SART: Professional Society Efforts in Parallel with Government Regulation

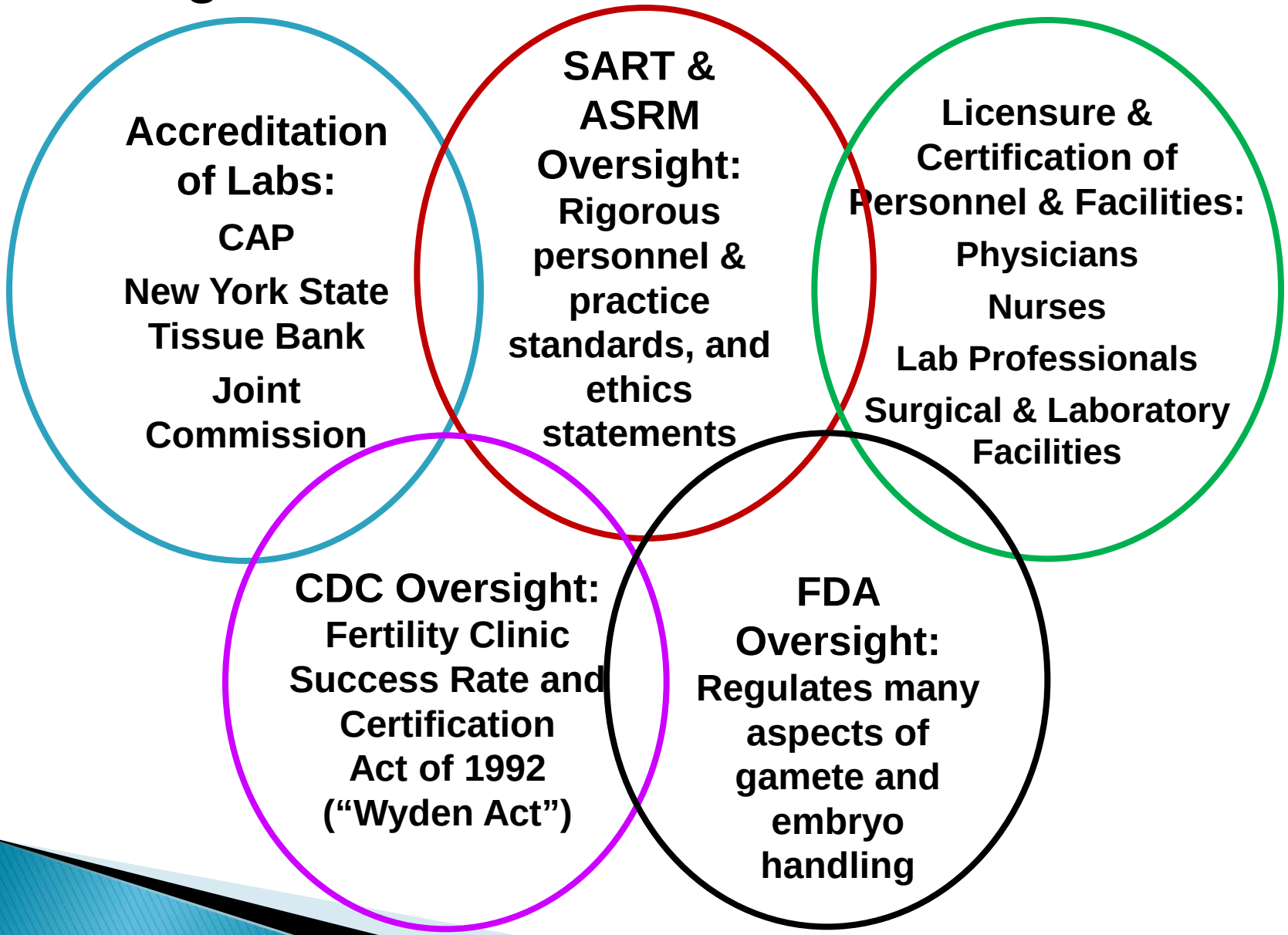
Assisted ReproductiveTechology: One of the most regulated fields

