

Lawsuit frequency and claims basis over lost, damaged, and destroyed frozen embryos over a 10-year period

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Objective: To review the claims, claims basis, and frequency of lawsuits over lost or damaged frozen embryos and to estimate their frequency over a 10-year interval.

Design: Retrospective analysis of case law.

Setting: Private in vitro fertilization clinic and school of law.

Patient(s): None.

Intervention(s): Case law identified using Bloomberg Law, Westlaw, and Lexis Nexis databases for coverage of court dockets regarding allegations and claims.

Main Outcome Measure(s): Lawsuits brought and settled in state and federal court, with data extracted included claims basis and location in federal or state courts.

Result(s): We reviewed case law from January 1, 2009, to April 22, 2019, using the terms frozen, discarded, lost, and damaged embryo/s, and calculated clinical cases using frozen embryos from Centers for Disease Control and Prevention data. We identified 133 cases: 122 and 11 lawsuits in the state and federal court dockets, respectively. Of these, 87 cases involved alleged freezer tank failure in California and Ohio in 2018–2019. In the remaining 44 cases, the majority (37 cases) were brought for personal injury, breach of contract or warranty, product liability, professional negligence, unfair business practices, and miscellaneous tort. A minority (7 cases) were brought for medical malpractice. During this interval, a total of 398,256 embryo-thaw procedures were reported nationally.

Conclusion(s): Allegations range from business practices to product liability and are seldom for medical malpractice. Our results suggest that best practices in storage of frozen embryos should include not only improvements in hardware and monitoring of storage conditions of specimens but also setting standards for communications among patients, providers, and embryology laboratories regarding disposition of embryos. (*Fertil Steril Rep*® 2020;1:78–82. ©2020 by American Society for Reproductive Medicine.)

Key Words: Lost embryos, lawsuits over cryopreserved and damaged embryos

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Cryopreservation techniques have dramatically improved since their introduction into reproductive medicine in 1949 (1). Storage and transportation of frozen specimens are essential to assisted reproductive technology (ART) such as in vitro fertilization (IVF) and preimplantation genetic testing (2). Two recent catastrophic losses affected thousands of cryopreserved embryos

(3). These events spotlighted the legal, ethical, and regulatory challenges to current practice patterns and professional liability, and they attracted substantial media attention.

The considerable attention garnered in the press aside, the frequency and causes for such losses remain largely unexplored. Liability for gametes and embryos in cryostorage will increase alongside the expanding indications

such as fertility preservation and embryo creation for long-term family building. The increasing number of specimens will also increase the need for reliable techniques and tools to create a haven for them. Case reports have yielded the best available insights into the causes of these and similar accidents and may enable root cause analysis and offer options on how improve care. We studied the facts, merit, and outcome of claims for lost, damaged, or destroyed embryos in U.S. courts over a 10-year period.

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MATERIALS AND METHODS

Case collection

Relevant embryo loss cases were identified using the court dockets on

Bloomberg Law, Lexis, and Westlaw Edge. The case search was limited to cases filed between January 1, 2009 and July 1, 2019. An additional search was run on Westlaw's function for "Jury Verdicts and Settlements" and Lexis Advance's "Jury and Settlement Analyzer." Database coverage ran from January 1, 2009 to July 1, 2019. These results were carefully reviewed for relevant claims of negligent embryo damage or destruction. This analysis yielded a total of 133 cases: 122 in state court and 11 in federal. Access to the cases was gained through a variety of search engines of public records. Bloomberg, Lexis, and Westlaw databases were used in combination to cover the state court dockets. Federal court dockets were accessed through Bloomberg. These data are a matter of public record, do not involve any risk of disclosure of identity, and do not include any human subject experimentation. The study is a description and classification of publicly available data and as such was deemed exempt from institutional review board process.

Review of cases

The cases were divided between federal and state, and between open and closed. Case status was derived from the dockets available on Bloomberg, Westlaw, or Lexis. Open cases, those still in the process of being resolved, were set aside with a brief description of facts and status. Closed cases were recorded with a summary of the allegations, claims, outcome, damages, judicial reasoning, and other relevant facts. Allegations and claims were based on the plaintiff's complaint.

