

COMMENTARY

The plight of orphaned or abandoned embryos

SOWBARNIKA ARUNKUMAR, PUVITHRA THANIKACHALAM, RADHA PANDIYAN, PANDIYAN NATRAJAN, ELI ADASHI

Abstract

Excess embryo generation in assisted reproductive technology (ART) cycles is a common practice due to the inherent uncertainties at various stages of the procedure. The remaining embryos, after the transfer of one or two, are cryopreserved. However, ethical, legal, financial, religious and emotional issues arise when these stored embryos are left unclaimed for various reasons. ART clinics then face significant challenges, despite the availability of embryo disposition methods. Judicious minimal ovarian stimulation and detailed counselling with explicit written consent, prior to the initiation of cycles, becomes crucial to prevent this crisis.

Keywords: assisted reproductive technology (ART), human embryos, embryo disposition, cryopreservation, vitrification, abandoned, orphaned or unclaimed embryos

Introduction

Assisted reproductive technology (ART), including in vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI), helps treat couples with infertility by generating embryos in the laboratory followed by embryo transfer, aiming for pregnancy.

In most IVF/ICSI cycles, multiple embryos are generated, with one or two transferred [1] while surplus embryos are cryopreserved for future use. This addresses the challenge of accurately predicting the optimal number of oocytes or embryos required for a successful live birth in a single cycle, unless we resort to natural cycle IVF, which has very low success rates.

Uncertainties exist at every stage of ART cycles, affecting clinical outcomes. Improved ovarian stimulation protocols, higher post-thaw survival with vitrification, and the ability to perform multiple embryo transfer cycles following one oocyte retrieval have contributed to higher cumulative pregnancy rates [2], leading to the common adaptation of an embryo “freeze-all” strategy. However, when couples abandon frozen embryos, it imposes a significant ethical and financial burden on ART clinics.

The modalities by which the fate of the embryos is decided, depending on the existing regulations in each country, are termed as “embryo disposition” [3]. Counselling prior to an ART cycle includes discussion about embryo cryopreservation and mandatory consent is obtained regarding the disposition of embryos in case of any eventuality.

Vitrification and cryostorage of human embryos

Cryopreservation enables embryo storage at extremely low temperatures for future use. Advances in freezing techniques have improved post-thaw survival, reducing embryo wastage.

Previously, multiple embryos were transferred due to unreliable freezing methods, increasing the risk of multiple gestations and related complications. The adoption of vitrification and single embryo transfer has lowered multiple pregnancy rates and improved cumulative success.

Elective embryo freezing, where embryo transfer is deferred by freezing all the available embryos, is done to manage ovarian hyperstimulation syndrome and any other condition which precludes a fresh transfer [4]. It is also done in instances like donor oocyte programme, where simultaneous endometrial preparation of the recipient is not done. When surrogacy is planned, to overcome practical difficulties faced with synchronising cycles of the intending parent and the gestational carrier, cryopreservation of all the embryos is generally performed and transferred in subsequent cycles to achieve pregnancy. As a result, the “freeze-all” strategy is now common in ART, with embryos stored in liquid nitrogen cryo-tanks.

Emergence and ethical challenges of orphaned/ abandoned embryos

The state of embryo orphaning or abandonment arises when the couple who own the embryos

- successfully give birth and render the remaining embryos unnecessary
- fail to pay renewal charges and are lost for follow-ups
- undergo separation
- face an untoward event such as the death of one or both partners
- change personal choices or circumstances, such as deciding to remain childfree

The growing number of embryos in cryostorage requires ART clinics to arrange for expansion of storage facilities, increase in personnel for record-keeping, liquid nitrogen maintenance, continued patient communication, and legal oversight. The rising demand for infertility treatments is

contributing to a steady increase in embryo cryopreservation and unclaimed embryos, heightening the responsibility of clinics for long-term storage risks, cryopreservation failures, natural disasters, and financial burdens proportional to storage volume [5].

Orphaned, abandoned or unclaimed embryos — historical issues

The issue of abandoned embryos was first highlighted in 1984, when an American couple died in a plane crash, leaving two embryos stored in an Australian clinic [6]. The lack of prior consent regarding the embryo's disposition raised ethical and legal concerns, including questions about their potential rights as legal heirs.

In 1990, the United Kingdom established the Human Fertilisation and Embryology Authority (HFEA) to regulate ART procedures and set a five-year limit on embryo cryostorage. By 1996, this policy affected over 3,000 embryos, forcing clinics to decide the fate of unclaimed embryos. Attempts to contact couples often failed due to non-response, outdated contact information, or separation. Despite these challenges, no extensions were granted, and nearly 3,300 embryos belonging to 900 couples were disposed of [7], creating a controversy. This drew more attention to the ethical implications of discarding unclaimed embryos [8].

