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Cryoport SRBT Webinar – SART Registry Update
January 28, 2014, 12:00 pm
Responses by Kevin Doody, MD

Question Log

Q: I work at a clinic that is not a SART member will all of these changes be on the NASS website as well?
These proposed changes will be published in the Federal Register as a draft. After allowing time for comments, the final rules will be published with responses to comments. We expect the Federal Register publication this summer.

Q: What CDC fields were deleted from data collection?
To be clear, the CDC intends to collect more data fields. Many desired fields were discussed and ultimately not added because the value was felt to be less than the reporting burden could justify. We deleted some fields related to more detailed smoking history. Other fields have changed slightly.

Q: What qualifies or determines minimal stimulation cycle?
Minimal stimulation will be defined by the clinic. We will collect data on the type and dosage of medications used for all cycles including minimal stimulation. Ultimately, the definition may be more restrictive if it is perceived that cycles are being done without intent to minimize medication cost, monitoring visits and / or egg numbers. As always, outlier programs are subject to validation visits for purpose of chart review.

Q: It seems that any cycle where a transfer is not intended is best reported as fertility preservation, so that if a transfer does not occur, you are not penalized. Is this correct?
Correct. If a transfer is not intended to occur in the near future (12 months following the start of stimulation) this should best be designated as Fertility Preservation. Fertility Preservation cycles are not currently planned to be included in the Clinic Summary Report because these cycles are relatively uncommon and pregnancy success rates with low denominators will be of less value for predicting outcomes for patients. If Fertility Preservation cycles become more common in the future, it is very possible that the outcomes of the thaw cycles will be included in the clinic report.

Q: How about same sex couple? Are we reporting on GC's age and outcome, right?
I assume you are asking about a same sex male couple. We would report this outcome as an egg donation cycle. The patient would be the gestational carrier. We might plan to be able to filter to view outcomes of egg donation cycles that were also gestational carrier cycles. It makes no difference whether the intended parents were same sex male, male / female or single parent (male or female) in terms of how this would show on the report.

Same sex female couples in which the source of the egg is one intended parent and the uterus (gestational carrier) is the other intended parent is a more difficult reporting issue. We plan to bring this issue to the CDC to determine the best way to report. For now, this can be reported as an egg donation or as a gestational carrier cycle, but neither is accurate.

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Q: How would you report donor egg banking in a split situation where there may be more than one recipient linked to only donor egg retrieval?
The report format for this has not been finalized. We have at least two options: 1) the first embryo transfer to occur chronologically to either recipient could be reported as "primary" and any subsequent embryo transfers to occur to this same or other recipients could be reported as "subsequent", or 2) we can report "primary" and "subsequent" success per recipient monitoring / intended transfer / thaw cycle. The "primary" transfer would relate to the first transfer following thaw of eggs, while the "subsequent" label would be used for any additional embryo transfers resulting from freezing of supernumary embryos resulting from that egg thaw. The first option gives a better estimate of the efficacy of the donor stimulation / retrieval. This is a statistic that may be of great interest to the egg bank. There would be some difficulty, however, if eggs are split between clinics for a clinic to know whether a given transfer should be reported as "primary" or "subsequent". The second option gives a better estimate of success from the standpoint of the recipient undertaking the process. It is for this reason that we currently are more in favor of the second option. The purpose of the Clinic Summary Report is to benefit the consumer of fertility services. Although the egg donor is a patient involved in the provision of these services, she would have less of a vested interest in predicting the outcome (success rate) associated with the process than the recipient.

Q: How will stimulation and egg recoveries for donor egg freezing be tracked? These are not initially linked to a recipient and the IVF & ET cycle may be years later.
The language of the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA or "Wyden Law") specifies that cycles involving handling and processing of eggs are considered ART. For this reason, data relating to both autologous and donor egg freezing must be tracked and outcomes reported. SART-CORS will be able to collect the data and link the recipient transfers to the donor stimulations even if the two cycles are done in different years.