There were two broad reference sources for reviewing outcomes, damages, and reasoning: dismissed and adjudicated. For cases that were dismissed, this came from court orders and stipulations for dismissal. For cases that were adjudicated, by contrast, these dimensions came from opinions issued by the court. This analysis resulted in 133 cases for consideration. These 133 cases were analyzed in detail and sorted into one of five incident categories, based on the fact patterns of embryo outcomes: lost or misplaced in laboratory; lost or misplaced in transit; damaged or destroyed through mishandling; damaged or destroyed through miscommunication; and damaged or destroyed through storage tank failure.

The 90 closed cases were analyzed for trends in legal claims, outcomes, and damages. The number and outcomes of frozen embryo transfers were compiled from the most recent annual report published by the Centers for Disease Control and Prevention (CDC), Division of Reproductive Health. This number provided a denominator to gain insight into the approximate frequency (percentage of cases) of these events.

RESULTS

One-hundred and thirty-three cases were filed from January 2009 through June 2019 that credibly alleged the negligent destruction of cryopreserved embryos. Of those 133 cases, 11 cases (8.3%) were filed in federal court, and the remaining 122 cases (91.7%) were filed in state court. We sorted the cases into five incident categories (Fig. 1). Of the 133 total lawsuits,

the vast majority of 111 cases (84.1%) involved damage or destruction due to storage tank failure in two clinics in two states. Just three (2.3%) involved damage or destruction from other forms of mishandling; eight (6%) involved embryos lost or misplaced in the laboratory; five (3.8%) involved embryos lost or destroyed in transit; and six cases (4.5%) involved damage or destruction due to miscommunication or other human error.

Most of the 111 cases originated from two separate incidents that occurred in early March of 2018, one in California and the other in Ohio. In both situations, the nitrogen level in a storage tank dropped, causing the frozen embryos to possibly warm and lose viability. In the California incident, the drop in liquid nitrogen and subsequent warming did not trigger any alarm. Thirty-three consolidated cases currently remain open from this incident. In the Ohio incident, the drop in liquid nitrogen triggered an on-site alarm, but no employees were present to respond, and a remote alarm system had been silenced. Seventy-eight cases were filed as a result of the Ohio incident, most of which had been settled by late September 2018 although 12 consolidated cases remain open.