- State
  - State medical boards license physicians
- Federal
  - CDC- collects and publishes outcomes data
    - Performs annual audits of ~10% of programs
  - FDA- controls approval of drugs, biologic products and medical devices.
    - Screening/testing reproductive tissues
  - Center for Medicare and Medicaid Services (CMS)
    - Responsible for Clinical Laboratories Improvement Act (CLIA) to ensure quality of laboratory testing

Self-Governance

- Specialists certified by ABOG and ABU
  - Must complete residency and pass examination
  - Sub-specialty training in Reproductive Endocrinology and Infertility
- CME requirements
- Annual re-certification
- Periodic re-examination
- ASRM/College of American Pathologists (CAP) accreditation program for reproductive labs
- Practice Guidelines
- Committee Opinions
- Ethics Guidelines
- SART monitors member clinics for adherence to guidelines, data submission, qualifications of staff

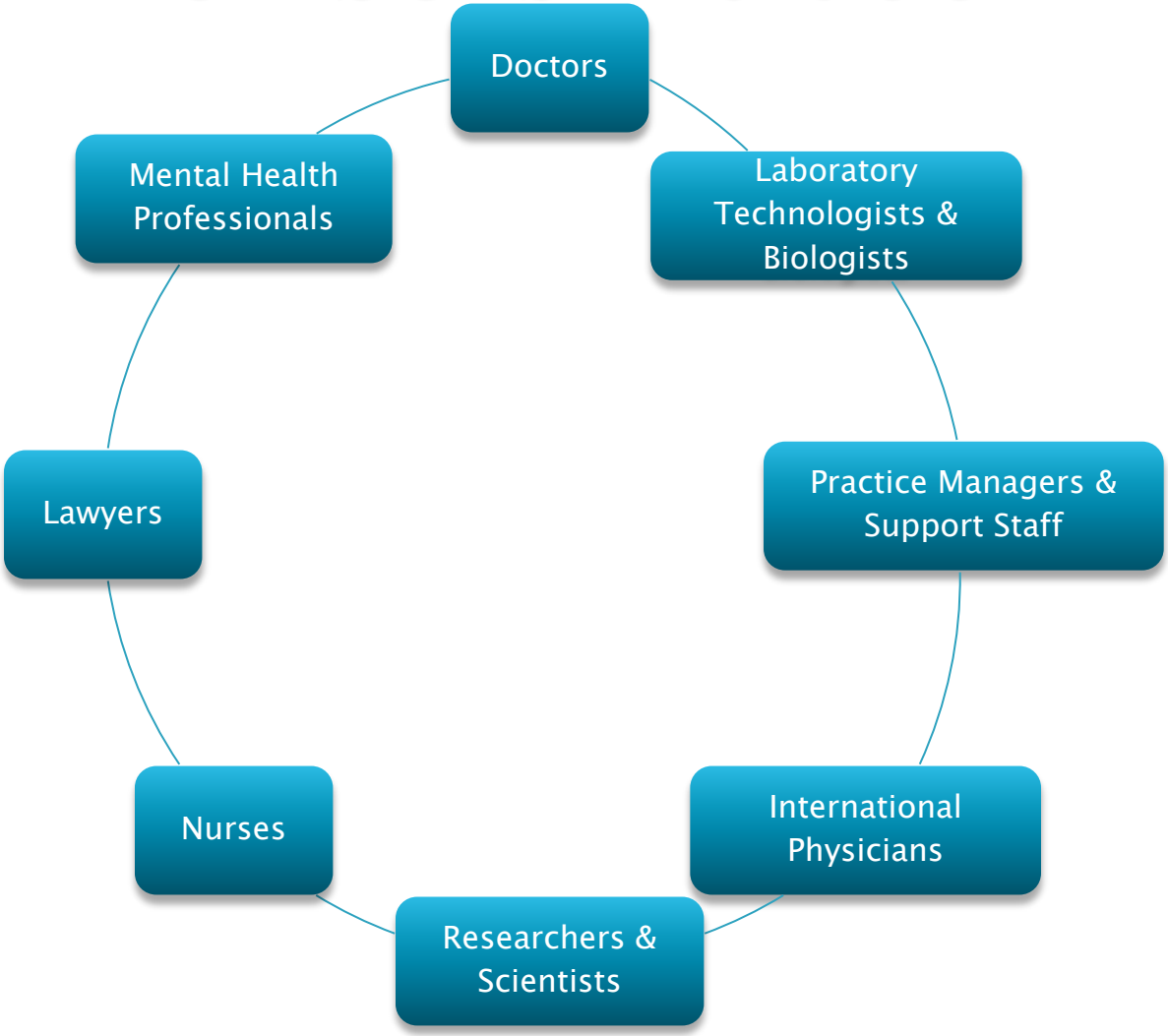
Regulation of ART in the United States



SART Mission Statement

- Founded 1985
- Affiliate Society of ASRM (1944)
- SART is the primary organization of professionals dedicated to the practice of assisted reproductive technologies (ART) in the United States. …The mission of our organization is to set and help maintain the standards for ART in an effort to better serve our members and our patients.

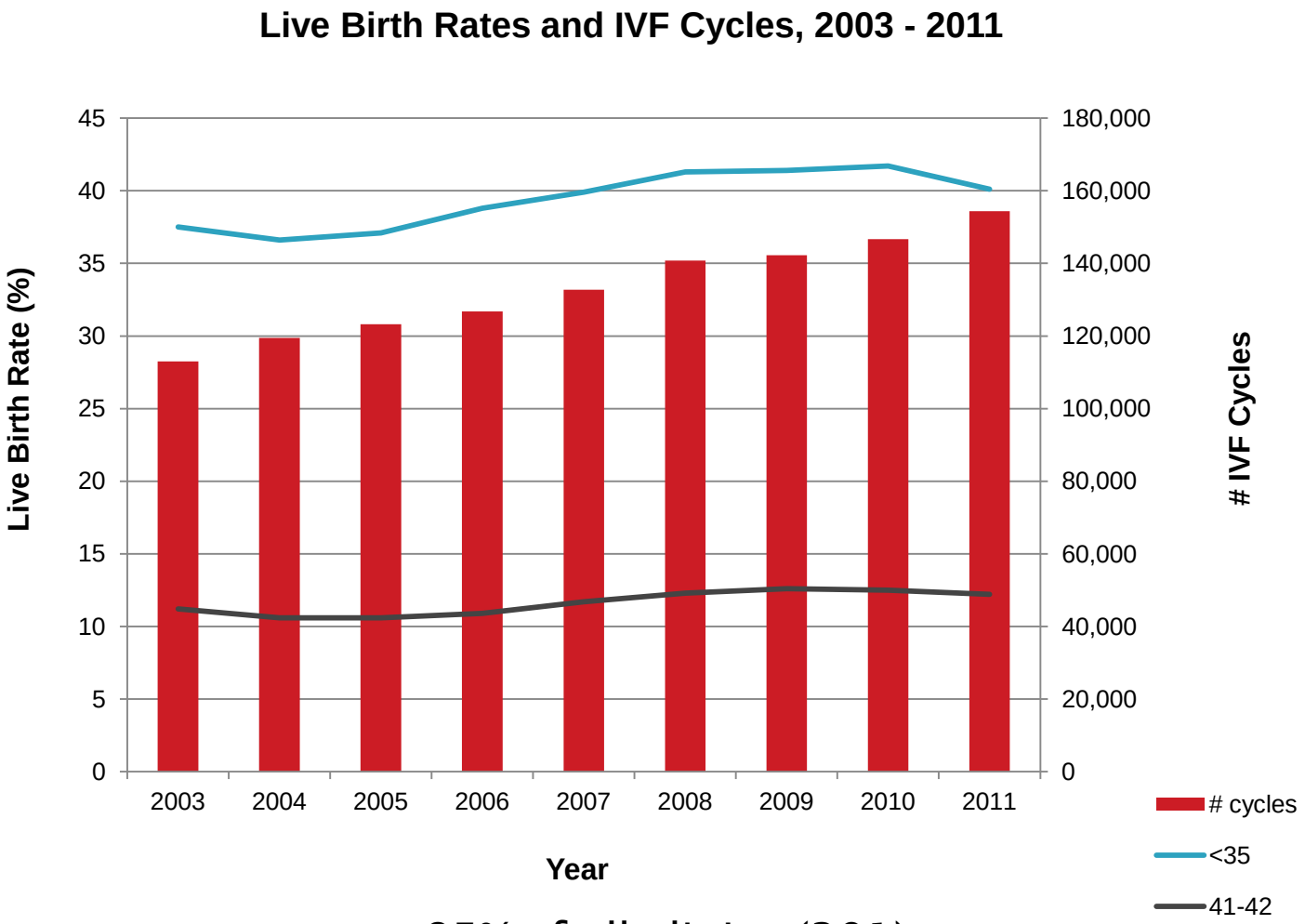
SART Members include:



