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ASSISTED REPRODUCTION TECHNOLOGIES

Liability for embryo mix-ups in fertility practices in the USA

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Abstract

Purpose To study recent legal cases involving the transfer of the incorrect embryo into patients and learn how fertility clinics can better serve clients, protect themselves financially, and safeguard their physicians' personal assets.

Methods The Nexis Uni database was used to review legal cases, news, and business publications of previous cases of embryo mix-ups. County and district courthouse dockets were also queried for filings and court documents related to lawsuits involving embryo mix-ups using Public Access to Court Electronic Records (PACER). Emphasis was placed on court decisions, awarded damages, and legal and media coverage related to embryo mix-up events.

Results A case law review of US legal databases and courthouse dockets was conducted for cases between 2000 and 2020, focusing on lawsuits against reproductive endocrinologists and in vitro fertilization (IVF) facilities offering embryo transfer (ET). Improper labeling and ineffective communication led to errors in the cases reviewed.

Conclusion It is prudent for clinics to protect themselves from embryo mix-ups, which can subsequently lead to undesirable clinical outcomes, as well as lawsuits stemming from these errors. This article emphasizes following labeling guidelines when storing embryos, employing a two-step read back method prior to ET, and offering genetic testing when a discrepancy is found in the record. In the case an embryo mix-up does occur, it is recommended to protect personal assets through business organizing procedures and consider settlement offers for policy limits.

Keywords Embryo transfer · IVF error · Liability · Medical negligence · Mix-up

Introduction

Transferring the incorrect embryo into a patient is an intolerable event for all parties involved. Doing so can expose reproductive endocrinologists and in vitro fertilization (IVF) facilities to substantial liability and financial burden. In a recent analysis of claims made under one malpractice insurance provider, errors in embryo handling and lab practices were the most common reason for litigation against reproductive endocrinologists resulting in financial settlements [1]. Such allegations and the subsequent public scrutiny may tarnish the reputation of even the most reputable IVF centers. Obstetrics and Gynecology (OB/GYN) is traditionally one of the highest litigated medical specialties. A recent American College of Obstetrics and Gynecology survey found that nearly 75% of physicians had at least one professional liability claim against them in their career [1]. Litigation specifically within Reproductive Endocrinology was evaluated in a recent analysis of claims handled by a single insurance provider covering 10 Reproductive Endocrinology practices over the course of a decade [2]. During this time, providers performed 184,015 IVF cycles, with 176 claims filed and payments made to plaintiffs in 21 cases. A total of $15 million was awarded across the 21 cases and the average settlement claim for those involving embryo issues was $199,188. Errors in embryology laboratory were the most frequent cause for claims and accounted for 38% of claims paid, with an overall incidence of 0.03% among the total IVF cycles.

Inadvertent embryo mix-ups can not only tarnish the reputation of the involved facility and providers; they can also lead

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to lawsuit damage awards that may surpass the policy limits provided by medical malpractice insurance plans. Defending allegations of improper embryo management can be both costly and time-intensive. For one of the cases studied, embryo labeling errors resulted in a class-action claim as 93 IVF cycles were affected. The IVF center subsequently closed permanently due to the financial hardship induced by this error. Due to the consequences of embryo mix-ups, it is prudent for clinics to protect themselves from embryo mix-ups and labeling mistakes, which can subsequently lead to undesirable clinical outcomes, as well as lawsuits stemming from these errors. In this paper, we explore lawsuits against IVF clinics pertaining to embryo mismanagement. We hope that by bringing to light these recent cases, IVF clinics can better protect themselves financially, and physicians can safeguard their personal assets. The objective of this study is to learn through recent legal cases where errors are occurring and provide suggestions for how IVF clinics can lessen the risk of embryo mislabeling and liability exposure and mitigate financial damages arising from embryo mix-ups. This article will emphasize following labeling guidelines when storing embryos, understanding insurance policy limits, and protecting assets through business organizing procedures.