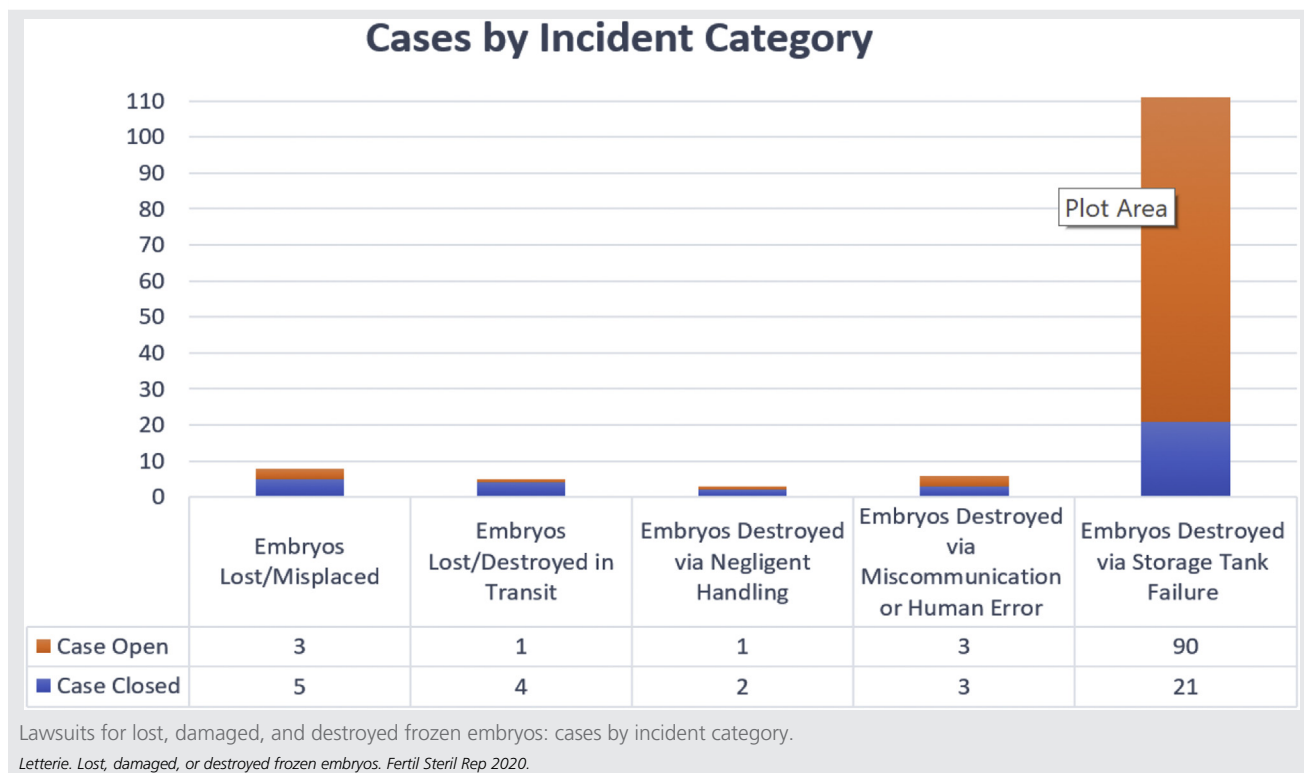
Of the 133 embryo-loss lawsuits, 90 cases were closed. These cases resolved 25 different legal claims in total (Fig. 2). Most claims included breach of contract, bailment (improper property transfer), and negligence (failure to meet the standard of care). Just two other claims appeared in a substantial minority of cases: breach of fiduciary duty (37.1%) and conversion of personal property (28.6%). Additional details of the clinical events, bases for claims, and settlements are found in Supplemental Tables 1, 2, and 3 (available online).

The closed cases provide insight into how negligent embryo destruction cases are resolved (Fig. 2). Of the 90 closed cases, all but two (97.8%) were settled out of court. Of the 88 cases that settled, 65 did not mention any details about court cost or attorney fees, whereas 22 ordered the defendant to pay court costs. In the last of these settled cases, each party bore its own attorney fees and costs. The average court cost (i.e., clerk's fees, computer fees, court special projects fund, legal aid, legal news, and legal research) for the 22 cases that required the defendant to pay was US\$523.32. The remaining two closed cases that did not settle were outliers. One found that mislabeling did not constitute libelous false statements damaging to the plaintiff's reputation. The other involved federal removal back to state court for lack of jurisdiction, where the case was later settled.

These cases are complex, nuanced, and vary considerably in the details of their claims. Cases studies are presented as supplemental tables (Supplemental Tables 1, 2, and 3), which are intended to give a sense of the facets of these cases and their varied claims. Although they are not exhaustive of all case law, these studies illustrate that the claims extend far beyond a loss of embryos and into the impact on options for family building.

During this time period, a total of 398,256 embryo thaw procedures were reported to the CDC, including frozen transfers of embryos derived from autologous and donor oocytes and donated embryos. A frequency of 131 cases during the observation interval translates to an incidence of much less

FIGURE 1



than 1%, making these events very unlikely clinically—but far more impactful on a case by case basis.

DISCUSSION

Assisted reproductive technology has undergone dramatic changes in recent years. Cryotechnology has emerged as an integral part of contemporary care for patients seeking options for family building (4). Freezing embryos is now standard care and a hoped-for outcome in the IVF process (5). Patients who use this technology often depend on their frozen embryos for future family building (6). This dependency is predicated on safe storage and on the maintenance of the storage facilities to protect the long-term viability and availability of this inventory. But unique risks attend this implementation. Risk management in the area of gamete and embryo cryopreservation has gained greater urgency, given the recent mass freezer malfunctions in Ohio and California (7, 8). Analysis of these claims could help identify the root causes of adverse events and provide guidance for improved care.