Membership Requirements

- *The practice, medical and laboratory directors must be members of ASRM.*
- Medical Director, ABOG Board certified or eligible
- Lab Director CAP, CLIA or NYSTB certified
- Laboratory accreditation through CAP, Joint Commission, or NYSTB
- Perform at least 20 IVF cycles per year
- Submit data to SART CORS
- *Meet the currently published ASRM IVF Minimum Standards and adhere to all ASRM/SART published guidelines*
- must sign a statement that, if accepted as a member, the applicant will adhere to the ethical, practice, laboratory and advertising guidelines published by SART and ASRM
- Membership dues annually and per cycle

SART Programs



85% of all clinics (391)
>90% of all cycles
~1% of all US Births

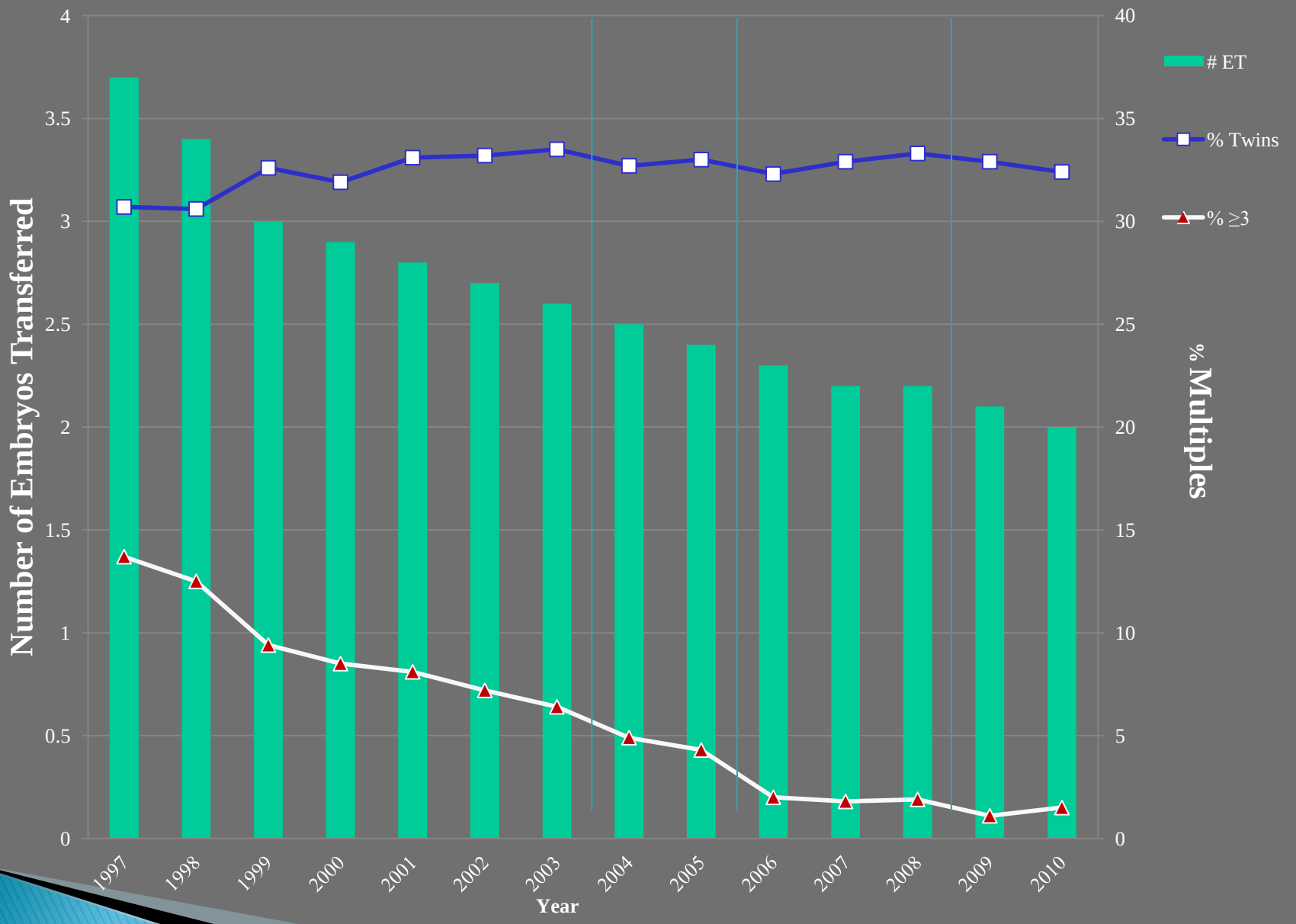
SART Sets The Highest Standards of Medical Practice