Q: What is the new definition of DOR?
The previous definition of DOR allowed clinics to make this diagnosis based on age>40. It was felt that this was not necessary as the age of the patient (egg source) is known. Although egg quality is reduced for women > 40, many women in this age range can have a good response to gonadotropins. The new definition relies primarily on sonographic (AFC), biochemical (AMH, basal FSH) markers and prior response.

Q: Will one be able to query PGS/D pregnancy rates from all other cycles?
The current plan is to be able to apply filters to view these outcomes distinctly.

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Q: So, in 2014, if you have 2 delayed transfer IVF cycles, and one fresh IVF cycle (where fresh and frozen embryos are transferred) and that transfer outcome is a clinical pregnancy, is the outcome 1/3 for clinical/cycle and 1/1 for clinical/transfer?
The above is a correct interpretation. Our plan is to be able "click to view" the success metrics that might be perceived as somewhat less important by the patient. Some metrics (e.g. live birth per cycle initiated) will be displayed prominently on the default report. We recognize that there will be differences of opinion as to what metrics are more important or less important to patients. In general, we believe that live birth is more important as a numerator than clinical pregnancy and that cycle initiated and egg retrieval are more important to the patient than embryo transfer as a denominator. The final design has not been confirmed and we continue to seek input from SART members. The CDC must abide by the Wyden Law with regard to the metrics reported and SART will take this into account as we want to minimize confusion to patients that might occur if we were to have a completely different report.

Q: Will these rules encourage direct comparison by patients of clinics? How will this affect access to care to poor prognosis patients?
Registry data is not appropriately used by patients to compare clinics directly. We will discourage this use as best we can, but realize that comparisons will be made. For this reason, we will consider additional "click to view" success statistics that may help those clinics that do not refuse treatment to poor prognosis patients. We are considering a "first cycle" success metric that will minimize the impact of treating patients that may require multiple cycles to achieve live birth. Success per patient is also being considered.

We also want to encourage clinics to minimize multiple gestations by performing single embryo transfer when appropriate. For this reason, a cumulative live birth metric might also be considered as a "click to view". A success would be achieved if a live birth were to result from the first or any subsequent transfer following a single stimulation.

Implementation of some of these success metrics will be quite tricky because stimulations and transfers can occur in different reporting years. Additionally, "subsequent transfers" can involve thaws of embryos that result from more than one stimulation.

Q: What is the current prospective reporting time frame?
The cycle should be reported as initiated within the first four days of stimulation in a medicated / stimulated cycle. Natural cycles should be reported within four days of cycle start.

Q: Under "Patient Medication" during an FET cycle, if a patient uses Gonadotropins; what box do we check? The 3 options are "minimal stimulation, aromatase Inhibitors, and unstimulated"?

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Minimal stimulation, aromatase inhibitors, gonadotropins and "unstimulated" are terms that apply to IVF cycles. Although transfer of previously frozen embryos can occur during these IVF cycles, these labels / designations are not appropriately applied to planned FET's. We have discussed this issue and will move to collect fields related to medications used to stimulate the endometrium rather than the ovaries. For now, "unstimulated" would be chosen for the vast majority of FET cycles.

Q: Prospective rules - FET lists cycle start "within four days of thaw" - does this mean that the cycle start must - repeat must - be done within that four day window, and not before or after - for example, will a cycle start based on medicine start date be valid for FET prospective reporting?
We have given much thought to the prospective reporting requirements of FET cycles. In the end, the registry committee has concluded that we should treat as we do fresh ART cycles. If stimulation is done, the cycle should be reported within four days of the start of stimulatory medications. For FET, these medications would be the medications used to stimulate the endometrium (as opposed to the ovaries). For natural cycles, the cycle should be reported within four days of the start of menses. We understand that this will require the patient to call in when menses starts to notify clinics even if baseline monitoring is not clinic protocol.

Q: If there is a cycle with both egg freezing for preservation and embryo freezing for < 12 months, how do we classify cycle type?
The cycle is considered an "IVF cycle" (with delayed transfer) and not a "banking / fertility preservation cycle" whether the "freeze all" involves eggs, embryos or a combination.