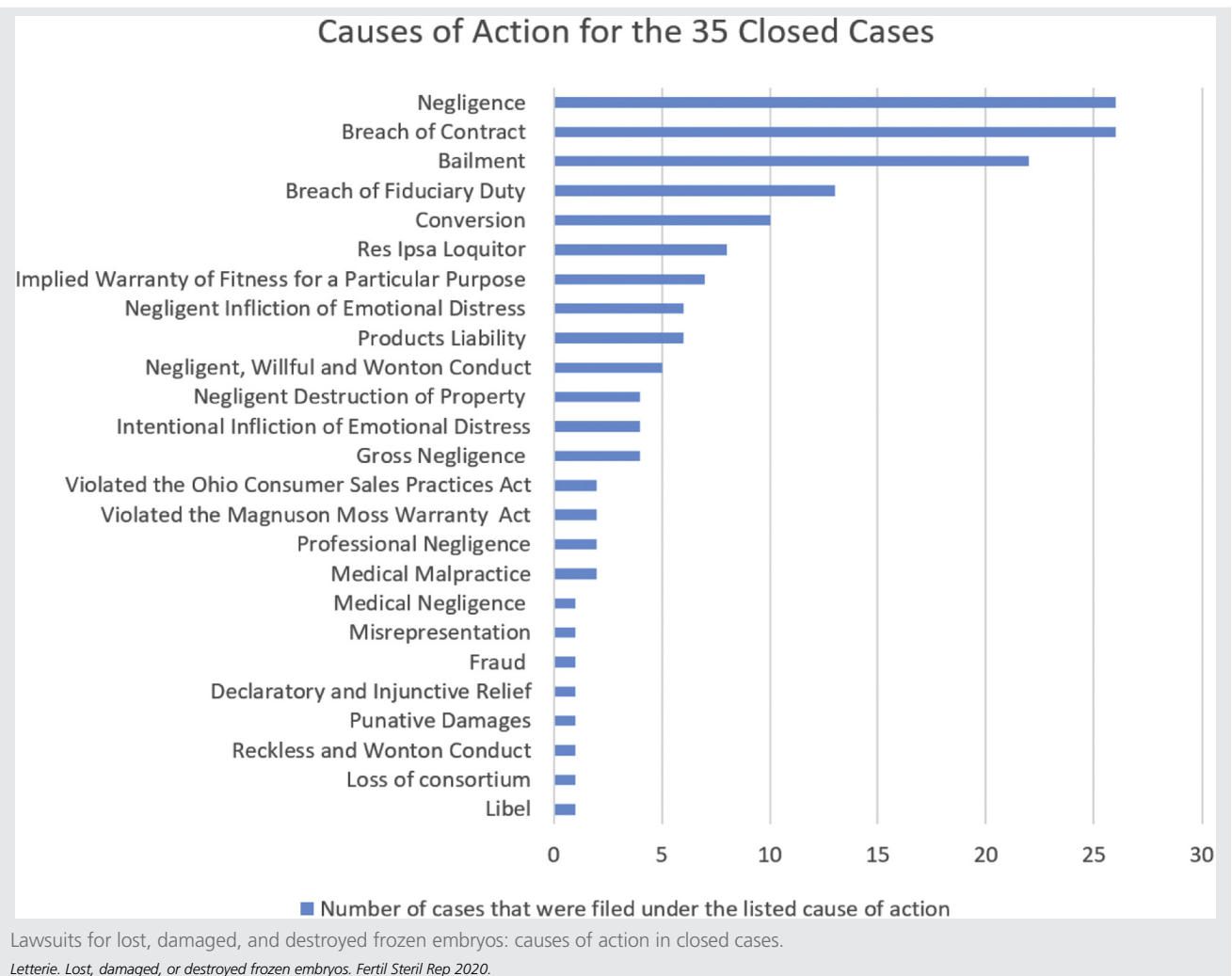
Our data suggest that lost, damaged, or destroyed embryos have a variety of causes but fall outside the scope of generally defined medical malpractice. For purposes of this discussion, we define medical malpractice in a more expansive sense than simply the absence of skill and good judgment that results in injury during clinical care. We use the term and its related legal tenet of negligence to apply broadly to failure of a practitioner to provide equipment and its monitoring and

maintenance to ensure optimal outcomes. These claims reach beyond the familiar issues of medical malpractice and breach of professional duty (9).

