

# SRBT WEBINAR

## SART Registry Update

**Presenter:**

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Chairman of the SART Registry

**Moderator:**

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President SRBT

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# Hosts

**SRBT**

Sue Gitlin, Ph.D., SRBT  
Education Committee Chair



**CRYOPORT**

Shannon Curiel, Business  
Development Manager,  
Cryoport



# Learning Objectives



After attending this webinar, the participant will be able to:

1. Discuss the history and goals of the CDC and SART ART registries
2. Discuss the changes in the ART outcomes report planned for 2014 cycles
3. Explain the changes in ART data collection necessary to implement accurate reporting for cycles with “delayed” embryo transfer
4. Interpret the reporting of fertility preservation cycles

# Kevin Doody, MD



- Chairman of the SART Registry
- He and his wife, Kathy, direct the Center for Assisted Reproduction in Bedford, Texas
- Dr. Doody received his Medical Degree and completed his residency at Baylor College of Medicine in Houston
- He completed his fellowship training from University of Texas Southwestern Medical Center and is board certified in Obstetrics and Gynecology along with the subspecialty board certification in Reproductive Endocrinology and Infertility.

# SART Registry Update

Kevin Doody MD, HCLD

SART Registry Chair

# Changes

- Data collection
- Clinic summary report

# Changes in Data Collection and Reporting

- Purpose / goal
  - Keep pace with changes in clinical practice
  - Comply with the ART data collection and reporting requirements of the Fertility Clinic Success Rate and Certification Act (FCSRCA) aka Wyden Law
- Input from membership has been essential

# FCSRCA - Background

- Consumer protection legislation - 1992
- Defined “assisted reproductive technology”
  - All treatments or procedures which include the handling of human oocytes or embryos
- Defined data reporting mechanism
  - Reporting to Secretary of Department of Health and Human Services through the Centers for Disease Control and Prevention



# FCSRCA - Background

- Defined the pregnancy success rate metric
  - “by dividing the number of pregnancies which result in live births by the number of ovarian stimulation procedures attempted by such program”
- Also defined a second success rate metric
  - “the live birth per successful oocyte retrieval”
- Lastly indicates that additional success rate definitions be developed in consultation with appropriate consumer and professional organizations (e.g. ASRM / SART)

# FCSRCA - Background

- Rules / regulations (administrative law) describing the details of who shall report, the reporting system and the process for reporting by each clinic are published by CDC in the Federal Register initially in draft versions. Final rules are published after solicited comments to the draft version are reviewed.

# Federal Register Publications

- Draft Aug 26, 1997
  - SART in conjunction with CDC made a number of revisions to the reporting process shortly after publication
- Draft Sept 3, 1999
- Final Notice Sept 1, 2001
- Notice Feb 5, 2004 and Feb 1, 2005

# Federal Register – September 2001

- Who reports
  - ART program is defined as a legal entity practicing under state law, recognizable to the consumer
  - Can be an individual physician or a group of physicians who practice together and share resources and liability
- Reporting deadline
  - January 15 of the year 2 years subsequent to the reporting year
  - SART in conjunction with CDC may change the deadline if needed

# Federal Register – September 2001

- Prospective reporting anticipated
  - Clinics will be provided at least 90 days notice of this requirement
- External validation of reported data
  - CDC contracted with SART to perform
  - Note – SART participation in validation efforts was removed from the contract for 2013

# Federal Register – September 2001

- Describes data to be reported including the data items and definitions
  - Embryo banking cycle
    - Cycle initiated with the intent of cryopreserving all fertilized embryos for later use
    - Does not apply to cycles initiated with the intent to transfer embryos but for which all embryos were cryopreserved regardless of the reason
  - Egg freezing not included
  - Minimal stimulation not included
  - In vitro maturation not included

# Federal Register – September 2001

- Describes the content of published report
  - National component
  - Clinic specific component
- Pregnancy success rate defined
  - Pregnancy per all ovarian stimulation or monitoring procedures
  - Live birth per stimulation or monitoring
  - Live birth per oocyte retrieval procedures
  - Live birth per embryo transfer procedures

