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PRF NEWS

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Assisted Reproductive Technologies: Risk Assessment and Prevention

BY NAM TRAN, MD, PHD

Since its inception in 1978, the underlying technology of in vitro fertilization (IVF) treatment has evolved dramatically, especially during the last decade. Innovative techniques such as intracytoplasmic sperm injection (ICSI), extended embryo culture, vitrification, preimplantation genetic diagnosis (PGD), and preimplantation genetic screening (PGS) have revolutionized the treatment of infertility. Not surprisingly, rising success rates have created an increased demand for assisted reproductive technology (ART) and IVF services. Currently there are over 400 ART clinics in the United States, providing more than 180,000 IVF treatments per year. The first IVF baby was one of the most momentous medical events of the 20th Century, yet a generation later, approximately 1.5 percent of all births in the U.S. are a result of treatment with ART.

As the number of patients who undergo ART have increased, so has an appreciation of the associated risks involved. Although the overall complication rate of ART treatment is low at 0.5 percent, women who undergo fertility treatment face risks associated specifically with the treatment process and the resulting pregnancy.

ART TREATMENT-RELATED RISKS

An April 2017 study published in the *Journal of Assisted Reproduction and Genetics* looked at 10 years of malpractice claims related to 184,015 IVF cycles performed at ten IVF centers in nine states. Coincidentally, this represents approximately the same number of IVF cycles performed annually in the entire United States. There were 176 claims made for an incidence of 0.01 percent per IVF cycle. Twelve percent (21) of the claims were settled with an average indemnity payment of $721,000. The most frequent settled claim categories were:

- Misdiagnosis
- Informed consent
- Laboratory errors
- Surgical complications
- Ovarian hyperstimulation syndrome (OHSS)

RISKS RELATED TO GENETIC DIAGNOSIS

Almost half of the settled claims (and over three-quarters of the indemnity payments) involved misdiagnoses and inadequate informed consent after an IVF-conceived child was born with a debilitating genetic defect. The resultant claims alleged either a failure to offer genetic carrier screening or a failure to inform patients of the accuracy and limitations of PGD/PGS technology. While the overall rate of PGD misdiagnosis is low (0.16 percent), it represents the major risk in ART due to the potentially catastrophic outcomes. Thus, it is imperative that ART centers work with genetic laboratories that perform PGD/PGS on a regular basis with a proven track record of competency. Furthermore, because reproductive genetics is such a rapidly advancing field (and evolving to become a standard of care in ART), reproductive endocrinologists and infertility specialists may not be adequately trained to give comprehensive genetic informed consent. A prudent step would be to enlist trained genetic counselors to provide adequate informed consent in appropriate cases.

RISKS RELATED TO LABORATORY ERRORS

The embryology and andrology laboratories at IVF centers were frequently cited for inappropriate specimen handling that resulted in sperm, oocytes, or embryos being lost. While these laboratory errors were relatively common, they were usually classified as either system error or unintentional human error. Because negligence was rarely found, the average indemnity payments were lower than

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Inside PRF News

Breast MRI

BY BONNIE N. JOE, MD, PHD AND WILLIAM H. GOODSON III, MD

Because MRI is the most sensitive technology we have available to detect breast cancer, there is a temptation to think of MRI as the solution to all breast diagnostic situations. When compared to mammography and clinical breast exam, MRI identifies cancers that would otherwise be missed. Yet MRI has not been recommended for general screening because of a high false positive rate. For example, in some studies the MRI was reported as abnormal in five times as many women who actually had a breast cancer. It is also important to note that mammography and MRI are complementary. While in general MRI can detect more cancers than mammography, mammography can still find cancers not seen on MRI.

Breast MRI for cancer screening requires the use of gadolinium contrast. In 2015 the FDA issued a "Safety Communication" that gadolinium may accumulate in the brain. As yet, there are no known adverse effects related to this observation. What is recognized is that Nephrogenic Systemic Fibrosis (NSF) can occur in patients with poor renal function. Therefore, patients need to be screened for renal function prior to receiving gadolinium.

There are no definitive guidelines as to who should have a breast MRI. Insurance companies (not necessarily an appropriate indicator) generally follow National Comprehensive Cancer Network (NCCN) guidelines. NCCN (**www.NCCN.org**) bases its guidelines on whether a woman has a 20 percent or greater lifetime (age 85) risk of breast cancer. When to start screening is also controversial. For example, for a woman with a known BRCA mutation, MRI screening may start as early as age 25 and should continue annually.

