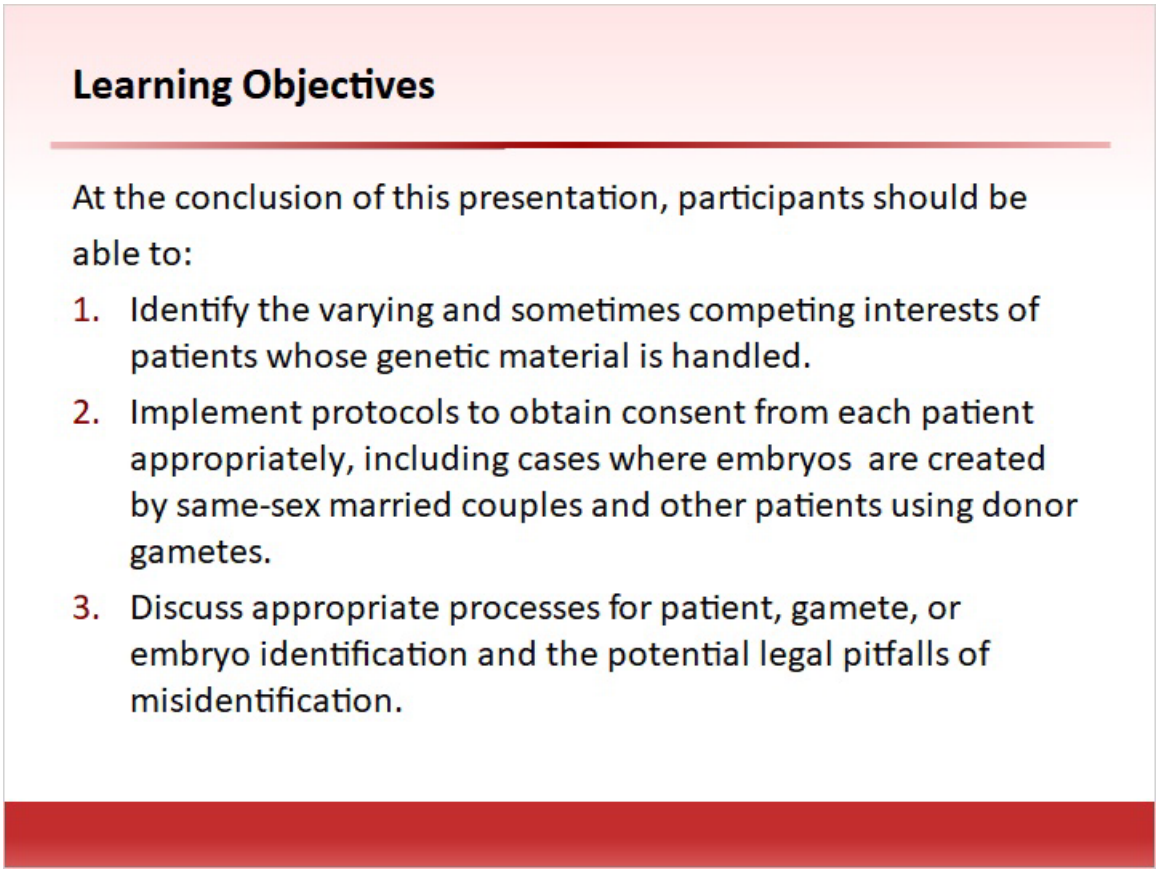
LABCC100 Lesson 40

1.1 Legal Aspects of Patient Interaction for the ART Laboratory

Notes:

Welcome to the American Society for Reproductive Medicine's eLearning modules. The subject of this presentation is Legal Aspects of Patient Interaction for the Assisted Reproductive Technology Laboratory.

1.2 Learning Objectives

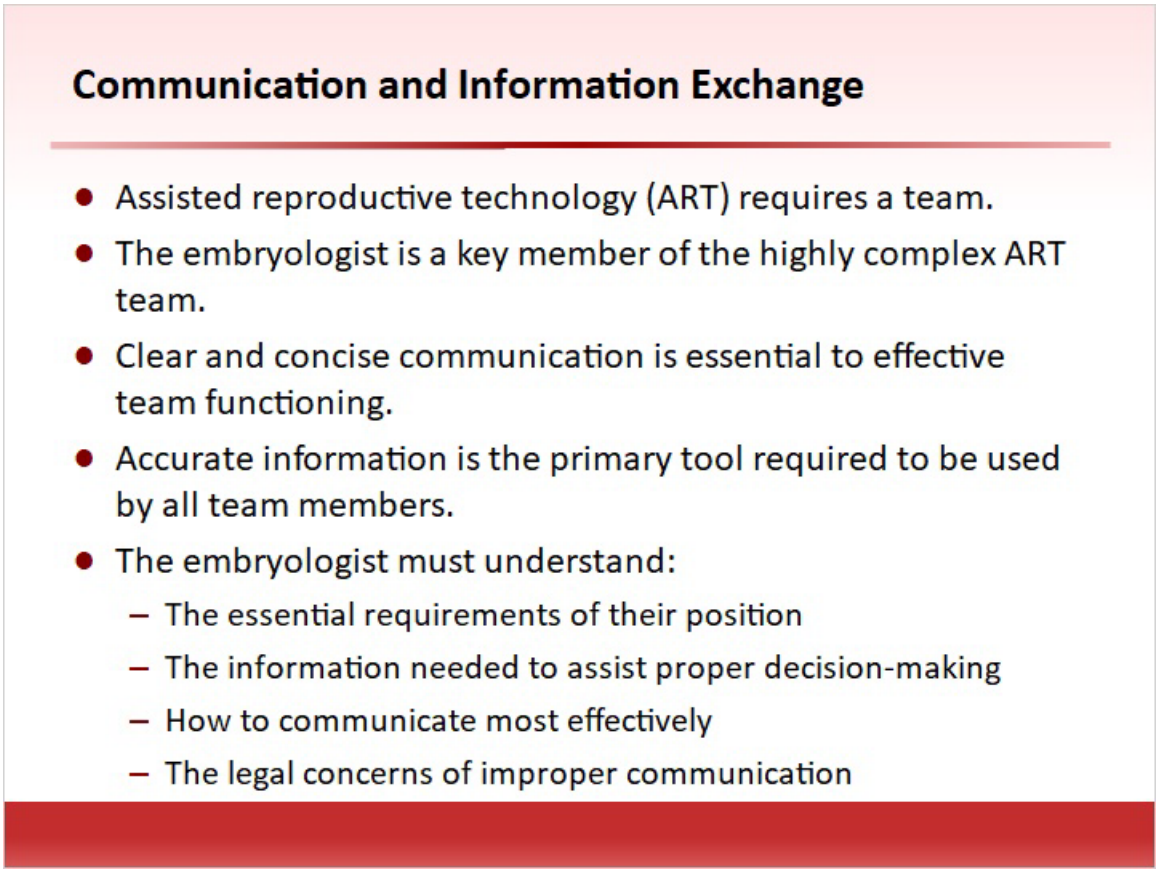


Notes:

At the conclusion of this presentation, participants should be able to:

1. Identify the varying and sometimes competing interests of patients whose genetic material is handled.
2. Implement protocols to obtain consent from each patient appropriately, including cases where embryos are created by same-sex married couples and other patients using donor gametes.
3. Discuss appropriate processes for patient, gamete, or embryo identification and the potential legal pitfalls of misidentification.

1.3 Communication and Information Exchange



Notes:

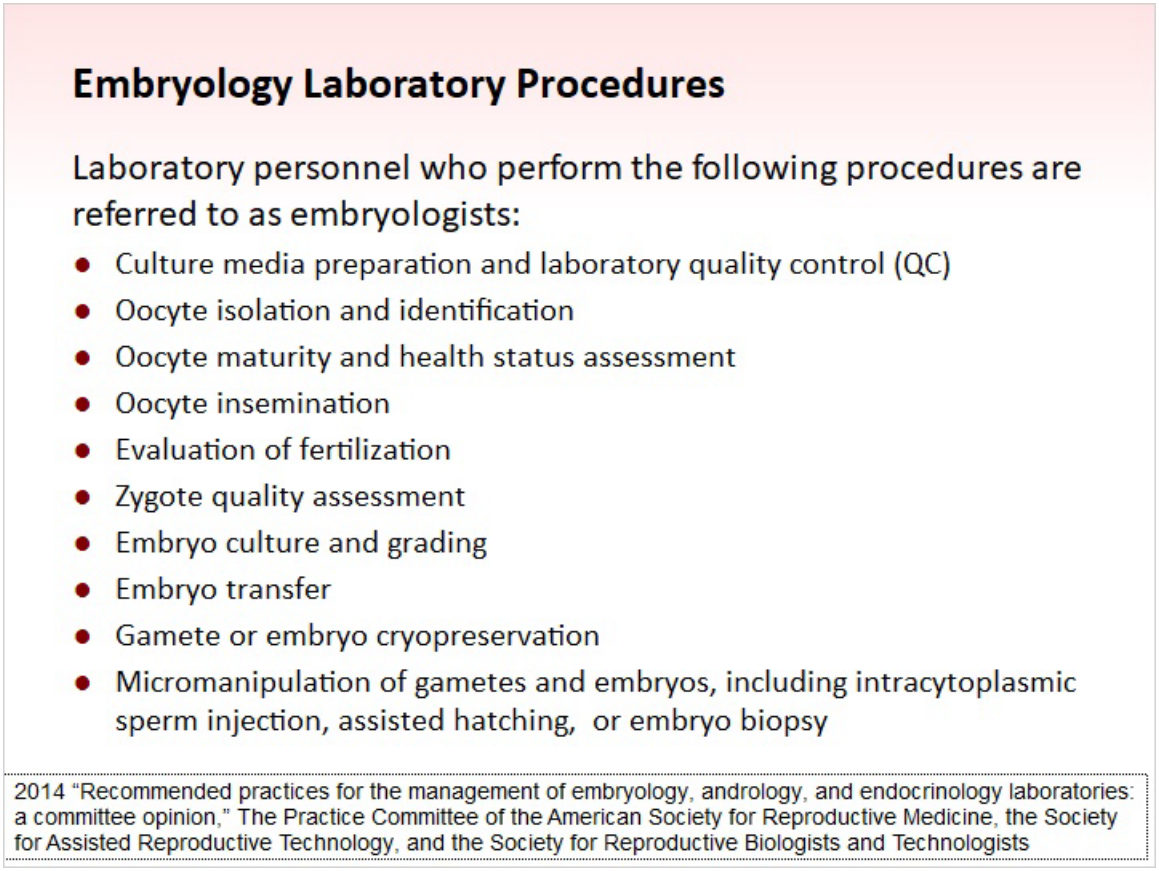
With hundreds of reproductive medicine centers and medical practices throughout the world, assisted reproductive technology teams come in many shapes and sizes. The numerous physicians, nurses, clinical and administrative support staff, embryologists, and laboratory personnel must coordinate many complex communications and procedures to be able to provide their patients with quality medical care. This coordination requires reliance upon adequate training, accurate communication, and appropriate information exchange.

No ART team is complete without a trained and skilled embryologist. The technical skill set of an embryologist contributes to the ART process and is essential to its completion.

However, in most settings, the embryologist is called on to contribute more than laboratory proficiency. Embryologists must also be adept at interpreting gamete and embryo qualities, development, and potential for pregnancy. This calls for hands-on skills, objective data-gathering expertise, insightful reasoning ability, and the capacity to share all of this with other ART members.

Communication is key to being a successful ART team member. The embryologist should be aware of all communication methods available to him or her in collecting and sharing accurate information. In order to gain this awareness, embryologists must understand what they are expected to "bring to the team," or in other words, their essential job requirements. In addition, the embryologist must learn what information the rest of the ART team needs from them in order to allow for making the best treatment decisions for each patient. Knowing *what* to share must then be followed by knowing *how* to share the information the embryologist holds. This includes understanding: 1) the embryologist's areas of responsibility in the patient care process, 2) the best methods to meet these responsibilities, and 3) the potential legal consequences of inadequately met expectations.

1.4 Embryology Laboratory Procedures



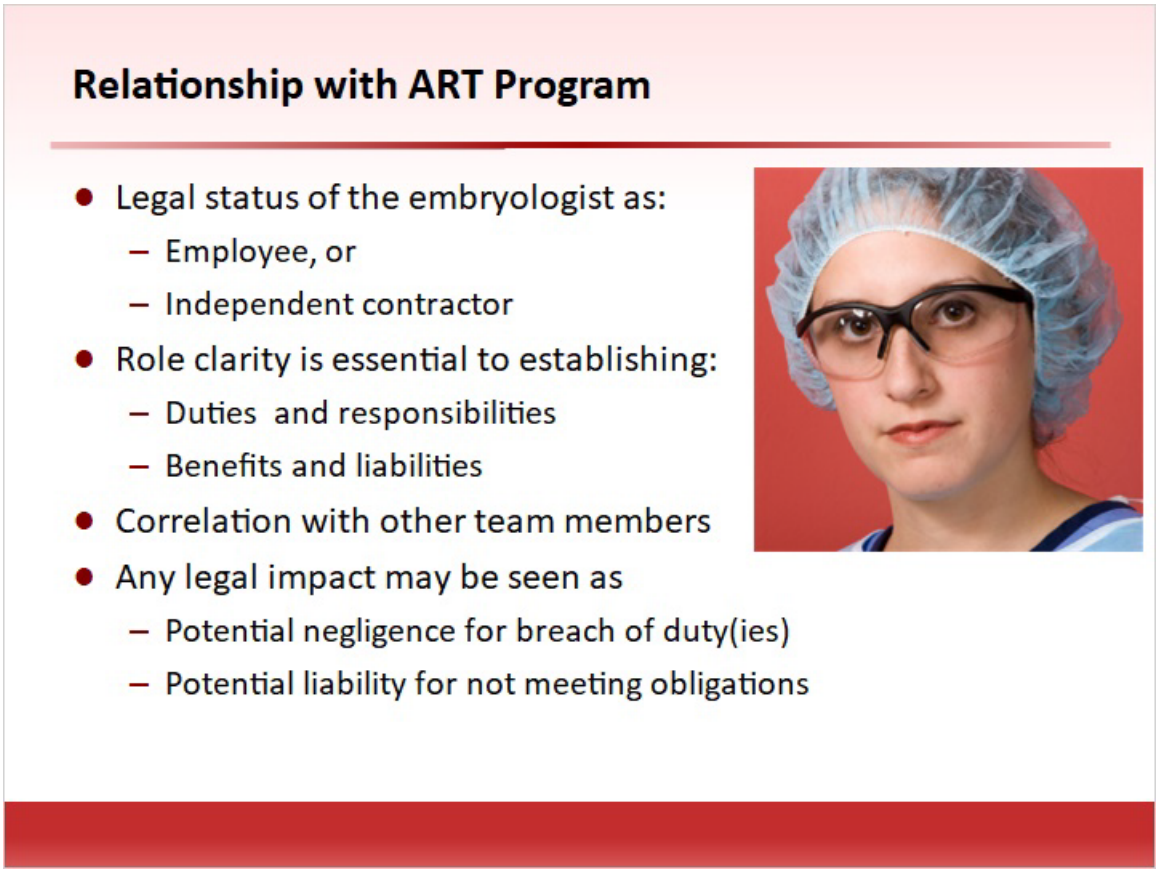
Notes:

The embryology procedures that compose the essential job functions of an embryologist include culture media preparation and laboratory quality control (QC); oocyte isolation and identification; oocyte maturity and health status assessment; oocyte insemination;

evaluation of fertilization; zygote quality assessment; embryo culture and grading; embryo transfer; gamete or embryo cryopreservation; and micromanipulation of gametes and embryos, including intracytoplasmic sperm injection, assisted hatching, or embryo biopsy. In addition, the embryologist must participate in all laboratory procedures that support patient safety and overall laboratory quality assurance.

It should be noted that these essential job functions are in addition to the professional requirements of educational training and competency documentation for embryologists and laboratory directors.

1.5 Relationship with ART Program



Notes:

As for any individual who holds a job in an organized entity, the embryologist acquires legal status through the means in which they come to work for an ART program. Benefits and responsibilities are conferred based upon that legal status. In practice, a program may either 1) employ the embryologist, or 2) contract with the embryologist to provide embryology services.

An “employee” designation means that the individual performs duties dictated or controlled by the program. The employee is trained for the work to be done and works for only one program. In addition, the program is responsible for paying all employee taxes for federal and state income taxes, Social Security, Medicare, and unemployment and workers’ compensation contributions, as well as providing all available employee benefits, including health insurance, retirement, vacation, etc.

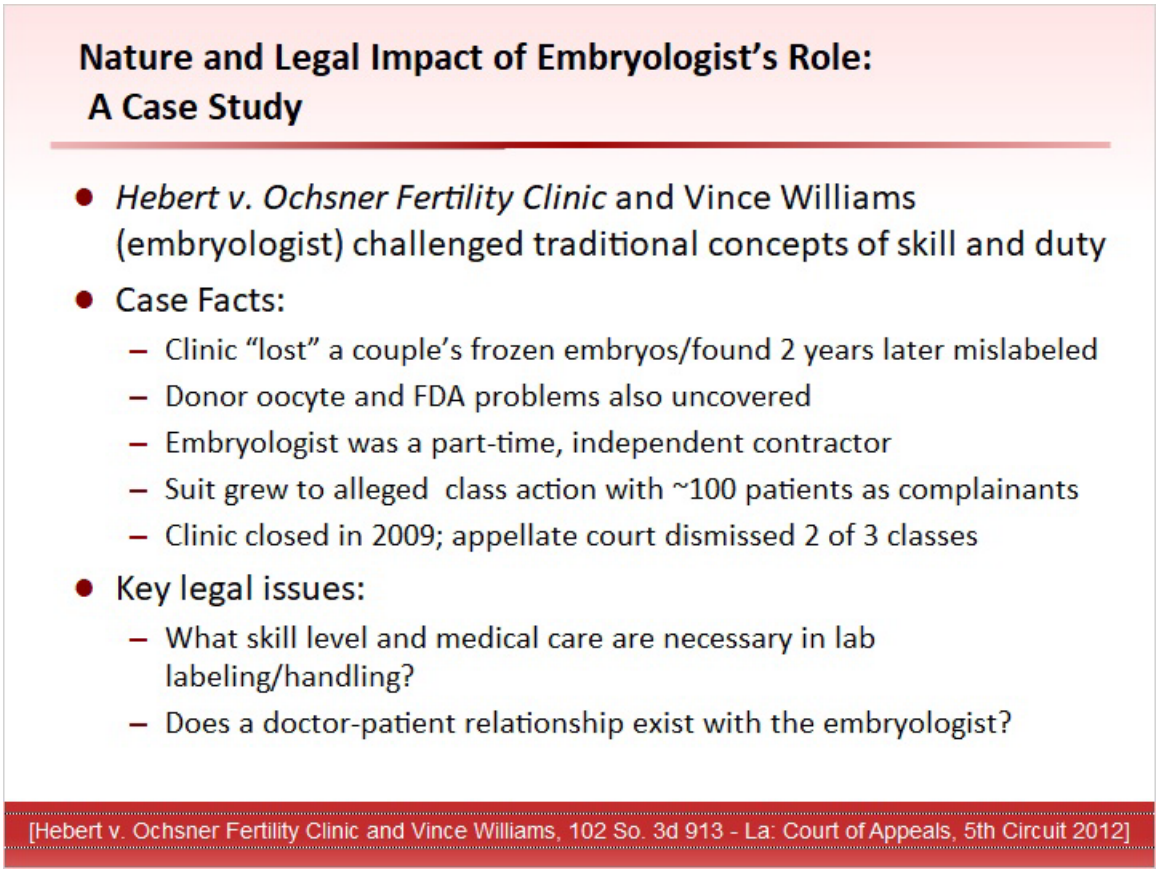
An “independent contractor” designation means that the individual is not relying on the program as the sole source of income, working at his or her pace as defined by an agreement, is not eligible for program-provided employee benefits, and retains a degree of control and independence. While the independent contractor is his or her own “boss,” the services provided must conform to the definitions of an oral or written contract and adhere to certain requirements, such as the laboratory’s policies and procedures. Most importantly, the independent contractor – not the program – is responsible for all tax liabilities.

Clarifying the status of the embryologist is essential to establishing who does what in the laboratory. Generally, independent contractors are not responsible for internal laboratory reporting procedures; however, they are usually held to the same performance standards (otherwise they would not be working there).

The embryologist’s position as either an employee or an independent contractor may delineate the amount of interaction they have with patients and other ART members. However, basic communication and recording roles in the program are generally the same, regardless of legal status. All embryologists are responsible for being competent in their embryology skill sets, and in following policies and procedures for documentation in all areas of laboratory processes.

While benefits such as employee benefits, preferential scheduling, and special internal duties (e.g., direct communication with staff and patients) may be reserved for employed embryologists, general legal principles place liability for individual acts on each person performing embryology duties. Responsibility for the performance of others in the laboratory is generally NOT extended to the independent contractor, unless such supervision is an explicit job requirement that is delineated in the contractor’s agreement with the program.

1.6 Nature and Legal Impact of Embryologist's Role



Notes:

Having delineated the embryologist's qualifications, competencies, and role, questions may arise as to WHY all of these matter? In a legal setting, credentials are necessary to assess situations where embryology performance may be in question. Further, credentials are always used to determine the appropriate standard of care in lawsuits that involve any level of embryology involvement in an alleged wrongdoing.

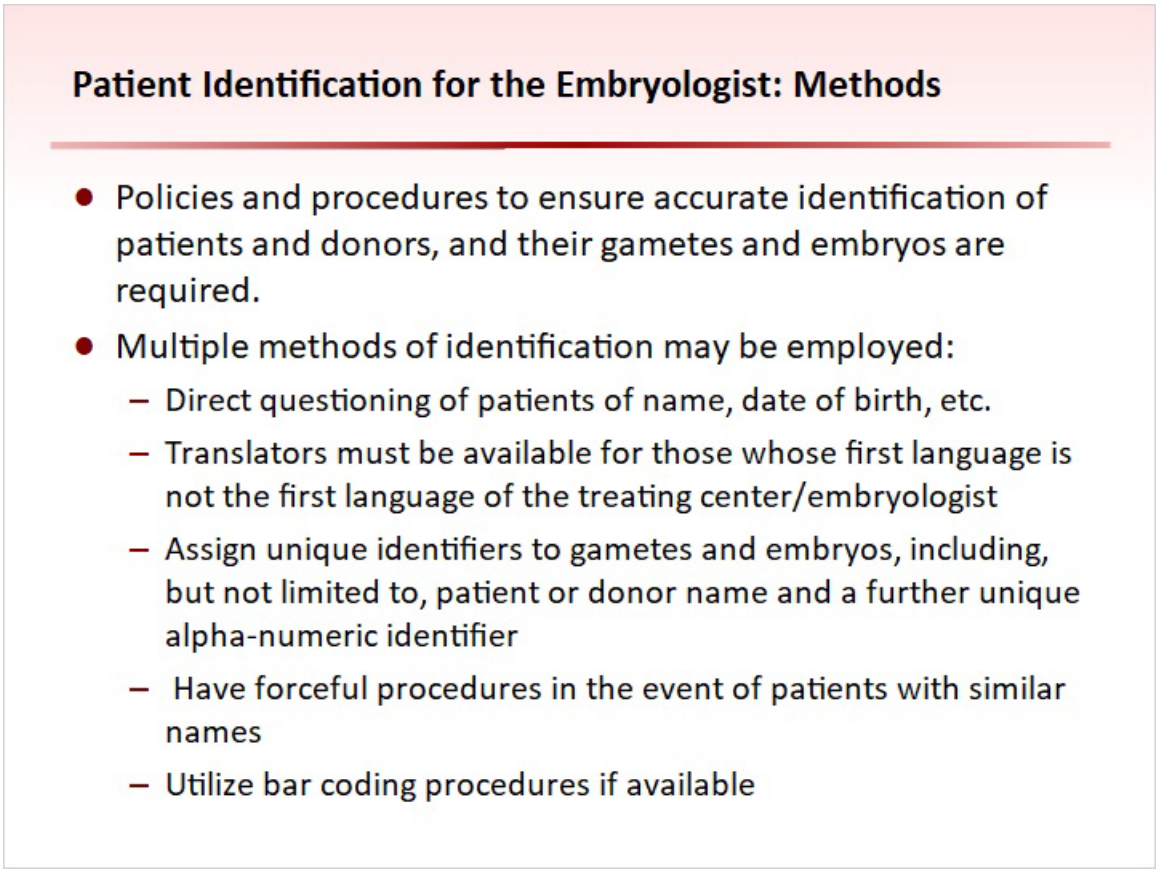
For example, the qualifications and role of the embryologist were central to the issues in the ~~ongoing~~ legal claims against Ochsner Fertility Clinic in Louisiana, which opened questions as to skill sets of embryologists and their explicit duty to patients.

What began as a single couple's claims for mislabeled frozen embryos grew as their counsel recruited additional patients with a variety of storage-related issues. As in many states, a malpractice claim requires an initial screening through a medical malpractice tribunal before it can proceed; thus the defendants argued that any suit without such preliminary procedure was "premature" and should be dismissed. The plaintiffs' expert testified that embryo labeling is not difficult and should be done with several patient identifiers (not just a lab number as had been done), that a high schooler or clerical staff

could perform these duties with direction, that cryopreservation was a byproduct of patient treatment as opposed to treatment itself, and finally that embryologists are required to have general liability and not malpractice insurance. The defendants' expert testified that a "treatment cycle" includes cryopreservation and labeling as an essential part of treatment. The trial court found for the plaintiffs on this issue, ruling that the, "mere act of labeling, storing, handling and/or transferring the eggs [sic] is not treatment-related" and that there was no need for expert testimony on the handling of embryos. In late 2010, the defendants lost their appeal on the question of medical malpractice. The class certification issues were largely dismissed and individual settlements that may have moved forward are generally not reported. Ironically, given Louisiana's unique status as the only state in the country to define an IVF preimplantation embryo as a "juridical person," the Ochsner court concluded that caring for those embryos is nonetheless not patient treatment. However, an earlier NY case allowed action against an embryologist. [Hebert v. Ochsner Fertility Clinic and Vince Williams, 102 So. 3d 913 - La: Court of Appeals, 5th Circuit 2012]

This is not the first case where an embryologist was held liable for professional actions, and is a clear reminder that your role on the ART team matters. In a 2007 sperm mix-up case that resulted in a couple giving birth to child not biologically related to the intended father, a NY court found that the embryologist was negligent, in part because he had held himself out to the patient "as a competent embryologist, competent in the fields of embryology, sperm collection and transfer." (Andrews v Keltz 2007 NY Slip Op 27139 [15 Misc 3d 940] March 7, 2007)

1.7 Patient Identification for the Embryologist: Methods



Notes:

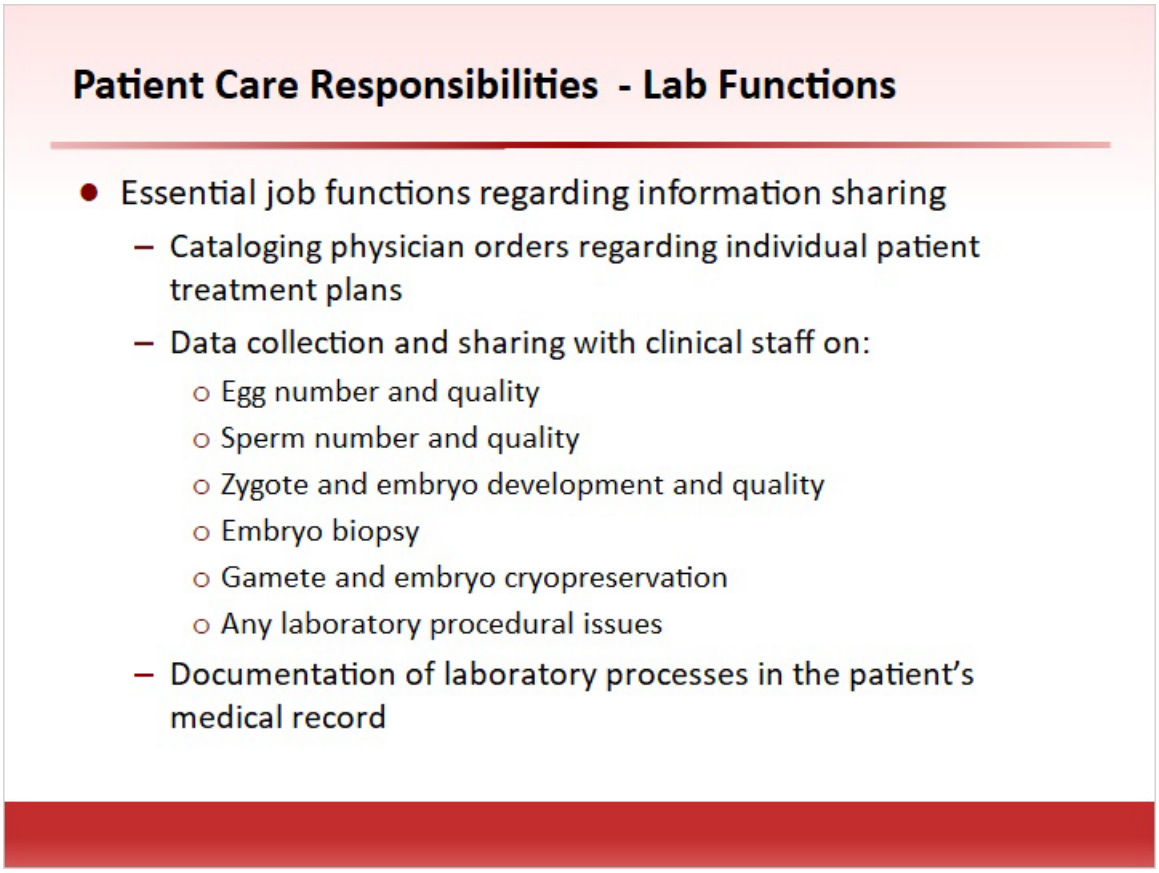
Methods of patient identification may vary according to the ART program; however, all programs must have adequate and clear policies and procedures in place that delineate the appropriate method for identifying patients and any of their laboratory specimens—whether it is blood, tissue, semen, oocytes, or embryos.