Materials and methods

The University of Nevada Las Vegas Institutional Review Board (IRB) considered this study exempt as the design of this study did not qualify as human subjects research (45 CFR 46.102(I)(1)-(4)). The Nexis Uni database was used to identify and review legal cases, news, and business publications of previous cases of embryo mix-ups. This database contains legal rulings and court cases that have been appealed, both at the state and federal level. Nexis Uni was queried with broad search terms for embryo mix-ups, and publications from 2000 to 2020 were selected and reviewed. Nexis Uni allows users to search for documents that contain two words in 1 paragraph by typing a connector "p" between the two words. For example, when looking to discover the terms "embryo" and "mix-up" in one paragraph, "embryo/p mix-up" is searched. This tool allows for more targeted results relevant to the topic of interest. Further information about cases of embryo mix-up found in Nexis Uni was found using the online portal Public Access to Court Electronic Records (PACER), which provides access to United States Appellate, District, and Bankruptcy records.

Public Access to Court Electronic Records Portal along with County and Superior Court websites were used to obtain publicly available court documents. Arguments and judicial rulings were studied, and judicial arguments were organized by recurring themes among the cases. Analysis of each case and information collected included causes of action, details of the events surrounding the incident, and the legal rulings which resulted.

Best practices in the literature were reviewed for recommendations. PubMed was used to retrieve background information on legal considerations relevant to physicians, and specifically to reproductive endocrinologists. Publications by the Centers for Disease Control and Prevention (CDC) and the American Society for Reproductive Medicine (ASRM) were used to identify best practices in the literature and prepare specific recommendations applicable to IVF clinics and practicing reproductive endocrinologists.

Results

The results of the Nexis Uni searches are shown in Table 1. There was a disproportionate number of news articles compared to the number of legal cases. For example, there were 14 legal cases that mentioned embryo mix-ups in the same paragraph that were identified compared to 441,449 news articles that mentioned embryo mix-ups in the same paragraph. Details from lawsuits involving ET mix-ups were found through public court documents. From the database results, 5 references were utilized directly, in addition to 3 legal cases

Table 1 Nexis Uni search results. This table demonstrates the search results from queries made on the database Nexis Uni of two words within one paragraph. The database finds publications that have both search terms in one paragraph and categorizes the search results into different forms of publications

Search results		Type of publication					
Search terms	Cases (*n*)	Newspaper articles	Web-based publications	Magazines and journals	Law reviews and journals	Legal news articles	Newswires and press release
Embryo p/mix-up	14	441,449	52,241	17,671	231	21	109,830
Misdirected p/embryos	1	68	5	2	8	0	7
Embryo p/swap	1	738	39	18	28	0	83
IVF p/mix-up	3	391,656	55,267	11,400	143	4	80,304
Embryo p/switch	4	1042	191	110	83	5	649

from county and district court dockets. Claims against IVF clinics and reproductive endocrinologists included breach of contract, lack of informed consent, negligence, and emotional distress. Due to strict non-disclosure agreements and confidentiality agreements in settlements, details of cases were sparse. Three cases were selected which had the most publicly available information to facilitate discussion.

Recent and ongoing embryo mix-up lawsuit

In August 2018, two couples, one from California and the other from New York, had ETs performed at the same IVF clinic in Los Angeles. The New York couple's ET was successful and resulted in pregnancy. Despite achieving pregnancy, this couple started to have concerns early on in the pregnancy after discovering they were having twins, as they had only consented to a single embryo transfer. This concern became more serious when they delivered Caucasian twin boys, since the New York couple was of Korean descent. Genetic testing confirmed that the boys were not related to the couple, and, in fact, despite both being Caucasian, the 2 boys were not biologically related to each other either. Later it was found that 1 of the boys was the biologic son of the California couple who had their embryo transfer on the same day in the same clinic. The other boy was the biologic son of a third, unrelated couple who had their embryo wrongly transferred as well. The California couple went to family court in New York to gain custody of their biologic child. The judge ruled in their favor, and the New York woman of Korean descent who carried and delivered the Caucasian child was ordered to surrender custody to the boy's biologic parents when the boy was 6 months old [3]. Following the custody case in New York, the California couple filed a separate suit against the IVF clinic in Los Angeles County, *Manukyan v CHA Health Systems*, seeking damages to cover their emotional distress and $100,000 of legal expenses for the New York custody case. The California couple's lawsuit included multiple allegations. The first was for violation of California's penal code, which states "it shall be unlawful for anyone to knowingly use sperm, ova, or embryos in assisted reproduction technology, for any purpose other than that indicated by the sperm, ova or embryo provider's signature on a written consent form" [4]. Violation of this statute is punishable by imprisonment for 3 to 5 years, a fine of no more than $50,000, or both. The Los Angeles Superior Court heard their case, and in October 2019, the two parties settled out of court for an undisclosed amount [5]. The New York couple, who did not want to be publicly identified, is in an ongoing lawsuit with the IVF facility, *P. et al. v. CHA Health Systems*, in US District Court in New York after alleging medical malpractice, negligence, and intentional infliction of emotional distress, among other counts [6].