Women at increased risk for breast cancer can be identified through the use of various models. However, different models produce different risk estimates. The Gail Model (**https://www.cancer.gov/bcrisktool/**) is commonly used but has been criticized for overestimating risk. Another model is Tyrer Cuzik. By whatever method of risk assessment, a woman at a 20 percent or greater risk of developing breast cancer should have annual MRI screening. Other high-risk patients requiring annual MRI screening include:

- Women with a BRCA 1 or 2 mutation or a first-degree relative with a mutation
- Women with a strong family history of breast cancer (2 or more first degree relatives)
- Women with mutations in PTEN (Cowen's Syndrome), p53 (LiFrameni Syndrome), PALB2, TP53, STK11, ATM, CHEK2, and CDH1
- Women with previous mantle radiation exposure of the breasts

Some patients have an intermediate lifetime risk (15-20 percent). Currently there is no strong data for or against annual breast MRI screening in this population, although studies have demonstrated a similar cancer yield in this population as compared to screening high-risk patients. These patients need to be evaluated on a case-by-case basis. Intermediate risk patients include:

- Women with a personal history of breast cancer
- Women with a prior biopsy showing lobular carcinoma-in-situ
- Women with a prior biopsy showing atypical ductal or lobular hyperplasia in a single focus

Perhaps the most daunting issue for clinicians is how to advise women with a mammography or tomosynthesis (3D mammography) report of dense breasts. Women with dense breast tissue have a higher relative risk of breast cancer. The increased risk, however, is less than 10 percent over a 10-year period and **only** in women with **extremely** dense breasts **and** who have had a previous biopsy or have a first degree relative with breast cancer. There is a relative risk model that incorporates breast density **(https://tools.bcsc-scc.org/bc5yearrisk/calculator.htm)**. The one study comparing ultrasound and MRI in women with dense breasts and additional risk factors found an increased detection rate beyond mammography of 3.7/1000 for ultrasound and 14.7/1000 for MRI. While NCCN guidelines acknowledge the risks associated with breast density, they also state that there is not a clear reason to recommend for or against breast MRI screening. These patients can be considered of intermediate risk.

Beyond screening for cancer, breast MRI is useful for:

- Evaluation of neoadjuvent chemotherapy response
- Screening when axillary adenopathy is present without a known primary
- In the presence of breast cancer, screening the contralateral breast
- Evaluating the extent of disease in breast cancer
- Assessing the integrity of silicone breast implants (gadolinium not necessary)

MRI is a cost-effective modality for breast cancer screening when used in the proper setting with the right indications. It is important to remember that as a woman grows older without developing breast cancer, the risk for her remaining expected lifespan decreases simply because she has already lived through some of the period of risk. Thus, while a BRCA mutation may represent a 65-85 percent lifetime risk in a 40-year old woman, the risk to a 70-year-old is only 20 percent. ■

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Dr. Joe is chief of Women's Imaging in Radiology at UCSF Medical Center and Dr. Goodson is a member of the Risk Management & Education Committee of Physicians Reimbursement Fund, Inc.

Learnings From Recent Claims Analysis

BY STEPHEN J SCHEIFELE, MD, MS

As a physician-owned medical professional liability company, PRF has always sought to keep its premiums as low as possible. The 2016 Edition of PIAA's *MPL Closed Claim Comparative*, an analysis of 10 years of national data involving closed medical liability claims made between 2006-2015, sheds light on where to concentrate our risk management activities and thereby minimize costs. The analysis only addressed claims or demands that were made and did not include incident reports that did not result in a claim or demand.

A total of 90,000 claims were reviewed with a combined indemnity of $9 billion. Only 27 percent of all claims resulted in some payment or indemnity—the remaining 73 percent incurred defense costs only. The average payout for claims paid (adjusted for 2015 dollars) was $360,000, with 10 percent of the claims resulting in an indemnity of more than $1 million. Noting that the largest indemnity was over $14 million, PRF has obtained stop-loss coverage to protect the company in the event of such a catastrophic loss.