Q: What's the difference in new report between doing a cycle with an intended transfer vs. doing a "banking" cycle and knowing you're not going to have a transfer. Per the new report, you get a negative result for one but not the other?
The difference is the intent of the cycle to achieve a pregnancy in the near future (<12 months) versus the intent to preserve fertility for the more distant future. It is reasonable to expect to be able to report an outcome for the cycle start for delayed transfer within the planned reporting timeframe.

Q: If a patient returns > 365 days after a primary cycle for embryo banking, in the following year, would this then become a secondary outcome (FET)?
Fertility preservation are not correctly categorized as "subsequent" transfer cycles. They are their own category. These cycles are relatively rare and are not expected to make up a large proportion of a clinic's cycles. We do not currently plan to report the outcome of these cycles on a per clinic basis because we expect the denominator to be low. We will collect the outcomes. If these cycles become increasingly common, it is likely that they will be added to the Clinic Summary Report.

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Q: If would be helpful to get a mock example of the end of year report? This will help us educate our patients on this new report. Can we get written break down of these new fields?
This question has been answered above.

Q: Will SART ever distinguish in their outcome report, CCS vs. non CCS cycles?

The current plan is that PGS and PGD outcomes will be able to be viewed by application of a filter. At present, we do not plan to differentiate between PGS methods (FISH, CGH microarray, SNP microarray, PCR, sequencing etc.)

Q: This way of handling PGS encourages doctors to refuse to treat older patients. The older they are, the less chance they have a normal embryo.
The age of the patient decreases the chance of the primary success metric (live birth per stimulation cycle) whether or not PGS is performed. This is the reason that the outcome reports (national and Clinic Summary Report) are stratified by age. It has been contended by some that PGS may be used to increase the likelihood of live birth in some older women. Clinics and laboratories proficient at embryo biopsy and karyotype may be significantly incentivized to perform PGS on older patients by our handling of reporting.

Q: Is it possible to see a sample report?
The report has not been finalized because of the intricacies and details described above. We expect to get substantially more input and have more detailed discussions before a "mock up" would approximate the final report. Expect that the report should be close to finalization with a realistic "mock up" by this fall. We expect to be able to present this to the SART membership at ASRM.

Q: Have they made the SART data entry more efficient? I spend a lot of the time waiting for the next input and/or screen, or having to re-enter data when it freezes.
This may be related to your connection speed, browser, computer etc. Please contact support@sartcors.com if you think this is not on your end.

Q: How do we get in touch w/speaker post talk
The best way to provide input or get further details is to contact me by email at kjd@embryo.net

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Q: As of now, the gestational carrier needs to be entered in SART. We have a couple that is using an egg donor that was only available in January. We needed to cryo her eggs for a future cycle when they will be thawed and fertilized and replaced in a GC. How is that entered?
This should be entered as a donor egg banking cycle. We hope to begin collecting these fields in the very near future. Currently, there is no way to input.

Q: How will the cycles be "linked" in the system?
The cycles will be linked by selection of the appropriate retrieval dates in the thaw cycles.

Q: Cycle starts unreported or outcome unreported for short-term banking
The term "short-term" banking is discouraged because it is confused with banking for the purpose of fertility preservation. It is best to consider these cycles as "regular IVF cycles" with a delayed transfer. Like all IVF (non fertility preservation) cycles. These will be shown on the Clinic Summary Report. It is important to clarify that all cycles (including fertility preservation and research cycles) are reported by programs to SART and CDC. Fertility preservation and research cycles approved in advance by SART are "excluded" from the CSR.

Q: When will the CSR report template be available for review?
This question was answered above.

Q: Please address how gestational carrier cycle data will be collected going forward, or the plans for this.
These cycles are collected as any IVF cycle is with the difference being the designation of the pregnancy carrier. These cycles will be included with other IVF cycles in the default report with specific outcomes viewed by application of filter.

Q: What would be the maximum unit dose for a minimal stim cycle?
This question was answered above.

Q: Can you repeat the rules for primary and secondary outcomes in the subsequent year? If a delayed transfer cycle occurs in 2014, and two frozen transfers occur in 2015, both of those outcomes will be collected for 2014 data?
The 2014 cycle will be reported in 2015 for the first ("primary") transfer and the second ("subsequent") transfer. No cycle will be reported in 2014 unless a transfer is done in 2014 or it is determined that no delayed transfer will ever take place (e.g. lack of euploid embryos).

