

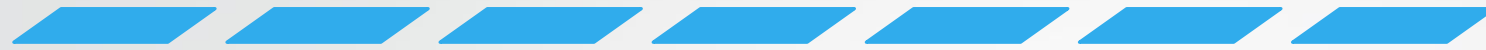


*PROBLEMS AND PRESPECTIVES OF  
GAMETE CRYOPRESERVATION  
TECHNIQUES*

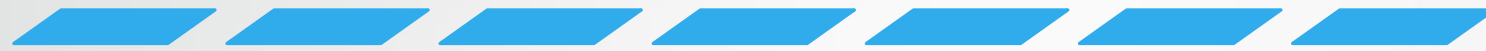




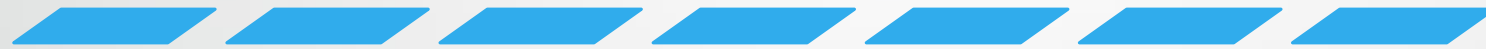
Concept



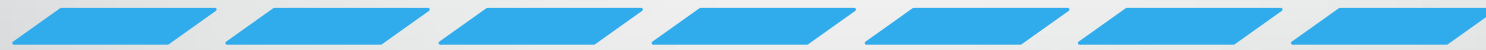
Data from EU Members



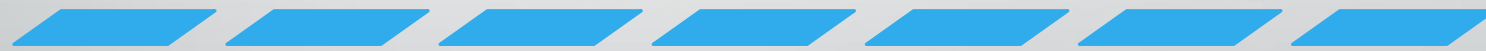
Legislation in Italy



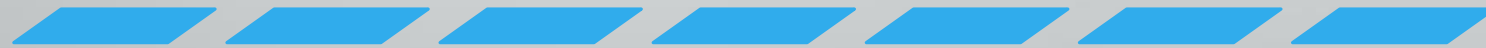
Ethical issues



Social issues

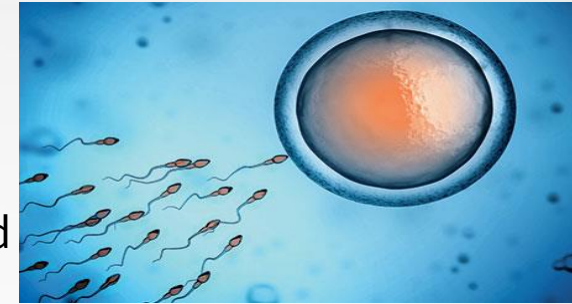


Court cases



## **Cryopreservation of embryos**

The process involves oocyte retrieval from the woman and subsequent in vitro fertilization with her partner's or donor sperm. The embryos are then exposed to cryoprotectants and are stored at subzero temperatures until desired for use.

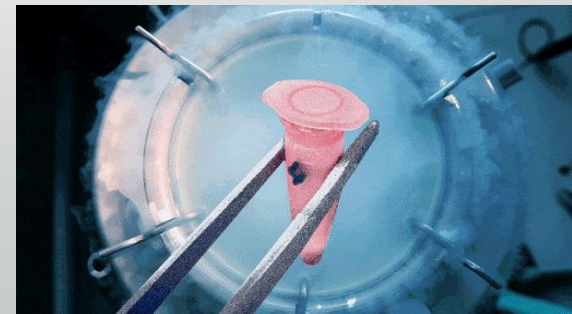


## **Human oocyte cryopreservation** (egg freezing)

is a procedure to preserve a woman's **eggs (oocytes)**. ... The intention of the procedure is that the woman may choose to have the **eggs** thawed, fertilized, and transferred to the uterus as embryos to facilitate a pregnancy in the future.



**Semen cryopreservation** (commonly called **sperm banking** or **sperm freezing**) is a procedure to preserve **sperm** cells. **Semen** can be used successfully indefinitely after **cryopreservation**. For human **sperm**, the longest reported successful storage is 24 years.



# Females

In females, the most common option at all ages is storage of **ovarian strips** or biopsies. In post-pubertal women, there is the added choice of cryopreservation of immature or mature oocytes.

The third possibility is the cryopreservation of human embryos either with the sperm of their partner or the sperm of an anonymous donor.

# Males

There are sufficient data concerning the efficiency of sperm freezing, which is generally possible from the age of 12 years (median age for spermatarche 12.5 years).

Pre-pubertal males. The only option here is testicular tissue freezing.