- Develops practice guidelines and committee opinions for members
- Ethics guidelines published by ASRM
- Research committee provides data for members
- Advertising committee Guidelines to keep clinics from false advertising
- QA committee monitors member programs for adherence to guidelines and issues warning letters
- Provides financial assistance and consultations for programs identified as “poor performers”
- Assists clinics to remain compliant with government regulations
  - FDA “approved” donor screening questionnaire
- Developed standardized consent forms
  - Risks of ART
  - Disposition of excess embryos

SART Generated PC Documents

- Intracytoplasmic sperm injection (ICSI) for non-male factor infertility
- Recommendations for practices utilizing gestational carriers
- Mature Oocyte Cryopreservation
- Guidelines for gamete and embryo donation
- Elective single-embryo transfer.
- Minimum Standards for Practices offering ART
- Criteria for number of embryos to transfer

Multiple Pregnancy Data; <35 Years of Age



ASRM Generated PC Documents

- Multiple gestation associated with infertility therapy
- Fertility Preservation in Patients Undergoing Gonadotoxic Therapy or Gonadectomy
- Informed consent and the use of gametes and embryos for research
- Donating embryos for human embryonic stem cell research
- Definition of experimental procedures

Definition of experimental procedures: A committee opinion

- Considered experimental until published medical evidence regarding their risks, safety and efficacy is sufficient to regard them as established medical practice. Relevant medical evidence can derive only from appropriately designed, peer-reviewed, published studies performed by several independent investigators, including a description of the materials and methods sufficient to assess their scientific validity and to allow independent verification.
- Should not be represented or marketed as established or routine medical practice.

ASRM practice committee Fertility Sterility 2013

Advertising Committee

- Adherence to advertising policies required as condition of membership
- Print, broadcast, verbal and electronic media
- Must comply with guidelines of the FTC
- Must be supported by verifiable data
  - Live birth data from SART
  - Cannot omit cycles
  - Includes denominator
- Review of all websites on an annual basis
- Investigates all complaints
- All requests for changes in advertising thus far have been complied with

Quality Assurance

- QA committee evaluates
  - Program performance relative to mean
    - Live Birth/cycle women <38
    - Triplet pregnancy rates
    - Excess mean # of embryos transferred
    - Any single transfer of excess # of embryos without clinical justification
  - First offense
    - Warning letters sent requiring response and plan
  - Second offense
    - Probation and mandatory evaluation/consultation
    - SART provides financial assistance
  - Third offense
    - Review by SART EC and possible loss of SART membership

Disciplinary Policy

- Termination of Membership
  - Receipt by the Executive Council of the written resignation of a member or his or her duly authorized attorney-in-fact
  - The failure of a member to submit data to the IVF Statistical Registry for one year;
  - The failure of a member to pay dues, fines, or assessments for six months
  - Failure to conduct IVF (or ART) treatments for a two-year period of time;
  - Loss of laboratory accreditation
  - Loss of membership in ASRM
  - For Cause

