Impact of shifting legal and scientific landscapes on in vitro fertilization litigation

Understanding the scope, nature, and results of malpractice litigation surrounding reproductive medicine can guide practitioners toward a higher standard of care by revealing potential avenues of legal exposure. Applebaum et al. (1) add value to our understanding of the liability landscape by amassing and analyzing approximately 3 decades of in vitro fertilization (IVF)-related lawsuits that provoked some resolution in US courts. Although the total number of claims is minuscule compared with the number of IVF cycles performed during this period, trends and predictions can be ventured from the sorting and commentary provided. Looking ahead, we believe that several factors external to the delivery of IVF care will impact the malpractice litigation docket over the coming decades. Advances in direct-to-consumer (DTC) genetic testing, greater accessibility to preimplantation genetic testing (PGT), and shifting the legal treatment of preimplantation embryos will influence the patient–provider relationship when treatment is perceived to go awry. In vitro fertilization providers can better prepare for tomorrow's challenges by adhering to evolving standards of care and monitoring the external factors likely to drive malpractice litigation in the future.

DISCOVERIES AFTER DTC GENETIC TESTING

One of the prominent external factors affecting the practice of reproductive medicine is the rapid expansion and democratization of genetic technologies. Applebaum et al. (1) note the increase in DTC usage, the legal liability that can follow the discovery of switched gametes or embryos years down the line, or inaccurate carrier screening detected years after the results were reported. While the recovery of plaintiffs may be tempered today by the existing statutes of limitation requiring claims to be filed within a few years of the negligent act. However, these time bars are unlikely to withstand advocacy because of their unfairness to patients and their offspring who suffer immeasurable harm on detection of the wrongful act. Cases involving swapped or misdirected genetic material and the failure to detect or disclose known genetic anomalies are straightforward negligence. The more difficult scenarios will be those in which a previously unknown mutation poses health risks to the patient or offspring years after a sample was analyzed. At what point should a provider be held accountable for emerging genetic findings? The plaintiff and defense counsel will spar over the discoverability of health-affecting genetic information, leaving IVF providers potentially vulnerable to judge and jury sensibilities on risk allocation in the realm of genetic testing.

INCREASING ACCESS TO CARRIER STATUS AND PGT

Screening individuals and couples for the carrier status of genetically inherited diseases and screening embryos for both aneuploidy and single gene disorders have become more widely accessible and less expensive over the past decade. This rapid expansion has led to new potential areas of litigation, as evidenced by the finding that >20% of claims involved genetic testing liabilities.

The use of preimplantation genetic testing for aneuploidy (PGT-A) has expanded 10-fold, from 4.5%–44.9% of IVF cycles, in the interval between 2011 and 2018 (2). In some centers, PGT-A is a nearly ubiquitous offering. This raises the question of whether all embryos should be screened with PGT-A or all patients counseled about the availability of this technology (3). One of the lawsuits described involves a child born with trisomy 21, an outcome that could likely have been averted had PGT-A been utilized. However, the universal application of PGT-A is not supported by data. Evidence of benefit, particularly in women aged <35 years, is controversial (4). A similar liability can occur when PGT for monogenic disorders (PGT-M) is not offered, as in the reported case of a child born with cystic fibrosis. However, laboratory error can result in the unintended transfer of an affected embryo even when tests are performed, thereby increasing liability. The more elements that are screened in the embryo, the more is the likelihood of both testing and embryology errors resulting in the unintended transfer of an affected embryo.

The use of genetic carrier screening should be offered to all patients contemplating reproduction. For patients undergoing IVF at risk of having a child with an inherited disease, should PGT-M be mandatory? How does this translate to patients who are not infertile, and who are not contemplating utilizing IVF for procreation? Will obstetricians and gynecologists be found liable when patients opt against genetic carrier screening and bear offspring affected by an inherited disease that could have been avoided had they undergone IVF and screening of embryos through PGT-M? These questions remain unanswered.

THE STATUS OF "UNBORN HUMAN BEINGS" IN A POST-*DOBBS* WORLD

On June 24, 2022, the US Supreme Court issued its decision in *Dobbs v. Jackson Women's Health Organization*, overturning approximately 50 years of constitutional protection of previability abortion rights (5). The Court reasoned that abortion is not expressly or impliedly protected by the language of the US Constitution. Without federal constitutional protection, abortion is now subject to regulation, including total restriction, by state lawmakers. Although the Court did not address the legal status of reproductive technologies, including IVF, it did elevate the protection of "potential life" and "unborn human beings" over the interests of pregnant women, provoking concern about restrictions on fertility treatments in which preimplantation embryos are discarded or cryopreserved for later use. Interestingly, the utilization of PGT may increase because of the fear that restrictions on abortion would limit patient choice in the event of the fetus carrying a genetic anomaly.

In the context of malpractice claims surrounding IVF, *Dobbs* and its aftermath may significantly alter the liability landscape. Applebaum et al. (1) report on the US courts' reluctance to award damages for wrongful death when embryos are lost or destroyed, adhering to longstanding jurisprudence

that such claims require the death of an existing human being (1). Before *Dobbs*, the notion of fetal personhood, namely an embryo or fetus as a fully rights-bearing individual, was inconsistent with protected abortion rights. Now that the Court has paved the way to fetal personhood by permitting states to regard "potential life" as a significant matter, recovery for loss or damage to laboratory-based embryos can surely follow. Any refuge that IVF providers took in a court's unwillingness to assess damages for the loss of an "unborn human being" was lost after the *Dobbs* trial. The legal questions now cluster around the frailties of damage calculation when an embryo is destroyed or lost. Questions, such as "What is the likelihood that the embryo would have been born?" or "What would have been the economic value of that person's life?" could soon dominate the docket in courtrooms across the nation.

CONCLUSION

Malpractice litigation is a small but impactful aspect of the practice of reproductive medicine. Looking ahead, external factors in both science and law may shift the landscape of IVF legal liability. Genetic technologies continue to evolve, and best practices have not yet been established. The growing usage of DTC genetic testing may increase claims that providers must be aware or foresee the health impacts of undiscovered or emerging disease-causing variants. Greater access to PGT may pose a risk as it will become the standard of care based on cases in which testing was not offered. Lawsuits can claim that it should have been utilized. This is despite the fact that PGT may not be universally beneficial. Shifting laws on the status of embryos could usher in new claims when they are lost or destroyed. Counseling is essential to allow patients to understand the risks and benefits of fertility treatment. Although counseling does not forestall malpractice claims, it serves the best interests of patients, providers, and the field of reproductive medicine.

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