# Federal Register – February 2005

- Describes change in the data collection contractor
  - Web-based data reporting system developed by Westat called the National ART Surveillance System (NASS)
  - Deadline for reporting moved to December 15 of the year following the reporting year
  - Clarifies that all collection of information must be approved by the Office of Management and Budget under the terms of the Paperwork Reduction Act of 1995



# Data Collection Updates

- Synchronization of definitions with CDC (NASS variables)
- Minor modifications
  - e.g. definition of diminished ovarian reserve
- Addition of new data fields
  - Donor and autologous egg freezing
  - Egg / embryo banking details expanded
  - IVM
  - Minimal stimulation (SART not CDC)
- Deletion of some data fields felt to be of lesser value

# Changes in CSR

- Necessary due to recent changes in clinical practice
  - Delayed transfer is becoming more common and must be distinguished from true “fertility preservation”
  - Many clinics offer both “lower-cost” and “premium” ART options and would like to distinguish these different outcomes to the consumers of fertility services
  - Egg freezing is no longer “experimental” and is being offered commercially by clinics

# Changes in CSR

- Prospective reporting percentage will be clearly shown
- Natural cycles, minimal stimulation and IVM will be included in the default report, but filters will allow views of these cycles independently as well as a view of the report with these cycles removed
- Outcomes for autologous frozen embryo transfer cycles will be reported per thaw rather than per transfer
- Outcomes for egg donation will be by cycle start rather than per transfer
- Labels for autologous non-donor cycles will change from “fresh” and “frozen” to “primary” and “subsequent” to allow linkage of delayed embryo transfers to cycle starts

# Egg / Embryo “Freeze all” Cycles

- Fertility preservation (banking)
- Short-term autologous delayed transfer (cryo all with intent to use within 12 months of cycle start)
  - PGD / PGS
  - Endometrial receptivity concerns
  - Risk of OHSS
  - Inability to obtain sperm
  - Planned multiple cycles (egg / embryo accumulation)
  - Other
- Donor egg banking

# Delayed Embryo Transfer / Short-term Egg / Embryo Banking (Autologous cycles)

- Recognized need to distinguish between this and true “fertility preservation”
  - Outcomes from “delayed transfer / short term banking” are available in a reasonable time-frame and should be included in the CSR
  - Fertility preservation outcomes cannot reasonably be included in the CSR