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Q: During injectable FET cycles, we use injections as times. During reporting, is the minimal stimulation the correct box to check now?
This question was answered above.

Q: We do many frozen embryo transfers more than two years after the embryos are frozen. Why is this a problem for NASS? It constantly asks us to double check the freezing date. It takes a couple years to complete a pregnancy and weaning.
The soft edits are set up to minimize input error. I believe this is an edit that CDC has removed. Please contact support@sartcors.com

Q: How do you enter a cycle using egg donor and GC when the couple are male?
This question has been answered above.

Q: What about male same sex couples?
This question has been answered above.

Q: How does the clinic summary report look for 2014? An example/template?
This question has been answered above.

Q: Will GC cycles be clinic specific or pooled?
These will be reported both pooled (National Report) and clinic specific (CSR) via application of a filter.

Q: Will the CDC conduct their own validation visits separate from SART?
SART views validation as an essential function. Although previously SART has performed these visits in conjunction with CDC, SART will select clinics for validation and perform these visits independently. We will try to coordinate with CDC when possible, however, some clinics may receive validation visits by both entities.

Q: In a PGS cycle with all aneuploid embryos and nothing to transfer...why is this a clinic negative since nothing was transferred NOT referring to not being pregnant, basically, why is a clinic being penalized for not transferring any embryos due to there not being any euploid embryos to transfer?
The purpose of reporting failed attempts at IVF is not to "penalize" a clinic. The purpose of the report is to help a patient predict the likelihood of success within a clinic should they choose to undertake a cycle. Failure to obtain success can be a result of patient factors, clinical factors or laboratory factors. The purpose of PGS is to aid in selection of embryos. If no euploid embryos are obtained, the cycle will fail

whether or not PGS is performed. It is possible that application of PGS in appropriate patients by skilled professionals may improve outcomes by enhancing embryo selection.

I will also play devil's advocate here. Lack of euploid embryos might be related to clinical issues (poor stimulation selection / management or poor retrieval techniques), laboratory issues (problems with ICSI technique, extended culture, biopsy technique) or even testing issues (false positive results).

Some have suggested that the primary outcome metric should be live birth per embryo transfer. There are many good reasons that this should not be the case. Perhaps the most important reason is that the Wyden Law spells out clearly that the Clinic Summary Report should convey the number of pregnancies resulting in live birth divided by the number of stimulation or monitoring cycles. It is required by law to include those cycles that do not result in euploid embryos in the denominator of the primary outcome statistic.

Q: How is prospective reporting enforced? Will prospective reporting be indicated on summary report?
The percentage of cycles prospectively reported will be indicated on the CSR. The CDC has expressed intention to do this as well. Prospective reporting outliers will be warned and / or selected for validation visits. Failure to remediate might ultimately result in forfeit of SART membership.

Q: Will SART be collecting data on FROZEN donor oocytes?
This question was answered above.

Q: What about data on FROZEN oocytes from women who had fertility preservation a few years ago, and are returning to conceive w/ their banked oocytes?
This question was answered above.

Q: For centers who split fresh donor VORs in order to allow patients to conserve costs do both ETs count?
Yes, both ET's would count. The clinic can explain the financial benefits to splitting while helping the patients understand the outcome statistics. We may consider a filter for split cycles for a "click to view" report item.

Q: I have a question about reporting on a delayed cycle. Since the primary and secondary cycles will be linked would we give a new cycle number to the secondary cycle? Or would it be linked to the primary cycle and use the same cycle number?

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The cycles are linked, but a new number is assigned for each cycle.

Q: How will the new SART address cycles where donor embryos (not oocytes / eggs) are used? Will these be separated from frozen embryo transfer that use embryos created using donor oocytes from those using embryos created by one couple that later donated them to another infertile couple? What allowances are being made so that this data is accurately recorded?

This is an excellent question. I see no reason that these cycles should not be able to be viewed distinctly from other types of egg donation. We could do this as a filter in the egg donation/ subsequent transfer.