For Cause

- Conviction of a felony or of any crime relating to or arising out of the practice of medicine, or involving moral turpitude.
- Loss of medical license
- Improper financial dealings or engaging in any activities which put personal financial consideration above the welfare of patients.
- Performance of unjustified medical or surgical treatment.
- Immoral, dishonorable, unethical, or unprofessional conduct.
- Failure or refusal to cooperate reasonably with an investigation by SART of a disciplinary matter.
- Participating in communications to the public which convey false, untrue, deceptive, or misleading information through statements, testimonials, photographs, graphics, or other means, or which omit material information without which the communication is deceptive.
- Failure to follow guidelines or policies established by SART/ ASRM.
- Failure to follow the standards of ethics of practice established by SART / ASRM.

Fertility Clinic Success Rate and Certification Act –"Wyden Act"

- 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
- SART already collecting data since 1985
  - SART awarded contract
  - Provided de-identified data to CDC

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

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Clinic Summary Report

All SART Member Clinics

Filter CSR

Treatment: All Treatment Types | Diagnosis: All Diagnoses | Year: 2011

Apply Filter | Clear Filter

Total Cycles: **154412**

Treatment Type	
IVF	>99%
GIFT	<1%
ZIFT	<1%

Procedure Frequency	
ICSI	66%
Unstimulated	1%
PGD	5%

Diagnosis Frequency			
Tubal Factor	6%	Male Factor	17%
Ovulatory Dysfunction	7%	Other Factor	8%
Diminished Ovarian Reserve	16%	Unknown Factor	12%
Endometriosis	4%	Multiple Female Factor	11%
Uterine Factor	1%	Female and Male Factor	18%

Fresh Embryos From Non-Donor Oocytes

	<35	35-37	38-40	41-42	>42
Number of cycles	39721	19930	20130	10277	6033
Percentage of cycles resulting in pregnancies	46.2	38.5	29.3	19.5	9.1
Percentage of cycles resulting in live births	40.1	31.9	21.6	12.2	4.2
Reliability Range	(39.7 - 40.6)	(31.2 - 32.5)	(21.0 - 22.2)	(11.5 - 12.8)	(3.7 - 4.7)
Percentage of retrievals resulting in live births	42.9	35.2	24.8	14.5	5.3
Percentage of transfers resulting in live births	46.3	38.4	27.5	16.6	6.5
Percentage of cycles with elective single embryo transfer	11.7	6.5	1.9	0.6	0.5
Percentage of cancellations	6.4	9.5	12.7	16.3	20.7
Implantation Rate	36.0	27.3	17.5	9.4	4.0
Average number of embryos transferred	1.9	2.1	2.5	3.0	3.1
Percentage of live births with twins	30.8	26.7	21.1	14.9	10.6
Percentage of live births with triplets or more	1.2	1.3	1.3	0.7	0