These two specific incidents led to widespread awareness about the increasing number of abandoned, orphaned, or unclaimed embryos in ART clinics. This also underscored the importance of ethical considerations and the need for policies to implement preventive measures regarding this global issue.

Embryo cryostorage: regulations on duration and disposition

In 2017, the Brazilian Federal Council of Medicine authorised the disposal of cryopreserved embryos after three years with the couple's consent and permitted the discarding of abandoned embryos if the pre-established contract was not adhered to [9].

An ethics committee opinion (2021) stated that embryos may be deemed unclaimed if a couple cannot be reached after a reasonable period despite reasonable efforts, allowing clinics to define this time frame. With prior consent, such embryos may be donated for research; however, in the absence of written instructions, they cannot be donated or used for research [10].

The revised ART regulations of the Government of India specify that embryos can be stored for up to 10 years, after which they must either be destroyed or donated for research, in accordance with the terms of consent obtained from the couple [11].

Although committee opinions and regulations in some countries define the cryostorage duration, ethical debates

persist on the grounds of available options for embryo disposition, patient counselling and obtaining consent. In addition, a blanket law on abandoned embryos cannot be created for all ART clinics, as the final decision on embryo disposition is dependent on ethical, social, religious, cultural and other aspects of each country.

Informed and written consent

ART clinics have increasingly implemented routine counselling and obtained prior written consent from couples to address future embryo disposition. Available options are explained to each partner and jointly to the couple, particularly regarding scenarios where embryos may be left unclaimed and written consent is obtained accordingly.

In cases of embryo abandonment, some clinics act on pre-procedural consent, while others seek renewed consent after the storage period to avoid legal complications. Notably, 40% of couples change their disposition decisions in the second consent, adding to the clinic's burden through consent comparison and additional counselling to support informed decision-making [12].

Embryo disposition: possibilities

Cryopreservation of embryos and their handling is dependent on the laws governing the land [13] and on policies of individual clinics [13]. Possible embryo disposition methods include:

- **Continued storing for a future pregnancy:** Couples adhere to clinic policies, including making timely renewal payments may continue storage. The specific policies and renewal modalities vary by clinic.
- **Donating embryos for research:** With the consent of the commissioning couple, embryos can be donated for research purposes, provided this is permitted by the laws of the relevant country. In Australia, Italy, Russia, Turkey and Germany, the use of human embryos for purposes other than reproduction is not allowed [14].
- **Donating embryos to another individual or couple:** With proper consent, the commissioning couple can donate their embryo to another individual or couple. However, this method of embryo disposition is not permitted in 14 European countries [15] and in India [11].
- **Discarding the embryos:** In most countries, regulations allow abandoned embryos to be discarded or to perish, after obtaining proper informed consent. However, methods adopted in discarding embryos are not yet standardised and a survey among embryologists highlighted the need for an accepted protocol [16].

- **Compassionate embryo transfer:** This is an embryo transfer procedure performed during a phase of the menstrual cycle when implantation is unlikely to occur. It is carried out as an alternative to discarding embryos. However, the procedure is controversial and not widely accepted by many physicians. It is important to note that a few pregnancies have been reported following this method [17].

Intending parents' perspectives in deciding on embryo disposition

A 15-year Belgian study (1992–2006) found embryo donation to another couple was the least preferred option and declined over time; while donation for research was most preferred and its popularity steadily increased [18]. In Japan, sociocultural principles heightened stress around embryo disposition, indicating a need for psychological support to make informed decisions [19]. In China, cost and social factors led most couples to choose embryo disposal over research donation. [20]. A survey of 187 Canadian couples with embryos stored for over two years found satisfaction with pre-procedural counselling but uncertainty about embryo disposition [21], suggesting a need for improved post-procedural counselling by healthcare professionals.

Thus, the Intending parents' perspectives on embryo disposition vary widely, highlighting the need for detailed counselling to support them in making informed decisions about embryo disposition methods.

Ethical concerns surrounding embryo disposition options

Moral status of embryos

Differences of opinion among people in deciding the status of embryos make it difficult to design standardised and universally acceptable methods for embryo disposition. The question of when human life begins remains a fundamental concern in medical ethics, posing major difficulties for clinical practice and policymaking. Perspectives vary widely, with some asserting that human embryos are complete persons from the moment of conception, while others argue that personhood develops gradually over time [22]. The moral, legal, and property status of human embryos are interpreted differently across religious, legal, cultural, and philosophical contexts, adding complexity to the ongoing debate [23].

Persistent disagreement remains about who "owns" the embryos and what the responsibilities are of the individuals or couples who create them [24]. Important ethical questions include whether embryos themselves have any rights, whether our duties toward them are fixed or depend on the situation, and how to fairly address these issues when people's beliefs differ substantially [25].