Most claims relate to hardware, to lapses in monitoring, record keeping, or communication with patients regarding disposition, and in one case to employee relationships with the IVF clinic. Our analysis shows that the failure of liquid nitrogen tanks is by far the more common contributor to loss. These data are influenced by the recent events in Ohio and California, in which thousands of embryos were allegedly lost due to tank breakdowns. Beyond these events, the losses were due to inadvertent events and were very low in frequency. The basis for claims suggests that medical malpractice claims were relatively low on the scale (a value of 5) compared with the most common claims basis of negligence and breach of contract (with values of 26 each). Medical malpractice claims require showing that patients were harmed in physical or economic ways. These showings are hard to make in claims for embryo loss. In terms of liability risks, practitioners may do better to invest and insure against contract and property claims associated with storage malfunctions.

It is notable that the changes in the management of ART that are enabled by freezing embryos occur against a background of intense debate about definitions of unborn life and legal personhood (10). In this respect, one of the claims filed against University Hospitals in Cleveland warrants special mention: in addition to their negligence claim, the plaintiff couple sought a legal declaration that their lost embryos

FIGURE 2



should be given legal standing as persons, sufficient to let them sue for wrongful death (11). The Cuyahoga County Court of Common Pleas dismissed their case without giving a reason or explanation about whether any settlement was reached. The couple said they would appeal their claim to Ohio's Supreme Court. This case is noteworthy both for its emotional impact and for touching on a hotly debated issue (*Just what is personhood?*). The ultimate disposition of this case also has the potential to greatly impact options for embryo freezing and the liability risks that clinics and providers face—not just for harm to fertility patients, but also to potential children. However, even in the current climate the chances for a successful claim are very low.

Our study has two main limitations. First is the lack of access to settlements details. The parties are not required to file the terms of their settlements in these cases, which comprised the majority of our sample set. Not knowing which party paid how much or for what reasons limits the robustness and utility of our findings. Nevertheless, we were left with sufficient cases to generate evidence-based insights into root causes,

best practices, and insurance liability. The second limit concerns the absence of comprehensive reports or reliable methods into the frequency and cause of adverse events associated with embryo loss.

No public or private body tracks errors or accidents aside from the popular media, and such cases tend to be settled within the legal system without further disclosure. Clinic reporting of success rates and utilization is voluntary (12), and there are no rules to mandate the reporting of errors in handling or processing specimens (13). Adverse events still look rare compared with the total number of cases reported to CDC that involve frozen embryos. The main importance of these events lies in their devastating impact on families and individuals, and the events' prospects for reshaping the legal environment.

CONCLUSION

Our study provides insight into the basis of claims and the clinical and laboratory events that resulted in these losses. We identified no single factor as recurrent, but we did identify

a broad claims basis beyond the more common basis of medical malpractice and breach of professional duty. Our data suggest that these events are infrequent, and the actual number of events when viewed against the practice of ART and management of frozen embryos is quite small, at less than 1%.

A detailed review of contributory factors suggests their avoidance will depend on not just reliable equipment but also effective monitoring systems for managing the storage facilities for frozen embryos (14). The U.S. Food and Drug Administration classifies these tanks as Class II devices, which are not subject to even premarket approval (15). In the absence of federal oversight, the manufacturing and use of cryopreservation tanks could be regulated at the state level to minimize the risk of embryo loss. Our findings suggest that clinics must improve not just their storage hardware and maintenance systems, but also their labeling mechanisms. In addition, clear, verified lines of communication between patients and the laboratory and clinic personnel are strongly recommended.

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