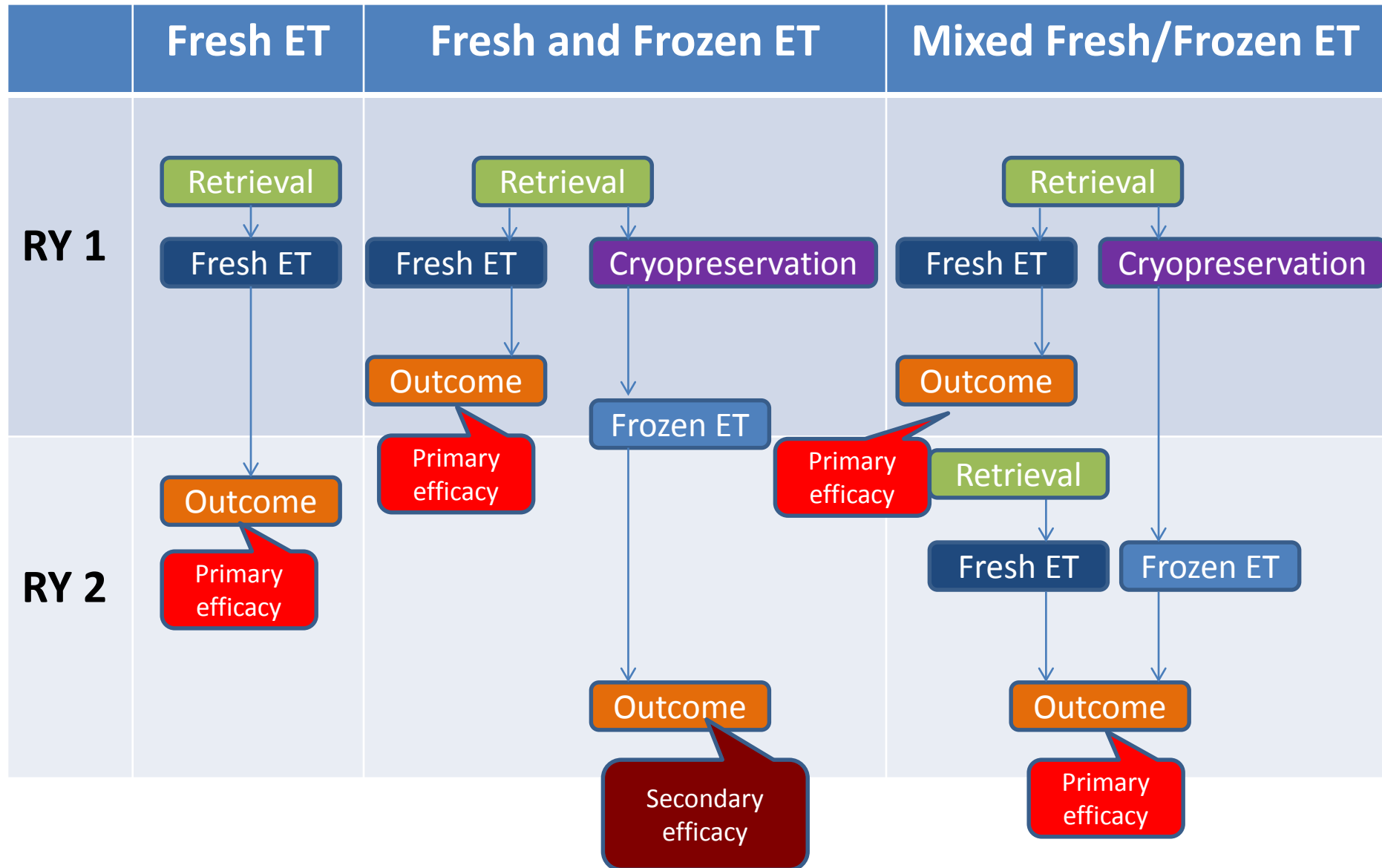
# Delayed Transfer – Key Elements

- All cycle starts are included in the denominator of the outcome report
- Delayed transfer can be intended at cycle start or decided at any point prior to transfer
- The outcome of the first embryo transfer following stimulation will be included in the numerator of the outcome statistic
  - This transfer can occur within the year of the cycle start or the following year if within 12 months of cycle start
  - The outcome will be reported in the year of cycle start if possible
  - If the transfer is significantly delayed, the outcome of the cycle will in some cases be reported the year following the cycle start

# Delayed Transfer – Key Elements

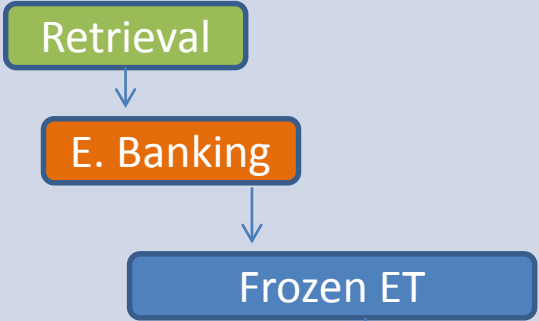
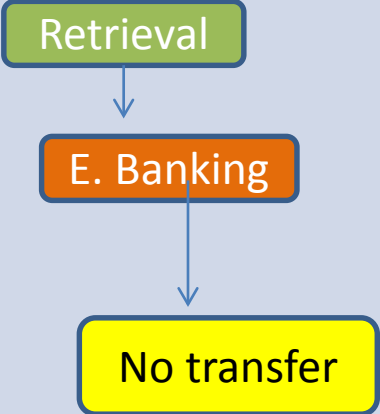
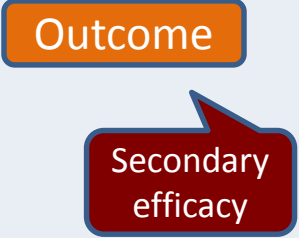
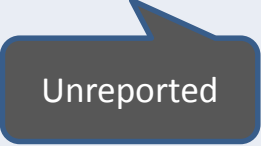
- Lack of embryos (or lack of genetically normal embryos following PGS/PGD) available for transfer will result in a negative outcome for the cycle
  - This should be reported during the year that lack of available embryos is determined
- Lack of embryo transfer in the year of the cycle start or within 12 months of cycle start will result in a negative outcome for the cycle
  - This negative outcome will be reported in the year following the cycle start