Most programs employ a system with inherent double-checks that include direct communication with the patient and review of standard identifications such as driver's license or passport, and assignment of unique identifiers to patients and their gametes and embryos. These unique identifiers are generally used on all written documentation as well. Translators must be available for those whose first language is not the first language of the treating center or embryologist. Newer, more high-tech solutions to identification are being adapted to the embryology laboratory. While still expensive, some ART programs have added a system of bar coding or fingerprint identification to the more common methods of identification.

Whatever method is employed, there must be strict enforcement of compliance with patient identification policies and procedures, particularly in the situation of two or

more patients that have the same or similar names.

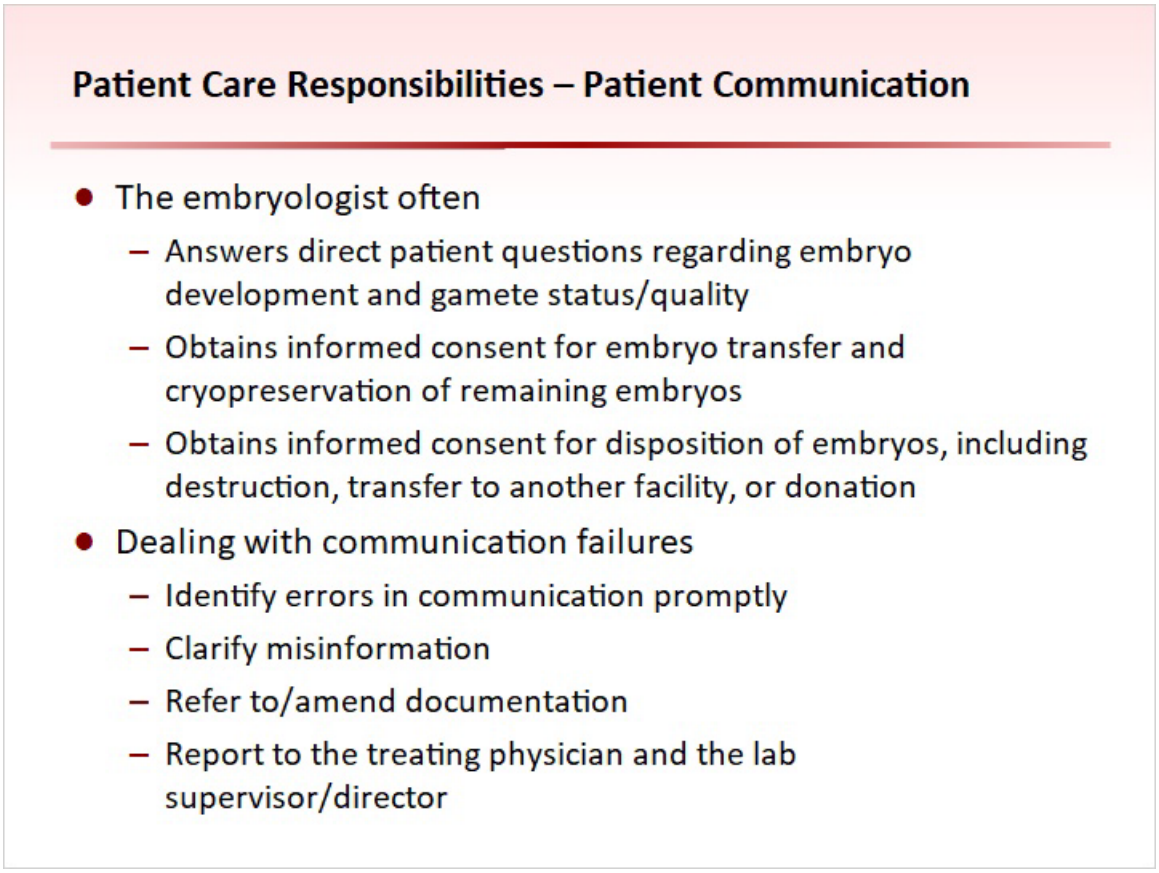
1.8 Patient Care Responsibilities - Lab Functions



Notes:

One of the essential job functions of the embryologist involves documentation and information sharing of key data. Cataloguing physician orders on individual patient treatment plans as well as all of the data involved in an in vitro fertilization cycle must be recorded accurately and in a timely manner. In addition, the embryologist must be able to synthesize and convey this information to the treating physician and the clinical staff so that appropriate decisions about patient care can be made.

1.9 Patient Care Responsibilities – Patient Communication

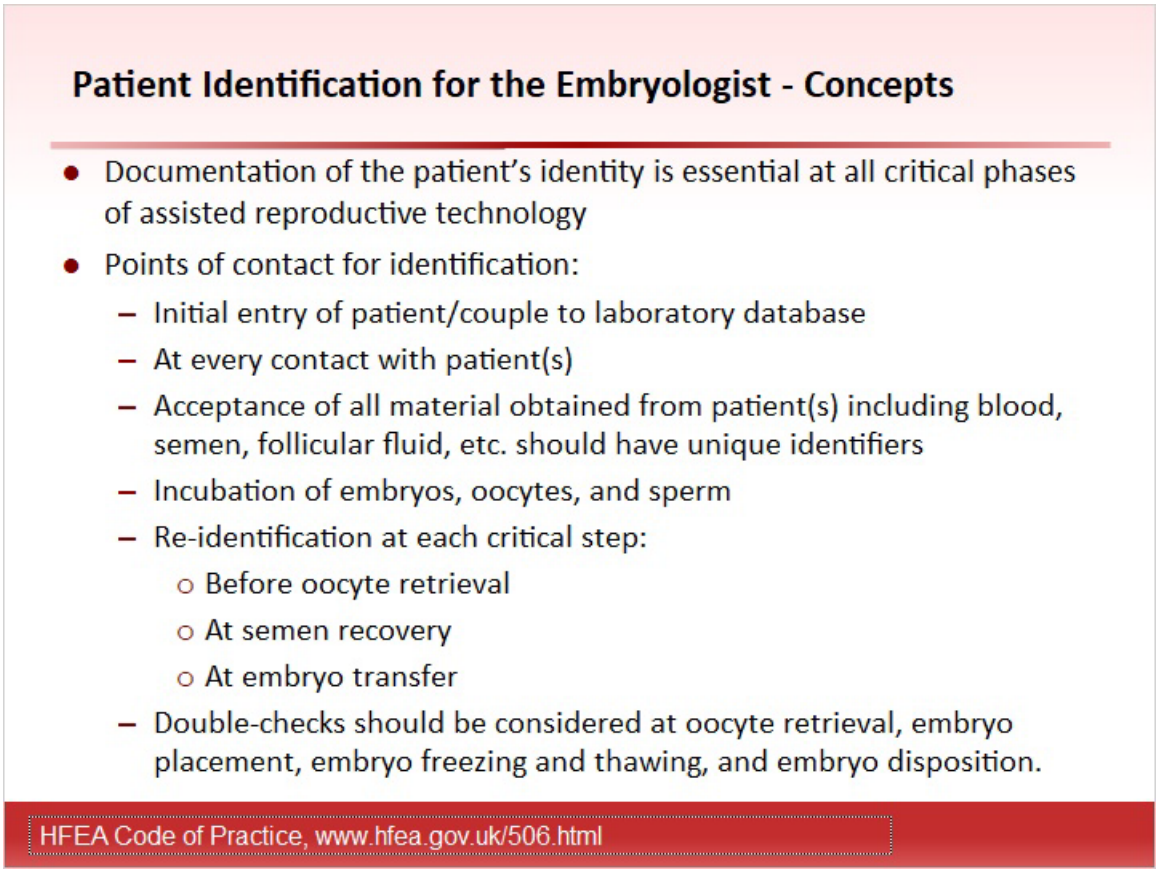


Notes:

As an integral part of the ART team, and because many fertility centers are smaller practices where team members wear several hats, it is not unusual for the embryologist to have direct contact with patients during their ART cycles. Many embryologists answer patient telephone calls and emails, which places them on the front lines of patient communication. In this direct contact, patients often expect information on the number and quality of eggs retrieved, the composition of the sperm specimen, the fertilization process employed, the number of 2PN embryos formed, and the further development and grading of any embryos. Many physicians rely on the data that the embryologist supplies to continue or alter the treatment protocol for his or her patients. In addition, embryologists are also delegated the responsibility for obtaining informed consent from the patient to transfer embryos prior to the embryo transfer procedure. In this capacity, embryologists are not only responsible for explaining the procedure to patients, but informing them of the number, quality, and, often, the possibility of pregnancy presented by the embryos that will be transferred. Finally, embryologists are generally the clinic personnel who receive patient directions about what to do with excess embryos, and may find themselves having to explain to the patient how to execute some of those directions or choices. They may include: destruction of embryos, long-

term cryopreservation of embryos (which may include explaining to the patient how to move embryos to a long-term freezing facility), moving embryos to another treatment facility, or donating embryos for research or to create a pregnancy in another unrelated woman.
All of these interactions require expertise by the embryologist in giving a patient clear information to ensure the patient's informed consent may be obtained if that has not already been obtained, and/or that the patient has a full understanding of the status and/or disposition of their gametes and embryos.

1.10 Patient Identification for the Embryologist - Concepts



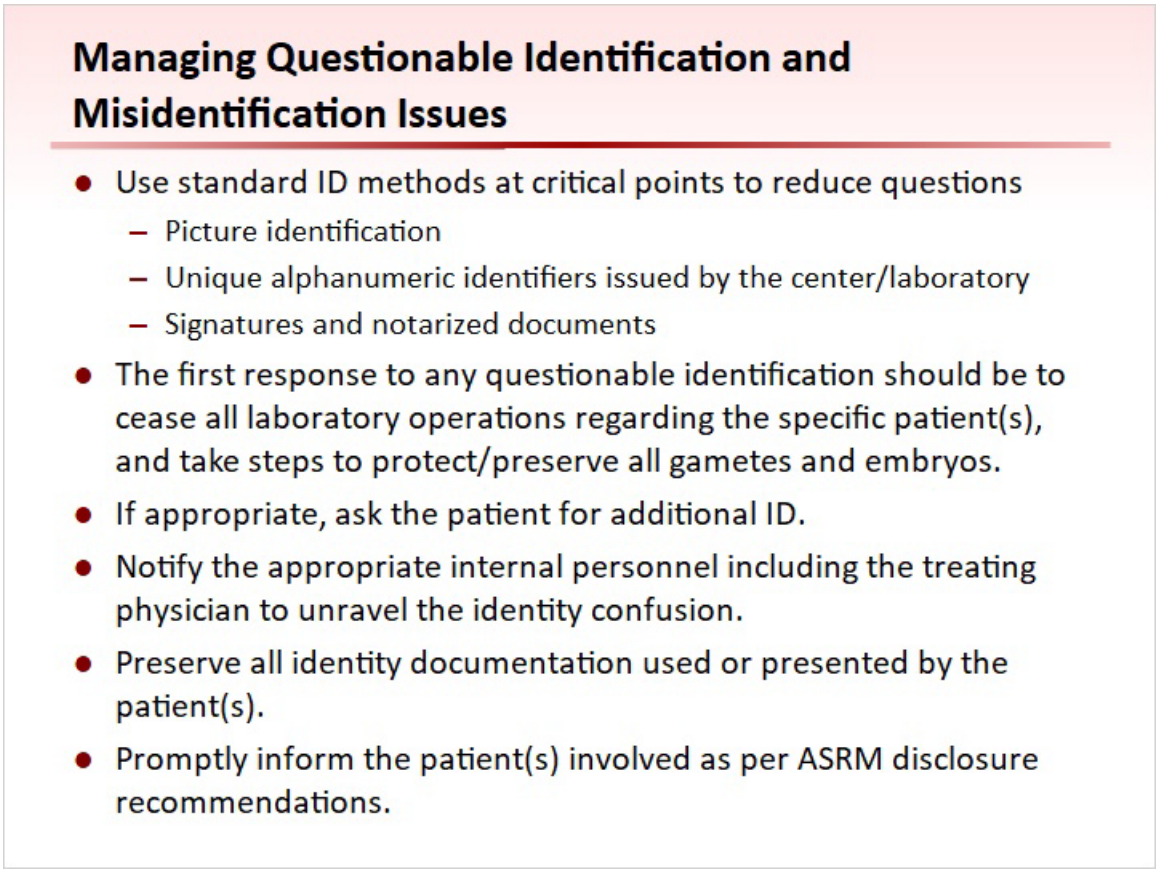
Notes:

Why is patient and genetic material identification a concern? Specimen mix-ups are the primary concern of patients, physicians, and laboratory personnel.

Also, identity theft is also a growing concern for medical providers as more patients use another's identity and may then get incorrect treatment that can lead to negative consequences.

Because of these concerns, certain points of contact in patient care require checks and re-checks of a patient's identity. The major identification points include any critical step in the embryology process, and, most especially, at oocyte retrieval, embryo placement, embryo freezing and thawing, and embryo disposition.
[Human Reproduction, vol. 15, no. 10, pp. 2241-2246, 2000; HFEA Code of Practice, www.hfea.gov.uk/506.html]

1.11 Managing Questionable Identification and



Notes:

When something feels "off," it probably is! At any point in the patient-care continuum, when people and data do not match it is imperative to re-check questionable identification. This is the first step in potentially preventing a mix-up or other mishap in the laboratory. In short, once a question of identity is raised, laboratory personnel should stop all procedures, ask for clarification and/or further identification, and notify the appropriate internal personnel, including the treating physician, needed to unravel the identity confusion.

If the misidentification rises to the level of possible or actual patient, gamete, or embryo confusion, the patient must be informed according to ASRM disclosure of error guidelines. This exact process will be discussed in more detail later in this module.

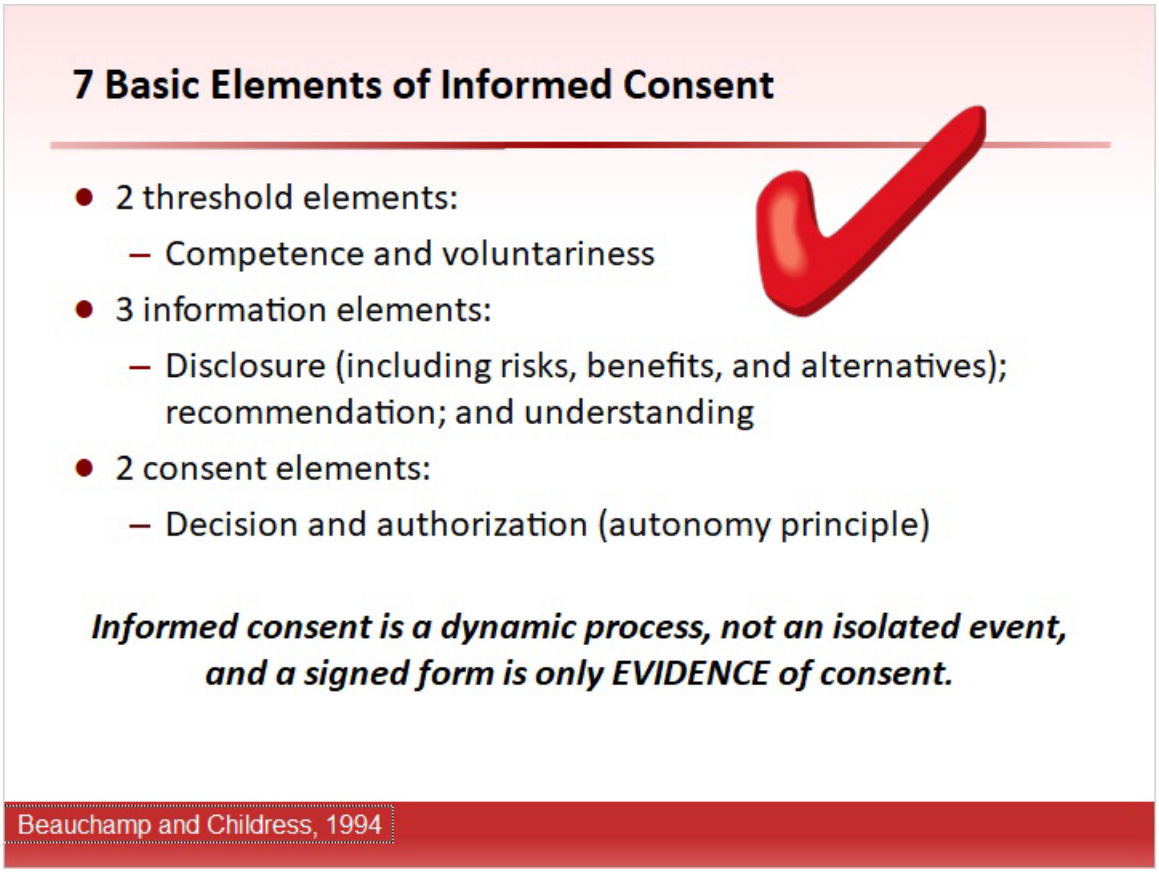
1.12 From a Legal Perspective

Notes:

A starting point for any understanding of the law's role in ART is an appreciation of 3 unique aspects of ART treatment that challenge existing legal principles. There is a large body of law, including clear guidance from the Supreme Court of the United States, on women's constitutional reproductive rights and choices surrounding procreation, contraception, and abortion, but those cases (known as legal "precedent") do not fully apply to ART where fertilization and the early stage embryos are in a lab, and not inside a woman's body. Legal principles protecting a woman's bodily integrity and reproductive choices are less forceful when applied to preimplantation IVF embryos, and balancing patients' rights may mean equal claims by a man or a woman who creates those embryos.

Secondly, cryopreservation means legal issues may arise for an extended time frame involving control over, or misuse of, gametes and embryos (including testing errors; loss; or unauthorized, mistaken, or intentional transfers to third parties). This may expose embryologists and others to legal vulnerabilities for extended time periods.
Finally, use of gamete donors and gestational surrogates brings additional participants into the medical process, to whom each is owed a duty of care, and from each of whom informed consent is required.

1.13 7 Basic Elements of Informed Consent



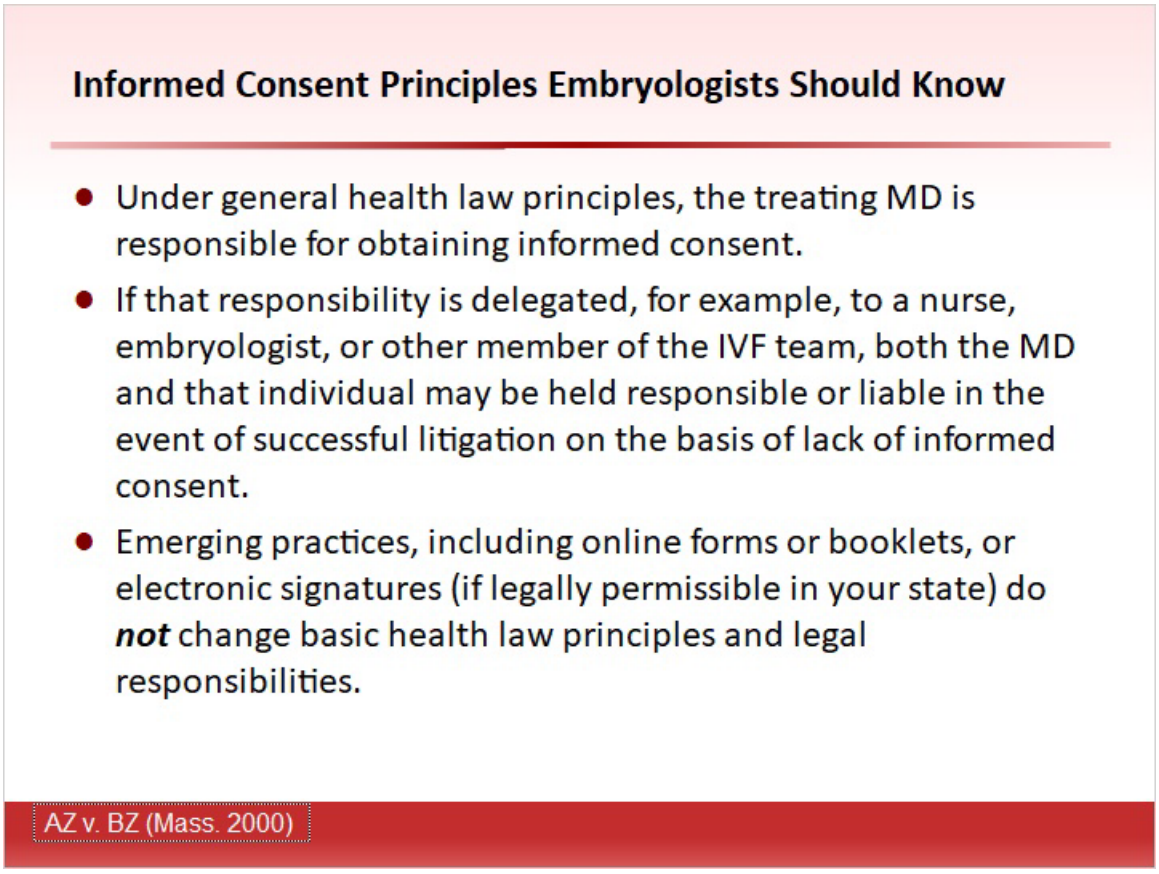
Notes:

Traditional principles and elements of informed consent fully apply to ART. Basic elements of health-care decision making are intended to ensure that every patient is competent to consent, and has both the volition and the necessary information and disclosures to give such consent. These 7 essential elements are the cornerstone of this doctrine, and subsumed within them is the expectation that every patient has what is needed to make, and does make, an informed decision about their treatment. Assuming a patient is competent and not coerced or unduly influenced, they must receive

sufficient information as to the risks, benefits, and alternatives to the proposed treatment (including the option of having no treatment), they must understand the information and any recommendations, and then have the autonomy to make a decision and authorize treatment.

In the absence of these essential elements, medical providers may be subject to malpractice claims or other tort (civil wrongs) claims. While written documentation may not be required, it is almost universally believed to be preferable over only an oral consent as it serves as evidence of the informed consent process. However, a written document merely handed to a patient, or one delivered or made available over the internet, without being accompanied by a deliberate process of providing information and obtaining consent, is not sufficient.
Finally, the law of informed consent may be different or have different nuances in a given state. For example, some states use a "reasonable patient" standard while others apply the standard of the actual individual patient, so it is important to always consult legal counsel in your state to confirm any general principles and fully understand the applicable law in your state.

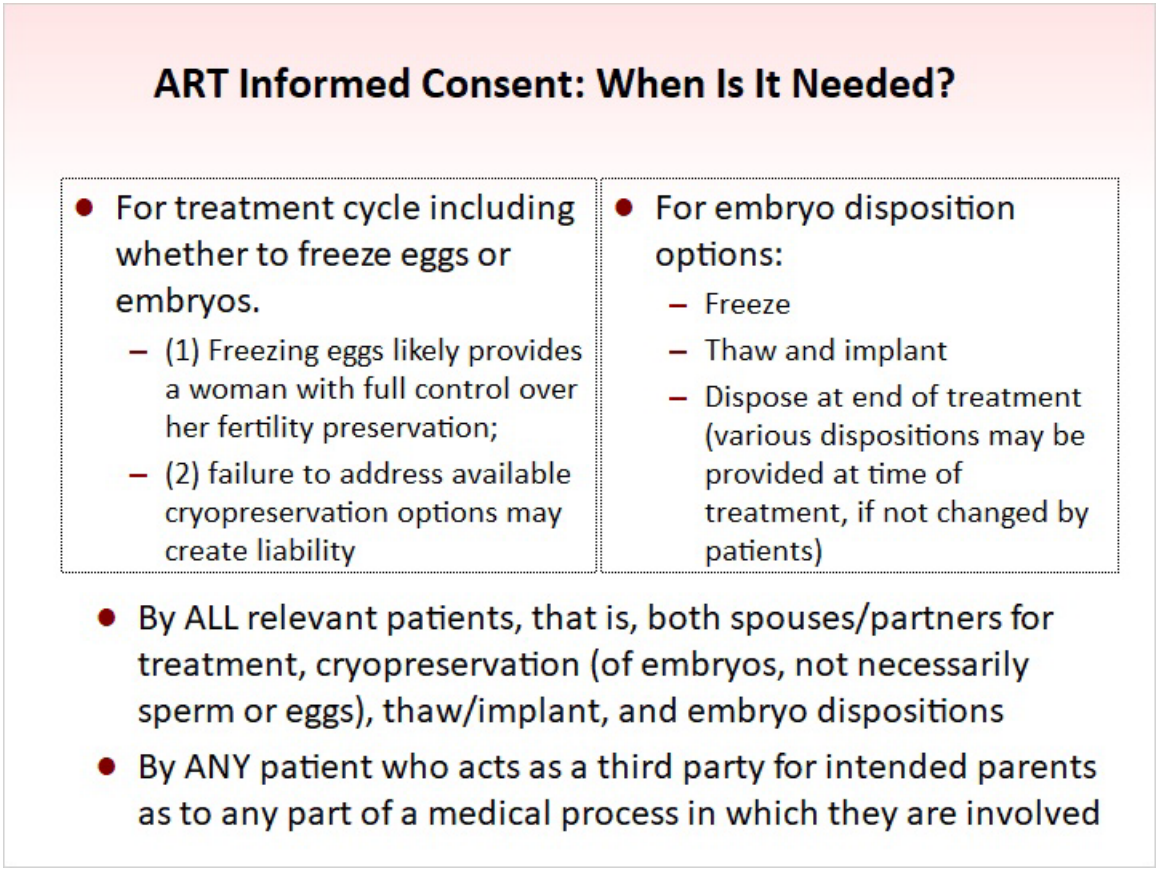
1.14 Informed Consent Principles Embryologists Should Know



Notes:

Obtaining informed consent is the responsibility of the physician and a signed consent form is evidence, but not conclusive proof, of legally adequate informed consent. While that responsibility may be delegated, which is common in busy practices including those that treat patients from multiple states or countries, the physician remains responsible. Additional responsibility may fall on the individual to whom the process was delegated. Embryologists and others in an IVF practice should be aware of this.
Online forms, booklets, summaries of lengthy consent forms, or sending documents home with patients to review, are all ways in which medical programs attempt to make the process more patient-friendly and manageable. In one notable case involving a divorcing couple's directives over their frozen embryos, the ex-husband testified that his wife placed blank cryopreservation forms from the program in front of him, which he signed without reading or completing. While these practices may be both acceptable and potentially helpful, nothing removes the obligation to ensure a patient's full understanding and voluntary consent.