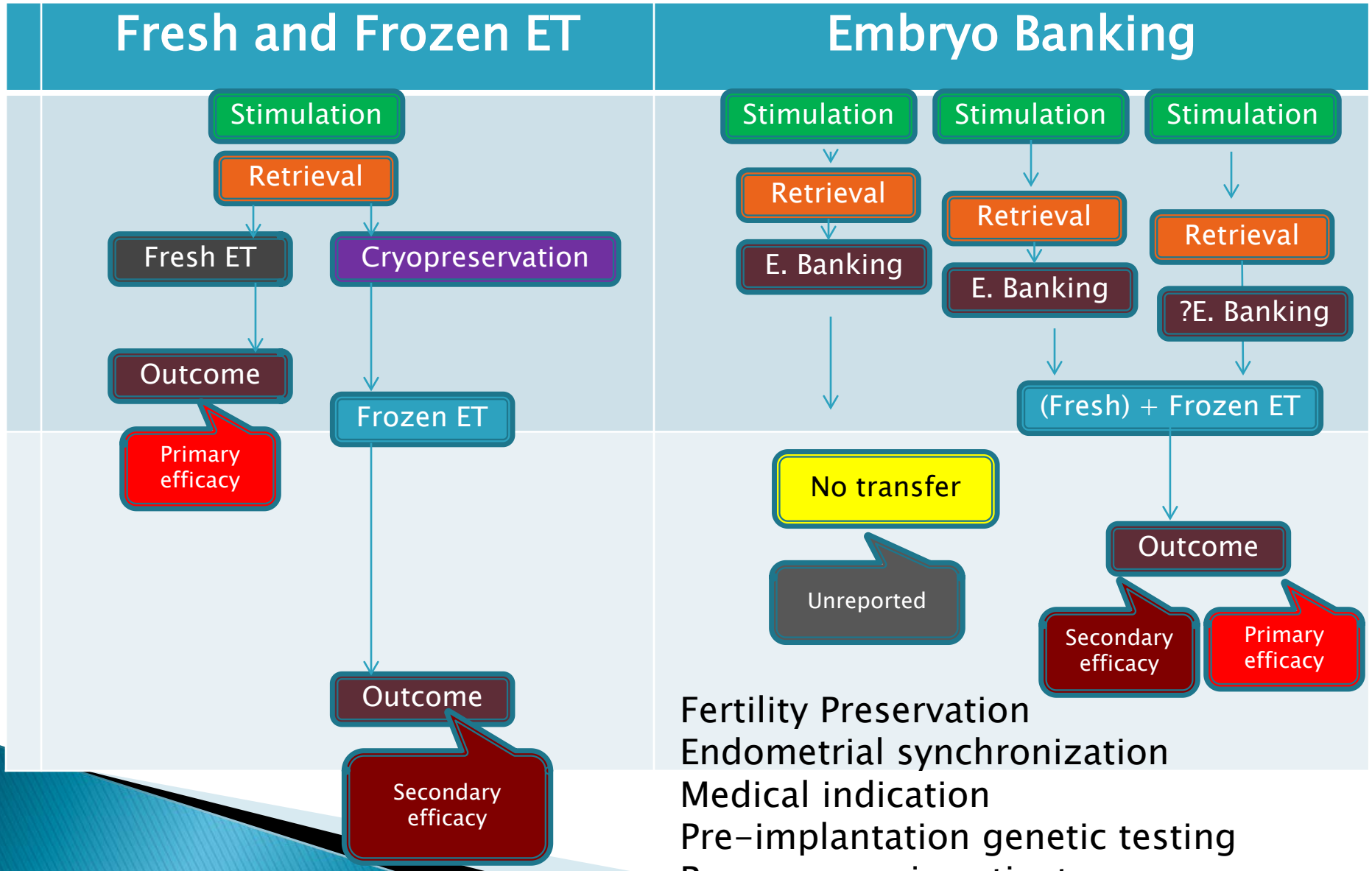
Thawed Embryos From Non-Donor Oocytes

	<35	35-37	38-40	41-42	>42
Number of Transfers	13480	6665	4956	1781	1284
Percentage of transfers resulting in live births	39.3	35.7	30.3	24.5	16.5
Average number of embryos transferred	1.9	1.8	1.9	2.0	2.1