Post-pubertal males. The most common option here is freezing of ejaculated sperm, but storage of testicular tissue is also a possibility..

### **Medical Indications**

- Women whose cytotoxic cancer treatment threatens their ovarian reserve.
- Severe endometriosis , genetic disorders such as mosaic **Turner's** syndrome .
- Other medical but **ART**-specific indications include emergency freezing in **IVF** when sperm is not available on the day of oocyte retrieval
- Prevention of ovarian hyperstimulation syndrome (**OHSS**)
- Accumulation of oocytes either in cases of poor responders or to increase their availability for **PGD**

### **Non Medical Indications**

In contrast, the other indication, variously labelled as '**non-medical**', '**social**' or '**elective**' because of age-related loss of oocytes has led to vigorous semantic debates. These debates include ethical issues, as respect of women's autonomy, as well as social concerns of equity and public funding.

**Table 1** Regulations, indications, and funding for OoC in 2015 for 27 European countries.

Country	Specific regulation	ART register		Indications for freezing			Funding	
		General	OoC*	Age (years)	Medical	Non-medical	Medical	Non-medical
Austria	Law	Yes	No	No	Yes	Forbidden	No	No
Belarus	No	No	No	No	Yes	No	No	No
Belgium	No	Yes	Yes	<45	No	No	Yes	No
Bulgaria	No	No	No	No	Yes	Yes	No	No
Czech Republic	No	Yes	No	No	No	No	Yes	No
Denmark	Law	Yes	2016	<46	Yes	No	Yes	No
Estonia	No	No	No	No	No	No	No	No
Finland	Law	Yes	No	No	No	Yes	Yes	No
France	Law/COP	Yes	2017	18–42	Yes	Forbidden**	Yes	No
Germany	Law/COP	Yes	Yes	20–49	Yes	Yes	No	No
Greece	No	No	No	No	No	No	No	No
Hungary	Law	Yes	No	No	Yes	No	No	No
Italy	Law	Yes	2016	No	Yes	Yes	Yes	No
Ireland	No	No	No	No	No	No	Yes	No
Lithuania	No	No	No	No	No	No	No	No
Malta	Law/COP	Yes	No	25–42	Yes	Forbidden	Yes	No
Netherlands	Law/COP	No	2016	No	Yes	Yes	Yes	No
Norway	Law	Yes	No	No	Yes	No	Yes	No
Romania	COP	Yes	No	No	No	No	No	No
Russia	No	No	No	No	Yes	No	No	No
Slovakia	No	No	No	No	No	No	No	No
Slovenia	Law	No	No	<45	Yes	No	Yes	No
Spain	Law	Yes	No	>18	No	No	Yes	No
Sweden	No	Yes	No	No	No	No	Yes	No
Switzerland	Law/COP	Yes	No	No	No	No	No	No
UK	Law/COP	Yes	No	No	No	No	Yes	No
Ukraine	No	No	No	No	Yes	Yes	No	No

- *In February 2004, the Italian Parliament approved the law 40/2004 (rules in the field of medically assisted reproduction), which regulates MAR treatments.*
- *In art. 4 it is stated that the access to assisted reproduction techniques is limited to those cases of infertility or unexplained infertility documented with medical procedure as well as cases of sterility or infertility ascertained and certified by a medical act.*
- *On May 2009, the Italian Constitutional Court (N° 151/09) banned some restrictions set out in the 40/2004 law, declaring the constitutional illegitimacy of subparagraphs 2 and 3 of Section 14 that banned the cryopreservation and suppression of embryos and the fertilization of more than three oocytes at the same time during an IVF treatment and it obliged the implantation of all embryos obtained.*
- *Now, Italian reproductive specialists are able to decide how many embryos will be best in order to achieve a pregnancy trying however to limit the number of cryopreserved embryos, which cannot be destroyed or donated.*
- *Even though the Italian Constitutional Court removed some restrictions imposed by law 40/2004, problems such as the storage of cryopreserved embryos for an indefinite time remain unsolved*



# Statements by the Task Force Ethics and Law

For more than a decade (from 2001 until 2014) the Task Force Ethics & Law produced a set of ethical statements on specific moral issues in the practice of ART. The articles listed below were published in the ESHRE journal "Human Reproduction" after approval by the Executive Committee.



## **Storage period**

The reproductive tissues and gametes should only be stored until the age at which it is considered acceptable to be used for the achievement of a pregnancy, taking into account the welfare of the child and the risks to the pregnant mother. In particular, the welfare of the child is unlikely to be met when both parents are of highly advanced age.