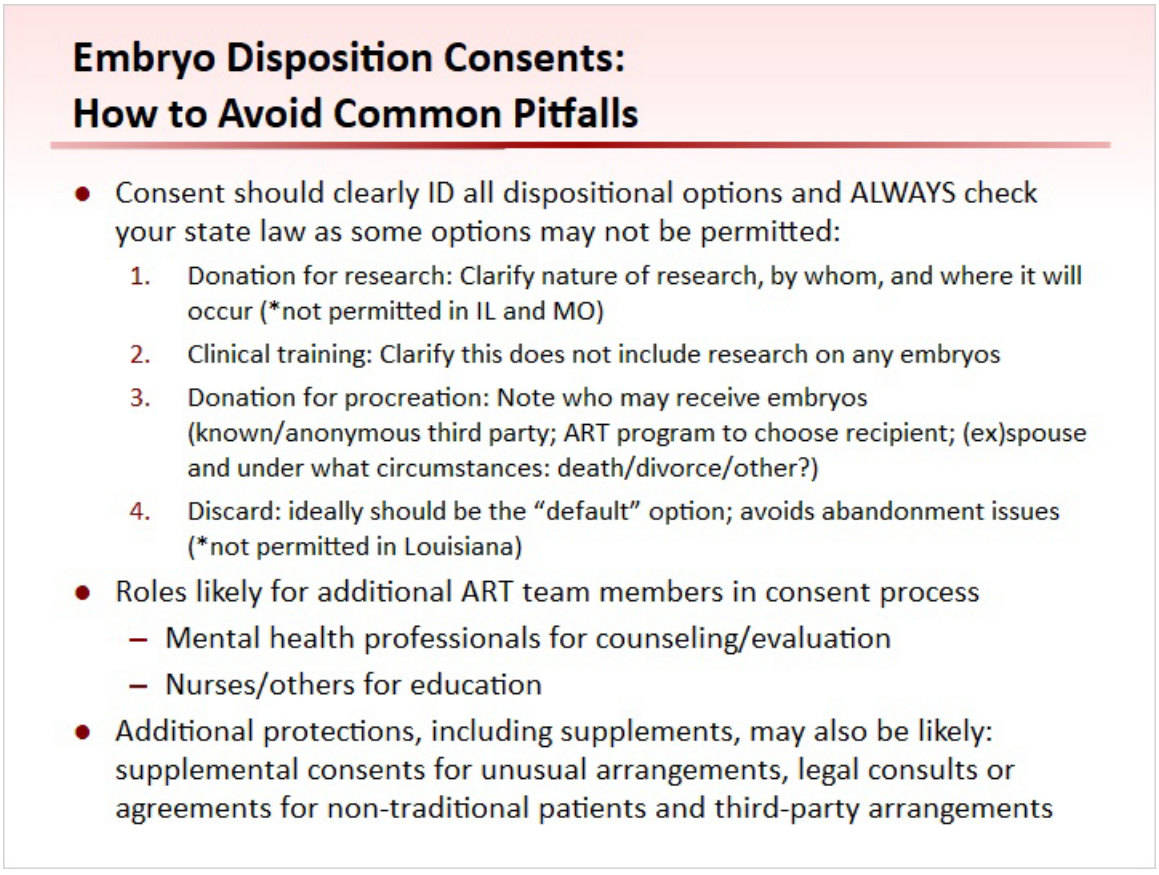
1.15 ART Informed Consent: When Is It Needed?



Notes:

Informed consent will be required for at least 3 different aspects of an IVF patient's treatment: 1) the cycle itself; 2) decisions by the couple surrounding embryo disposition at the end of both the initial treatment cycle and any subsequent treatments (i.e. freezing for subsequent potential use, or post-treatment donation for research or procreation or discard); and 3) contemporaneous consents to thaw and implant. Each of these decisions requires informed consent, with documentation to support it strongly recommended, regardless of whether state law mandates it. Also, all participants in a third-party arrangement who have treatment by the medical program are patients. This is a reminder that all donors and gestational surrogate carriers need to be fully informed and give written informed consent as patients.

1.16 Embryo Disposition Consents:



Notes:

Myriad decisions arise in the course of IVF treatment and must be addressed in some detail. Thus, donation for research needs to identify with some specificity the type of

research anticipated, as well as how and where that research will occur. As embryonic stem cell research becomes more available, anecdotally a growing number of patients are interested in that disposition option and ~~thus~~ increasingly choose the research disposition option. Donation for procreation also requires patients' clear understanding of, and consent to, such use. If patients want to restrict the recipients of their donation, it must be done with clarity and also be acceptable to a medical program; otherwise an alternate disposition must be provided. It is also prudent to confirm that any named recipients want the donation, or that a default option is in place if they do not. If dispositional choices include use by one of the spouses following death or divorce, the consent must clearly establish when such a decision has been made, and—as the cases discussed later demonstrate—may nonetheless be found subject to a change of mind by one of the former spouses in the context of use after a divorce.
A default option is advisable so a program that may not be able to fulfill another dispositional choice has the authority to discard. Without such authorization, IVF patients may either refuse to make a dispositional decision or may be unreachable, and their embryos may under some circumstances be considered "abandoned." If that occurs, ASRM standards require a protocol to attempt to locate and glean patients' preferences for disposition, which can tie up a program's resources and time, and should be avoidable by careful consent form drafting.

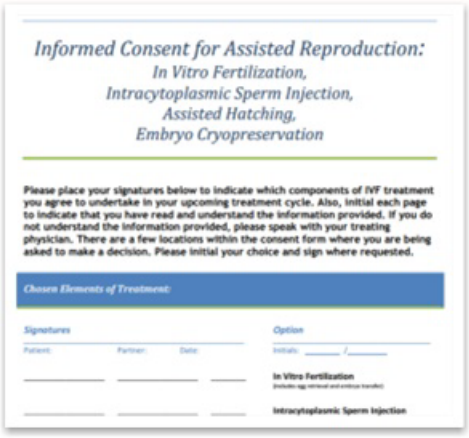
Any dispositional choice discussed with patients must comply with applicable state law. Always refer to your jurisdiction's mandates before adopting consent forms and offering patients dispositional choices or selecting a default option.

The 2009 SART Model Consent forms address many of the issues identified in this presentation, and the revisions in the upcoming 2017 Model Consent forms attempt to provide further clarity. For so-called "non-traditional" patients, including single patients, same-sex couples (which may include legally married same-sex couples in at least some instances), and those using third-party assistance, legal consultations and legal agreements may also be very helpful, if not mandated by a medical program, to clarify the roles and responsibilities of each of the participants. From a medical program's perspective, there should seldom, if ever, be a need or preference to be involved in drafting or signing onto any such third-party legal agreements. Medical programs will want to make clear that their consent forms will govern all decision making that impacts or affects the medical program. This will allow medical programs to hopefully "stay above the fray" and avoid liability in the event that intended parents and third-party participants have a future disagreement. If medical consents govern conduct involving the medical program, there should be little need to be involved other than to insist on being provided evidence that an agreement had been entered into. Such documentation may take the form of a letter or letters reflecting independent legal counsel for each party or set of parties attesting to their having reached such an agreement. This is often referred to as a "Clearance Letter."

1.17 The Model SART "Informed Consent For ART"

The Model SART "Informed Consent For ART"

- 2009: A mutidisciplinary effort; 35+ page model consent addresses:
  - Embryo disposition in a separate section
  - Death/divorce/dissolution of relationship
  - Discontinuation of treatment
  - Nonpayment of storage fees
  - Time and age limits for storage/transfer
  - Donation option
  - Discard included as a DEFAULT option
  - ONLY a model, needs state law customization
- 2014: additional model consents published
  2017: update to model consents in progress



Informed Consent for Assisted Reproduction:
In Vitro Fertilization,
Intracytoplasmic Sperm Injection,
Assisted Hatching,
Embryo Cryopreservation

Please place your signatures below to indicate which components of IVF treatment you agree to undertake in your upcoming treatment cycle. Also, initial each page to indicate that you have read and understand the information provided. If you do not understand the information provided, please speak with your treating physician. There are a few locations within the consent form where you are being asked to make a decision. Please initial your choice and sign where requested.

Chosen Elements of Treatment:

Signatures *Option*

Patient: Partner: Date: Initials: _____ / _____

In Vitro Fertilization

Intracytoplasmic Sperm Injection

Notes:

While lengthy—and criticized by some IVF programs on that basis while applauded by others for its thoroughness—the SART Model Consents have been designed to be both comprehensive and clear, with designated headings and graphics. All to try to ensure patients' understanding and provide clear and understandable choices to avoid much of the uncertainty and ambiguity that has accompanied past consents, as noted by multiple courts.

1.18 The SART Model Consent: Legal Issues Addressed

The SART Model Consent: Legal Issues Addressed

- The law may be unsettled, and more than one state law may be involved, depending on location(s) of patients and ART program.
- ART program is not giving legal advice; patients may wish to consult a lawyer for legal advice given the uncertainties of embryo cryopreservation and disposition
- Dispositional choices must be consistent with any gamete donors' consents and any agreements made with them
- All patient signatures notarized/witnessed in an attempt to ensure authentically signed consents

Notes:

Many of the provisions in the Model Consent were drafted to try to avoid uncertainties and litigation in light of the number of court cases involving embryo dispositions by former patients, and given the growth of multi-state practices and multiple locations for patients.

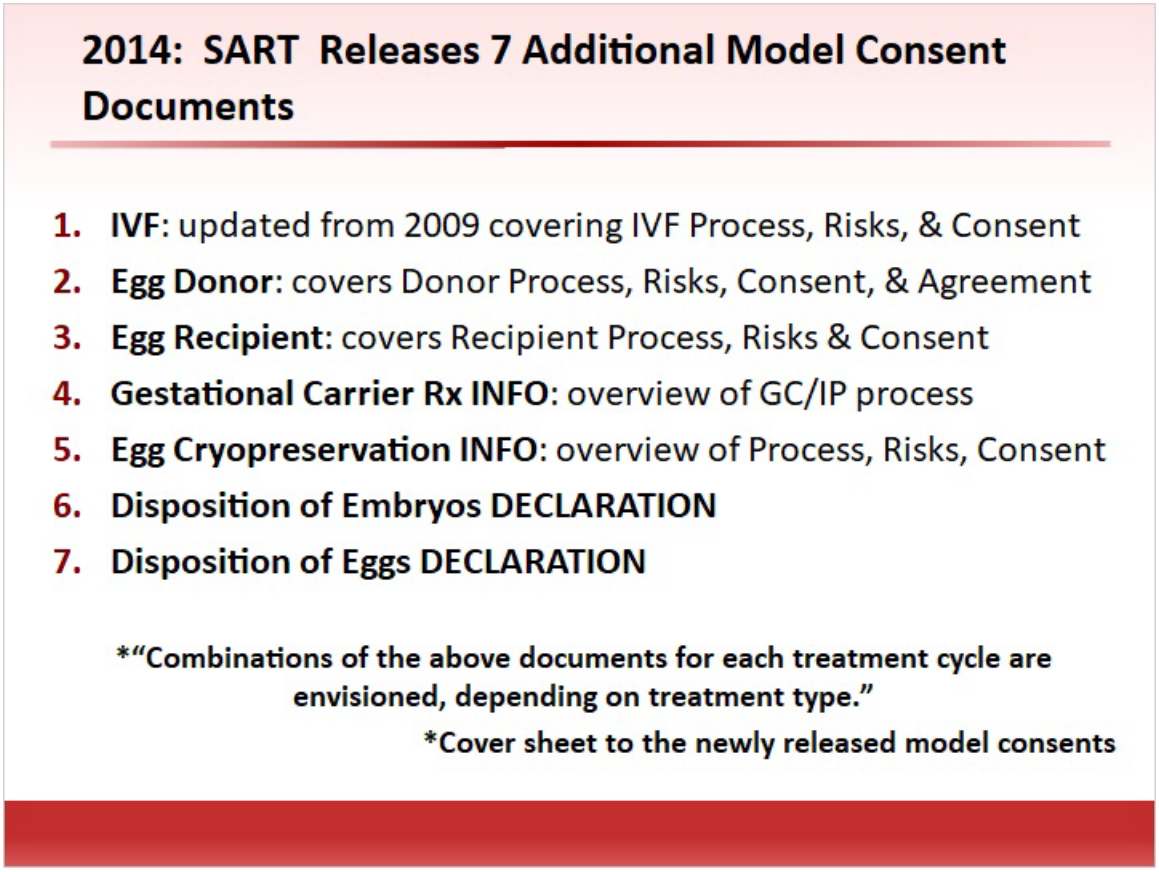
Some of these provisions include:

> **"**The law regarding embryo cryopreservation, subsequent thaw and use, and parent-child status of any resulting child(ren) is, or may be, unsettled in the state in which either the patient, spouse, partner, or any donor currently or in the future lives, or state in which the ART program is located…"
>
> "We acknowledge the ART Program has not given us legal advice, that we are not relying on [it] to give us any legal advice, and that we have been informed we may wish to consult a lawyer experienced in the areas of reproductive law and embryo cryopreservation and disposition if we have any questions or concerns about the present or future status of our embryos, our individual or joint access to them, our individual or joint parental status as to any resulting child, or about any other aspect of this consent and agreement..."

"…We understand we can change our selections in the future, but need mutual and written agreement... …in the event none of our elected choices is available, the clinic is authorized, without further notice from us, to destroy and discard our frozen embryos."

In addition, to ensure authenticity, notarized signatures are recommended. Many programs and individuals have suggested that this requirement may be burdensome, but it was included to ensure that a patient cannot claim they did not actually sign an important document. There have been reported cases where spouses or ex-spouses improperly signed their other partner's signature. A notarization requirement—or at the very least a witness requirement—reduces that concern.

1.19 2014: SART Releases 7 Additional Model Consent Documents

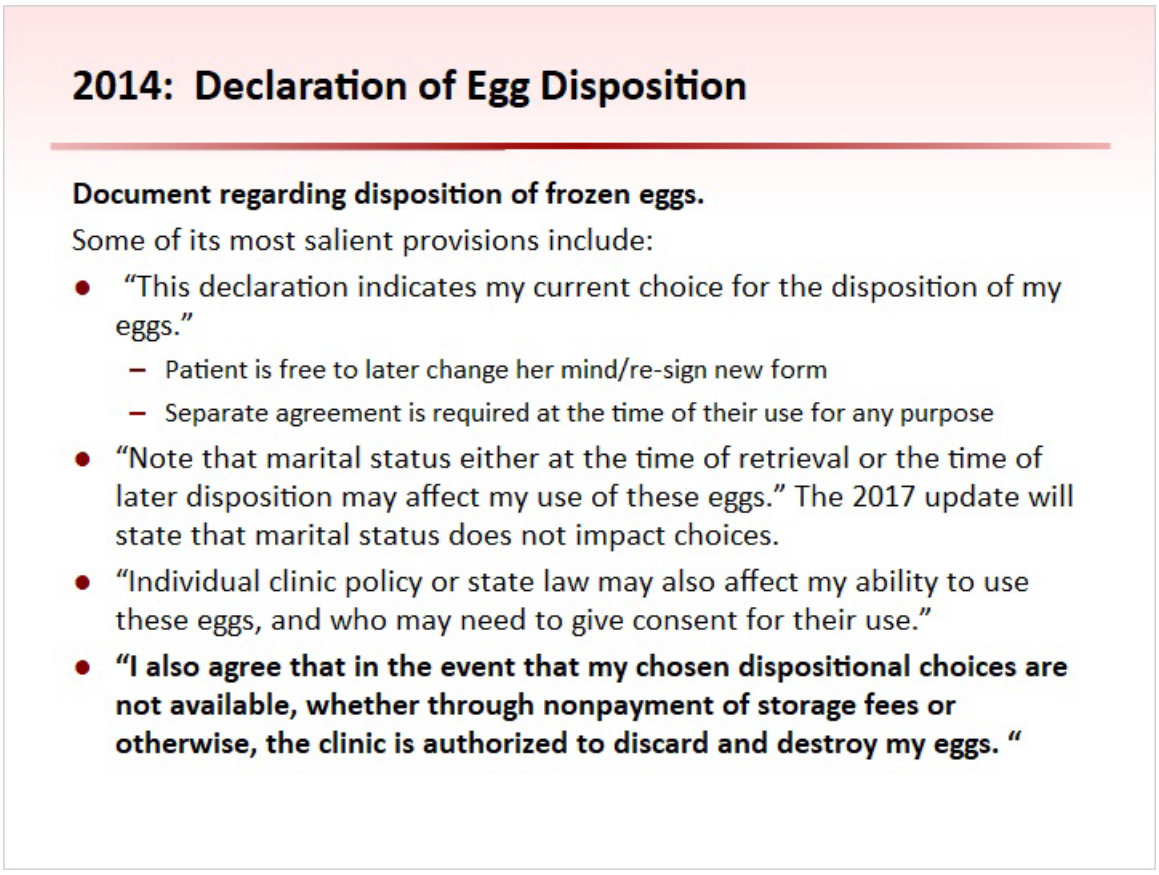


Notes:

The same ad hoc SART Committee on Informed Consent returned to work and produced these additional model consent documents. Again, they are intended as models, to be

reviewed in conjunction with and only as consistent with applicable state law.
Examples given by the Committee as to using the forms together were:
"For example:
1. Routine IVF with egg or embryo cryopreservation would involve the base IVF Consent along with the Disposition of Egg or Embryos Declaration.
2. In a typical gestational carrier/intended parent (GC/IP) cycle, the following documents might be needed: The IVF document, the GC/IP and Egg Cryopreservation INFO documents, as well as Disposition Declarations if eggs or embryos are cryopreserved."

1.20 2014: Declaration of Egg Disposition

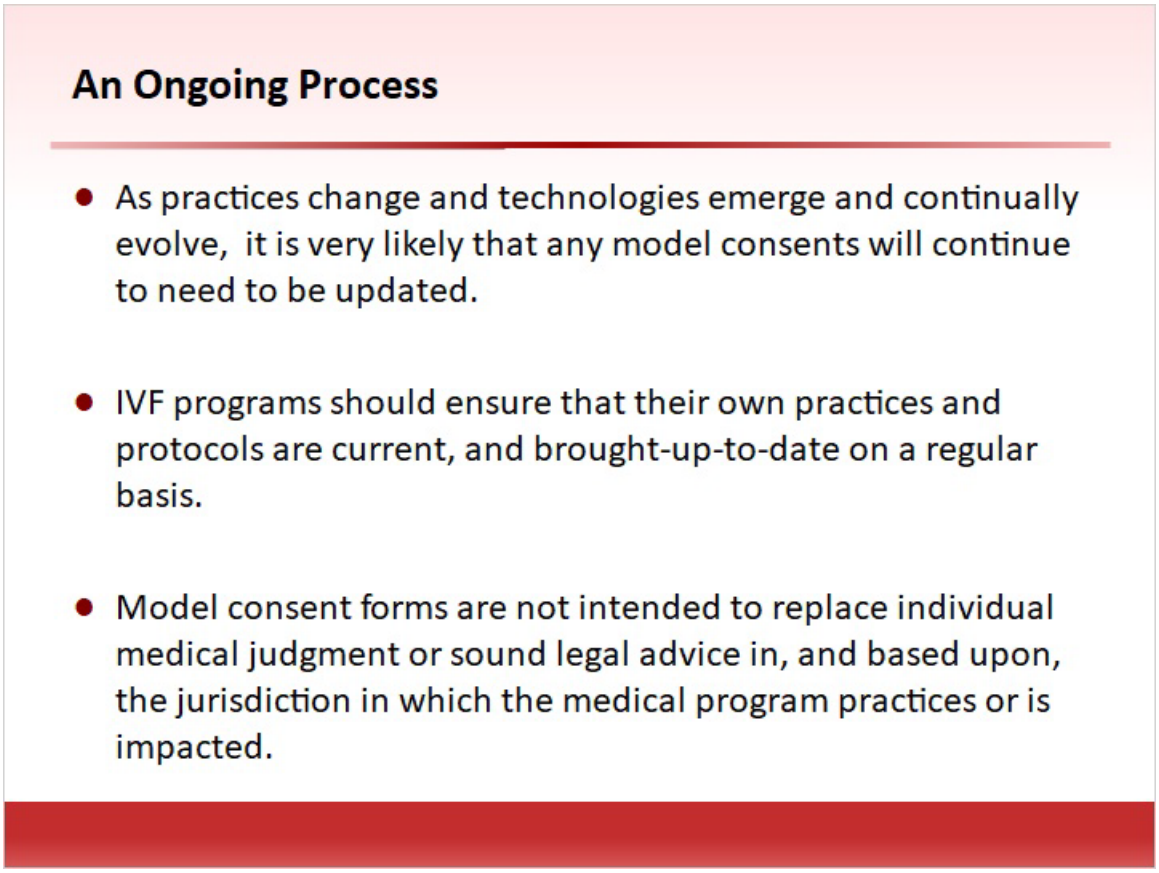


Notes:

The new 2014 model forms attempt to address evolving practices with egg freezing; since women alone can now freeze genetic material, a spouse may not be needed or appropriate to sign a freezing and disposition document; however, as the model points out, use of such genetic material may be subject to a different analysis as well as applicable state law which may give a spouse—who might become a legal parent as a

result of use of gametes during a marriage—more or less than anticipated rights.

1.21 An Ongoing Process



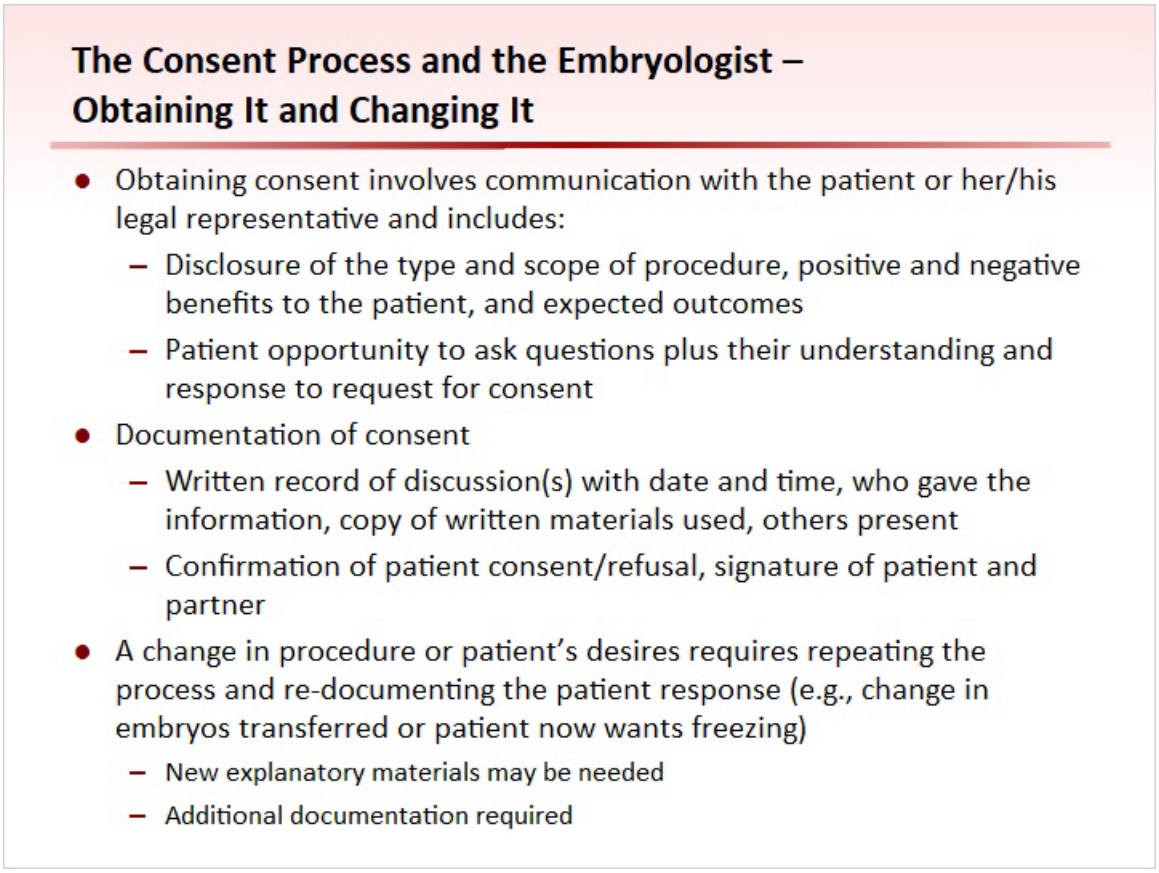
Notes:

Practices change and technologies emerge and continually evolve, which is the basis for the updated 2017 versions of the Model Consent forms. It is very likely that any model consents will continue to need to be updated.

IVF Programs should ensure that their own practices and protocols are current, and brought-up-to-date on a regular basis.

The model consent forms are *not* intended to replace individual medical judgment or sound legal advice in, and based upon, the jurisdiction in which the medical program practices or is impacted.

1.22 The Consent Process and the Embryologist –



Notes:

As already noted, obtaining consent from a patient is a process of communication that culminates in a writing that evidences the information conveyed, the patient's understanding, and his or her permission to proceed or not with the specified procedure. In obtaining consent from a patient for certain laboratory procedures, the embryologist is held to the same legal standard of disclosure as other health-care providers in the ART process. The embryologist must ensure that the patient is legally and mentally competent to give consent (generally not an issue in reproductive medicine), or the embryologist must obtain consent for the patient's legal representative (for example, if the patient is underage and is having fertility preservation treatment).

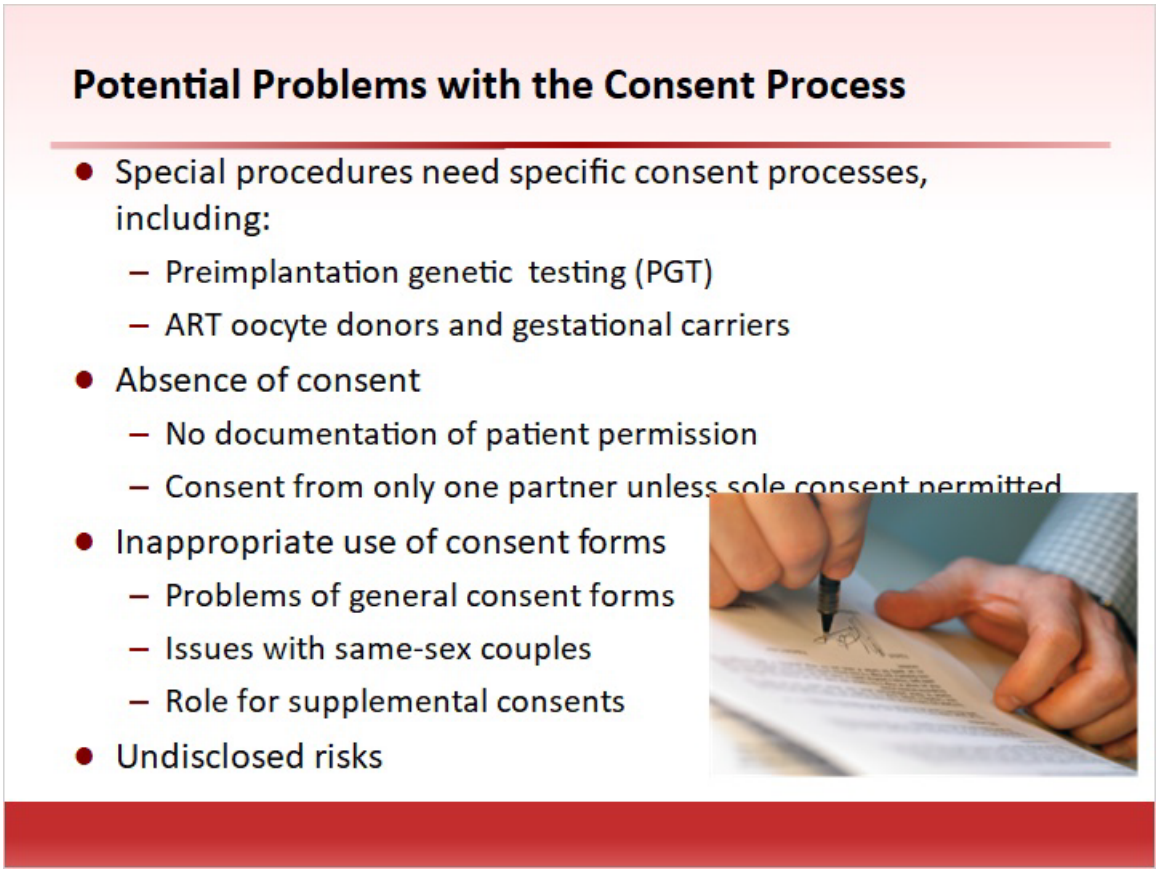
As the embryologist is usually asked to obtain consent only for those procedures where they may have the most expertise, such as cryopreservation, ICSI, or embryo numbers and quality as related to an embryo transfer, the embryologist must tell the patient the nature and extent of the procedure contemplated, what the benefits are to the patient of undergoing or utilizing the procedure (both positive and negative), the impact to the patient (if any) of not undergoing or using the procedure, and the expected outcomes of the procedure. Specific to ART, the embryologist should disclose the probable success

rate as related to the specific patient. It should be noted that this information is often a collaborative disclosure with the patient's treating physician. Sometimes the process of obtaining consent will occur over more than one patient interaction, and involve other members of the ART team. In all cases where it is applicable, a patient's spouse or reproductive partner must be included in the consent process to ensure that adequate information has been conveyed accurately.