# Current Report





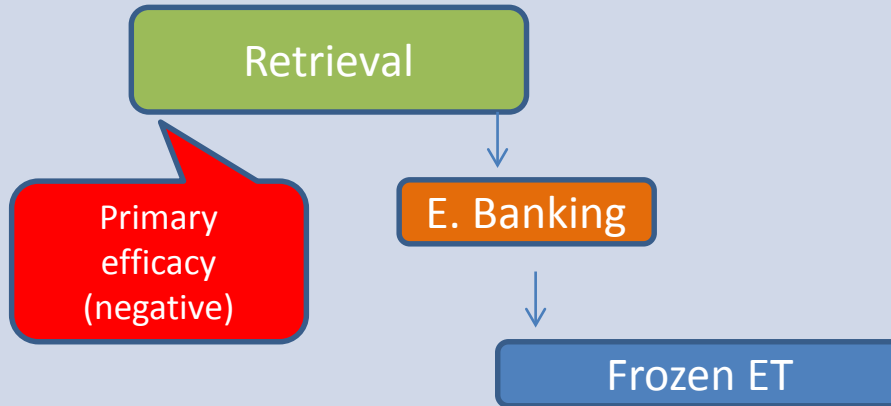
# Intentional Delayed Transfer – Current Report

	Short-term E. Banking with deferred transfer	Short-term E. Banking (no embryos available for transfer)
<b>RY 1</b>	 <pre>graph TD; Retrieval[Retrieval] --&gt; EB[E. Banking]; EB --&gt; FET[Frozen ET];</pre>	 <pre>graph TD; Retrieval[Retrieval] --&gt; EB[E. Banking]; EB --&gt; NoTransfer[No transfer];</pre>
<b>RY 2</b>	 <pre>graph TD; Outcome[Outcome] --&gt; SE[Secondary efficacy];</pre>	 <pre>graph TD; Unreported[Unreported];</pre>

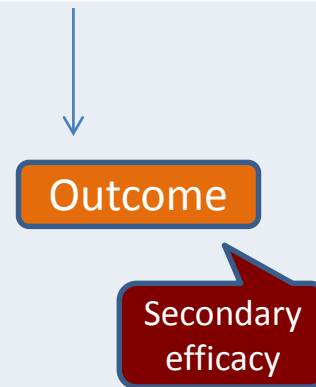
# Deferred Transfer to Prevent OHSS – Current Report