Case of labeling errors

The case of *Herbert v Ochsner* resulted after an IVF clinic had a Food and Drug Administration (FDA) inspection of their facility in which at least six frozen embryos were possibly mislabeled [7]. Two of these six embryos were those of the couple who filed the class-action lawsuit against the IVF clinic described above, claiming the IVF clinic had inadequate control and supervision of the procedures at their clinic.

Faced with these claims, the IVF clinic hired a medical auditing consultant to audit their entire operation, which included 348 cycles. This action is in line with the ASRM recommendation of root-cause analysis when errors or near-misses occur [8]. The consultant recommended that all embryos with a possibility of a minor or significant discrepancy should not be released without genetic testing to ensure correct parentage. Upon consideration of these recommendations, the IVF clinic decided to inform affected patients and genetically test, at its own expense, all embryos with any discrepancy in the records. Furthermore, after this mistake, this IVF center permanently closed [7]. The company's CEO held a press conference apologizing to patients and stated, "we do not plan to reopen the IVF center since these issues compromised the entire IVF center" [9].

Case of embryologist found liable

Andrews v Keltz provides an example in which a couple claimed medical malpractice and negligence against an IVF clinic for using the sperm from someone other than the husband to fertilize the wife's egg. The issue arose after the couple gave birth to a daughter who did not look like them [10]. The Supreme Court of New York County allowed the case to proceed against the owner, who was an OB/GYN and the manager of the clinic, but the court did not find him liable for the clinic's alleged medical malpractice and negligence since he did not participate in the care or treatment of the couple. The reproductive endocrinologist who performed the ET argued that there is no evidence he knew that the husband's sperm had not been used to fertilize the wife's eggs. All complaints against the reproductive endocrinologist were dismissed. However, the judge ruled the embryologist exhibited negligence and violated the plaintiff's right to informed consent. In these circumstances, the IVF facility is responsible for the actions of the embryologist due to the legal doctrine of respondeat superior. Under this legal doctrine, an employer is liable for the negligent act or omission of any employee acting within the course and scope of his employment [11].

Discussion

Embryo mix-ups can create significant liability for IVF clinics, and steps can be taken to minimize errors that lead to such embryo mix-ups. In addition, there are safeguards IVF clinics can take in case such errors do occur. These safeguards include changes in processes to decrease labeling errors, investing in malpractice for non-physician staff, and understanding the role of policy limits when offered a settlement.

Improper labeling

Adherence to labeling guidelines can be used to reduce the risk of embryo mix-ups. A systematic review by the CDC on the effectiveness of laboratory practices at reducing patient misidentification due to specimen labeling errors found development and implementation of standardized labeling policies and strategies by physicians in the organization to be most effective [12]. This practice is in line with the College of American Pathologists' requirements, which inspects embryology labs biannually and awards accreditation. Among their requirements are written procedures for specimen labeling and tracking requirements, as well as labeling all specimens with a minimum of 2 identifiers [13]. Similarly, ASRM recommends all embryo freezing containers, such as straws or vials, to be permanently labeled with at least 2 unique identifiers [14]. The identification can consist of asking the patient her full name and a second identifier, such as the partner's complete name, a personal identification number, or date of birth [15]. The ASRM guidelines also state, "a method of ensuring prompt, accurate retrieval of cryopreserved specimens must be employed. Duplicate records of all embryos in storage should be kept, in separate locations, exclusive of the patient chart information" [14]. The CDC also provides guidelines for specimen labeling, providing more specific directions than ASRM by stating each container should include patient name, patient identification number, specimen type, and date of collection [16]. Standard operating procedures such as automatic witnessing systems that employ barcode-based witnessing, labeling, and tracing can help prevent embryo mix-up events [17, 18]. By investing in technology that improves processes, the role of human error can be reduced.