Once the patient voices understanding and all outstanding questions have been answered, documentation, including the patient's signature and the embryologist's signature (as witness), must be entered into the patient's medical record. This documentation should include comprehensive information including who was present and on which date and time, and the information given to the patient, including any handouts. The use of templates and forms is acceptable and often helpful in this process as long as there is not mere reliance on reading a form and obtaining signatures.

The embryologist must be aware that at any time he or she learns that a patient has changed their mind about a previously accepted procedure (or any part of a procedure) or the treating physician has altered the medical orders regarding the patient's embryology treatment plan, the consent process must be re-initiated and updated permission received from the patient. Additional documentation of the change in the original consent granted must also be documented in the patient's medical records to reflect the changes, circumstances, and the patient's response.

1.23 Potential Problems with the Consent Process



Notes:

As in all processes, the embryologist may be faced with certain problems in obtaining patient consent for embryology procedures.

Applying different processes is often necessary for complex procedures, such as preimplantation genetic diagnosis or screening, or complex relationships as in third-party reproduction involving an oocyte donor or a gestational carrier. Obviously, complex technologies may need more time devoted to explanations to the patient and generally a highly detailed explanation of risks and outcomes. Likewise, complex relationships require even greater care and consideration to ensure that all parties' information and consent are coordinated and in agreement. Many programs utilize a "double-check" or second-witness process in these areas to document patient understanding and permission. This is especially useful if the embryologist is involved in obtaining patient consent for laboratory research studies or experimental procedures.

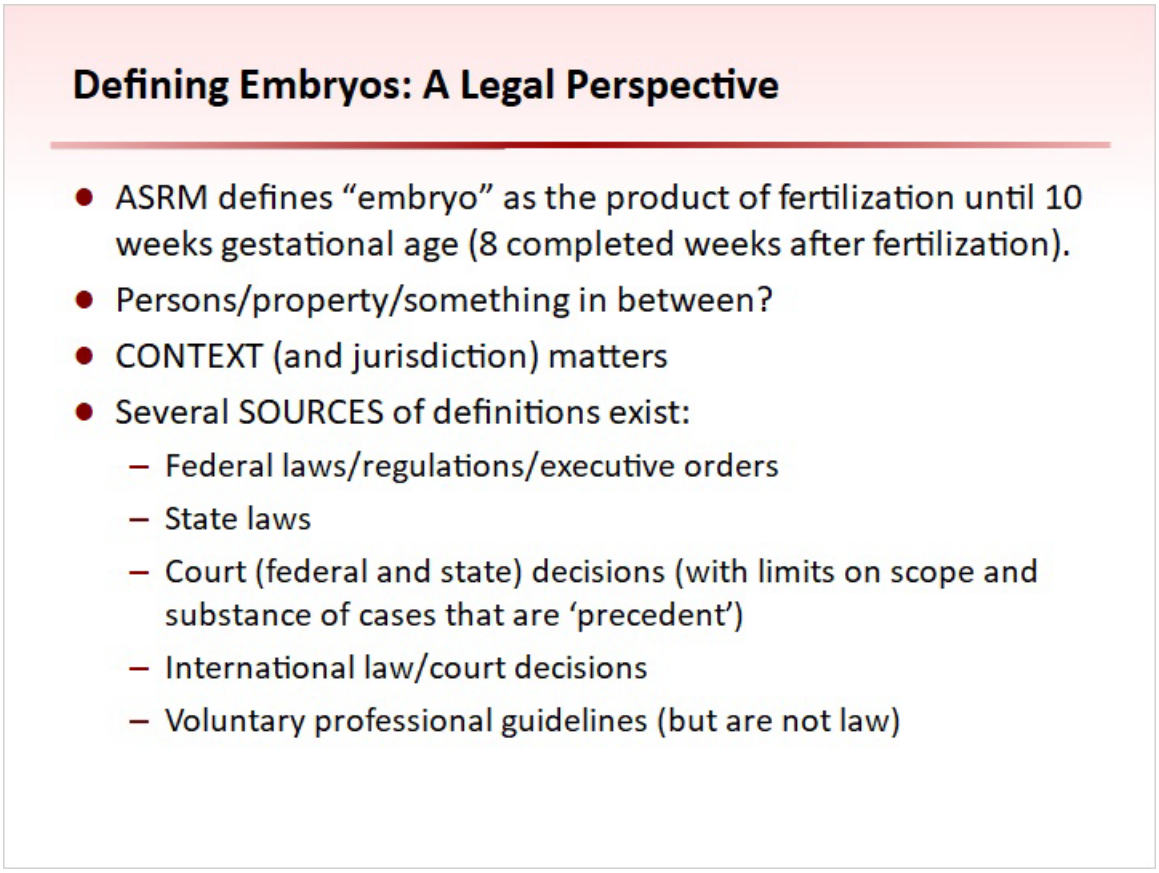
It is clear that no procedures can be performed, either on a patient or on a patient's gametes or embryos, without the patient's express consent. Therefore it is essential that documentation of the patient's consent is in the medical record—no matter which ART

staff member was responsible for actually obtaining consent.

In infertility practice, it may also be imperative to include documentation that the patent's spouse or reproductive partner has also granted permission to, or acknowledges, the procedure. An exception would be in procedures where it is clear that only one partner's signature is needed, such as destruction of frozen sperm; often, 'courtesy' consent is obtained from the other partner in these situations. Moving forward with procedures for which consent is absent exposes the embryologist and the ART program to legal liability, and case law has upheld their responsibility to obtain consent or face legal and financial consequences.

Additional problems may arise if the documentation used is not consistent with the specific patient history, relationship(s), or treatment plan. This lack of specificity is the main concern if using general consent forms as the only explanation in the consent process. Programs have also faced complex legal and social questions if they do not tailor documentation of consent to reflect the exact nature of the patient and her reproductive partner's roles in the contemplated ART. For example, using an oocyte donor consent form for a same-sex female couple where embryos will be created with the eggs of one partner and transferred to the uterus of the other partner can completely defeat their original intent to co-parent. The creation and appropriate use of supplemental consent documentation that allows each patient case to be explained and confirmed accurately may mean an initial time and cost investment, it will decrease the potential for liability at a later date.

1.24 Defining Embryos: A Legal Perspective



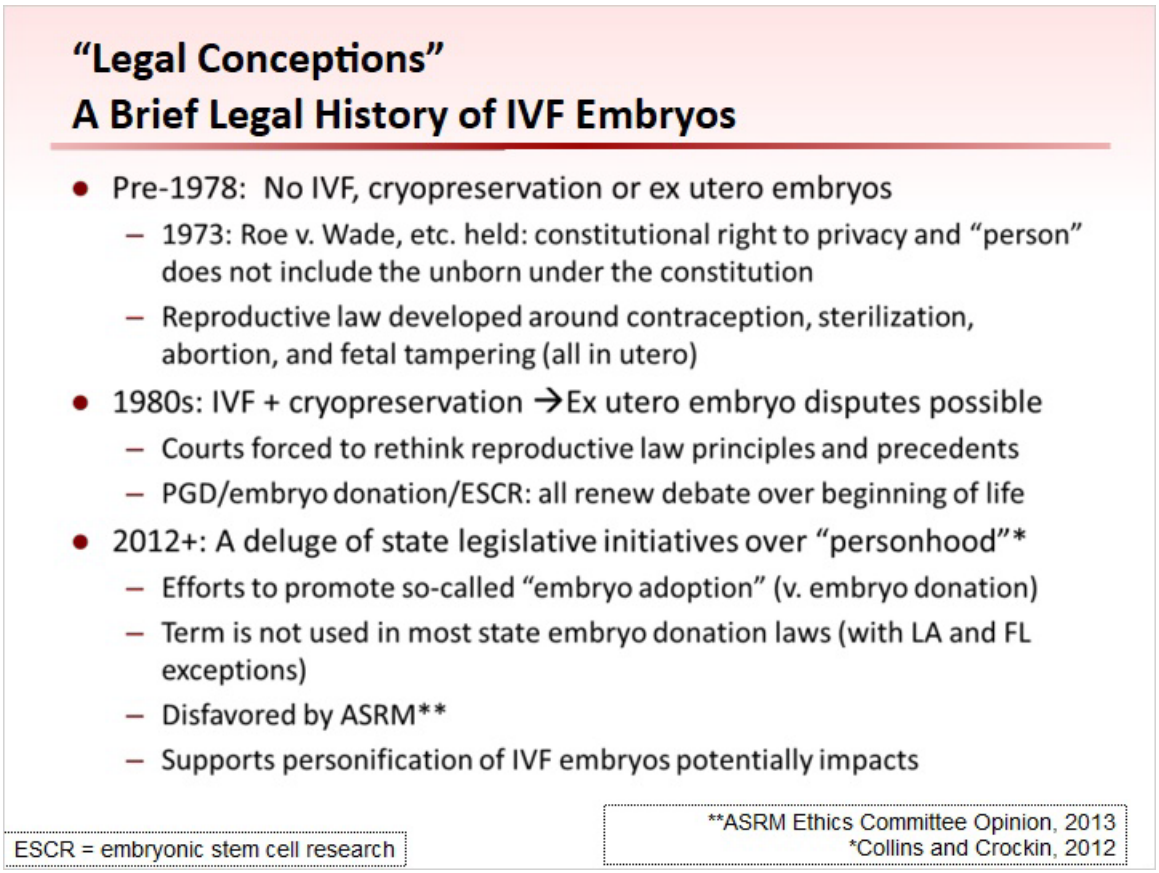
Notes:

ASRM defines "embryo" as the product of fertilization until 10 weeks' gestational age (8 completed weeks after fertilization).

Context always matters, because courts typically try to decide only the narrow question presented by a dispute and avoid sweeping pronouncements. Thus a dispute between patients and their doctor over who controls their frozen embryos may decide that question in favor of the patients using a property-based analysis (suggesting gamete providers have a stronger interest in their genetic material than the clinics who help them combine them) (see *York v. Jones*, VA 1989), while a dispute between a divorcing couple will likely focus on a pre-existing agreement or the parties' respective reproductive rights (e.g., *Davis v. Davis*, TN 1992). Deciding an embryo mix-up that has resulted in the birth of a child will look to parentage and child welfare standards (e.g., *Fasano v. Nash,* NY 2001).
Keep in mind that court decisions from one state or jurisdiction do not "control" (that is, apply directly) courts in a different state or jurisdiction (except decisions of the US Supreme Court), although they may be cited as guidance to follow or to distinguish a court's analysis and decision.

Voluntary professional guidelines or opinions, such as those issued by ASRM, may be seen as setting minimum standards, in particular for malpractice cases, but they do not have the force of law.
In developing law and policy in both legislative and judicial arenas, medical professionals, including embryologists, have played significant roles educating law and policy makers about scientific advances and nuances in ART as well as embryonic stem cell research and positively impacted court decisions and legislation. By being willing to engage and educate the decision makers, ART professionals can play a critical role in clarifying the issues, informing the debates, and ultimately helping shape law and policy outcomes.

1.25 "Legal Conceptions"

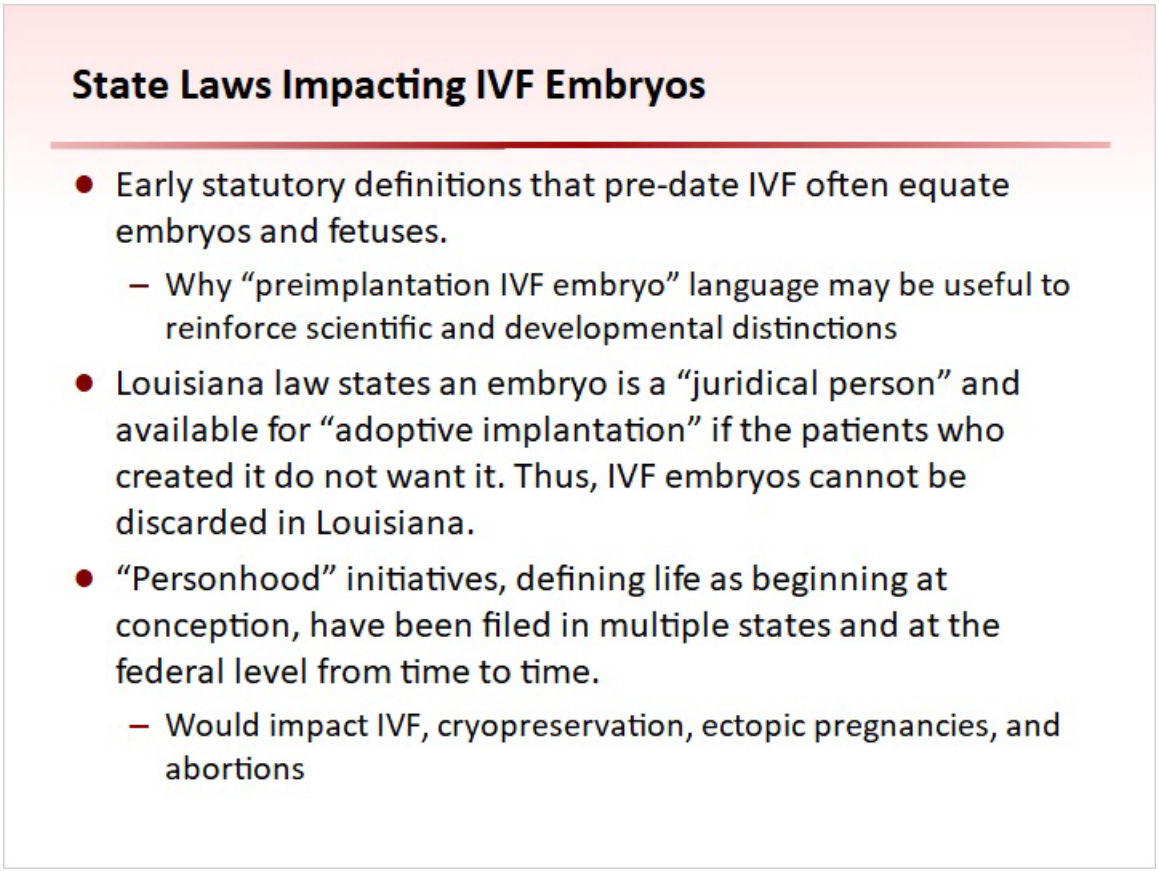


Notes:

Most of the US Supreme Court cases on reproductive rights were decided in the 1970s, long before IVF was an available option for most patients. The seminal abortion case, *Roe v. Wade*, US 1973, held that under the US Constitution, a person does not include the unborn, and that at least prior to viability a woman's right to bodily integrity essentially "trumps" that of any fetus she is carrying.

IVF and cryopreservation not only altered the constitutional balancing test by removing concerns over a woman's bodily integrity, but in the past few years have also opened the door to state initiatives (both legislative bills and ballot initiatives) to define life at the moment of fertilization, a principle that, if passed, would place preimplantation IVF embryos on a legal status with human lives, and leave medical professionals open to potential prosecution if they did not take every available step to preserve both preimplantation IVF embryos and any in utero fetuses. As Dr. Howard Jones remarked when a "personhood" initiative was proposed (and ultimately defeated) in Virginia, such a law would put any physician at risk who removed an ectopic pregnancy to save the life of the woman, as s/he would be choosing to end the life of the growing conceptus. While many suggest such state initiatives are designed to stop abortions, the impact of such laws would be readily felt on ART and obstetrical practices.

1.26 State Laws Impacting IVF Embryos

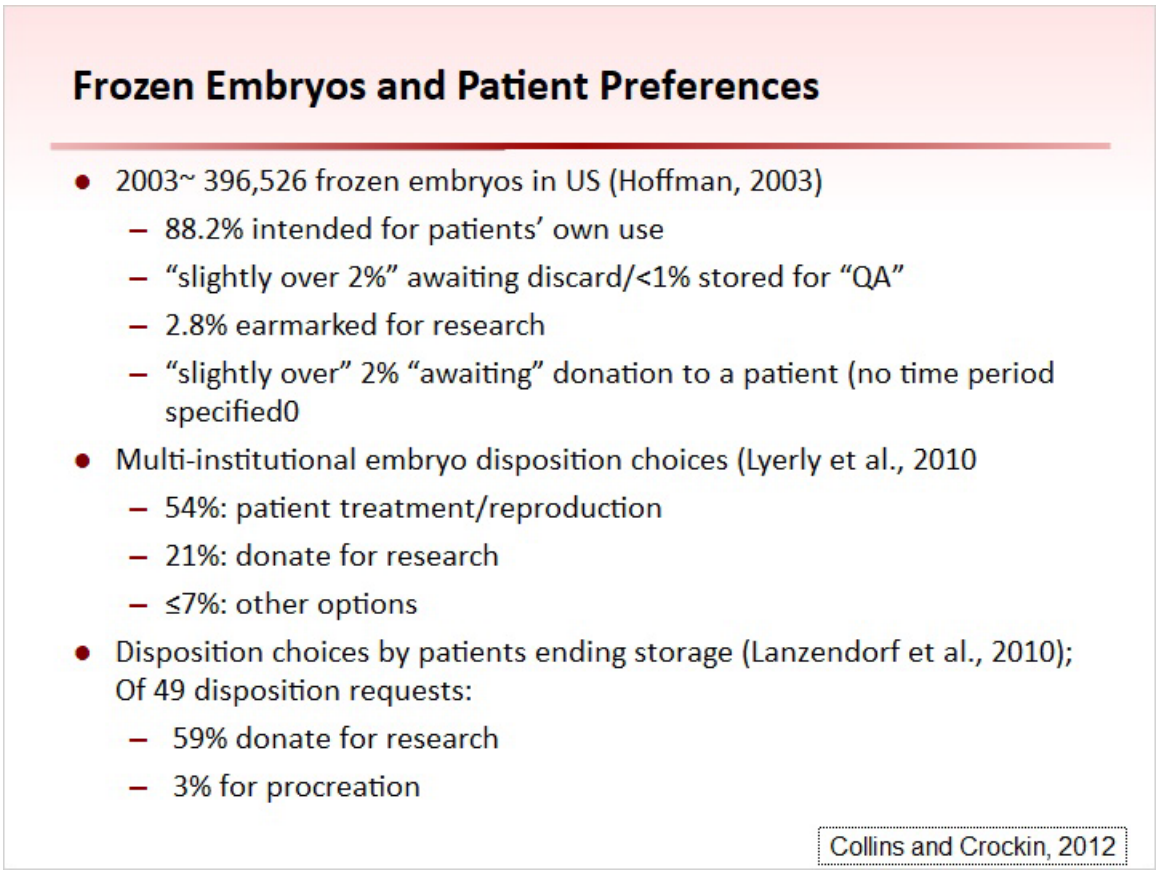


Notes:

Ironically, the Louisiana court in the *Ochsner* case rejected the argument that an embryologist performs medical treatment, and made it clear that a preimplantation IVF

embryo is not considered the equivalent of a human being despite the language of its statutory law.
According to an ASRM Ethics Committee Opinion: “embryo adoption” language is deceptive because it reinforces a conceptualization of the embryo as a fully entitled legal being and thus leads to a series of procedures that are not appropriate based on the ASRM Ethics Committee’s consideration of the embryo’s status.
The term embryo adoption continues to be used in the popular press, despite the very distinct legal practices involved in embryo donation via informed consents and agreements and adoptions of born children via court proceedings and adoption laws.

1.27 Frozen Embryos and Patient Preferences

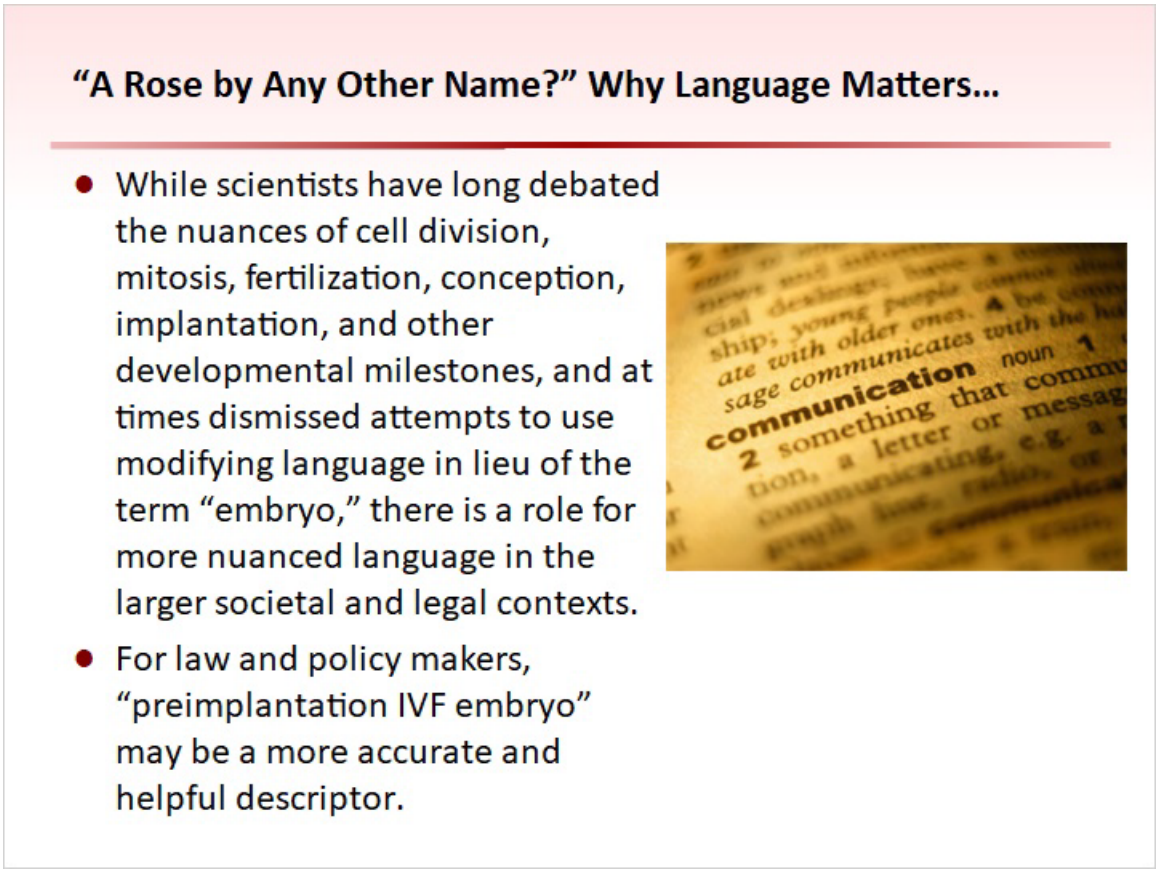


Notes:

Studies continue to show that donation for procreation is an option that is chosen by a relatively small group of potential donors. Some suggest that the reasons the numbers are both small and drop significantly from onset of treatment to end of treatment decisions is because patients see these as potential full-genetic siblings of their own IVF children. While embryo donation for procreation may well be a desired and desirable

option for a minority of donors and recipients, the publicity that surrounds it seems disproportionate to the actual practice and, together with the frequent use of “embryo adoption” language, supports those who suggest the subject and terminology are also being used to promote an anti-abortion and anti-embryonic stem cell research agenda.

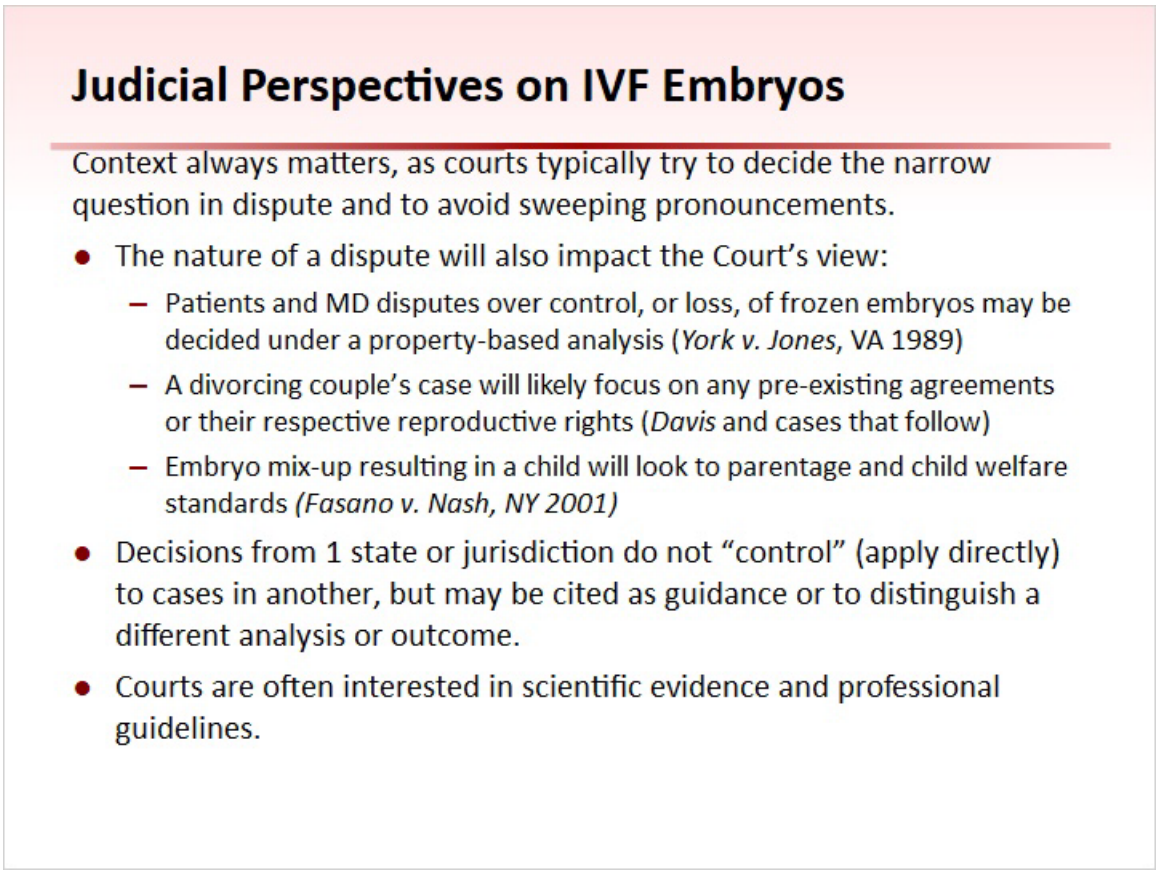
1.28 “A Rose by Any Other Name?” Why Language Matters…



Notes:

The previous section highlighted how language can significantly impact law and policy. While scientists have long debated the nuances of cell division, mitosis, fertilization, conception, implantation, and other developmental milestones, and at times dismissed attempts to use modifying language in lieu of the term “embryo,” there is a role for more nuanced language in the larger societal and legal contexts.
For law and policy makers, “preimplantation IVF embryo” may be a more accurate and helpful descriptor.
The following section will reinforce the critical role of language.