Research among US couples reveals that their perception of considering embryos as children or a potential life makes it difficult to decide on disposition options [26]. The American

Society for Reproductive Medicine (ASRM) has established ethical guidelines for conducting research on embryos, stating that such research is permitted when proper consent is obtained and the clinical significance is clearly emphasised [27].

These complexities highlight the need for ethically sensitive, culturally aware, and legally sound policies on embryo disposition as outlined below.

Informed consent and autonomy

Obtaining clear written informed and voluntary consent in advance from both partners is essential when making decisions about embryo disposition and should be done prior to commencement of the procedure. Ethical concerns arise when Intending parents are not fully aware of their options or do not understand the implications of the choices they make, which can happen with standard consent processes. The time gap between embryo creation and decision-making adds complexity, as values and circumstances often change over time [28].

Embryo disposition after the demise of one partner or after separation

Disputes over embryo disposition often arise in cases of divorce or death of one partner, highlighting ethical conflicts around reproductive autonomy (the right to have or not have children), honouring prior consent versus changing circumstances, and viewing embryos as property or potential life [29]. Partners may have differences of opinion on opting for storage or embryo disposal after a pregnancy, transferring treatment elsewhere, or opting out of treatment altogether. They may also disagree on whether to opt for or against cryopreservation. A common ethical and legal question is whether one partner should be allowed to use the embryos without the consent of the other.

Recent court cases have yielded inconsistent rulings, on whether the right to have genetic children is more important than the right not to have them. These situations raise complex issues about reproductive rights and responsibilities. Courts often find it challenging to resolve such situations, especially when there are no clear prior decisions between the partners [30]. This emphasises the need for clear and detailed written consent from the couple before commencing the treatment cycle.

Embryo abandonment/orphaning

Embryo abandonment occurs when the Intending parents stop communicating with fertility clinics or fail to pay cryostorage fees, leaving their embryos without clear instructions to clinics. This issue raises important ethical questions for clinics about using resources fairly, the duties of institutions toward embryos, and how to make practical choices while respecting the value of embryos [31].

Ethical and legal questions about who owns the embryos, who is responsible for them, and how consent should be handled arise in this situation. It remains unclear whether the biological parents retain continued responsibility for embryo disposition [5]. When this responsibility is relinquished, institutions require clear ethical guidelines to manage the embryos appropriately.

The lack of clear guidelines increases the burden on clinics, which may end up maintaining abandoned embryos at the cost of paying patients, which is unfair to the latter.

Donation for infertile couple

Embryo donation presents specific ethical challenges in clinical practice, including balancing parental reproductive choices with the welfare of the resulting child [32], addressing concerns related to genetic heritage and identity, and ensuring the appropriate disclosure of relevant medical information.

Under the latest ART regulations in India, embryos created for treating an infertile couple cannot be donated to other patients. Strict guidelines have also been established for screening of all gamete donors [11]. If embryo donation from infertile couples were allowed, ethical concerns would arise about the potential transmission of genetic disorders, especially in cases of unexplained infertility. Recent research indicates that comprehensive genetic testing may help address some concerns, although the debate continues over what level of risk is considered acceptable. The risk of accidental incest is also a major ethical concern when it comes to surplus embryo donation from a couple. This is because the offspring originating from the same donated embryo pool may unknowingly engage in consanguineous relationships, thereby raising serious genetic and ethical implications [33, 34].

Any ethical framework for embryo donation must therefore consider the rights and responsibilities of donors and recipients, the welfare of the resulting child, and the complexities of family dynamics. Even when legalised, as in a few other countries, using such embryos demands careful ethical evaluation to protect the child's welfare while respecting parental reproductive rights. Additionally, it should address the clinical implications of genetic relationships, including their influence on identity, medical history, and the need for appropriate genetic counselling [34].

Donation to scientific research

Embryos donated for research are typically destroyed during the process, raising ethical concerns. The use of embryos in research involves balancing potential scientific and medical advances against respect for their moral status. Ethical frameworks commonly apply the principle of proportionality, consider whether the embryos would otherwise be discarded, and define permissible research goals [27].

Although such research may offer important medical benefits, questions remain about whether consent alone sufficiently addresses the moral complexities of using embryos in research [25].

Proactive approaches to address ethical concerns

Opting for gamete freezing over embryo preservation

Gametes are owned by one person, making ownership easier to define than embryos, which belong to both partners. Hence, alternative options like gamete cryopreservation can be considered which will reduce the legal implications. However, there is increasing evidence that gamete abandonment is on the rise as well [35]. The routine use of gamete cryopreservation solely to avoid legal issues raises ethical concerns, particularly because post-thaw survival rates of embryos are generally higher than those of frozen gametes.

