidelines are meant to help ASRM members with clinical decisions regarding the care of their patients.

What about guidelines from other societies that may be of use to ASRM members?
The ASRM collaborates with other societies in the development of guidance documents and committee opinions of mutual interest. Collaborative documents are published simultaneously by both organizations. The ASRM has two categories of acknowledgement of Guidelines, COs and Guidance material published by other organizations: endorsement and affirmation of value. Endorsement means that the document "fully meets ASRM standards; ASRM can endorse all of the statements. The process used to develop the document is substantially equivalent to the process the ASRM uses to develop evidence based documents". Affirmation of Value on the other hand means that the document "either does not fully meet ASRM endorsement standards, or ASRM cannot endorse all of the statements. However, ASRM leadership determines it is of benefit to the membership."

How do I know if the information in an ASRM Guideline, Committee Opinion or Guidance Document is current?
All ASRM documents are reviewed for currency every 5 years. At the time of review, the document can be affirmed as is, revised or retired. Documents can be revised sooner than every 5 years if meaningful new data emerges before a scheduled review. Sometimes documents are retired because their content is substantially merged into a new or existing document.

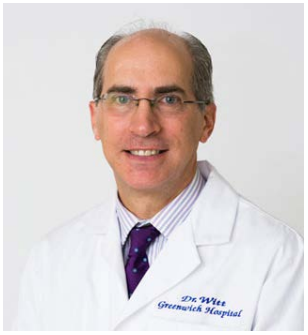
Producing high quality, evidence based material that has meaningful value to ASRM members in their practice or reproductive medicine is time consuming and resource intensive. The hope is that all interested members of the organization contribute to these documents, and that all members find them useful to provide evidence-based medicine for our patients.


Dr. Steven Spandorfer

SART Validation Committee

The SART Validation Committee has been hard at work to assure accurate reporting of ART cycle data. Accurate reporting is critical, so that all programs are on a level playing field, patients have access to verified accurate data, and researchers using the SART-CORS database can have the highest confidence in their conclusions.

De-identified raw data from SART-CORS for the most recent year's submission is analyzed and approximately 10 programs are selected for review based on unfavorable deviation from the mean for the following criteria:



Dr. Barry Witt

i. Low prospective reporting. It is expected that all stimulated cycles are entered into SART-CORS within four days of the cycle start. Thus, each program must have a mechanism in place for identifying all cycle starts and entering them prospectively. This assures that every cycle, including cancelled cycles, are included.

ii. High number of deleted cycles. While it is understood that occasional errors, such as duplicate cycle entry may occur, we have identified systematic reporting errors whereby cycles were inappropriately deleted. This can result in elimination of cancelled or failed cycles which makes the clinic summary report invalid.

iii. Low cancellation rate. Some programs truly have low cancellation rates, but others have been found to fail to report all cancellations, resulting in inflation of clinic cycle success. This may be a consequence of inadequate prospective reporting, not capturing all cycle starts, or inappropriately deleting cancelled cycles.

iv. Fertility preservation “pullback”. Fertility preservation cycles are defined as cycles where the intention is to freeze eggs or embryos and NOT transfer any embryos within 12 months of the cycle. Transferring embryos that were created in a “fertility preservation” cycle within 12 months is what we term “embryo pull-back”, and may indicate that the designation of fertility preservation was incorrect.

v. IUI conversions to IVF cycles. High numbers of IUI conversions in poor responders suggests that these patients are actually doing IVF cycle stimulations, and only those who make it to retrieval are being reported.

Programs that are selected will be asked to schedule a validation visit. Two SART validators will come to review patient records and the SART-CORS cycle data associated with them to confirm accuracy of the reporting. Personnel involved in data entry, as well as the leadership of the program, will need to be present.

If systematic reporting errors are identified, the program will be required to remediate their data for that reporting year. The link from sart.org to the program's clinic summary report is deactivated until the data is corrected. Data remediation requires a significant cost to the program and requires a follow-up validation visit to assure that the data is accurate.

The SART Validation Committee strives to identify the causes of systematic reporting errors and raise awareness of these in order to educate our members so that data submitted will be of the highest quality. Educational materials are being developed that may be used for orienting new data entry personnel to SART-CORS to reduce reporting errors and lower the chances of triggering a future validation visit. Please contact us if you have any questions about the validation process.

Steven Spandorfer, M.D.

Barry Witt, M.D.

Dr. Eli Reshef

New SART Advertising Guidelines for 2018

The SART Executive Council has just approved new SART advertising guidelines to go in effect January 2018. They can be found by logging into the SART website as a member and then clicking on "Member Resources."

Changes made to the previous guidelines (written in March 2017) include a new 14-day grace period, in which clinics that are notified about advertising violations, either by a phone call to the medical director, email, or through the new SARTCORS Advertising portal, can promptly make corrections without official letters or actions from SART.

Other changes include removal of language that denigrates other programs, and clarifying the actions SART takes if violations are not addressed promptly. The SART Advertising Committee will make every effort to address advertising violations and complaints fairly and promptly while maintaining collegial communications with member clinics. The vast majority of SART clinics, many of which are not aware of advertising policy violations, address such violations quickly.

As a reminder, failure to correct serious violations 30 days after an official notice by SART may result in a red warning banner on the clinic's SART Clinic Specific Report (CSR). After 90 days without correction, the clinic's SART data will be completely removed from the SART website. If 180 days pass without a satisfactory response, the clinic will be placed on AT RISK status and may lose SART membership.

Fortunately, membership in SART is highly valued by its clinics and drastic actions are rarely implemented. The SART Advertising Committee now has a portal on www.sartcorsonline.com that allows it to communicate directly with member clinics regarding violations. SART member clinics are encouraged to check for communications from the advertising committee on this website.

Eli Reshef, M.D.
Chairperson, SART Advertising Committee

SART Mobile App

The SART Mobile app is almost here! The finishing touches of the first version of SART Mobile have been completed and the app will soon be in the Apple and Google app stores. We believe SART Mobile will provide tremendous value to SART member clinics. The app will contain several features designed to appeal to the patient (pregnancy wheel, IVF success predictor and more).

SART Mobile can collect pregnancy outcomes directly from the patient. This information will populate SART CORS automatically and the information will be forwarded to the clinic. This will minimize the current human resource burden required for clinics to track down required information from patients after delivery. Additionally, functionality will help clinics manage the burden of prospective cycle reporting.

Scheduling and direct messaging functions are also optionally available to patients. Of course, all of this has been designed with HIPAA compliance in mind.

We will let you know when the application is available for download. We appreciate the financial assistance provided by Ferring and their continued commitment to patient education and support.

Reminder for REI SART Members!

Participation in your SART clinic's QA activities qualifies as completion of your ABOG MOC part 4 requirement.
Simply visit www.abog.org for more information.

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