1.29 Judicial Perspectives on IVF Embryos



Notes:

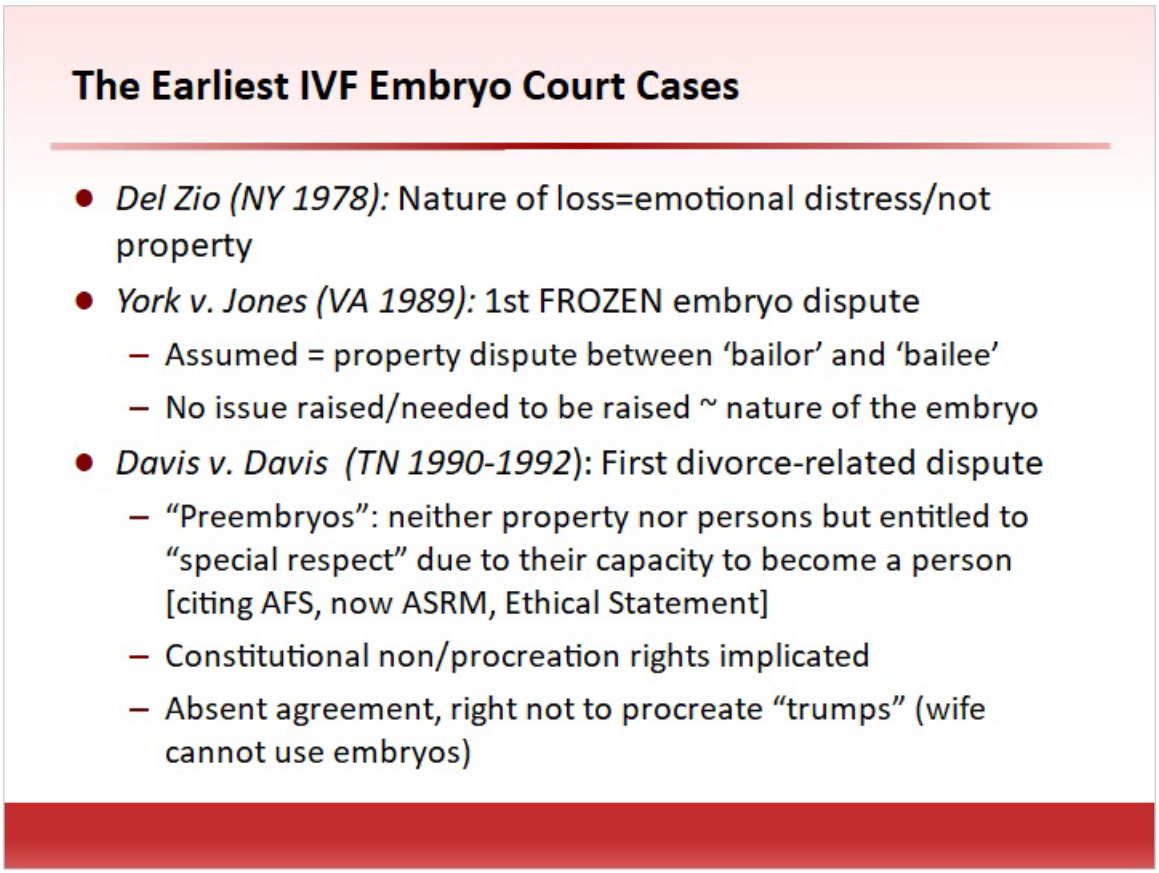
Context always matters. In a field that is still so novel and in which so little law has developed relative to more established areas of the law, decision makers often look outside their own legal precedent. Thus, scientific evidence presented by "experts" such as embryologists and reproductive endocrinologists has had significant impact in terms of educating courts on aspects of developing stages of gametes, embryos, and fetuses, and in the fields of third-party reproduction.

From a legal perspective, there is no commonly recognized definition of what an embryo is. Different states may adopt their own statutory (enacted) law on what is an embryo, or, if there is no statutory law, may also have developed case law (judicial pronouncements) which characterize embryos. It is critical to recognize that state laws can and do vary significantly from state to state and any attempt to generalize here cannot replace the need to have legal counsel check and confirm state law in a program's own state.

Most commonly, embryos are defined in the context of issues involving research and control and/or ownership over them. Over the past decade, some noteworthy cases

have arisen in various states establishing some legal principles involving human IVF preimplantation embryos.

1.30 The Earliest IVF Embryo Court Cases



Notes:

These cases represent some of the earliest and most prominent judicial decisions involving human embryos and issues surrounding their nature, "ownership," and dispositional options.

Del Zio involved a couple whose early IVF efforts were thwarted by the academic medical facility just as they were planning a transfer. The subsequent ride across New York City in a cab did nothing to enhance the chances of this early IVF effort to succeed, and the couple sued. The birth of Louise Brown during the trial made the possibility of IVF succeeding suddenly real, and the decision awarded the couple damages, but in the nature of emotional distress and not for lost property. While the wife was awarded money damages, the husband was only awarded $1.00, suggesting sexism was alive and well during the trial.

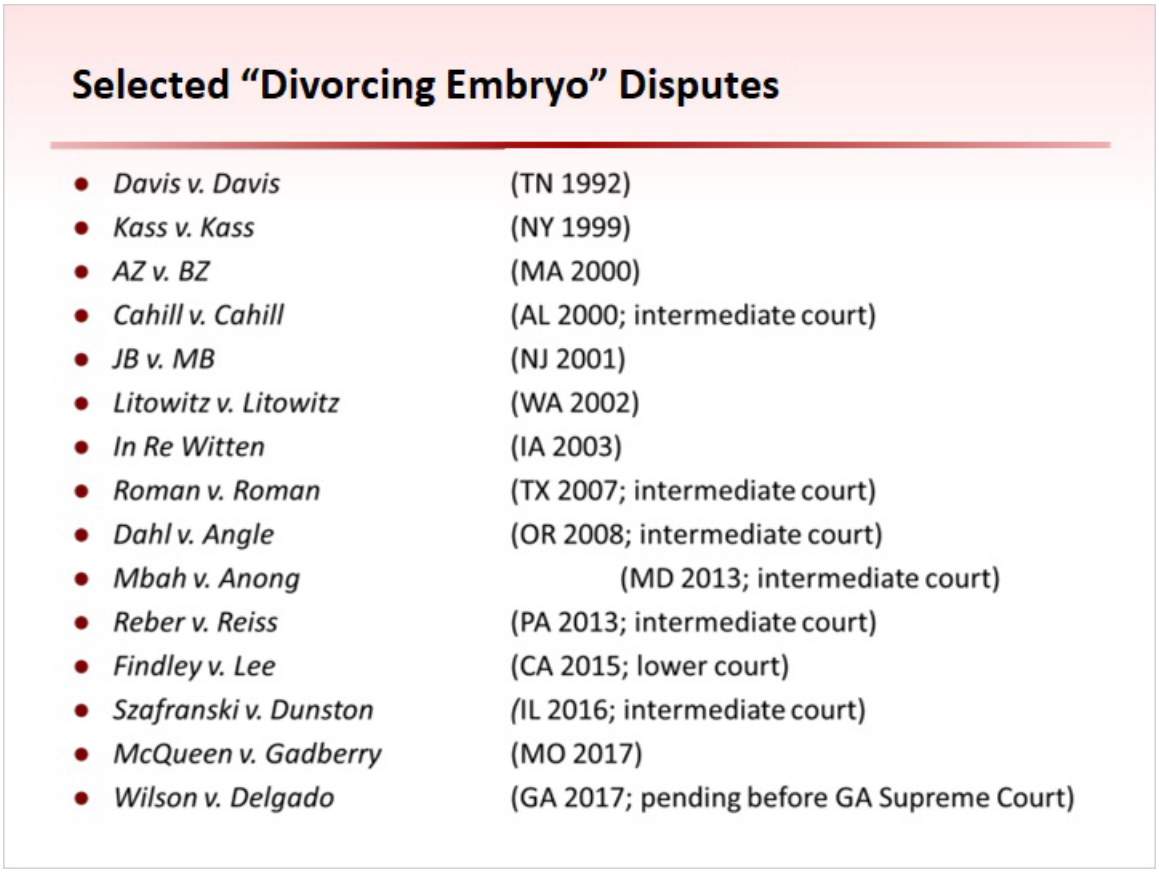
The second case involved a couple who sued the Jones Institute after their efforts there

were unsuccessful and they sought to fly their last embryo to California to attempt a transfer at another IVF program. The consents they had signed did not provide for transporting the IVF embryos, and Drs. Jones objected to releasing the embryos based on their expressed concern that there were no protocols or safeguards in place. The court treated the dispute as a property disagreement, and understandably awarded control over them to the couple. Given the nature of the dispute, there was no need for the court to consider the embryos as anything other than property.

In the *Davis* case, the Tennessee Supreme Court became the first state appellate court to wrestle with the novel question of custody of frozen embryos in a divorce. The ex-wife initially sought to use the embryos. Her ex-husband objected regardless of whether or not he could or would be relieved of his legal parental rights and obligations. The medical program, having just moved, had not unpacked their cryopreservation forms and the court had to weigh the couple's competing claims without the benefit of a written record of their initial joint intentions. The lower courts found for the wife, and at one point described the embryos as unborn children.

The Tennessee Supreme Court first concluded that embryos were neither property nor persons but occupy an interim category deserving of "special respect" due to their potential for becoming children, a characterization it found in an ASRM (then American Fertility Society) Ethics statement and repeated in many of the subsequent court cases. Ultimately the court ruled that there is both a constitutional right to procreate and not to procreate. In balancing those interests in the absence of a prior written agreement, the court found the husband's right not to procreate essentially trumped the wife's right to procreate, at least when she had an alternative method of parenthood. During the lawsuit, the ex-wife had remarried and the court found that she had other opportunities for parenthood without the embryos. For constitutional weighing purposes, the court said it must ignore any greater effort by the wife in the IVF process, and balance each genetic contributor's contributions equally.

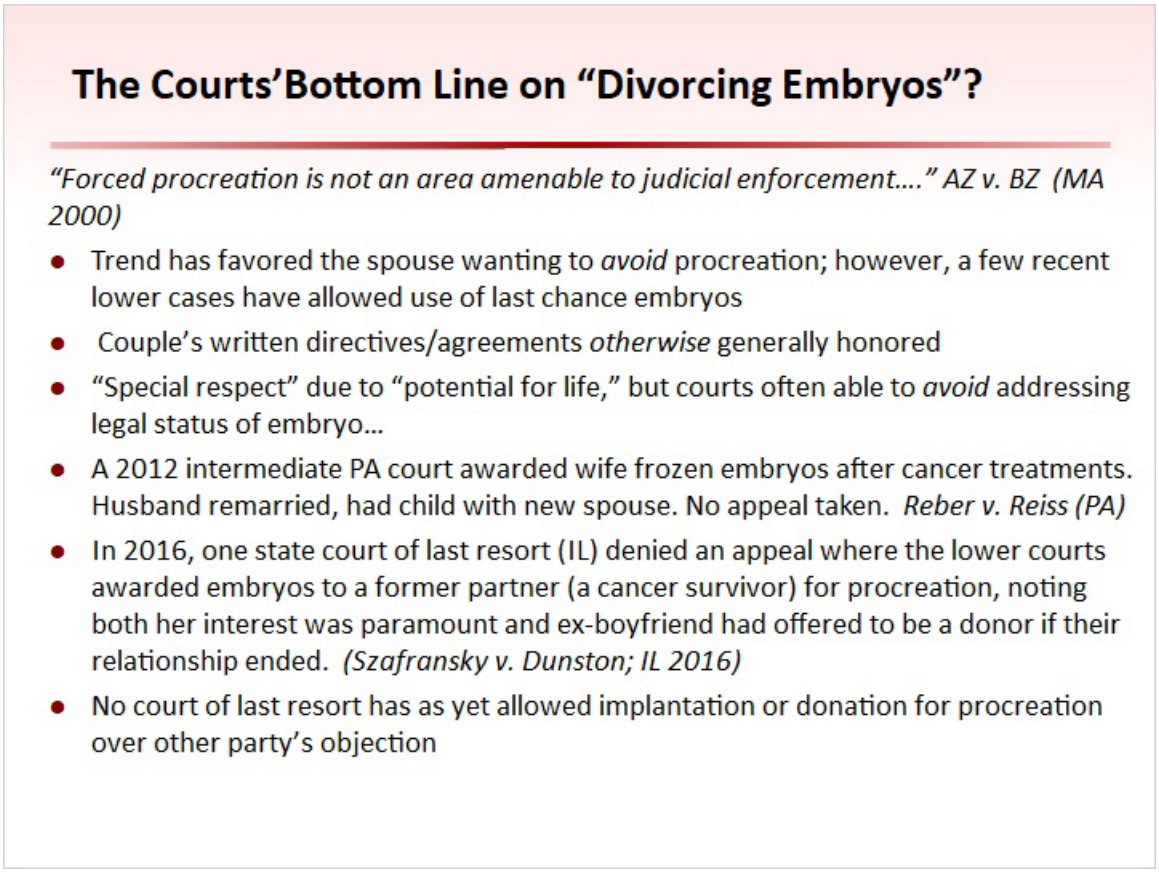
1.31 Selected "Divorcing Embryo" Disputes



Notes:

This list illustrates the relatively large number of courts that have wrestled with the fate of frozen IVF embryos in the context of a couple's divorce. Following *Davis*, a growing number of cases have explored several variations on this theme. While in *Davis* the couple had not issued a dispositional directive at the time that they began the IVF process, in *Kass*, such an agreement (to discard) did exist and the court enforced the agreement, while in *AZ* the court ignored the advanced directive (to let the ex-wife use), finding that a party seeking to avoid procreation (but not other advance directives) may change his or her mind at any time prior to transfer.

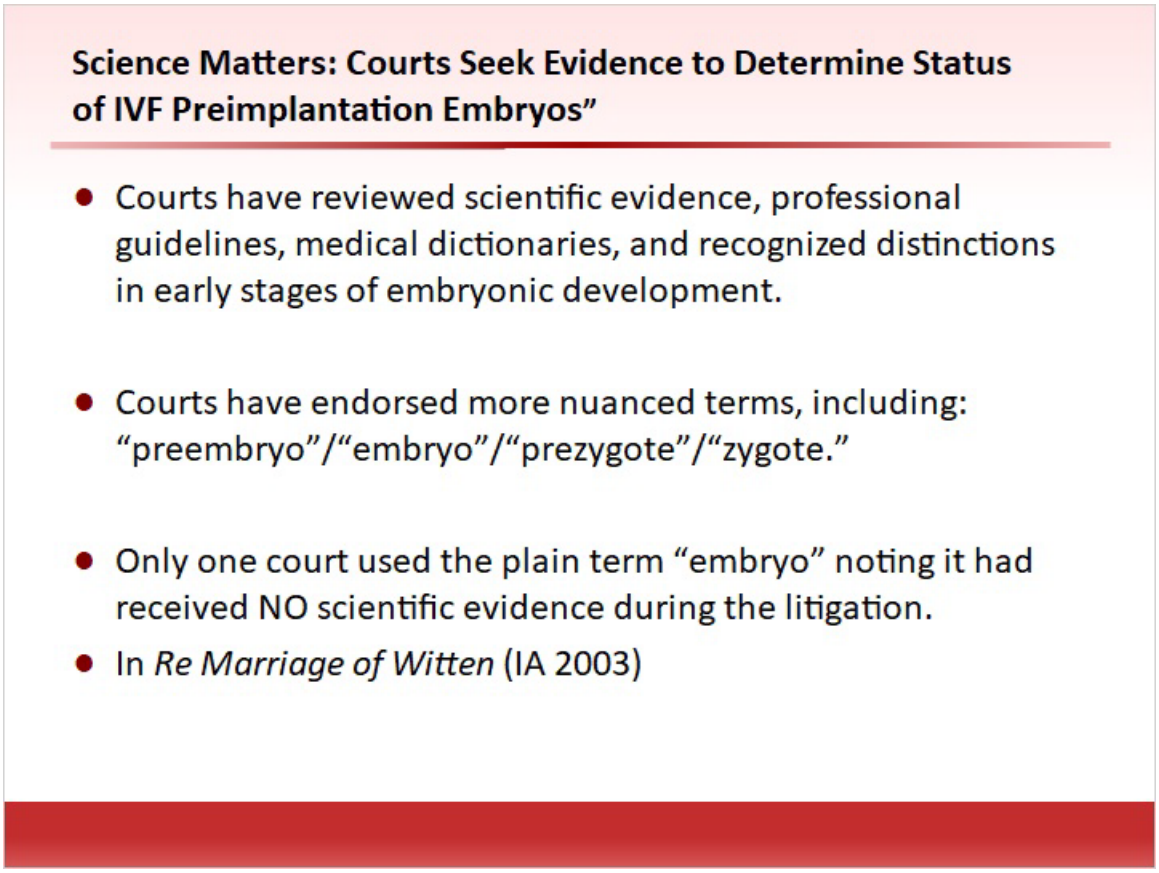
1.32 The Courts'Bottom Line on "Divorcing Embryos"?



Notes:

Intermediate courts' decisions have often been reversed by a state's highest court. The *Reber* case may suggest a trend shift, at least at the lower court levels, especially in a case with as sympathetic facts as presented in that case. The *Reber* court went to great lengths to point out the extensive cancer treatments the wife had endured, the likelihood that she could not have biological children as a result, the distinct differences between adoption and biological parenthood, as well as the low likelihood she would be able to adopt, the husband's remarriage and children, and the wife's offer to try to ensure he would have no financial obligations for the child but could, if he chose, be a part of the child's life. Similarly, in 2015, the IL Supreme Court denied the appeal of an intermediate appellate court that allowed a former cancer survivor to use embryos she had created with a former boyfriend—who the court found had also offered to be a sperm donor if the relationship did not last—under a somewhat similar analysis, putting the woman's interest to procreate above her "ex's" interest to avoid procreation, although his offer to be a donor was also found relevant. As of October, 2017, an embryo dispute involving donor eggs and the former husband's sperm is pending before the Georgia Supreme Court.

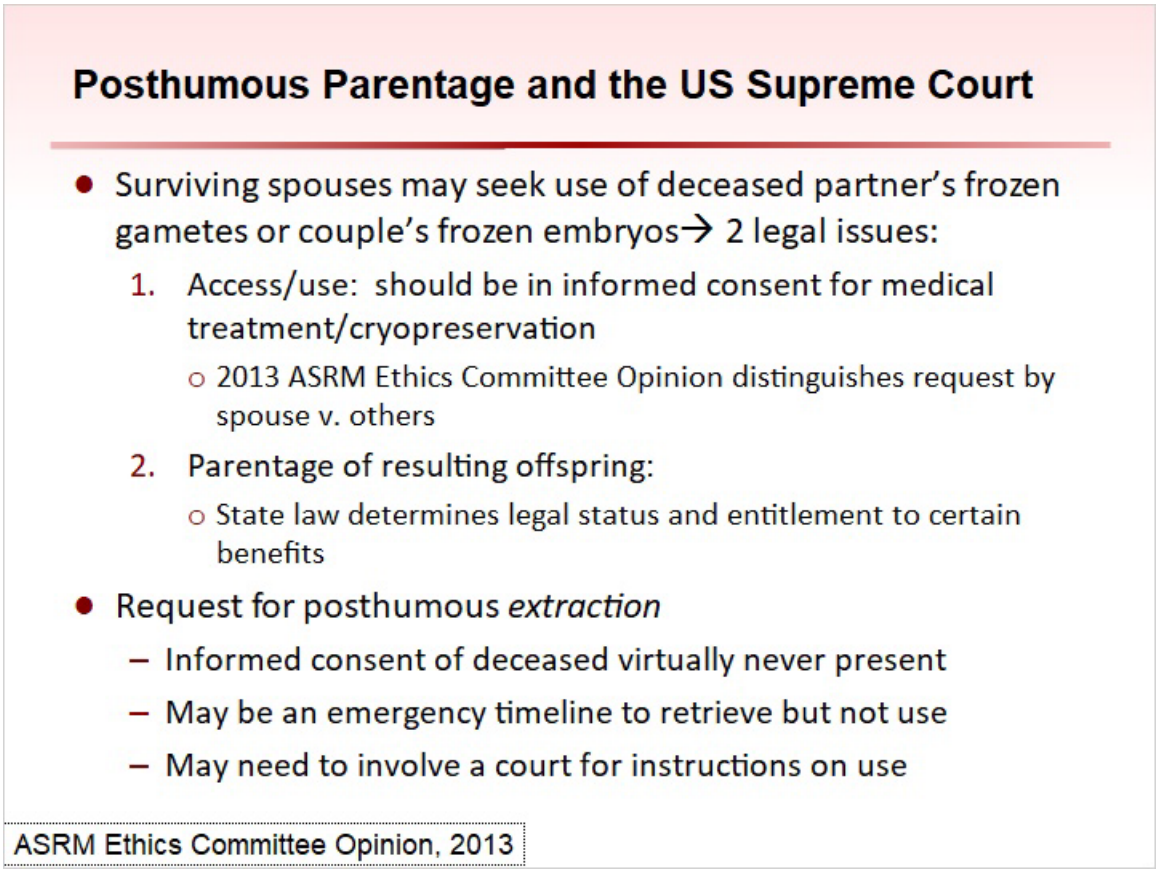
1.33 Science Matters: Courts Seek Evidence to Determine Status of IVF Preimplantation Embryos"



Notes:

As the Oregon Court of Appeals noted in *Dahl v. Angle,* "…[a]lthough we generally adopt the parties' use of the term "embryo"… to refer to a fertilized egg that has not been implanted in a uterus**,** the medically accurate term for an egg in that state is a "preembryo" or "prezygote"…[a] preembryo develops into an embryo only after implantation into a woman's uterus." [citing law review article].
The impact that scientific evidence can have on a court's understanding of the issues it must decide, and its ultimate ruling, which in turn may be precedent or influential guidance for future courts, simply cannot be overstated.

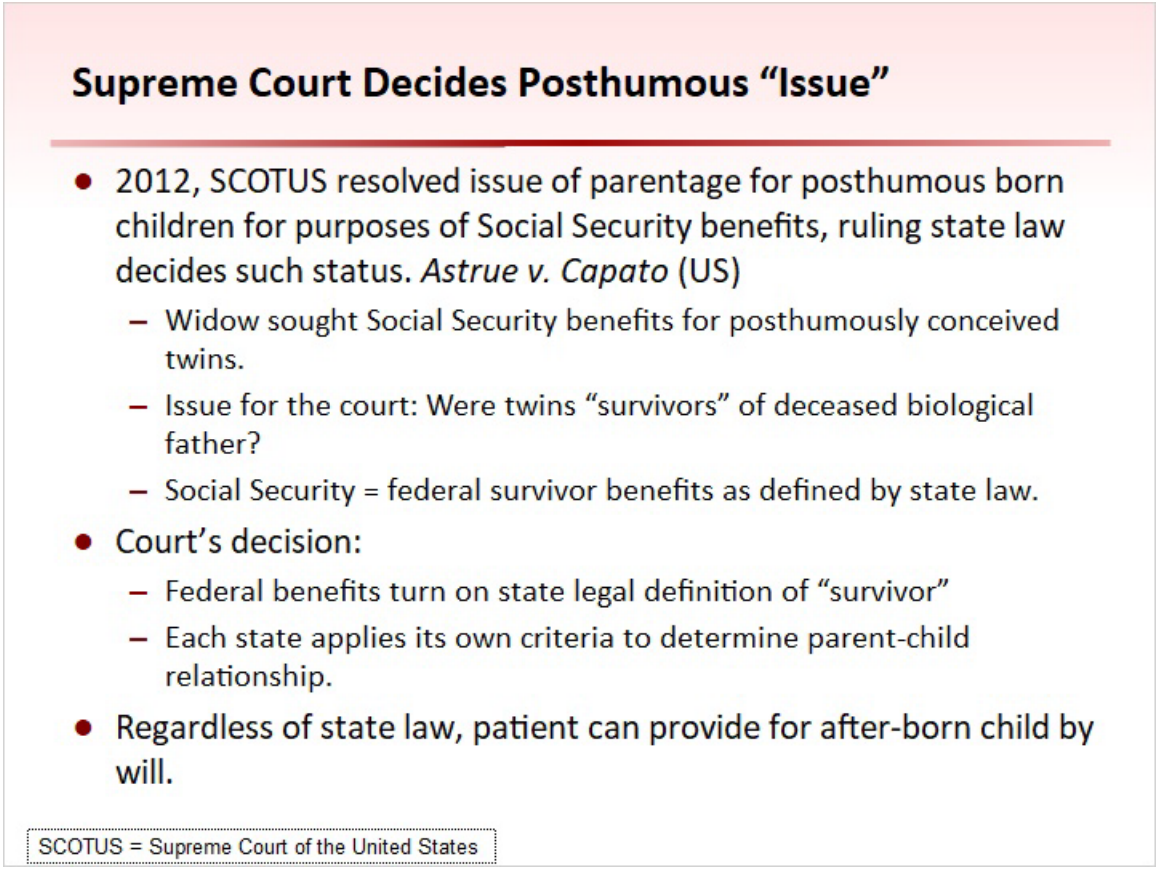
1.34 Posthumous Parentage and the US Supreme Court



Notes:

Posthumous use and, in more extreme cases, posthumous extraction of genetic material without a prior directive from the deceased is fraught with emotion, often with medical urgency, and potentially with legal liability. Regarding posthumous use, mental health professionals can play an important role in helping patients understand their options and feelings, and delaying use is commonplace. From a legal perspective, a prolonged delay may impact legal parentage status in some states based on state laws that establish time limits for legal recognition of posthumously born children and the patient may be well advised to seek legal counsel on this issue. With respect to extraction, anecdotally this is occurring regardless of a deceased's lack of consent issues. Decisions about what course of action to take will be fact specific. Professionals involved in such work may at times find the safest course of action is to follow requests, literally "freeze the status quo," to avoid loss of opportunity to procreate, but then require a court order or other protective legal steps and documentation, such as indemnification, before releasing the extracted genetic material for use.
The ASRM Ethics Committee Opinion from 2013 offers guidance on posthumous use, recommending considering the wishes of surviving spouses or partners but not others in the absence of a directive from the deceased.

1.35 Supreme Court Decides Posthumous "Issue"



Notes:

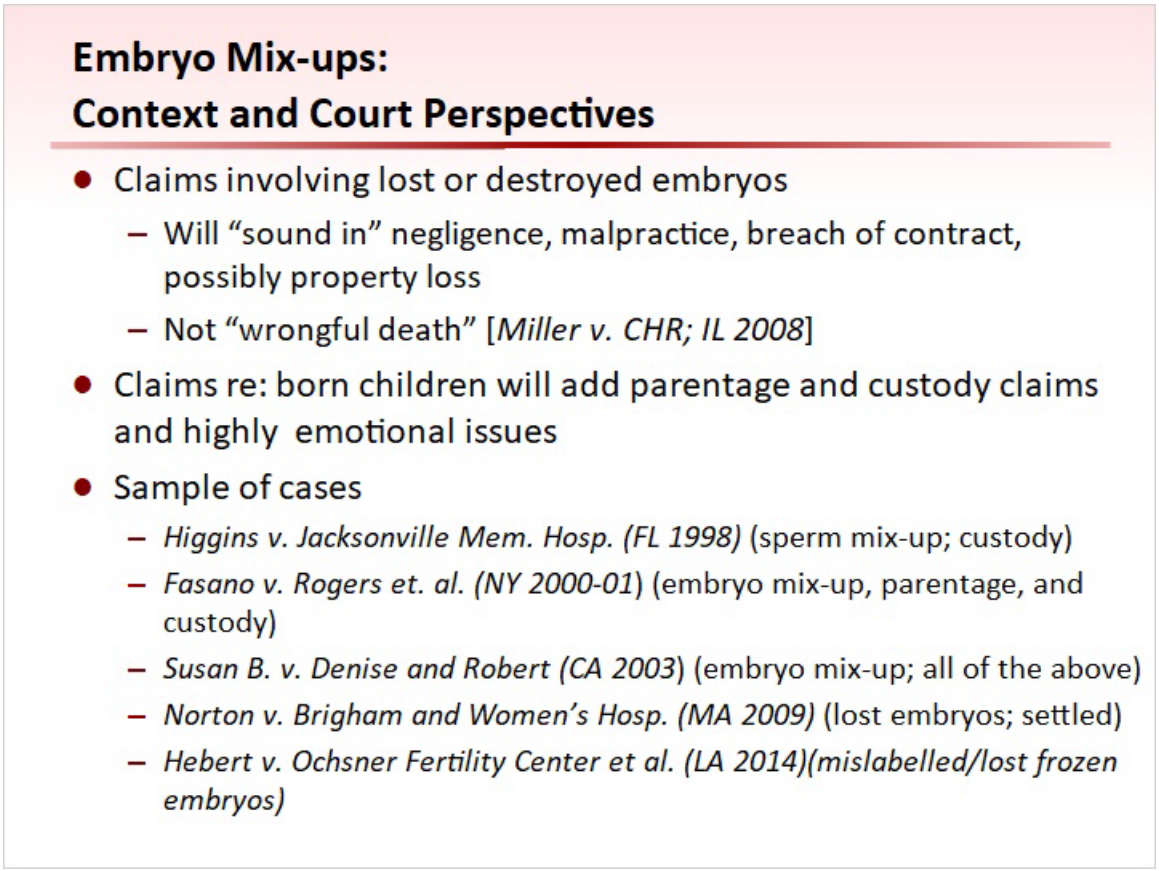
Astrue v. Capato settled the issue of whether state or federal law should apply to determine whether or not posthumously born children were entitled to federal Social Security benefits. Before *Astrue*, different states had come out with conflicting rulings. The federal law is relatively clear, stating that the question of whether a child of a deceased person legally qualifies as a "dependent" is a question of state law, thus inconsistent outcomes were understandable.