## **Interdisciplinary consulting is mandatory**

All specialties present in the caring team (oncologists, pediatricians, reproductive specialists, psychologists/counsellors) should be heard during decision-making about the best procedure



## **Posthumous reproduction**

Since one category of people who cryostore their gametes or reproductive tissues are patients affected by serious diseases, there is a real chance that some of them will die during storage of their reproductive material. Therefore, the possibility of death of the storage giver due to the primary disease should be raised and talked through in the counselling sessions.

***Children or adolescents*** . In the case of children or adolescents, the reproductive tissue and gametes should be discarded on the death of the provider. The parents do not have the right to decide about the (reproductive) use of the genetic material of their child after his/her death.

***Single adults*** . In the case of a single adult with serious disease, the material should be discarded on the death of the provider. In the case of a single healthy adult, posthumous donation to others is acceptable with prior consent in the case of sperm.

***Couples*** . in the case of couples, posthumous use of the sperm by the surviving partner may be acceptable if there is prior written consent of the deceased partner to this disposition. Posthumous oocyte donation is not recommended as it involves both a less reliable technique and the use of surrogacy.

## **Donation**

**3.3.1 *Donation for research*** . After implication counselling, all gametes or tissue providers or their proxy may donate the reproductive material for research.

**3.3.2 *Donation for reproduction by others*** . After implication counselling, this is only acceptable for adults who are healthy at the time of freezing.

# Social implications

- ***THE DILEMMA OF UNCLAIMED EMBRYOS***

Worldwide, federally regulated limitations on time limits for maintaining embryos in cryopreservation vary from 24 months to an infinite duration.

One quarter of couples in an Italian study allowed their embryos to be discarded without assuming the responsibility to designate their preference for a definitive act of disposal.

A significant concern related to the long-term cryo-storage of embryos is maintaining contact with the infertile couple from whom the embryos originated.

Financial factors were common elements in the decision-making process concerning the fate of the cryopreserved embryos.

The European Society of Human Reproduction and Embryology (ESHRE) Task Force on Ethics and Law has advocated standard time limits that can be renewed a limited number of times on a couple's demand

**What you need to know about egg-freezing, the hot new perk at Google, Apple, and Facebook**

**Couple has baby from 24-year-old frozen embryo**

**Court orders implantation of embryos frozen in 1996**

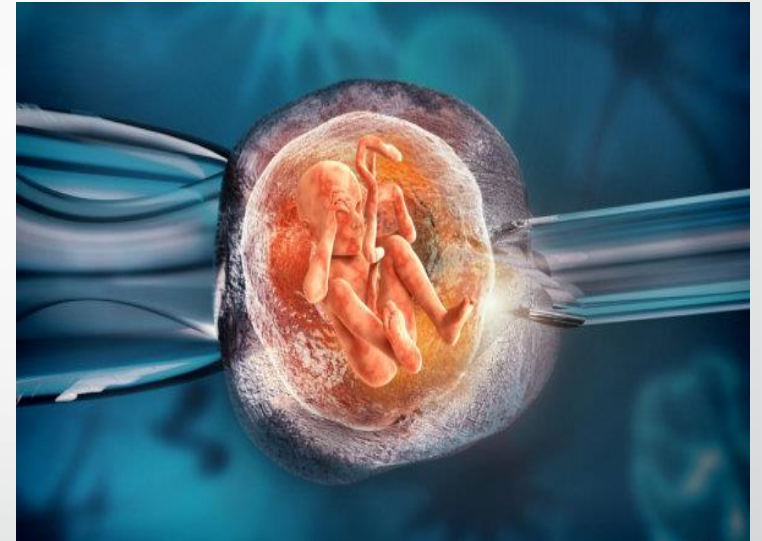
Husband of 50-year-old woman died in 2011

# Legal Cases

***HECHT v. SUPERIOR COURT: RECOGNIZING A PROPERTY RIGHT IN REPRODUCTIVE MATERIAL***

**Litowitz v. Litowitz [Brief] (2002)**

**Woodward v. Commissioner of Social Security**



# Consent

- Schuster et al. have noted that disposition agreements for cryopreserved embryos are most likely to be upheld if they are
- Precise
- follow the lines of public policy
- specify duration
- personal contact information
- individual provisions for embryo use in case of death,
- and explicit responsibilities of all parties involved including the clinic.

**Thank you for your attention!**