Malpractice coverage

Another issue for IVF clinics and reproductive endocrinologists to consider is the extent to which their medical malpractice insurance will cover lawsuits against employees involved in cases of embryo mix-up who are not physicians. It is advisable to consider separately insuring embryologists through a stand-alone policy or to add a rider to the IVF clinic or physician's malpractice policy [19]. A rider, sometimes called an endorsement, is a provision that changes the terms and conditions of the policy. Either through a stand-alone policy or by adding a rider to the IVF clinic or physician's malpractice policy, it is recommended to have coverage for embryologists and lab personnel working with human gametes and embryos [20]. By doing so, IVF clinics are better protected financially if a lawsuit arises that involves the actions of non-physician staff.

Responding to potential embryo specimen discrepancies with genetic testing

Despite an IVF clinic's efforts to prevent embryo mix-up events, if embryos of one couple are misdirected to another, the reproductive endocrinologist should not delay disclosure to both patients. IVF clinics may consider offering genetic testing to those potentially impacted. An Ethics Committee Opinion by ASRM states, "Clinics must disclose errors in which the wrong sperm are used for insemination, or gametes or embryos are mistakenly switched resulting in fertilization, embryo transfer, implantation, or the birth of a child with a different genetic parentage than intended, as soon as they are discovered" [8]. The principle of informed consent and the practice of disclosing mistakes are also either directly or indirectly affirmed by the American Medical Association, the American College of Physicians, and the American College of Obstetricians and Gynecologists [21–23]. Disclosing an error may be challenging; however, it is both the ethical and legal course of action. Failing to do so may lead to professional penalties, such as loss of the reproductive endocrinologist's medical license [24]. An older case occurred in June 2000 when a reproductive endocrinologist learned minutes after transferring three embryos that they were meant for a different woman. He did not disclose the information to the patient, and the result was a $1 million settlement with the patient and loss of his medical license for the misconduct [25, 26]. Additionally, some studies suggest patients who are informed honestly about mistakes are less likely to take legal action against their physicians [15].

In cases where a mismatched embryo is identified, it may be prudent for an IVF clinic to review all patients potentially impacted. IVF clinics may consider offering genetic testing to all patients with any discrepancy found in the record at the IVF clinic's expense.

Asset protection for IVF clinics

Reproductive endocrinologists should consider taking measures to protect their assets and reduce their exposure to liability if such a case proceeds to litigation. This action is significant when physicians are found responsible for covering amounts that exceed their malpractice insurance policy limits. Importantly, these measures must take place before a claim or its precipitating event occurs. Once either of these takes place,

changes may be deemed invalid, and creditors are more likely to be able to seize assets. Specific rules will vary by state; however, assets, such as Individual Retirement Accounts (IRAs), 401(k)s, and life insurance policies, are commonly exempt from collection by creditors [27]. Establishing an IVF practice as a separate independent business entity, such as a Limited Liability Company (LLC) or a Professional Limited Liability Company (PLLC), can protect a physician's personal assets from claims made against the practice [27]. Granted, if there is a mixing of a physician's finances with that of the company, creditors can make the case to "pierce the corporate veil." When this occurs, each stakeholder can be held accountable, as the company is no longer considered an independent entity [28]. Different approaches to asset protection involve splitting assets with a spouse, placing income-generating assets, such as securities, in a family limited partnership, or forming trusts [29]. Familial disputes can lead to uncertainty in the event assets are transferred to a spouse.

Meanwhile, physicians choosing to establish a trust must be careful in the specific type they choose, as not all are guaranteed to be protected from creditors [30]. Homestead laws exist in many states, shielding an individual's primary residence from creditors, given taxes and mortgages are paid [31]. Depending on the specific location, the coverage of homestead laws may be limited by the property's dollar value or size. In each case, physicians should consult with local legal experts familiar with the specific laws in their region.

Policy limits

When faced with a lawsuit, reproductive endocrinologists should be aware any damages awarded beyond their contracted malpractice policy limit will not be covered by the insurer [32]. For example, if the policy limit is $1 million and the claim is for $3 million, the insurer is contractually obligated to pay up to the policy limit of $1 million, but not any awarded damages that exceed the policy limit. If the award amount exceeds the policy limit, the reproductive endocrinologist and the IVF clinic could be liable for the difference between the amount awarded and the policy limit. Moreover, there may be a possible conflict of interest between the reproductive endocrinologist and their malpractice insurers. If the case has merit, and the damage award could potentially exceed the policy limit, the reproductive endocrinologist and IVF clinic should consider an offer to settle for their malpractice insurance policy limit. Accepting an offer to settle for the policy limit helps deter the risk of financial liability if the case goes to trial and the award amount exceeds the policy limit. An insurance carrier that is contractually obligated to pay only up to the policy limit has less financial risk compared to the reproductive endocrinologist and IVF clinic of going to court since they do not have to cover the award amount that exceeds the policy limit.