The expected result is that this qualifying dependent status varies from state to state, as each state applies its own criteria to determine a parent-child relationship. Ms. Capato lost under Florida law, whereas under Massachusetts law a posthumously born child would qualify if a three-pronged test could be met: proof of biological parentage of the deceased, and an intent to both have and financially support the child (presumably to distinguish donors).

Regardless of state law, any person can provide for anyone, including any after-born child, through explicit language in their will. *Astrue v. Capato* thus only restricts government benefits that flow as an operation of law from a state determined legal

status, not an intentional bequest by a deceased.

1.36 Embryo Mix-ups:



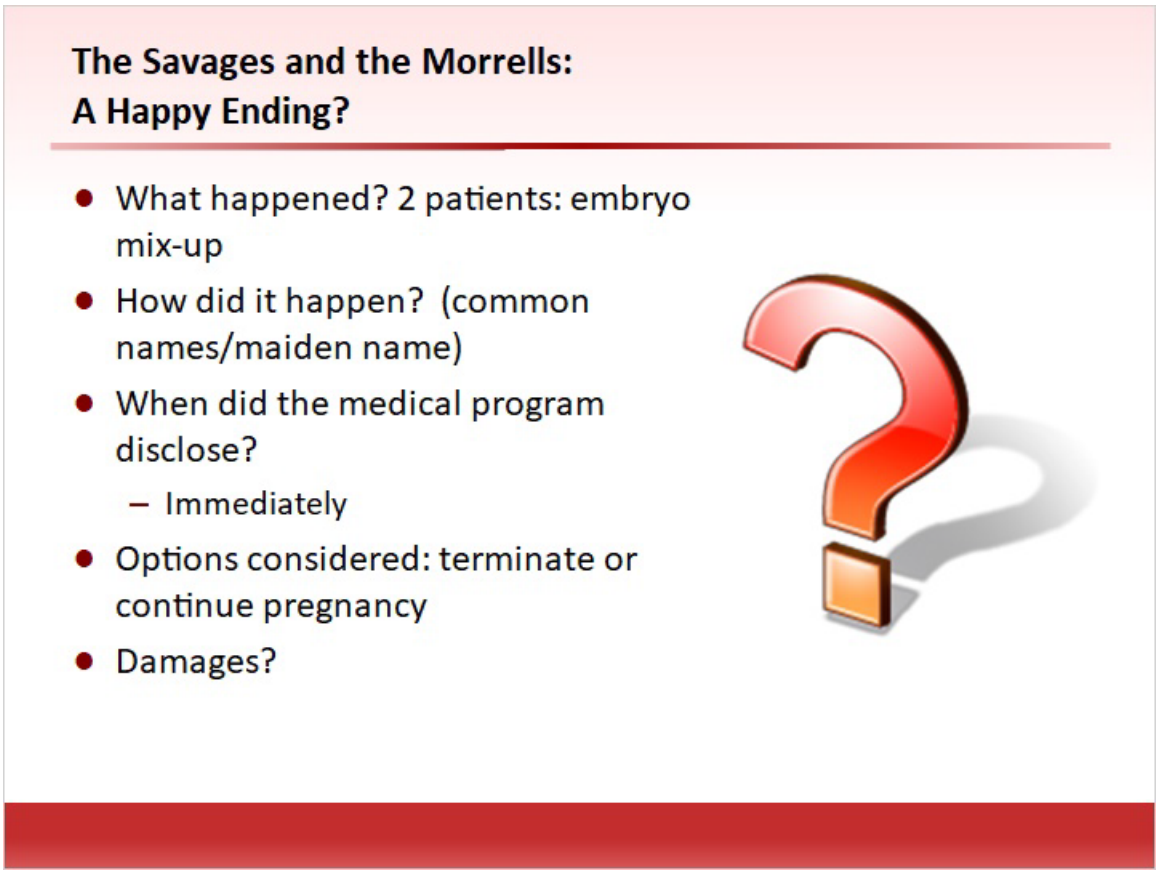
Notes:

There have been a limited number of reported court decisions involving embryo mix-up, including the first three cases noted here. In each, both legal parentage and physical custody were issues. In all three, there were also claims brought against the hospital, physician, embryologist, and/or practice, with financial settlements resulting. In the *Susan B.* case the physician, who was found to have intentionally withheld the information and surreptitiously attempted to cause a miscarriage, lost his medical license. It is quite likely that the number of such cases is larger than those reported decisions, as there is a substantial incentive to resolve such cases as quietly as possible, without litigation, to protect all involved. How to handle embryo mix-ups is discussed in a subsequent section.

Lost embryos such as the last two cases, do not raise parentage or custody issues because no child has resulted. In the *Norton* case, all embryos of a cancer patient were lost, and after the patient sued, the hospital relatively quickly reached a financial

settlement. In the *Ochsner* case, which is discussed in more detail in another section, there are ongoing issues and the case continues.

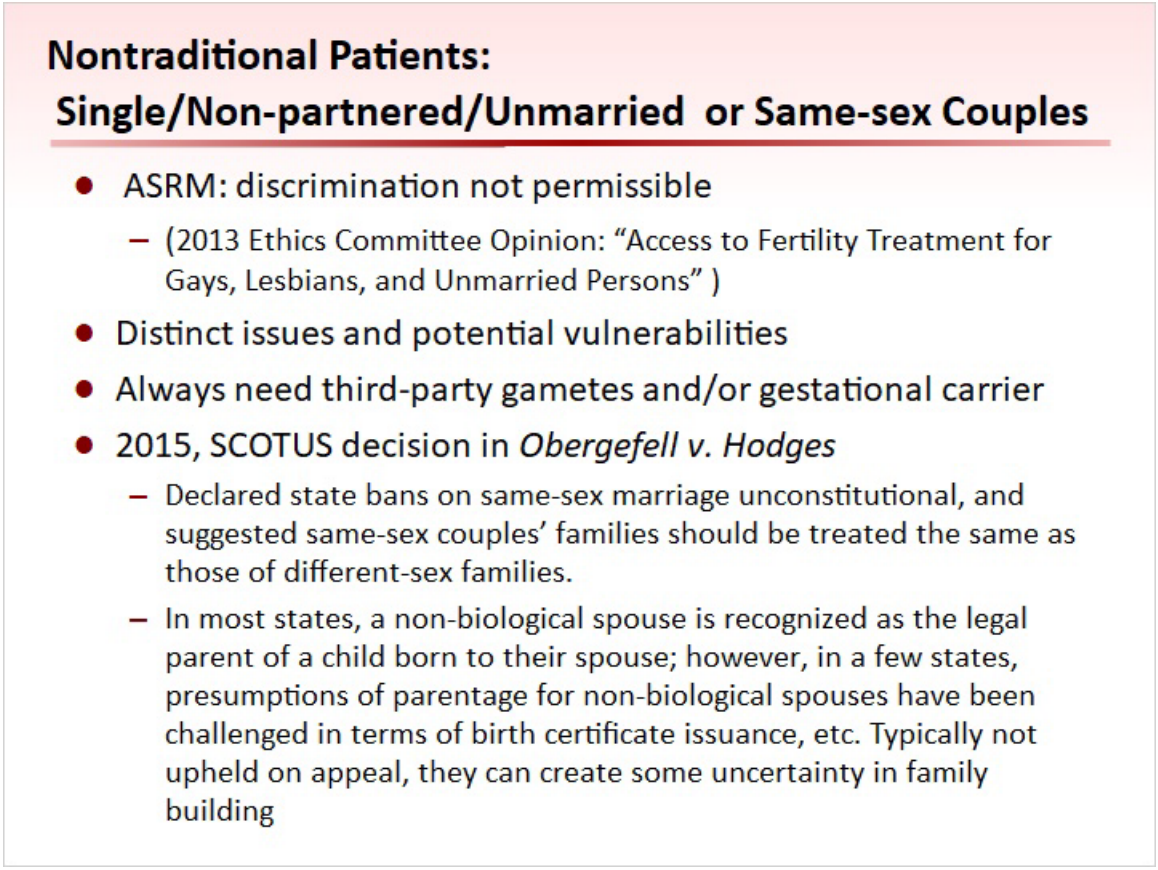
1.37 The Savages and the Morrells:



Notes:

Carolyn Savage became an inadvertent gestational surrogate while attempting to have her final pregnancy. The embryo mix-up and her decision to continue the pregnancy meant she could not carry another pregnancy for herself from a health perspective. Ultimately, she was able to use her own remaining embryos with a gestational carrier and had a child. Presumably part of the damages and settlement with the IVF program included the expenses and costs associated with the gestational carrier arrangement. Even this "best-case scenario" was fraught with emotion, including fear by the Morrells that Ms. Savage would terminate the pregnancy. The couples have each written a book ("Inconceivable" and "Misconception") and spoken publicly about their experience; these are sobering accounts for all involved in this field.

1.38 Nontraditional Patients:



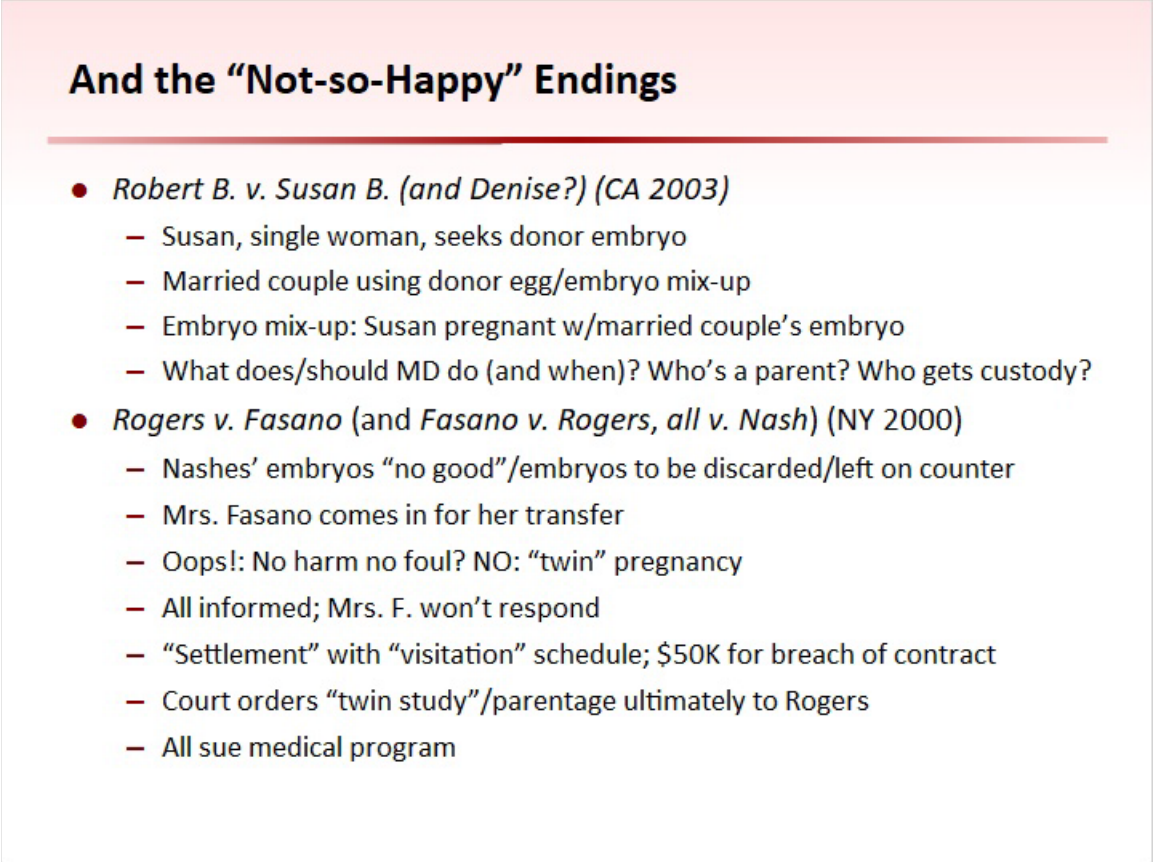
Notes:

Same-sex couples will always require at least donor sperm or eggs; single men or same-sex male couples also require a traditional surrogate or a gestational surrogate carrier.
In 1996, Congress passed a federal law, the "Defense of Marriage Act" ("DOMA"), which allowed states to disregard legally valid same-sex marriages from other states. Until this, most scholars agreed that marriage and other family laws were strictly the province of individual states.
In 2013, the US Supreme Court struck down a portion of DOMA as unconstitutional in the *Winsor* decision, thus requiring states to recognize a legal marriage from another state; but it did NOT require each state itself to permit such marriages.
In 2015, The US Supreme Court overturned state laws that banned same-sex marriage, noting that same-sex couples' families should be treated the same as different-sex couples' families. While this marital recognition has overcome many legal hurdles, difficulties remain in obtaining parental rights in many jurisdictions. A non-biological, unmarried parent may not have equal say in embryo disposition, parent-child relationship, etc., although a few very recent state courts have found equal parentage

rights for former non-married, non-biological parents with very strong facts as to joint parenting (MA and NY).

In addition, it is still best practice to recommend that same-sex couples seek legal counsel to advise them on any legal needs they may encounter in their family-building journey, including the potential advisability of undertaking a formal adoption.

1.39 And the "Not-so-Happy" Endings



Notes:

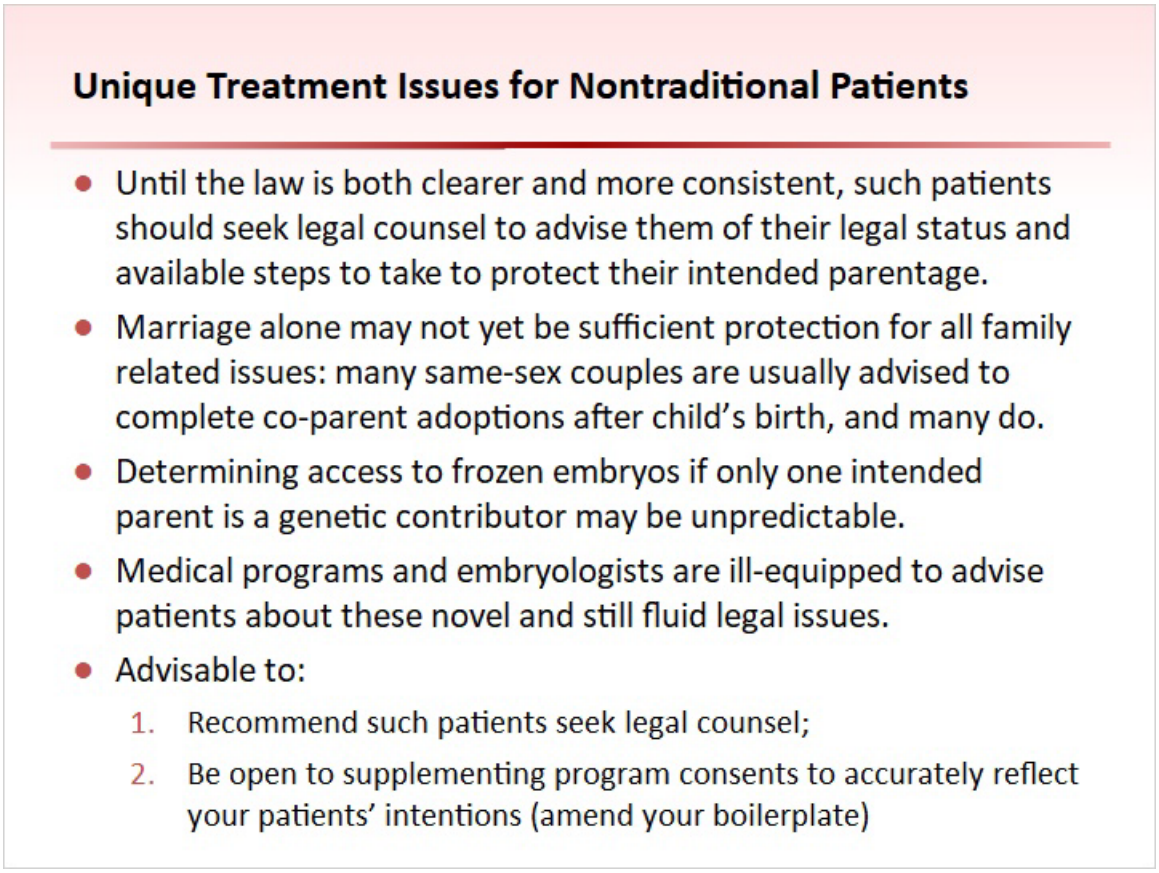
The not-so-happy-endings are more likely in the event of discovered embryo mix-ups. From a legal perspective they can involve potential claims for malpractice, negligence, breach of contract, and family law. Whenever an embryo mix-up results in a born child, parentage and custody determinations will be addressed under applicable state law. The California case involving Susan B., a single woman who had requested an anonymous donor embryo, and Robert and Denise, a married couple using a donor egg, points out the legal issues confronting patients, programs, and resulting offspring from an embryo mix-up. The medical program mistakenly implanted Susan with the married couple's embryos and both women delivered a child. The physician originally tried to keep the

mix-up from being discovered, but ultimately the patients were informed and a parentage and custody battle ensued.

All three patients claimed parentage of the child Susan delivered. Susan argued that she was the mother and Robert was simply a sperm donor. The court ultimately found that Robert was the father, as he never had the intent to donate his sperm to anyone, that Susan was the mother as she had carried the child and intended to be the mother, and that Denise had no claim since she was neither genetically nor gestationally related to the child. The court then ruled that the case came down to a custody dispute between an unmarried mother and father. The court could but did not consider that Denise was the intended mother of any child born from embryos that she and her husband created with a donor egg, and was indeed the mother of a child born from those same embryos, a full genetic sibling, to the child born to Susan B. Susan B's lawsuit against the physician resulted in a $1m financial settlement, and the physician's medical license was revoked.

In the Rogers v. Fasano matter, the parties were patients at the same New York IVF program, run by Dr. Nash. One couple was Middle Eastern, the other was African American. Through an inadvertent mix-up, Ms. Fasano first had Ms. Rogers' embryos transferred to her, after which the embryologist realized the mistake but, thinking those embryos were not viable, proceeded to also then transfer the correct embryos to Ms. Fasano. A "twin" pregnancy resulted, and both patient couples were informed. Ms. Fasano refused to cooperate and gave birth to both her and the Rogers' genetic children, an obvious fact because of the racial differences. She sought to maintain a relationship with the child, Joseph, whom she called by a different name. After the visitation arrangement broke down, the couples went to court over parentage and custody of Joseph. A trial judge, herself a twin, ordered a twin study. New York also has an irrebuttable presumption of maternity for the woman who gives birth to a child. Nonetheless, the courts ultimately ruled that this was more in the nature of a mix-up at birth, and awarded the Rogers parentage and custody of their genetic child with no rights for Ms. Fasano. Both couples also sued the medical program.

1.40 Unique Treatment Issues for Nontraditional Patients



Notes:

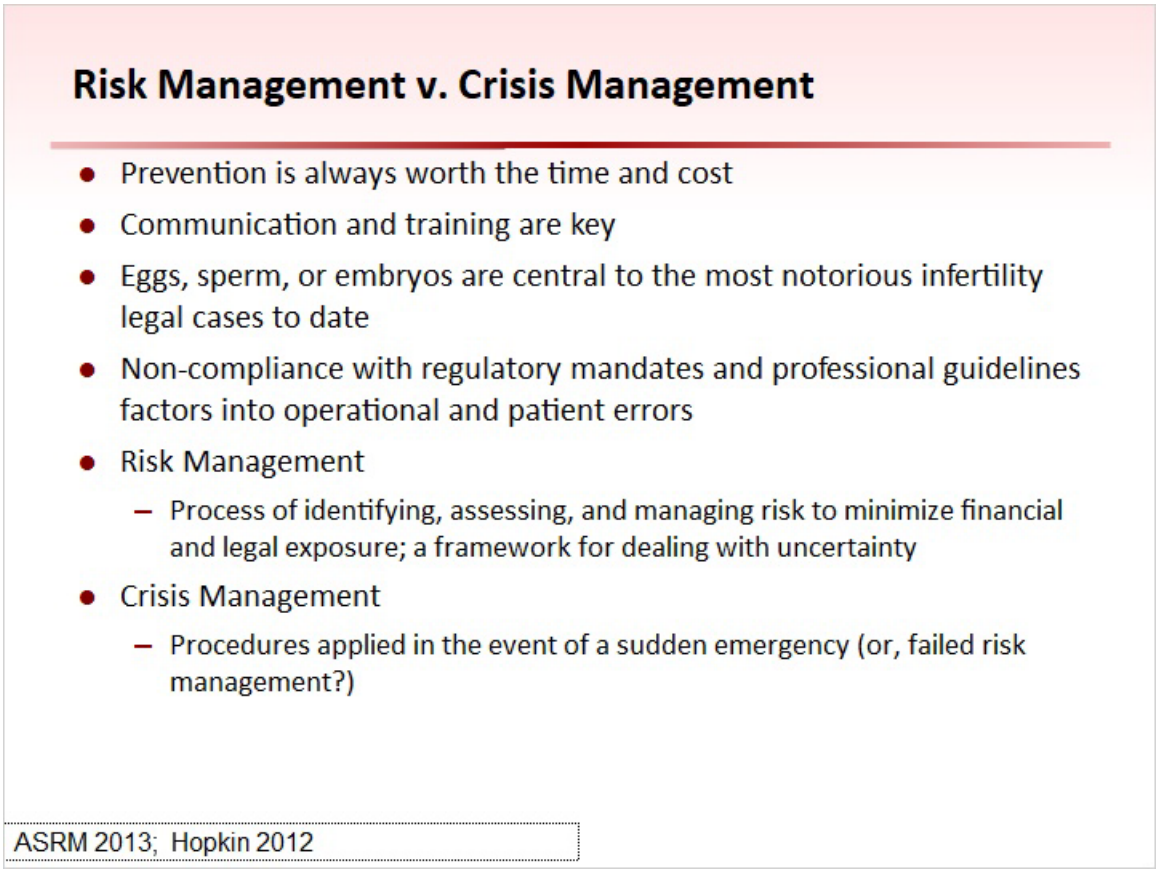
This is an extremely new and very fluid area of the law, in the wake of the federal legalization of same-sex marriage and ~~with~~ a myriad of lawsuits ~~pending~~ on same-sex marriage issues in multiple states.

Predicting legal status and protecting a parent-child relationship are outside the expertise of any medical professional. Thus, while ASRM or other voluntary guidelines may suggest treating all patients similarly, patients whose familial relationships are not clearly protected and legally recognized will be well advised (for example, single or unmarried couples) to seek legal counsel as they build their families. Even in many states such as Massachusetts where same-sex marriage has been legal for some years, co-parent adoptions are still considered standard recommended legal practice, to ensure the legal status of the nonbiological parent in any state or circumstance the couple may find themselves in. Adoption remains a time-honored and uniformly recognized legal status to protect parentage status for those who undertake the adoption.

There have been a number of cases where same-sex couples have broken up and bitter custody disputes have arisen between biological and nonbiological parents, as well as gestational and nongestational parents, with competing claims of single parentage and

donor or gestational carrier status. At times, medical programs that used standard consent forms were drawn into these disputes as they had inadvertently characterized an intended parent as a donor or gestational carrier. Patients need to understand that they need to take steps to protect their legal status is critical.

1.41 Risk Management v. Crisis Management



Notes:

Increased interest over the last few years from medical regulatory and accrediting bodies continues to highlight the emphasis on patient safety and risk prevention in all areas of medicine. ASRM guidance in this area also supports the risk and safety principles as applied to ART.

The complications of errors in the embryology lab have already been discussed. There is no disagreement that any and all of these instances should be avoided as the cost of such adverse events is astronomical as compared with time and money investment in preventing them.

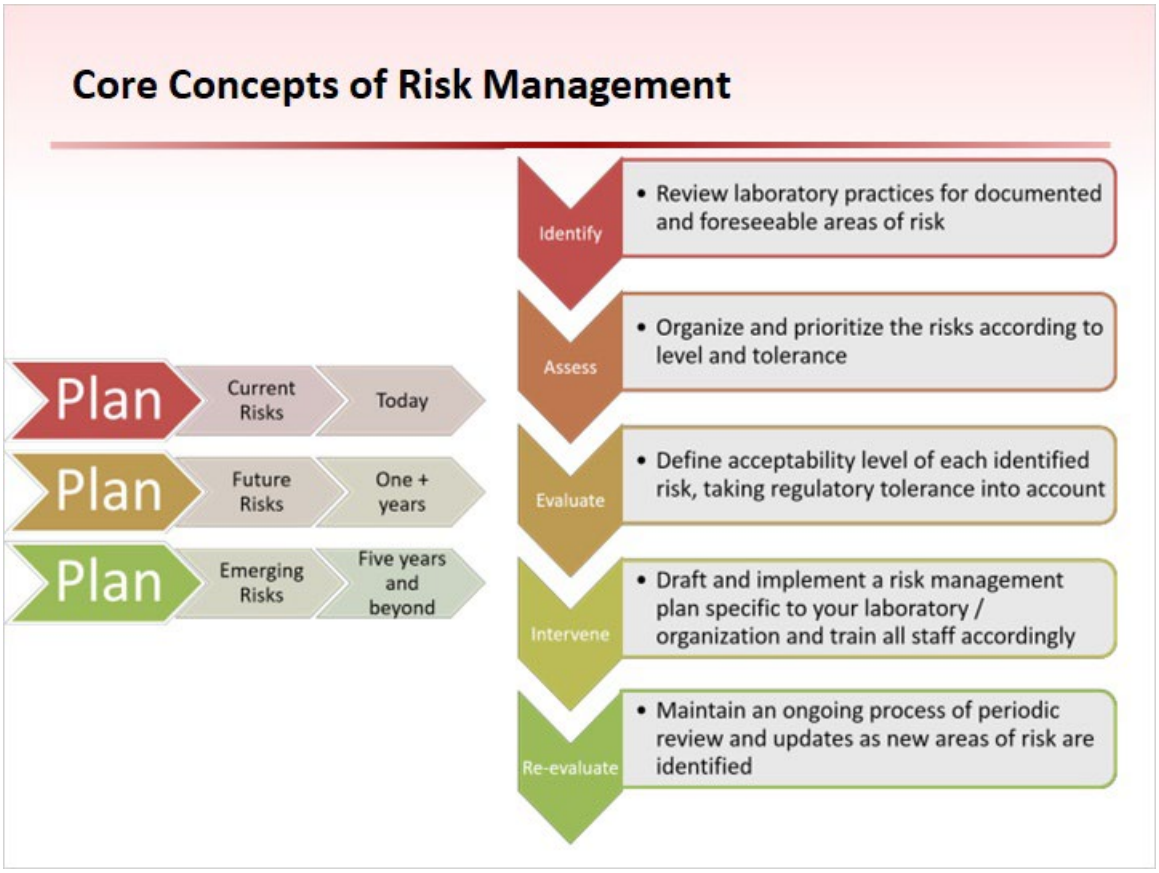
Every risk management program relies heavily on clear and objective communication between team members, and the initial and ongoing training of everyone involved in patient care in an ART program.

Reproductive medicine lawsuits, particularly those involving eggs, sperm, and embryos, draw media attention quickly and for prolonged periods of time. The most notorious legal cases to date include some claim of negligence or malice involving gametes or embryos.

Simply put, if one doesn't follow the rules, there is always the possibility of errors and an ensuing lawsuit. Noncompliance by lab personnel in following mandated regulations and/or professional guidelines factors into all errors, whether they are operational or patient-based.

The next section will encourage a culture of risk management over crisis management. Risk management is the process of identifying, assessing, and managing risk to minimize a program's financial and legal exposure. In other words, it is a framework for dealing with uncertainty. Simply, it is preparation and prevention. Crisis management, on the other hand, is the process used to manage a sudden emergency. It is reaction, not prevention, and, in that sense, may also be seen as failed risk management.

1.42 Core Concepts of Risk Management



Notes:

The core concepts of risk management are equally as applicable to the embryology laboratory as they are to any business or organization.
Planning is essential, not only for what is happening in the lab and the field of embryology today, but what is anticipated in the near future, perhaps 1-2 years out. However, that is not where planning ends. Comprehensive risk management involves even more forward thinking, perhaps to what may be relevant in 5 years or beyond. And, as embryologists are involved in key new technologies such as genetic screening, assessing and including emerging risks are mandatory.

