



Access and diversity of medically assisted reproduction in Europe

Legal and ethical aspects of own oocyte storage



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Declaration of Financial Interests or Relationships

Annagrazia ALTAVILLA

I have no financial interests or relationships to disclose with regard to the subject matter of this presentation.

Topic outline



- Issues raised by OoC (ethical, legal, social...)
- Human rights overview
 - Reproductive rights
 - Right to health
 - Dignity
 - Physical Integrity
 - Respect of autonomy/self-determination

Which human rights could be applied to OoC?
Which impact on practices and regulations ?

OOCYTE CRYOPRESERVATION

a fertility preservation technique that involves the extraction, cryopreservation, and storage of mature oocytes

After a series of hormonal stimulations to induce ovulation

mature oocytes will then be extracted through an ultrasound-guided needle during an outpatient surgical procedure

Oocytes can then be thawed, fertilized and utilized in assisted reproductive procedures (e.g. IVF)

To provide a genetically-related child



OOCYTE CRYOPRESERVATION

Provides women with a means by which they could attempt to preserve their fertility

'Experimental' label lifted from OoC
(ASRM - Practice Committees, 2013)

Medical Indications (MI)

When illness or medical treatment
likely to render them infertile



Non-Medical /Social Indications (NMI)

When postponing the childbearing
for individual and personal reasons
(wealthy/young women)

- **Treatment threatening the ovarian reserve**
(e.g. cancer, endometriosis, genetic disorders, severe Chron's disease)
- **Medical ART-specific indications**
(e.g. emergency freezing in IVF, prevention of OHSS)

- **Lack of a suitable partner**
- **Concerns about advancing age**
- **Will to access to further education and career opportunities**
- **Will to reach sufficient level of maturity/financial stability**

- **Gender reassignment surgeries**

OOCYTE CRYOPRESERVATION



PROS

- Provide women with the possibility to preserve their fertility in the face of disease or anticipated decline through the natural aging process
- Avoiding the need for egg donation when patient wishes for a pregnancy later
- Avoiding ethical debates about
 - the nature of the embryo and its cryopreservation
 - or legal disputes about embryo transfer when a couple breaks up

(ESHRE, 2017)

‘oocyte cryopreservation cannot be recommend for the sole purpose of circumventing reproductive aging in healthy women’

(ASMR, 2013)

OOCYTE CRYOPRESERVATION



CONS

Medical/scientific issues

- Risks linked to the OoC (ovarian stimulation, oocyte retrieval, cryoprotectants ...)
- Risks linked to the IVF (prematurity, congenital diseases for FIV babies ...)

Economic issues

- Costs of oocyte autopreservation and of pregnancy a later stage

Social/ethical issues

- Complication/medicalisation of pregnancy at later stage
- Risk of social and professional pressures
- Dissociation between a person and a component of that person's body
- Social concerns of equity and public funding (non-medical OoC)
- False hope among women who consider OoC as a 'really good insurance policy'

Non-Medical /Social Indications

CORPORATE OOCYTE CRYOPRESERVATION

Apple and Facebook offer to freeze eggs for female employees



Egg freezing and other fertility benefits are the newest trend to hit Silicon Valley.
Design by Aaron Robinson/CNET REUTERS TECHNOLOGY NEWS 14 THE OCT. 2014

“...We want to empower women at Apple to do the best work of their lives as they care for loved ones and raise their families.”



Initiative welcomed as revolutionary

- **Truly empowering measure for women to gain further control over their reproduction**
- **Providing them with more chances and options.**

(Bennet J. Time 2014)

Ethical/social issues raised

- **Lack of information** about ARTs efficiency (+35y) and decreasing fertility with age
- **Public policy for the child care** to avoid late pregnancy
- **Access/inequality**

(ESHRE, 2017)

OOCYTE CRYOPRESERVATION

Heterogeneity in practices, regulation, funding, indications

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	<i>2016</i>	<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	<i>2017</i>	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	<i>2016</i>	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	<i>2016</i>	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

OoC, oocyte cryopreservation; COP, code of practice.

*Dates later than 2015 mean a specific registry is planned (putative date in italics).

**Except for childless egg donors who may self cryo-preserve some oocytes since 2016.

(ESHRE, 2017)



- Lack of Code of Practices
- Differences in legal frameworks
 - no specific regulation
 - legislation forbidding N-MI
 - Legislation allowing both MI/N-MI
- Differences in founding regimes
 - Medical OoC predominantly funded (direct state funding or compulsory insurance system)
 - Non-Medical OoC never funded
- Lack of clarity/consistency for “medical indication” concept

Which human rights could be applied ?

Which impact could they have on practices and regulations ?