ART Reporting Contract

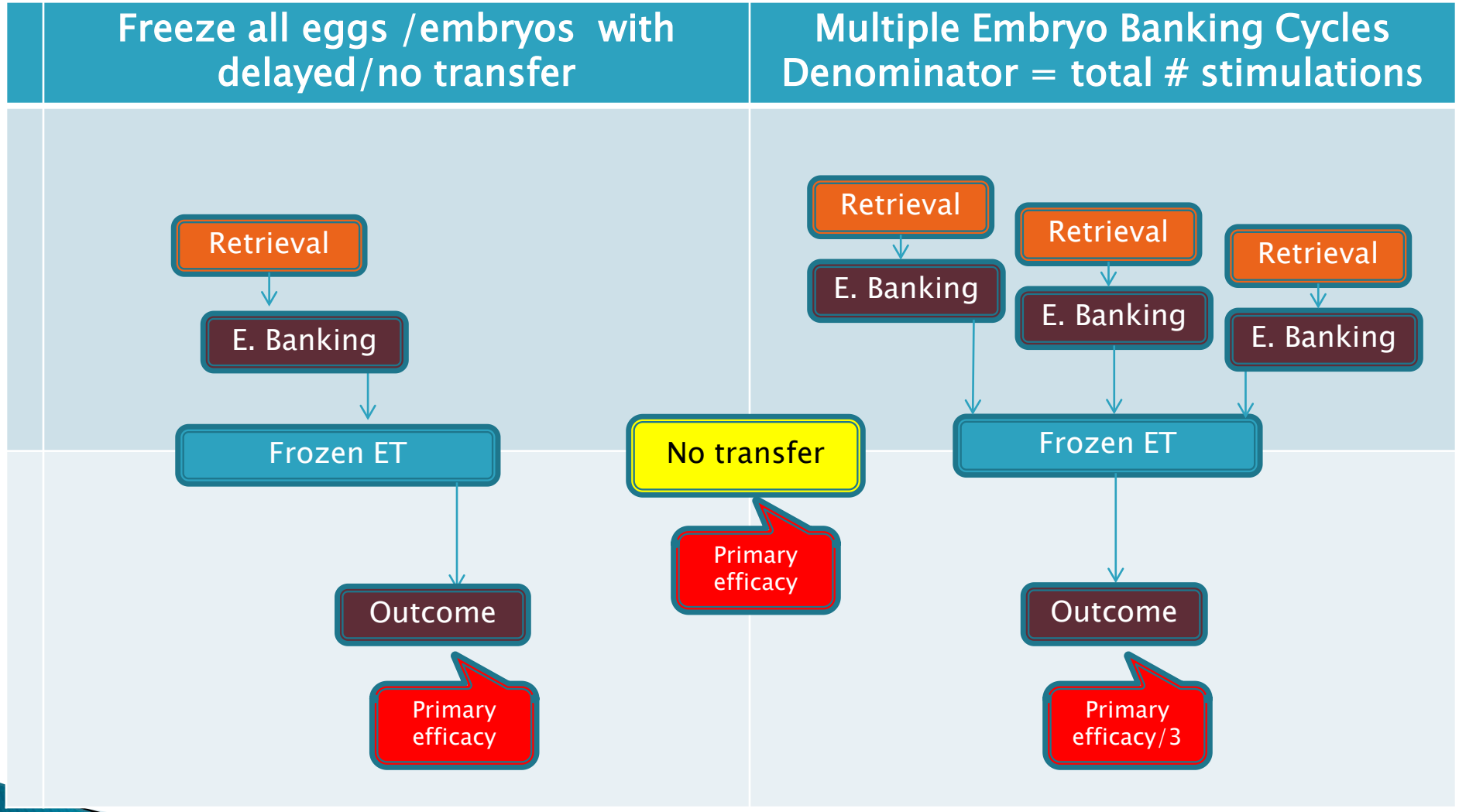
- Collection and reporting contract awarded to Westat in 2004
- SART assisted CDC and Westat in carrying out validation visits until 2012
- CDC modified contract to have SART perform QA in effort to reduce multiple pregnancy
- Changes in clinical practice recognized by SART
  - Necessitates changes in outcomes reporting
  - SART worked with CDC, in person meeting
  - Modifications agreed upon

Current Report



Fertility Preservation
Endometrial synchronization
Medical indication
Pre-implantation genetic testing
Poor prognosis patient

2014 Report


Freeze all eggs /embryos with delayed/no transfer
Multiple Embryo Banking Cycles Denominator = total # stimulations
Retrieval
E. Banking
Frozen ET
Outcome
Primary efficacy
No transfer
Primary efficacy
Retrieval
E. Banking
Retrieval
E. Banking
Retrieval
E. Banking
Frozen ET
Outcome
Primary efficacy/3

SART Efforts in Parallel With Government Agencies

- Self Regulation
  - Membership must be meaningful
  - Guidelines for practice
- Interaction with federal agencies
  - Cryopreservation of donor oocytes prior to the technology to do so efficiently
  - Changes in reporting to reflect current practice and provide for accurate outcomes data
- Regular and frequent interactions
  - NCOART (1996)
    - ASRM, SART, Resolve, AFA, CDC, FDA, AATB, ABA
    - Meets annually to discuss issues relevant to ART
  - CDC monthly conference calls and annual meeting