But thinking about embryology as it is today and what it may be tomorrow is not enough. There should also be a formalized approach that culminates in a written and dynamic risk management plan. This approach involves a process which includes the following steps:

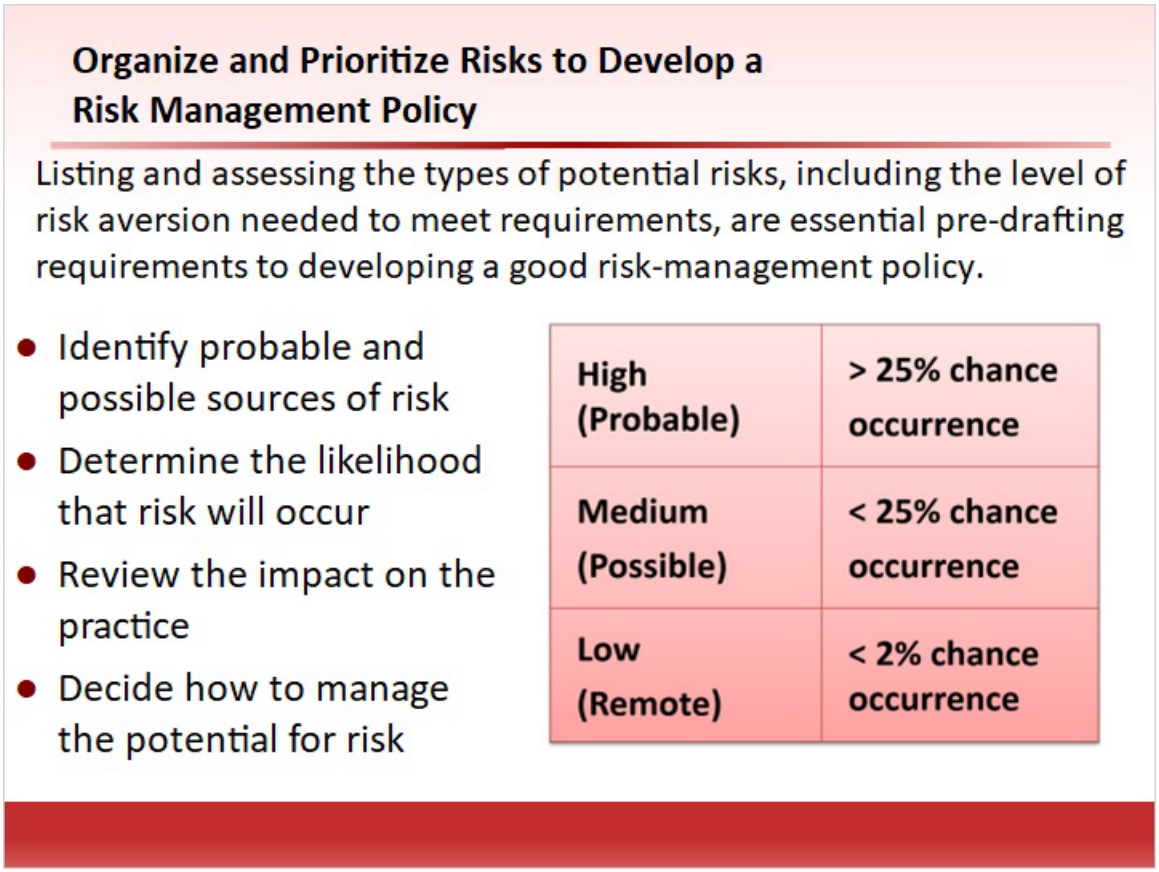
1. Identification of known and possible risks through a review of laboratory practices
2. Assessment of each risk so that all risks are prioritized according to level and program tolerance
3. Evaluation to define the acceptability level of each identified risk, taking regulatory

tolerance into account
4. Intervention to draft and implement a risk-management plan specific to your laboratory, including appropriate training of all staff
5. Continual evaluation of the risk management plan to maintain an ongoing process of periodic review and update as new areas of risk are identified.

[Hopkin, 2012]

As an aside, the embryologist may be more familiar with the concept of Quality Management, which is a large part of laboratory competencies and Key Performance Indicators. This approach differs somewhat from risk management as it is generally known as a process of assessment and improvement to maximize outcomes. Risk management is more focused on preventing legal and financial liabilities. Although the two approaches may appear in conflict at times, appropriate cooperation and information sharing would strengthen both programs.

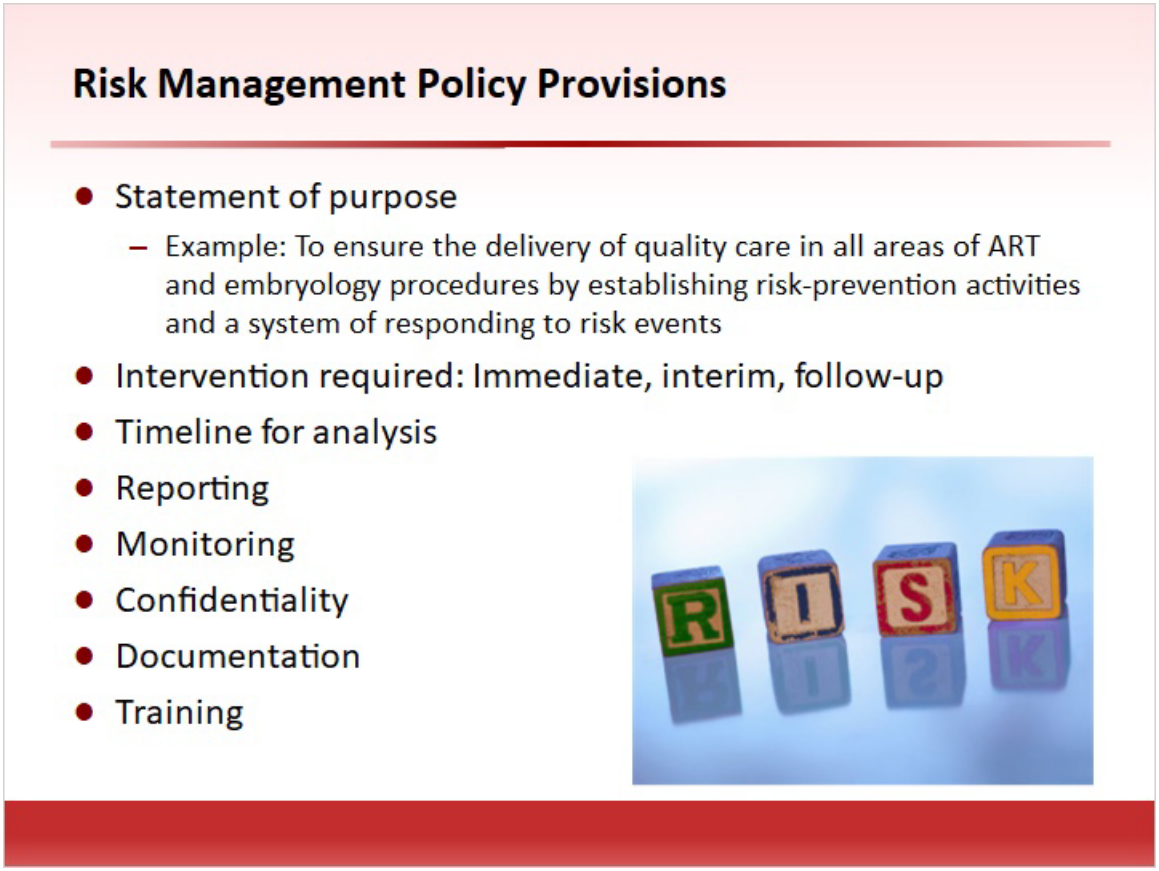
1.43 Organize and Prioritize Risks to Develop a



Notes:

To clarify a key component of risk assessment, review of the level of risk as probable, possible or remote is helpful to determining what response should be planned. Further evaluation of the impact to the practice should the risk occur, as well as the level of risk tolerance, must be included in any plans. Risk tolerance not only includes mandated responses in law and regulations, but specific program tolerances. For example, even though the probability that an embryo mix-up is deemed remote in most labs, there is "zero tolerance" to this error in all regulatory and ethical discussions of such instances. This situation requires specific delineated procedures that support regulatory compliance.

1.44 Risk Management Policy Provisions



Notes:

In developing a comprehensive risk management policy, the drafter should include standard policy provisions that are tailored to the highly specific needs of the embryology laboratory. These provisions include:

1.A clear general statement of purpose similar to the example here

2.The specific interventions required, including when immediate action, interim action,

and follow-up action should occur
3.A timeline for risk analysis of an adverse event
4.Reporting guidelines for internal and external reports
5.Description of monitoring procedures
6.A clear statement that all personnel must maintain confidentiality of the adverse event and the risk response
7.Process for appropriate documentation of the adverse event and the risk response
8.Methods to be used to train all personnel

1.45 Consequences of Risk Events

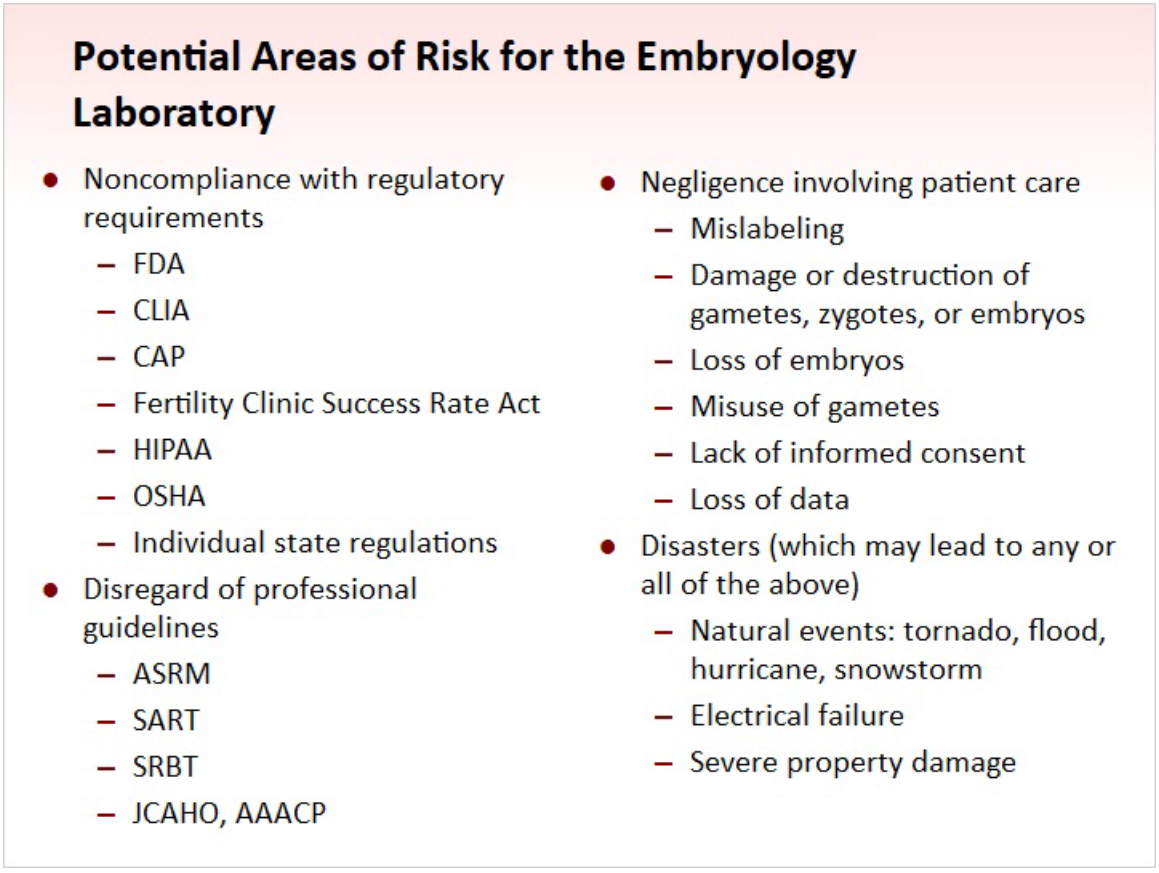
Notes:

Whether an adverse event occurs in the normal course of business, or is the consequence of a unique disaster, there may be severe consequences to the laboratory entity and the individual personnel involved or responsible for the acts leading to the incident. The consequences of lab errors may include:
1.Everyone's biggest fear: a lawsuit is filed by an affected patient, and/or legal action is taken by a regulating body.
2.There are also concomitant financial responsibilities, including costs of physical repair/clean-

up, insurance deductibles, and increased premiums, fines, settlements, awards, legal fees, training, etc., not to mention financial losses if patient volume declines due to the adverse event.

3. Noncompliance of mandated regulations may lead to an enforced compliance program.
4. Exposure to negative impact on a program's reputation, to an individual's reputation which may affect his or her ability to work or progress in the field.
5. The effect of an adverse event is keenly seen on the laboratory personnel. Their performance may be reduced or hampered because of fear of recrimination, personal involvement in legal proceedings, or mistrust of the program and its leaders.
6. Loss of personnel as a direct result of an adverse event will incur re-hiring and re-training costs.
7. As stated earlier, if the event included damage to laboratory property or equipment, these will need to be replaced or repaired, which may impact the ability of the laboratory to function normally.

1.46 Potential Areas of Risk for the Embryology Laboratory



Notes:

Potential risk for laboratories spans several distinct areas and can be quickly characterized in the list shown here.

Obviously, noncompliance with any applicable regulatory requirements, no matter which agency promulgates and enforces adherence, will expose the laboratory to the applicable penalties. These can be as severe as closing laboratories to minimal impacts of providing further information or revising procedures. Further, disregard of professional guidelines, especially those espoused by ASRM, may be used as evidence that the laboratory and/or the embryologist does not meet the standard of care. If the guideline avoided is one from a certifying body, the laboratory or the embryologist places their certification in jeopardy.

A majority of patient complaints and malpractice claims begin with clinical care; however, in ART the embryology laboratory often plays a key role in a patient's treatment. This integral role exposes the embryologist and the laboratory to a potential claim of negligence involving:

1.Mislabeling/damage/destruction of gametes, zygotes, or embryos by any means
2.Loss or misuse of embryos
3.Procedures done without proper informed consent, or
4.Loss of laboratory data through disasters or theft

Lastly, the embryology laboratory must be aware that real disasters do happen, as evidenced by the huge impact felt by ART programs in New Orleans, Florida and Puerto Rico after hurricanes destroyed medical practices and interrupted normal business operations. ~~Katrina~~. Disaster management, while a part of the overall risk management program, generally stands alone with its own set of preparedness standards.

1.47 How to Deter Laboratory Risk

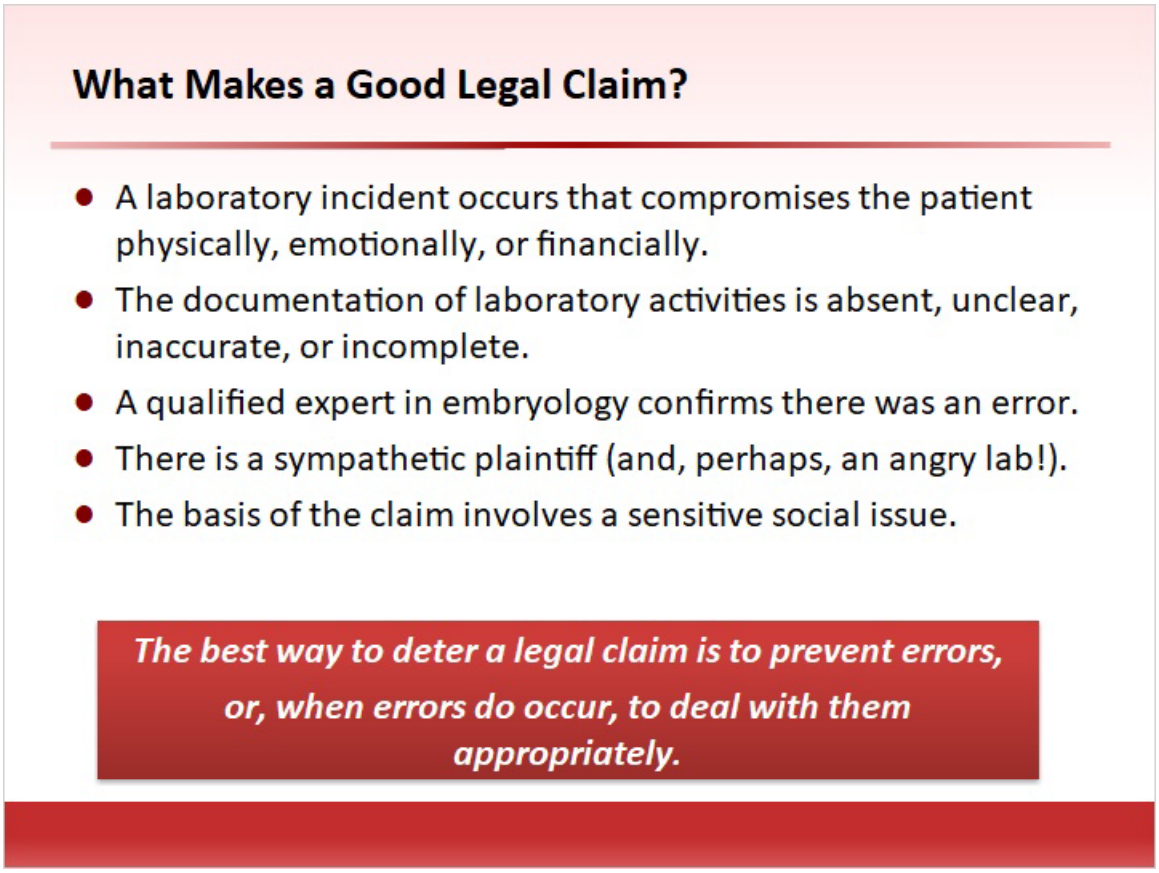
Notes:

The procedure to deter laboratory risk may sound simple, but it involves time, effort and, most importantly, diligence, in the assessment of all operational and patient care activities.

Deterrence includes:

1. Knowing the regulations, laws, and guidelines that apply to all laboratory practices
2. Implementing and enforcing policies and procedures
3. Educating staff on standards of care
4. Auditing laboratory practices to ensure compliance
5. Having an active compliance program and a designated compliance officer
6. Selecting and training laboratory personnel to maximize outcomes and reduce risk
7. Maintaining and adhering to all policies and procedures
8. Teaching laboratory staff how to deal with the events that are never expected to happen—but MIGHT, the rare times when an extra-prompt response is critical. Prevention of these “never” events may also include empowering laboratory staff to stand up and say “no,” so that negative consequences are minimized or avoided altogether.

1.48 What Makes a Good Legal Claim?



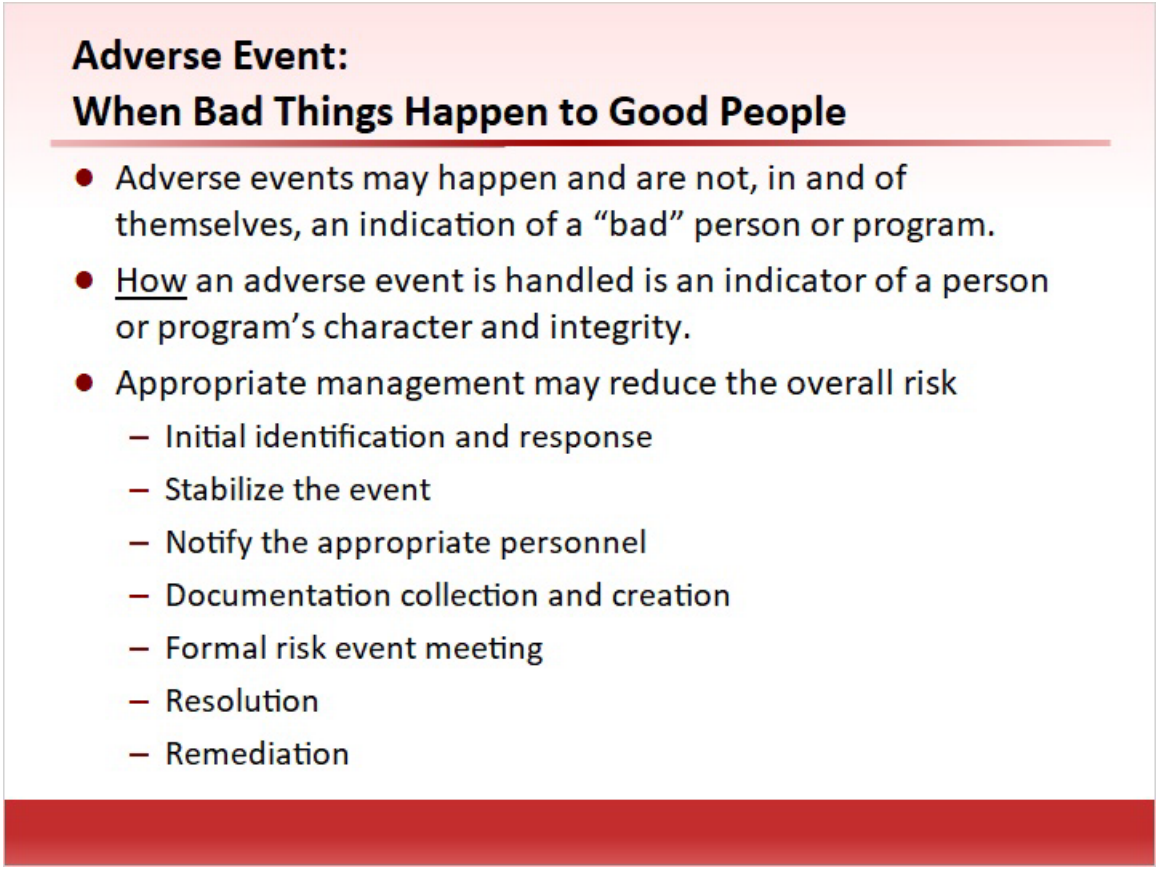
Notes:

In order to bring any claim to court the most essential element is a plaintiff willing to state that they have been wronged. That said, not all claims will progress to the point of involving the laboratory in a prolonged legal investigation and proceeding. However, a few progress. Most of the claims that get to court (or may require settlement in the face of a negative outcome for the program or the lab) are found to have certain elements. These include: an incident in the laboratory that somehow compromised the patient in a physical, emotional, or financial manner; and questionable documentation in that it is absent, unclear, inaccurate, or incomplete. All claims must be certified by an expert before they move into litigation. This requirement is met by having an expert in embryology (which may be a colleague in another program) state that the laboratory made an error. In addition, good claims are brought by a sympathetic patient (as are many whose embryos are impacted) and defended by “defensive” laboratory personnel (again, not unexpected). Finally, a good claim involves a sensitive social issue. Since its

debut into society, all areas of ART have touched the sensitivity nerve in most people.

The bottom line is that almost all laboratory errors could lead to a good legal claim; therefore, it is clearly important to know how to prevent errors, and in the face of the aftermath of an error, to deal with them accordingly.

1.49 Adverse Event:

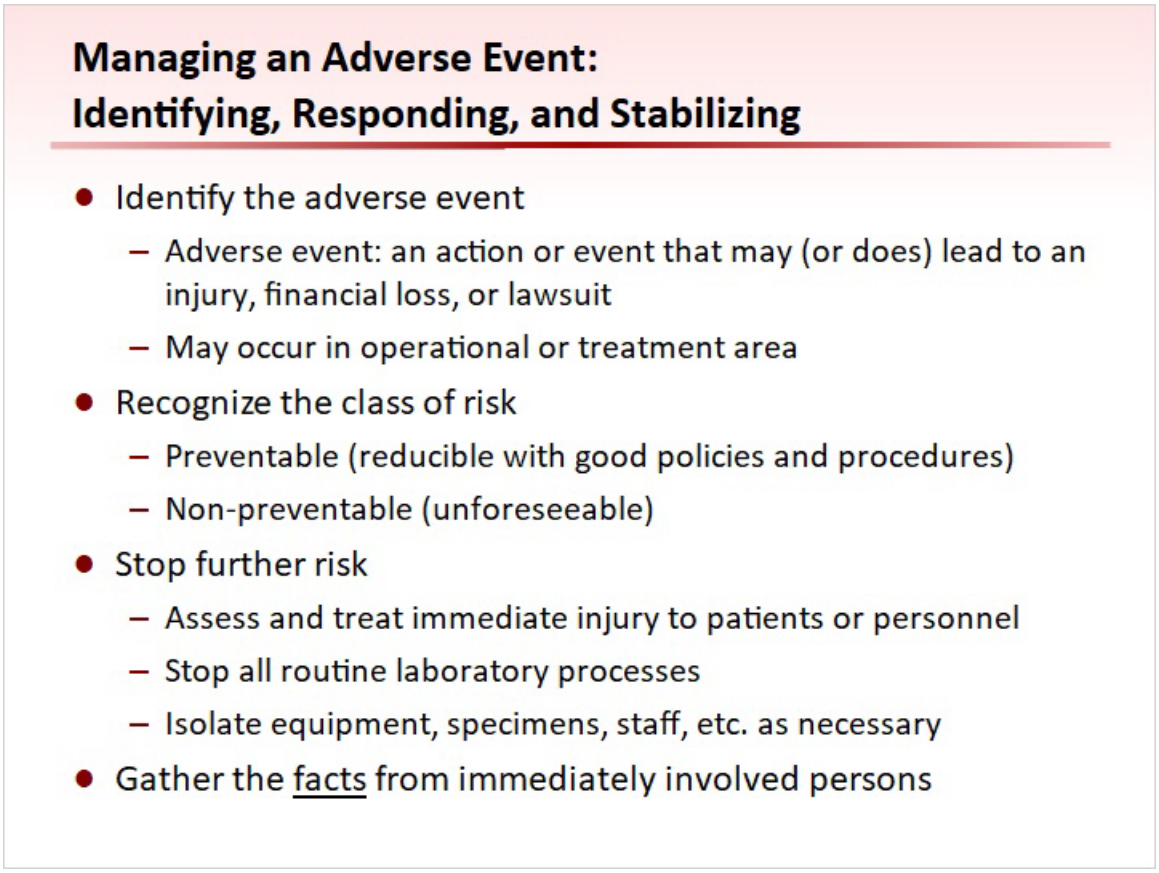


Notes:

Something happened in the lab. It's not good, but that doesn't necessarily mean that a particular staff member is not good or that the ART team is bad. Even with the best of preventions and risk and quality management programs in place, adverse events happen. It truly is important that the response to such a negative occurrence is appropriate.

Certain aspects to an adverse event, known as the risk response, will be defined in more detail to provide a seamless risk approach to what should not have happened.

1.50 Managing an Adverse Event:



Notes:

First and foremost, someone must raise the alarm that something has happened that rises to the level of a risk or adverse event. Defined as action or event that may or does lead to injury, financial loss, or a lawsuit, the adverse event may primarily affect a person(s), physical property, or genetic material, and may occur in an operational or a treatment area.

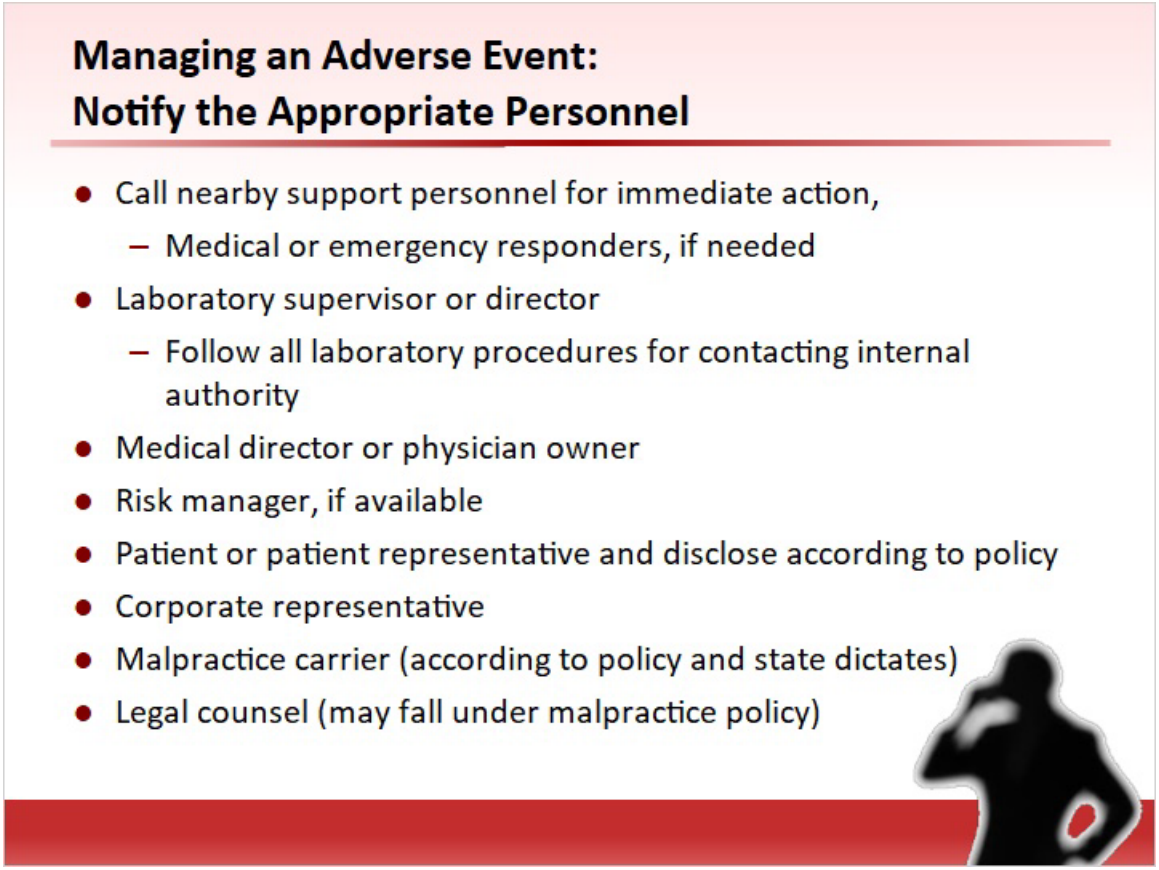
It's important to train all personnel to be able to identify an adverse event. While most people can react to the "oh no!" factor and feel pretty confident, other events that may lead to negative impact can arise that are less identifiable. Knowing the class of risk is also important. Risk may be classified as something that could be reduced or eradicated by adherence to policies and procedures, or non-foreseeable as in a circumstance that no one could have predicted. Establishing the class helps with the necessary response, follow-up, and documentation.