Table 2 Suggestions for IVF practices

1. Develop and implement standardized labeling policies and strategies.
2. Foster strong communication between the embryologist and the reproductive endocrinologist.
3. Employ a 2-person verification step or read back method immediately prior to ET and consider using an automatic witnessing system
4. Disclose information in a timely fashion to all patients in cases of embryo mix-up
5. Review all patients potentially impacted cases where a mismatched embryo is identified.
6. Consider offering genetic testing to all patients with any discrepancy found in the record.
7. Establish IVF practices as a separate independent business entity such as LLC or PLLC.
8. Add embryologists, lab directors, and other non-physician staff as under a rider to the IVF clinic's or physician's malpractice policy by adding an endorsement to the policy.
9. Accepting an offer to settle for policy limits helps deter the risk of financial liability if the case goes to trial, and the award amount exceeds policy limits.

For this reason, the insurance carrier may not be amenable to a settlement offer for the policy limit and may discourage settlement offers that are not substantially less than the policy limit. There is potential for a conflict of interests for the attorney retained by the malpractice insurance carrier to represent the reproductive endocrinologist and the IVF clinic when faced with settlement offers. When an offer to settle is discouraged by the attorney retained by the malpractice insurance carrier, one should be cognizant of the potential conflict of interest and consider retaining a different attorney than the one retained by the insurance carrier. It is also recommended that the reproductive endocrinologist and IVF clinic have written documentation through email or certified letter to the attorney retained by the malpractice insurance carrier indicating their desire to accept the settlement offer. Typically, when there is a clear written instruction to the malpractice insurance carrier to accept the settlement offer and the insurance carrier elects to proceed to trial, the insurance carrier will be responsible for the difference between the amount awarded and the policy limit.

Conclusions

Improper labeling or record keeping may result in the wrong embryo specimen being used in ET. It is essential that IVF clinics and all personnel involved in handling embryos be meticulous and diligent in labeling and accounting of specimens. Furthermore, clear and concise communication between lab personnel, such as the embryologist and the reproductive endocrinologist, can reduce the risk of wrongful ET.

Employing a 2-person verification step or read back method immediately prior to ET may be considered. Selecting and following labeling guidelines with multiple identifiers are a best practice that reduces labeling errors [12]. Doing so may help lower the incidence of embryo mix-ups and the subsequent lawsuits that potentially arise due to these errors.

Adhering to labeling guidelines mitigates—but does not fully eliminate—the role of human error. If the embryo of one couple is mistakenly transferred to another person's uterus, the fundamental principle of autonomy in medical ethics should be respected, and full, timely disclosure should be made to all potentially impacted patients. Full disclosure is important for ethical as well as legal implications. IVF clinics and reproductive endocrinologists can take steps to protect their assets should such situations arise. The authors recommend organizing the practice as a separate business entity, such as a limited liability corporation, to reduce the owner's personal liability for the practice's debts or liabilities. In the case of identifying discrepancies in the record, it is reasonable for the IVF clinic to cover the cost of genetic testing of all embryos in question.

Furthermore, through learnings from legal case reviews, which often found the embryologist's actions negligent, it is advised to add embryologists and lab personnel as a rider to reproductive endocrinologists' medical malpractice insurance. Unless specifically endorsed, malpractice insurance typically may not cover non-physician employees [30]. In cases where malpractice insurance will cover a claim, and the claim has merit with the potential for the damage award to surpass insurance policy limits, consider accepting an offer to settle for policy limit instead of going to trial. The author's recommendations have been summarized in Table 2. In conclusion, embryo mix-ups are an unfortunate occurrence that can happen even at the most reputable IVF facility; however, the above steps can be taken to mitigate this risk.

Code availability Not applicable.

Data availability Not applicable.

Declarations

Conflict of interest The authors declare no competing interests.

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