The average indemnity actually declined over the 10 years, but the cost to defend claims increased. It cost an average of $78,000 to defend each claim, but the cost to defend a case increased in parallel with indemnity payments. For example, on average a $1 million settlement incurred over $130,000 in defense costs.

PRF is working to keep defense costs down. Shannon Gates Esq., PRF's first attorney serving as claims administrator, has made a large difference by closely monitoring claims and keeping some costs in-house. As has been true since its inception, PRF strongly encourages filing timely management reports and invoking Code Green; these are effective tactics that members can use to prevent claims and minimize defense costs.

When analyzing claim payment by specialty, a new category of Advanced Practice Professionals was introduced. This category includes Nurse Practitioners and Physician Assistants. Their percentage of claims paid was 26 percent, with an average indemnity of $228,000. It is important that allied health professionals work within the scope of their practice and under adequate supervision. The highest cost specialties in average payout were neurosurgery, neurology and OB/GYN. OB/GYN had the largest total indemnity of $1.4 billion. PRF also insures oral surgeons. They experienced the highest percentage of paid claims, 45 percent, but lower average payments of $102,000.

Broad categories were used to analyze the presenting medical condition or complaint that ultimately resulted in a claim. While the data may not appear useful at first, delving deeper into the information can detect trends that will then be useful to focus risk management activities. The broad categories resulting in the most claims were:

- Symptoms involving the abdomen and pelvis
- Back disorders
- Plastic surgery
- Pregnancy
- Osteoarthrosis
- Obesity

The most relevant procedure performed by the insured based on the presenting medical condition was similarly categorized. The top five categories resulting in a claim were:

- Diagnostic evaluation or consultation
- General physical exam
- Medication prescription
- No care rendered
- Joint surgeries

Clearly what we do every day carries significant liability. Even what we don't do carries risk. Vigilance in even our most routine activities is necessary to prevent risk. Having policies and procedures in place will prevent oversights.

The medical condition that led to a claim was categorized by the chief medical factor named in the claim. The top five categories were:

- Improper performance
- Error in diagnosis
- No medical misadventure
- Failure to supervise or monitor a case
- Failure to recognize a complication of treatment

Failure to diagnose, especially breast cancer, is still a major cause for a claim. Early recognition and treatment of complications not only improves patient outcomes but also decreases risk. Even in the absence of a misadventure, we are vulnerable. Maintaining patient rapport and confidence is always our best protection. While these categories do not specify which claims were most successfully defended, preventing claims through disclosure, apology and Code Green, when appropriate, is our goal.

PRF has embraced binding arbitration as a core tenet of its operations since inception. This philosophy serves to argue cases before judges and insulate PRF Insureds from more public and unpredictable jury proceedings. The 10-year data also highlights the economic benefit of this philosophy as alternative dispute resolution (ADR), which includes arbitration, resulted in an average judgment of $288,000 versus $758,000 for a jury verdict. The defense costs incurred for ADR averaged $95,000, while the costs for a jury trial were $135,000 for a defense verdict and $222,000 for a plaintiff verdict. Staying out of court has clear economic (not to mention emotional) benefits.

PRF was founded in 1976 at the height of the malpractice crisis in California. Subsequent MICRA legislation in California stabilized the market and kept premiums down. MICRA became the model for other states to emulate. We are fortunate that challenges in California to MICRA, most recently Prop 46, have been thwarted. When the national data is broken down by Cap limits, the benefits, while not always linear, are clear. States with Cap limits below $300,000 (California is $250,0000) invariably have the lowest indemnity payments. Using OB/GYN as an example, the average indemnity payments by Cap limit are:

Cap Limit	Average Indemnity
<$300,000	$257,000
$300-$499,00	$336,000
>$500,000	$378,000
None	$517,000

As a PRF Insured, it is important to be informed and stay active and understand how PRF is working for you. ■

Dr. Scheifele is the chair of PRF's Risk Management & Education Committee. The data in this article is reprinted with permission from the MPL Closed Claim Comparative*, 2016 Edition, PIAA. Copyright 2016. The information provided may be used for personal use only. Any other use requires prior permission of the PIAA, the Physician Insurers Association of America.*

ASSISTED REPRODUCTIVE TECHNOLOGIES *(continued from page 1)*

average. The American Society of Reproductive Medicine (ASRM) has published guidelines for good laboratory practices that use a system of checks and validations to reduce these unintended errors.