All initial interventions should be aimed at stopping further risk, including treating any immediate injury to patients or personnel and/or removing harmful equipment or substances from further use/exposure. Once safety is ensured, all routine laboratory

procedures should cease as designated personnel isolate all people and elements involved in the adverse event.

As stated earlier, contemporaneous fact-gathering from those intimately involved in the adverse event is essential to preserving objective observations.

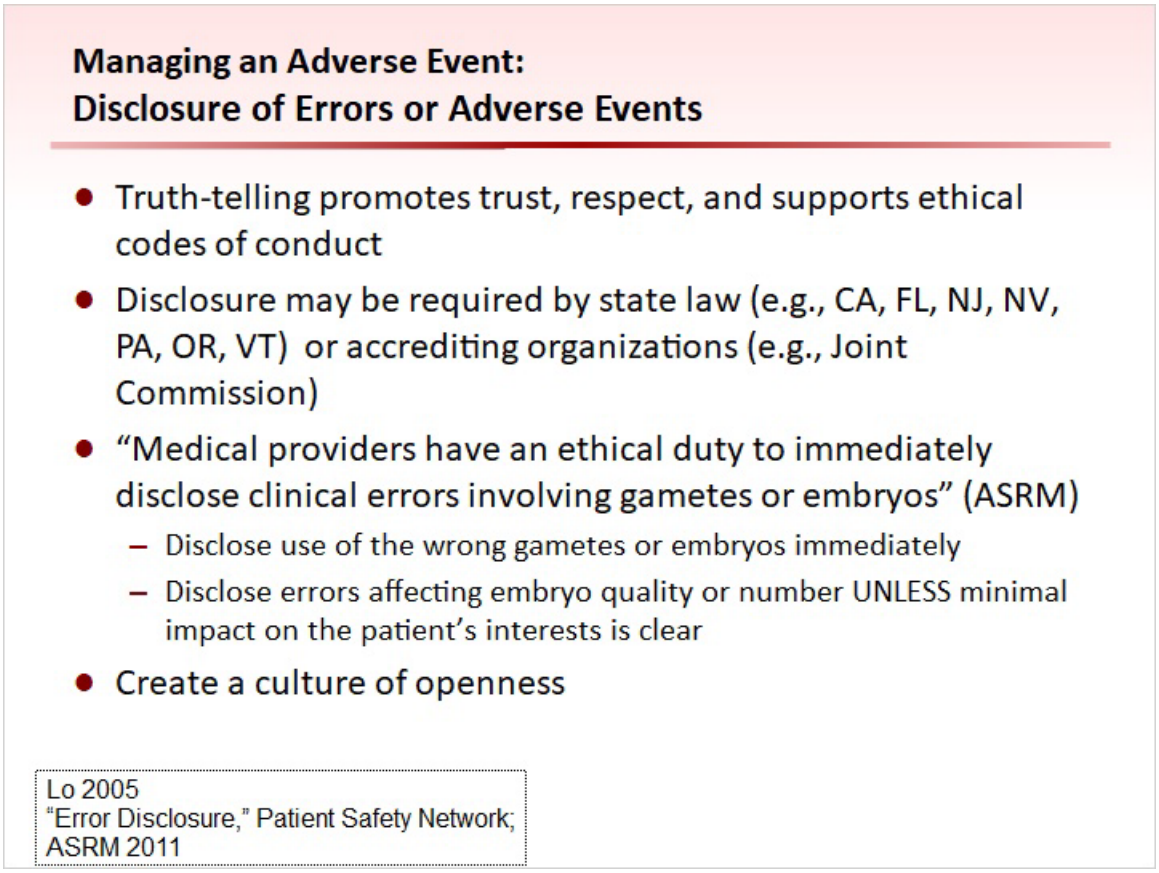
1.51 Managing an Adverse Event:



Notes:

While the list noted seems extensive, it is not an immediate to-do list! Except for the first two persons listed, judicious and timely release of information is essential, and confidentiality in the form of controlled information must be established early in the notification process.

1.52 Managing an Adverse Event:



Notes:

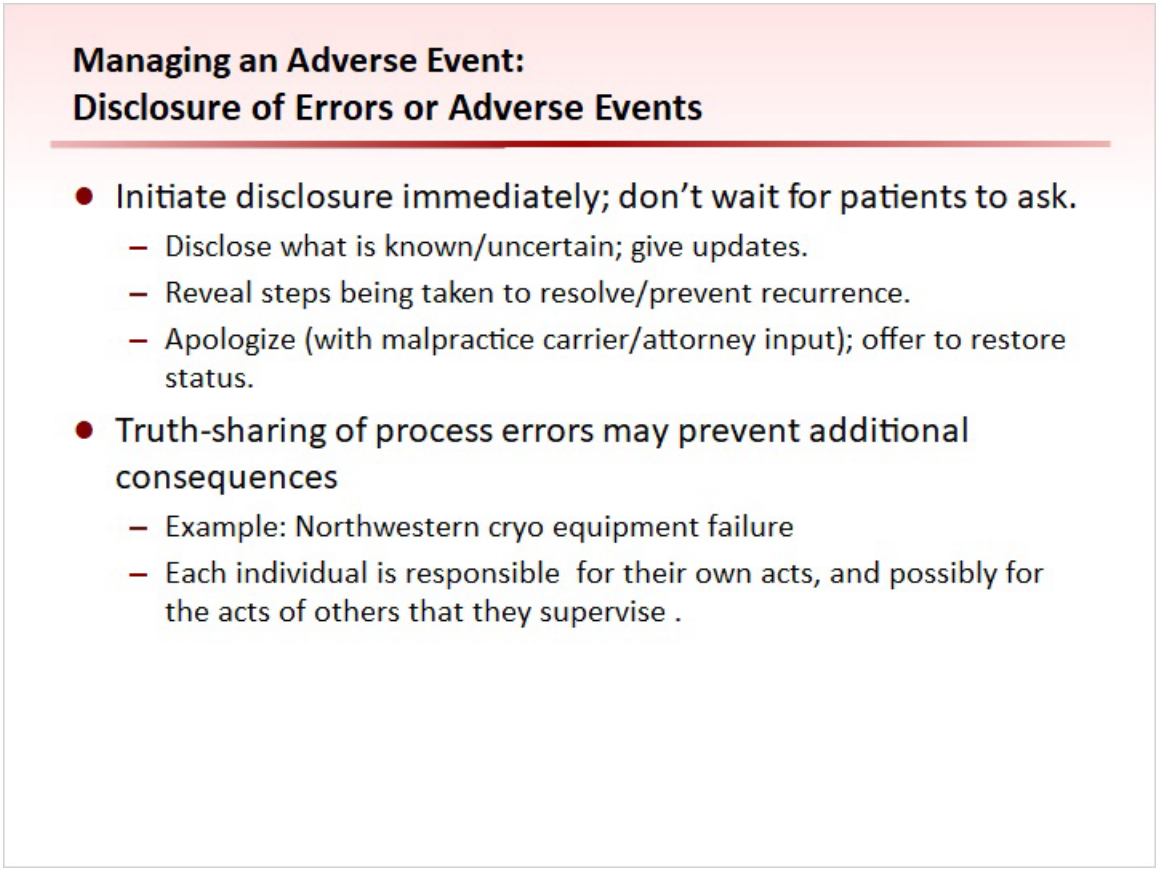
Errors happen and cannot be completely avoided no matter how hard we try. How one reacts to an error says a lot about a person and a program's integrity. A call for truth and honesty is not always the first human response to an error. Often, the reaction is to deny, suppress, or rationalize what happened instead of facing the facts squarely. However, the truth is simply the truth and should stand on its own. It is a fact, and health-care providers are generally adept at dealing with facts. The harder part is dealing with facts that do or may have negative consequences, and telling the truth to a patient or patients when something has gone wrong, or that an error was made. Disclosure of errors and adverse events is critical in ART. Guidance for the practical aspects of disclosure is supported by general ethics principles, law, and ASRM guidelines.

Promoting a culture of openness, which includes truth and disclosure in all clinical and laboratory practices not only supports general ethical codes of conduct, but it also encourages trust and respect by and between patients and staff. These are the essential elements of the physician-patient relationship, and are necessary to provide quality patient care. Lying promotes mistrust and takes a toll on the work environment in the form of uncertainty, fear, and decreased motivation—all of which are detrimental to the

team cooperation needed to achieve successful outcomes.

Mandatory disclosure of errors and adverse events has been codified by 7 states (California, Florida, Nevada, New Jersey, Oregon, Pennsylvania, and Vermont), and 36 states have enacted laws that minimize or prevent an apology for a medical mishap from being used in a lawsuit. In addition, organizations including the Joint Commission and the National Quality Forum included disclosure of "unanticipated outcomes" in its accrediting guidelines.
ASRM takes a strong and clear position on the topic of disclosing medical errors in ART, stating that "medical providers have an ethical duty to immediately disclose clinical errors involving gametes or embryos," particularly when the wrong gametes or embryos are involved, or there are errors with the number or quality of embryos.

1.53 Managing an Adverse Event:



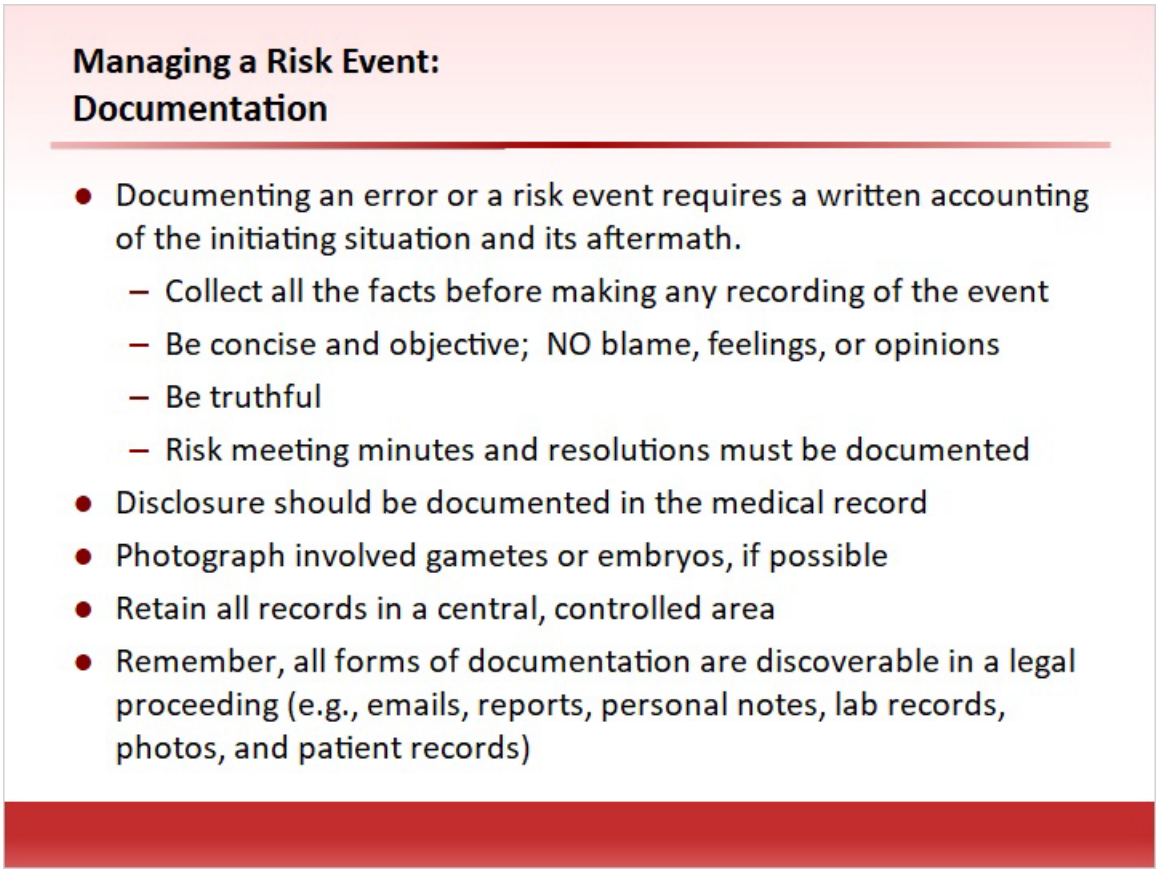
Notes:

Supporting respect for patient autonomy and a culture of truth-telling, ASRM delineates a process for disclosing errors to patients that includes revealing information before the patient asks, disclosing all known facts and uncovered facts as they become available, revealing the steps that were taken to investigate and resolve the event and/or prevent recurrence. [F & S, Vol. 96, No. 6, Dec. 2011]. The disclosure usually requires more than one discussion with the patient. While the initial meeting should include the patient's treating physician, the patient's partner, a laboratory representative, and a practice representative, often the patient is then given a contact person to update him or her on subsequent related events and resolutions. Patient empathy and an apology often are instrumental in ensuring an ongoing patient-provider relationship. Many insurers and legal representatives believe in this humanistic approach to risk management and encourage their clients to apologize from the start, and even to offer to restore or replace the patient's loss, if at all possible.

Adopting a policy of disclosure supports truth-sharing among the ART team members, which can reduce additional consequences of medical errors, especially when internal processes fail. Personnel should not be directly or indirectly encouraged to hide problems for fear of litigation. Nondisclosure alone could be evidence of malpractice. Consider the example of an ART program in Chicago where a lab member discovered that the nitrogen supply in the cryopreservation tanks had run dangerously low, damaging some patients' cryopreserved sperm and embryos. In addition, the alarm system failed to alert anyone in time to prevent the loss of gametes and embryos. The lab staff did not ignore the issue, but promptly tried to protect the remaining specimens and alerted the program authorities so that the patients involved could be notified of the nature of the adverse event and the exact status of their specimens in a timely manner. Lawsuits have been filed, but the integrity of the program stands intact because they acted, took responsibility, and disclosed appropriately. This in and of itself cannot prevent the ensuing lawsuits, but it will attest to the organization's culture of truth-telling.

Finally, general principles of malpractice law tell us that everyone is responsible for their own negligent acts. However, an individual may also be liable for the negligent acts of personnel they supervise. In other words, lab managers and directors can be liable if their staff makes a mistake. However, adhering to a risk management policy that endorses full disclosure may help mitigate anyone's exposure of legal risks.

1.54 Managing a Risk Event:



Notes:

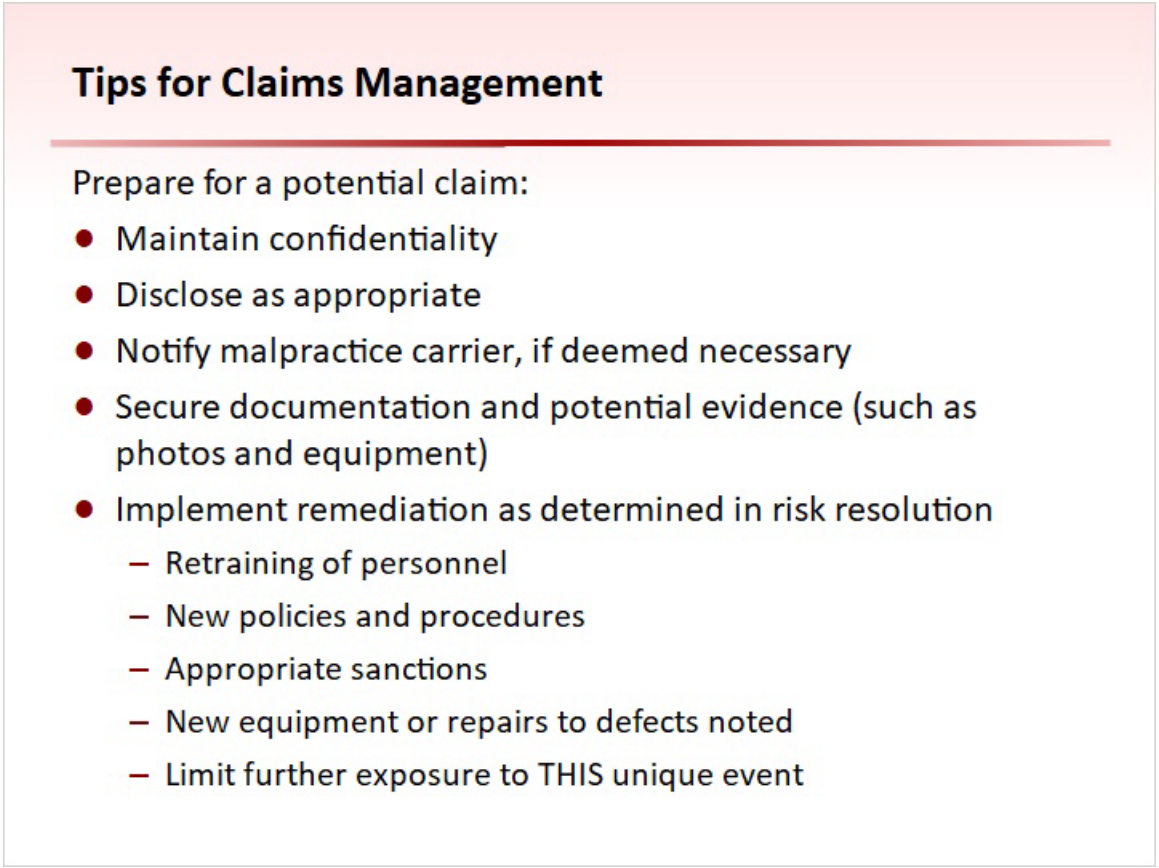
The manner of documenting what happened and the preservation of any written material is often essential to risk analysis and to the support of any position in a subsequent lawsuit. A good record accomplishes several things: substantiates clinical judgment and choices; demonstrates the skill and knowledge exercised during treatment; provides a contemporaneous assessment of the situation; and documents significant events, changes, and responses. Remember, an experienced defense attorney can work well with cooperative staff and a “good-enough” record, but a “bad record” doesn’t help anyone.

Be sure to gather all of the facts before completing any written record. Document the event factually by being concise and objective. Include the date and time, the names of persons involved, and who was notified when. Do not include subjective comments or any statements that place blame, or describe feelings or opinions. Always report the truth even if you feel it may be harmful to an individual or the practice. In the end, it may actually be helpful, and the truth is always easier to defend. Also, record all findings from any subsequent risk meetings, including any policy changes, actions recommended / taken and any resolutions.

The adverse event should also be documented in the patient's medical record—NOT designated as an "adverse event," but in clear factual terms of what happened. This is where the risk-management documentation may differ from the patient record as it may be more expansive.

Retention of all relevant records is also important. Original reports, documents, patient's medical and embryology records, photographs (if possible), and equipment should be isolated and retained within the program in a location that has controlled access (preferably the risk manager's office). As preserving integrity and preparing for potential litigation is a core concern of all risk management, be aware that ALL forms of documentation may be discovered in the future, including but not limited to electronic, typed, handwritten, and photographic program, laboratory, and patient records – in ANY form.

1.55 Tips for Claims Management

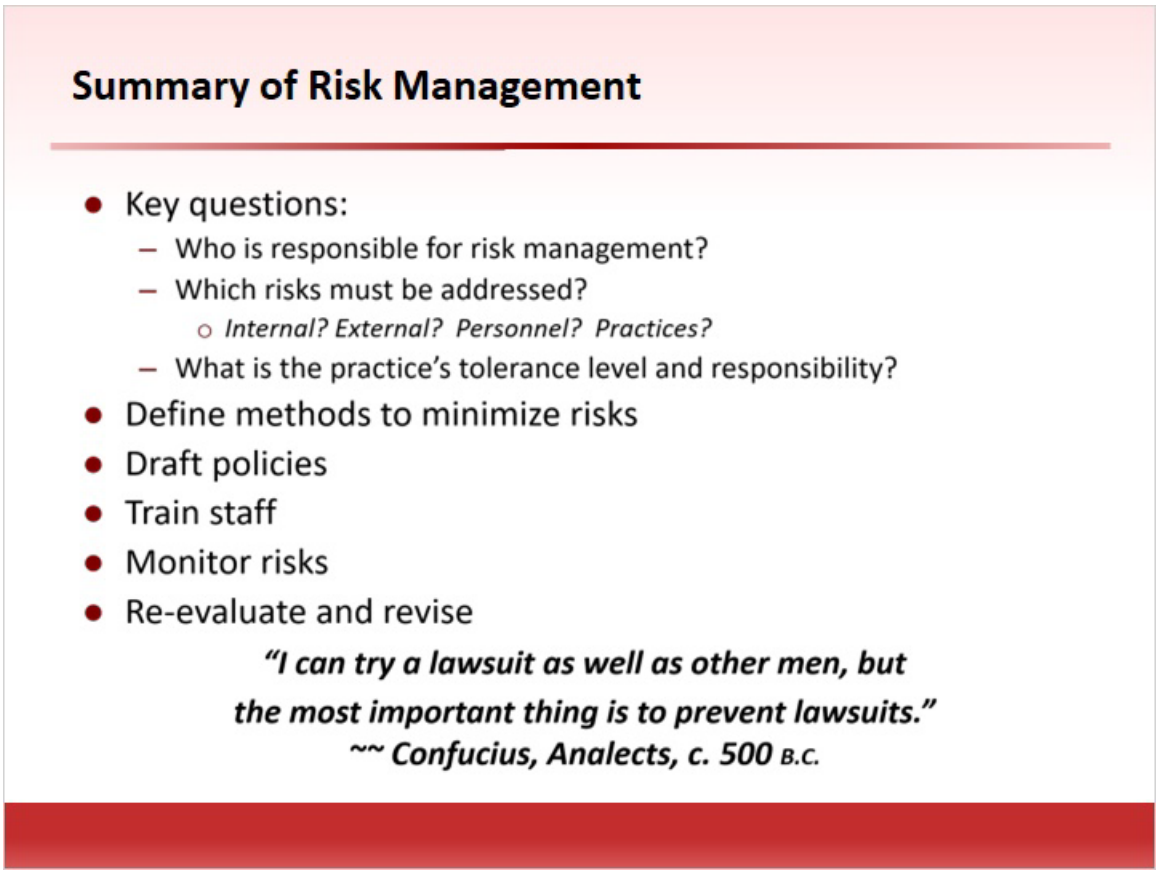


Notes:

In summary, prepare for a potential claim by doing the following:

- Maintain confidentiality
- Disclose as appropriate
- Notify malpractice carrier, if deemed necessary
- Secure documentation and potential evidence, such as photos and equipment
- Implement remediation as determined in risk resolution
  - Retraining of personnel
  - New policies and procedures
  - Appropriate sanctions
  - New equipment or repairs to defects noted
  - Limit further exposure to THIS unique event

1.56 Summary of Risk Management

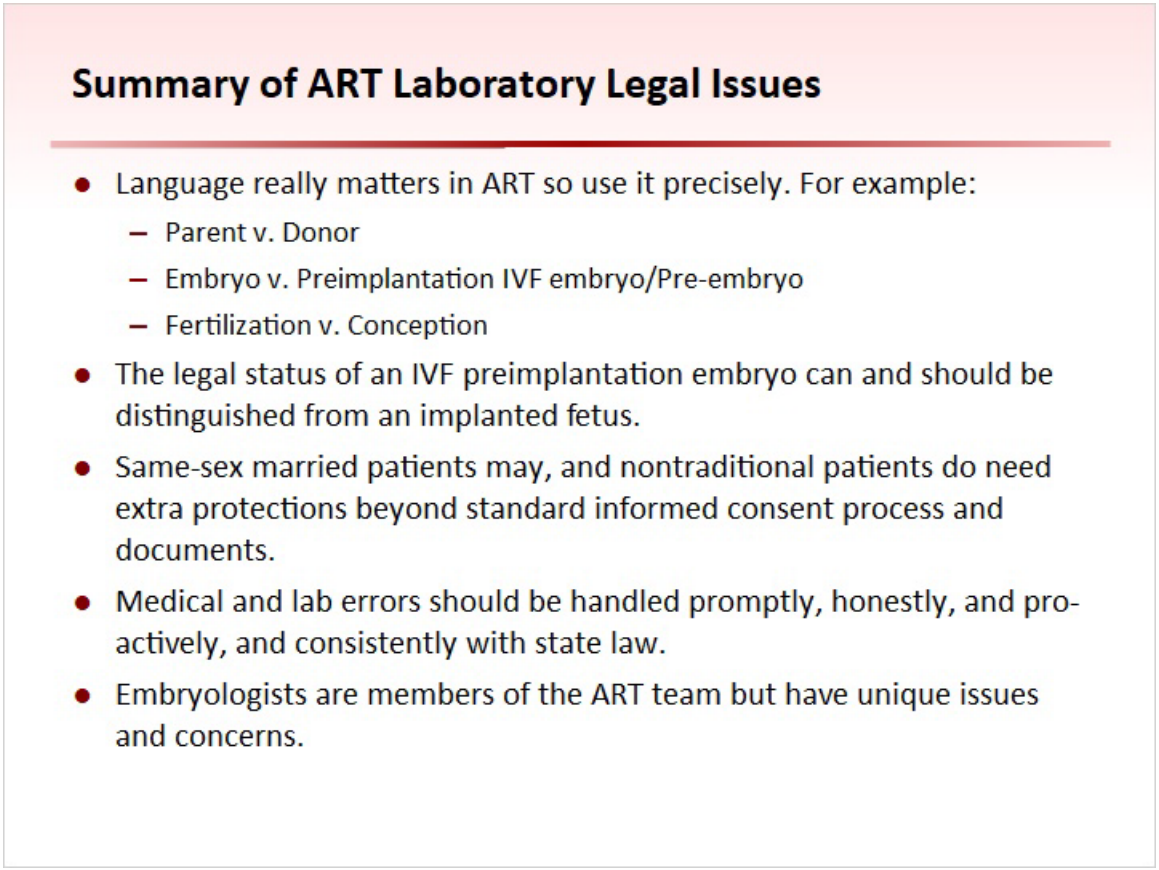


Notes:

To summarize risk management strategies, key questions to ask include: Who is responsible for risk management? Which risks must be addressed—internal, external, personnel, practices? And, what is the practice's tolerance level and responsibility?

Define methods to minimize risks
Draft policies
Train staff
Monitor risks, and
Re-evaluate and revise

1.57 Summary of ART Laboratory Legal Issues



Notes:

Finally, language really matters in ART so use it precisely. For example:
Parent v. Donor
Embryo v. Preimplantation IVF embryo/Pre-embryo
Fertilization v. Conception
The legal status of an IVF preimplantation embryo can and should be distinguished from an implanted fetus.
Nontraditional patients (single, same-sex unmarried couples) need extra protections beyond standard informed consent process and documents.
Medical and lab errors should be handled promptly, honestly, and proactively, and

consistently with state law.
Embryologists are members of the ART team but have unique issues and concerns.

1.58 Thank you!

Notes:

Thank you for participating in this educational activity.