FUNDAMENTAL RIGHTS TO BE RELATED TO OOCYTE CRYOPRESERVATION

Reproductive Rights

“fundamental right of couples and individuals to make decisions concerning reproduction free of discrimination, coercion and violence “

(1994 International Conference on Population and Development Programme of Action para. 7.3)

To ensure a full enjoyment

- Informed, **free and responsible decisions shall be enabled** by adequate information and education,
 - about child-bearing and
 - methods for regulation of fertility/family planning (not against the law)
- **Access to a range of reproductive health-care facilities and services shall be ensured** (including voluntary family planning)

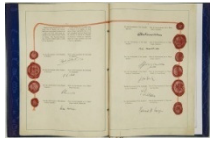
State obligations

in terms of availability, accessibility, acceptability and quality of reproductive health services

Respect of physical/mental integrity and autonomy of individuals

(ECOSOC General Comment No. 22, ICESCR art. 12)

FUNDAMENTAL RIGHTS TO BE RELATED TO OOCYTE CRYOPRESERVATION



Reproductive Rights



**Linked to right to life, to private or family life,
in combination with the non-discrimination principle**

Private life concept encompasses access to reproductive care (Evans v. UK, ECtHR 2007)

**States obliged to adopt positive measures securing
the right to procreate by means of IVF technology**

**OoC with
Medical
Indications**



**Ooc with Non-
Medical /Social
Indications**

NOTION OF “MEDICAL INDICATION” RELEVANT

FUNDAMENTAL RIGHTS TO BE RELATED TO OOCYTE CRYOPRESERVATION



Reproductive Rights



States obliged to adopt positive measures securing the right to procreate by means of IVF technology

In the case of a contested measure (e.g. ban on IVF and/or PGD , OoC?)

It should be verified :

- i) whether an interference is in accordance with the law and pursues a legitimate aim (e.g. protecting public morals or public health), and
- ii) whether the measures taken were “necessary in a democratic society”, reviewing if the reasons were relevant and sufficient for the purpose (not arbitrary or unreasonable)

FUNDAMENTAL RIGHTS TO BE RELATED TO OOCYTE CRYOPRESERVATION



Right to health



“Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices” ...

(art. 35 EU Charter of Fundamental Rights)

Member States (MS) have a **wide margin of appreciation** on how to organize and define the nature and scope of the healthcare scheme

when right to health is interpreted as a justiciable right,
Only “medical treatments” benefit
are guaranteed
under the conditions of national laws/practices

**ANY POSITIVE OBLIGATION FOR MS
TO PROVIDE OoC (especially N-MI)**

FUNDAMENTAL RIGHTS TO BE RELATED TO OOCYTE CRYOPRESERVATION



Right to health



“The provisions of this Charter are addressed to the institutions and bodies of the Union ... and to the Member States only when they are implementing Union law...”

(art. 51(1) EU Charter of Fundamental Rights)

Since single market rules also apply in the field of health and healthcare

**When ARTs are included in the national health benefit scheme,
Relevant EU provisions/standards have to be implemented in national measures**

(Tissues and cell directive, Medical Devices Directive/Regulation, Data protection/CT Regulation...)

**EU safety and quality norms, including donor rights shall be respected
(informed consent, anonymity, respecting privacy and confidentiality and non-
discrimination principles)**

FUNDAMENTAL RIGHTS TO BE RELATED TO OOCYTE CRYOPRESERVATION



Dignity



Human dignity is inviolable. It must be respected and protected

(art. 1 EU Charter of Fundamental Rights)

Recognising the importance of safeguarding human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine

(Preamble/art.1 Oviedo Convention)

“Foundation for both fundamental rights and democracy”

UN Declaration of Human Rights 1948

Cornerstone to address ethical/legal concerns related to scientific progress and biotechnologies”