## Short-term E. Banking with indicated delayed transfer without prospective intent

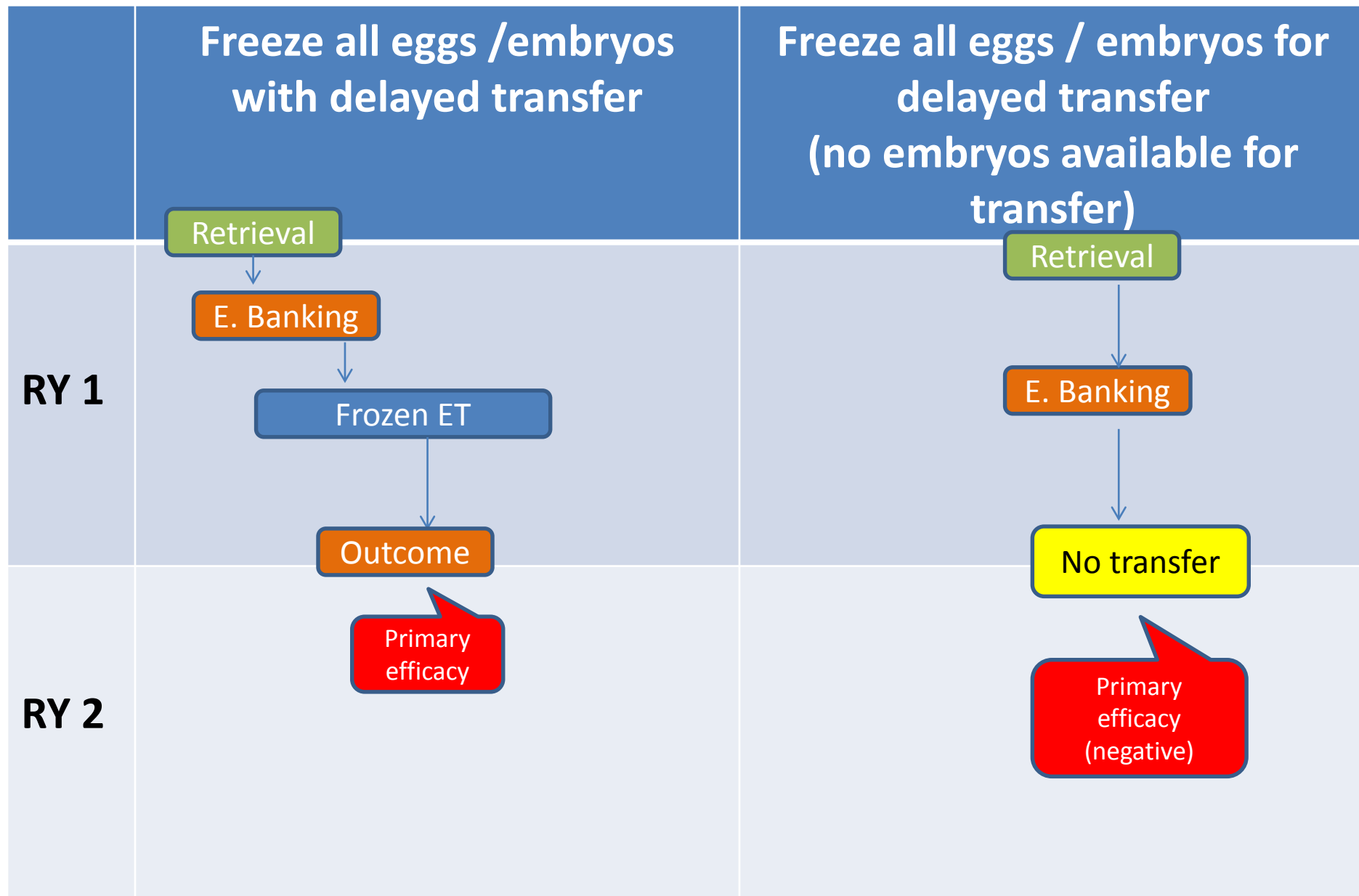
**RY 1**



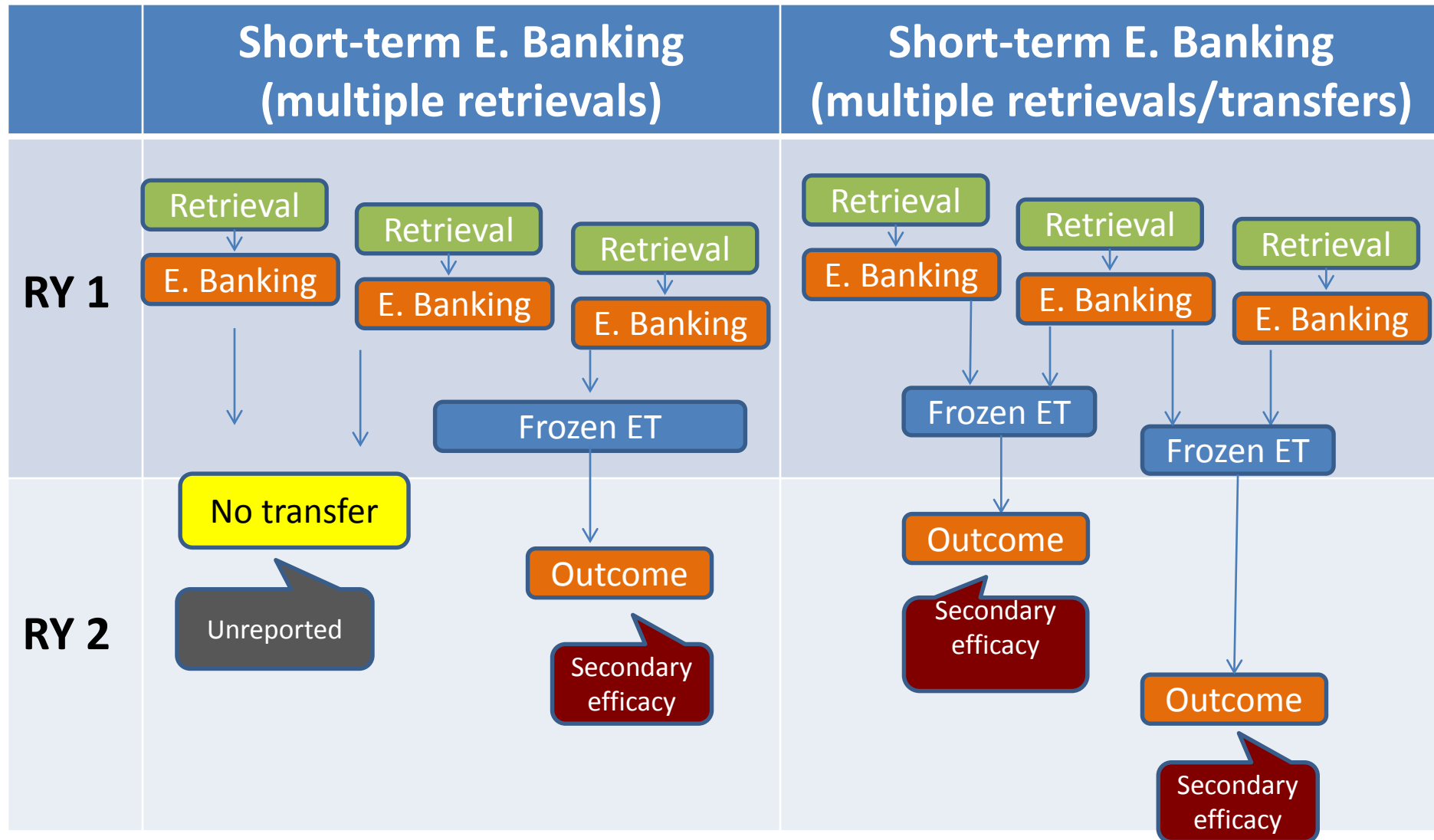
**RY 2**



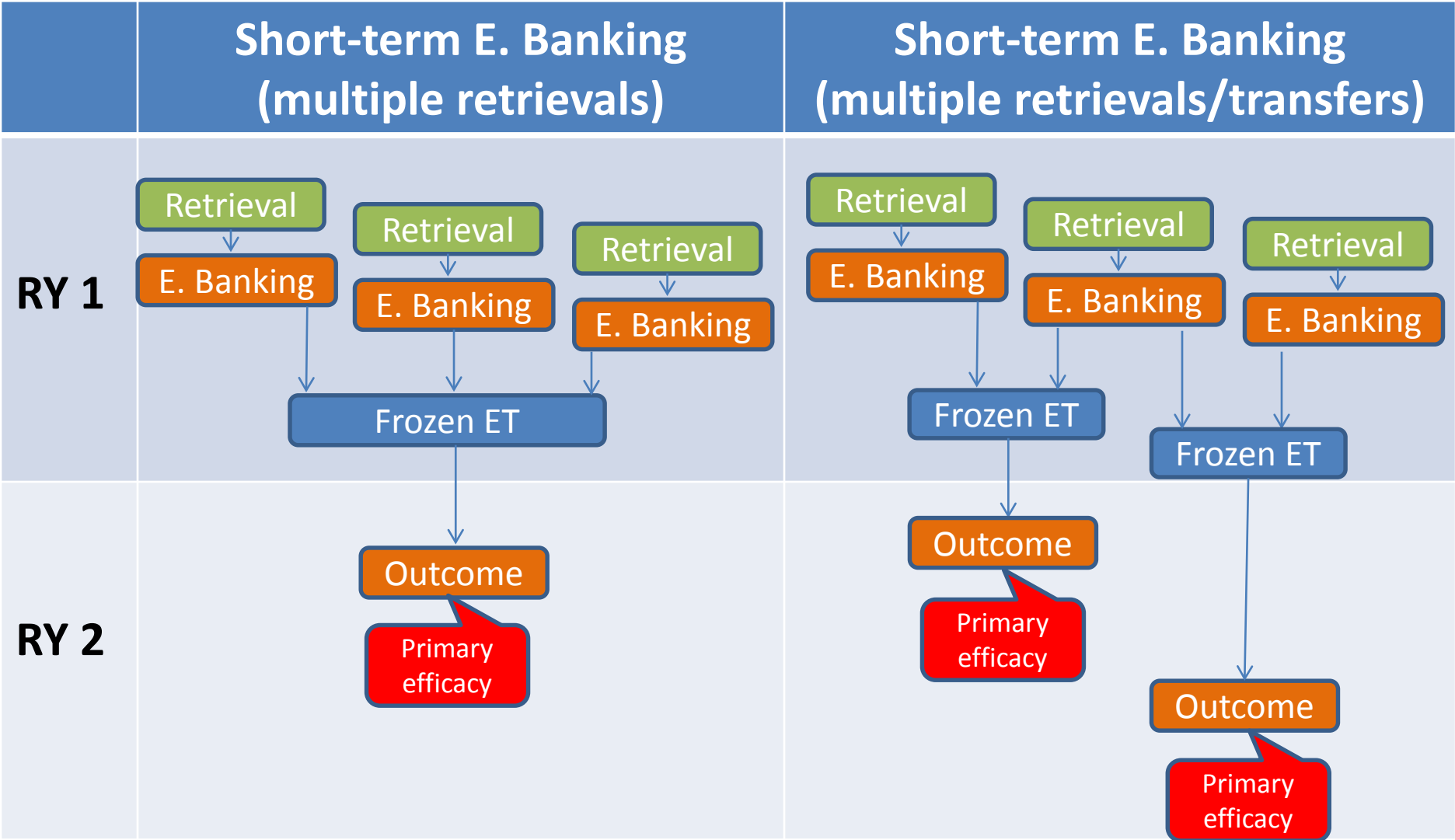
# Delayed Transfer – 2014 Report



# Delayed Transfer Multiple Cycles – Current Report



# Delayed Transfer Multiple Cycles– 2014 Report



# Delayed Transfer - Subtleties

- Some older patients (or younger patients with diminished ovarian reserve) may desire to bank eggs / embryos from multiple cycles for the purpose of having eggs / embryos for attempting additional later pregnancy (true fertility preservation)
  - It may be appropriate to do more than one cycle prior to primary transfer with different designations
    - Delayed transfer and
    - Fertility preservation

# Delayed Transfer - Subtleties

- When multiple cycles are done with different designations, the delayed transfer cycles will be included in the outcome statistic of the CSR and the cycles designated as “Fertility Preservation” will be excluded **unless**:
  - One or more embryos from that cycle are transferred within the reporting year or the year following
- If embryos are transferred within 12 months of cycle start for egg / embryo banking for “Fertility Preservation”, the transfer will be linked to the stimulation cycle and the outcome included in the CSR
  - We will treat as “delayed transfer”

# Delayed transfer subtleties - example

- Cycle start 12/31/2014
- Linked primary transfer allowed until 12/30/2015
- Finalization deadline for 2014 is 11/15/2015
- “Soft edit” sent at finalization to confirm plan to transfer within 365 days of cycle start
  - Clinic indicates “no”
    - Cycle will be reported in 2014 report
  - Clinic indicates “yes”
    - Cycle will be reported in 2015 report