Adapting milder stimulation protocols and limiting embryo generation aiming for a single birth

Milder ovarian stimulation protocols lead to the retrieval of fewer oocytes, consequently reducing the number of embryos created. Limiting embryo generation to achieve a single live birth can help decrease the number of surplus embryos; however, this may also lower the chances of a successful outcome in terms of cumulative pregnancies. This situation presents ethical challenges in balancing successful treatment outcomes with patients' reproductive autonomy and financial challenges especially in a developing country like India, where insurance coverage is not available for ART procedures.

Preferring fresh embryo transfer procedures

Fresh embryo transfer procedure — where an embryo created in the lab is transferred to the prospective mother's uterus just days later — reduces the need for embryo freezing and the ethical issues of surplus embryos. It can improve implantation rates by utilising an optimal uterine environment but must be balanced against risks like ovarian hyperstimulation and tailored to clinical indications. However, it is important to recognise that fresh transfer is not feasible in all cases, which may limit its broader application.

Managing abandoned embryos: ethical and policy considerations

A registry for abandoned embryos can help with tracking and ethical oversight, but privacy and donor consent must be respected. Government support in managing these embryos may ease this process, though it raises questions about resources and responsibility. Decisions like discarding, adoption, or using embryos for research involve complex ethical concerns, so clear and fair guidelines are essential based on the country's law.

How ethically sound are our decisions in these matters?

As we navigate the complexities of assisted reproduction, we are often left with more questions than answers, highlighting the need for greater clarity to guide future practices.

Conclusion

Natural cycle IVF is losing popularity due to the increased cycle cancellation rate. Therefore, ovarian stimulation and generating more embryos have become an inherent component of ART cycles. ART clinics are becoming biorepositories as the number of abandoned embryos continues to rise. It is of crucial importance to be aware of the amassing of abandoned, orphaned, or unclaimed embryos before taking up a couple for ART. Informed consent obtained before the procedure will legally aid the ART clinic, whereas at this point the only possible way to overcome or at least reduce ethical challenges is by generating a smaller number of embryos through mild stimulation protocols. This is the moral responsibility of the physician and the clinic treating infertile couples. Regulatory bodies, in concurrence with ART clinics, have to bring about regulations for these abandoned or unclaimed embryos considering the ethical and legal aspects associated with them.

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COMMENTARY

Steering medicines towards patient safety: Challenges and possible solutions

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Abstract

Medicines provide therapeutic benefits but also cause harm due to inappropriate use and adverse drug reactions (ADRs). ADRs may cause serious health consequences, imposing a significant burden on healthcare systems. Ensuring patient safety by minimising risk requires optimal ADR monitoring, transparency, accountability, and adherence to ethical principles throughout the stages of drug research and development, the approval process, and use in the real world. The current systems for assessing and assuring medicine safety have certain weaknesses and challenges, thereby increasing the risk that ADRs go unrecognised. This commentary, therefore, delves into the issues surrounding medicine safety, the risks entailed, challenges in detecting ADRs and potential solutions to address these issues. It is hoped that this piece will help stakeholders, including regulatory agencies, improve accountable systems, enhance patient safety, and foster public trust in medicines, thereby improving both individual and public health.

Keywords: Pharmacovigilance, ADR, benefit versus harm, medication errors, AI in healthcare

Introduction

Medicines have both beneficial and harmful effects. These may vary based on the medicine or individual. Clinicians should, therefore, weigh therapeutic benefit versus harm while prescribing. Appropriate medicine use involves informing patients about medicines in prescriptions, weighing risk versus benefit, and involving patients in the

decision-making process. Each process has ethical implications, involving autonomy (patient information and decision making), justice (ensuring adequate representation of diverse groups, access, availability, and affordability), beneficence (ensuring maximum therapeutic benefit) and non-maleficence (implementing measures to prevent adverse drug reactions).

An adverse drug reaction (ADR) is a “noxious and unintended response to a medicine administered at doses normally used for diagnosis, prevention, or treatment of diseases” [1]. Serious ADRs may be life-threatening, lead to hospital admission, prolong hospital stay, cause disability or teratogenicity, or result in death. The economic burden due to ADRs was approximately \$6.7 billion per year in the UK [2]. Estimates of preventable medication-related harm amount to 5% of the population [3].

Historically, the thalidomide disaster raised a global alarm regarding consequences of undetected ADRs and the need to test medicines systematically and thoroughly for potential harm [4]. This systematic monitoring is done through pharmacovigilance. The World Health Organization (WHO) defines pharmacovigilance as the “science and activities relating to the detection, assessment, understanding and prevention of adverse drug effects or any other drug-related problem”. The WHO Programme for International Drug Monitoring (PIDM) created in 1968 facilitated the collection of evidence of patient harm from multiple sources [5,6]. This international collaboration enabled data sharing across