SURGICAL COMPLICATIONS

Oocyte retrieval in IVF involves passing a needle through the posterior vaginal wall into the peritoneal cavity under ultrasound guidance. The overall rate of surgical complications (hemorrhage, infection, anesthesia-related) is less than 4 cases per thousand retrievals, with an estimated half resulting from unintended injuries to small ovarian blood vessels. The surgical infection rate with oocyte retrievals was reported to be as low as 0.01 percent and is likely due to direct inoculation of bacteria when passing the retrieval needle through the non-sterile vaginal mucosa. There is limited evidence suggesting that patients with a history of pelvic inflammatory disease, endometriosis, endometrioma, pelvic adhesions, or pelvic surgeries should be given prophylactic antibiotics to minimize the risks of infection. Only one of the 21 settled claims was for surgical infection.

OVARIAN HYPERSTIMULATION SYNDROME (OHSS)

In order to retrieve as many oocytes as possible, IVF patients are given supra-physiologic doses of follicle stimulating hormone. The resulting high levels of estrogen may trigger OHSS; i.e. fluid shifts resulting in ascites and hypercoagulability with hemodynamic, pulmonary, and renal complications. Because IVF can be very expensive and the stimulation of multiple oocytes is often associated with higher pregnancy rates, patients may request aggressive stimulation even knowing that they may incur a higher risk of OHSS. As a result, OHSS is the most common IVF complication and occurs in up to five percent of all cases. Fortunately, recent advances in the prevention and treatment of OHSS have reduced the incidence of hospitalization and complications.

PREGNANCY-RELATED RISKS

Ectopic pregnancy may occur up to 5 times more commonly after IVF than in spontaneous conceptions. Clinical hypotheses include the presence of pre-existing tubal disease, the technique of embryo transfer, the transfer of embryos two to three days before uterine implantation, and the effects of supra-physiologic stimulation on the hormonal and endometrial environment. Recognizing this risk should translate into more timely diagnosis and a reduction in the medical-legal risks and surgical consequences of treating a ruptured ectopic. All ART patients with positive pregnancy tests should be followed carefully (even in the absence of symptoms) with serial hCG and early pregnancy ultrasounds to document intrauterine pregnancy as early as possible (typically by six weeks gestational age).

Although fertility treatments account for approximately 1.5 percent of all births, they account for more than a third of all twin births and more than three-quarters of other multiple gestations. Overall, the rate of twins and higher order multiple gestation is 20 and 100 times higher, respectively, with fertility treatments in comparison to natural conception. While even ART singleton pregnancies are known to have increased risks of preeclampsia, gestational diabetes, low birth weight, very low birth weight, preterm labor, and preterm delivery, the risks are far greater in multiple gestations. Historically, the primary factor that contributed to the increased rate of multiple gestations was the transfer of multiple embryos after IVF—often at the patient's request. Following trends in Europe (where single embryo transfer is often legislatively mandated), the goal in IVF has shifted to transferring fewer (but higher quality) embryos.

Recent technological advances in extended embryo culture and vitrification have allowed physicians to advocate for the use of elective single embryo transfer in ART more confidently. Extended embryo culture allows for the survival of embryos to the blastocyst stage (day 5-6), where they can be selected based on chromosomal normality (as in PGS) or using more detailed descriptions of morphologic criteria. This advancement in embryo culture has been shown to significantly increase the rate of elective single embryo transfer (eSET) in ART along with a concurrent decline in the rate of multiple gestation. Similarly, the new advancement in embryo freezing known as vitrification allows for the storage of embryos so that they can be transferred one at a time, with pregnancy rates equivalent to fresh transfers.

Fertility treatments account for more than a third of all twin births and more than three-quarters of other multiple gestations.

Finally, the use of gonadotropin injections in conjunction with intrauterine insemination is also falling out of favor as oral agents such as clomiphene and aromatase inhibitors are recommended for milder and cost-effective stimulation that minimizes the risk of multiple gestation.

As innovative treatment options for ART are being rapidly implemented, comprehensive care in ART now requires that a coordinated team of physicians, nurses, genetic counselors, and laboratory specialists stay abreast of these developments to minimize risk and maximize the chances for a happy and safe outcome. ■

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