Any comprehensive definition of this notion exist

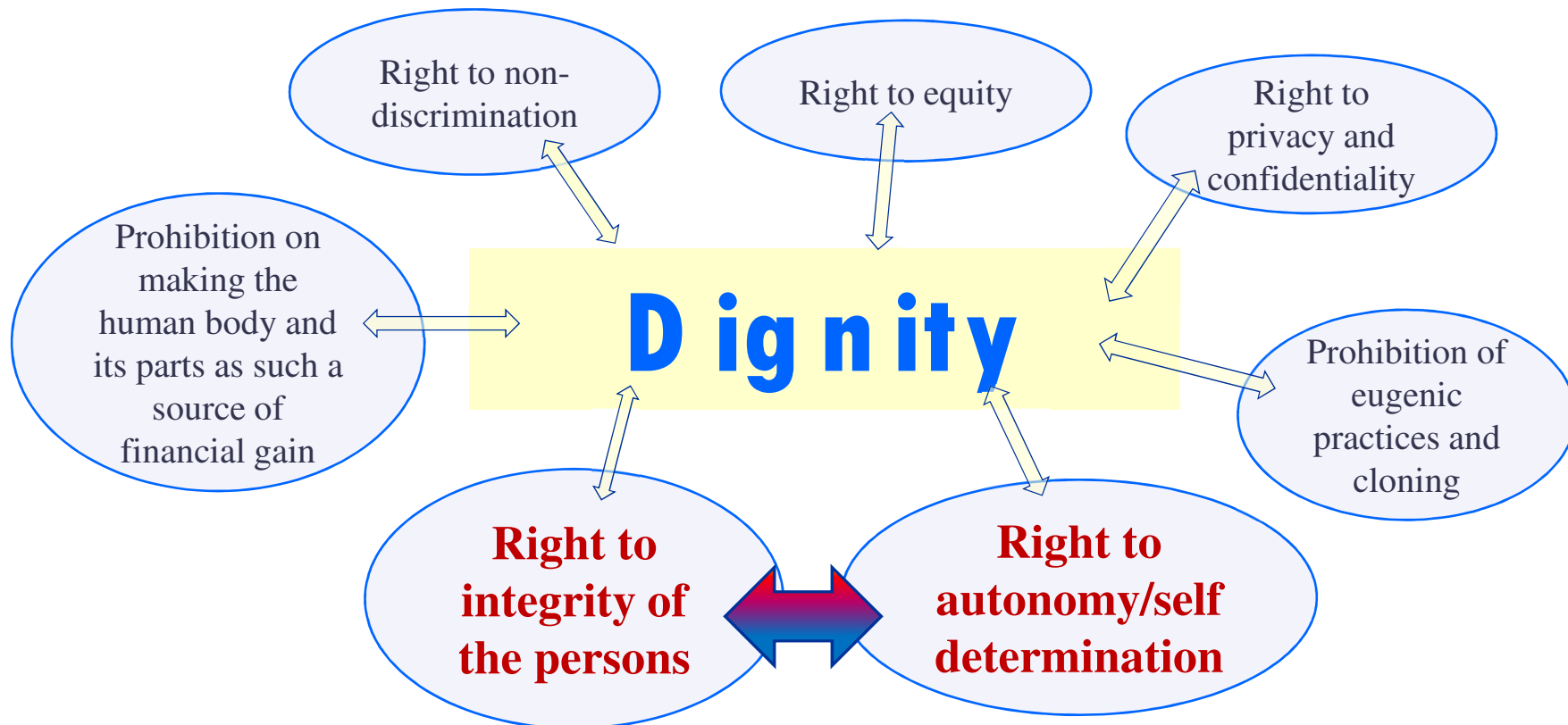
FUNDAMENTAL RIGHTS TO BE RELATED TO OOCYTE CRYOPRESERVATION



Dignity



**Within biotechnologies and scientific development,
to consider if a practice is in accordance with the principle of human dignity
more concrete notions have been developed**



FUNDAMENTAL RIGHTS TO BE RELATED TO OOCYTE CRYOPRESERVATION



Right to integrity of the persons



In the fields of medicine and biology,
right to respect for person physical and
mental integrity implies

- prohibition on making the human body and its parts as such a source of financial gain
- the free and informed consent of the person concerned, according to the procedures laid down by law

(Art. 3 EU Charter of Fundamental rights – Oviedo Convention)



**Attention should be
payed to avoid that
industry economic
interests prevail**

FUNDAMENTAL RIGHTS TO BE RELATED TO OOCYTE CRYOPRESERVATION



Right to integrity of the persons



CONSENT / PRELABLE APPROPRIATE INFORMATION

(Article 5 Oviedo Convention)

An intervention in the health field may only be carried out after the person has given free and informed consent to it, after having received an **appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.**

VALID CONSENT



Adequate, liable and comprehensive information



BENEFITS

- The real chance to have a genetical related child)
- The efficiency of the OoC at different age

RISKS/HARMS RELATED TO THE

- Ovarian stimulation /oocyte retrieval cryoprotectants
- IVF babies prematurity/ diseases
- Complication/costs of pregnancy a later stage
- Social concerns of public funding

FUNDAMENTAL RIGHTS TO BE RELATED TO OOCYTE CRYOPRESERVATION



Right to integrity of the persons



Adequate, liable and comprehensive information

is respected in OoC practices?



OoC with Medical Indications



OoC with Non-Medical /Social Indications

Single and wanting a baby?
Act while your biological clock is still ticking
If you feel you are ready for motherhood and haven't found 'Mr Right' yet, then we have a number of solutions for you to consider.

- Fertility assessment
- Donor sperm programs*
- Egg freezing

Enquires & Appointments
(02)9389 1177
www.fertilityeast.com.au

* DONOR SPERM LOCAL & IMPORTED IMMEDIATELY AVAILABLE

FUNDAMENTAL RIGHTS TO BE RELATED TO OOCYTE CRYOPRESERVATION



Right to autonomy/self determination



Consent/decision have to be free from any form of coercion, undue influence or discrimination

**Informing/decisions
are
context dependent**



**They are formed within social
relationship and
shaped by complex and
intersecting social determinants
(race, class, gender, ethnicity,
cultural background, social
inequalities)**

FUNDAMENTAL RIGHTS TO BE RELATED TO OOCYTE CRYOPRESERVATION



Right to autonomy/self determination



Are we sure that women decisions are really free from any form of coercion, undue influence or discrimination?

OoC with
Medical
Indications



Ooc with Non-
Medical /Social
Indications

- Weak maternity and children policies
- Social pressures and Risk/fair of stigma of infertility
- Constraints at work, family life or with childcare
- Power imbalance/subordination between employer and employee
- Corporate benefits v. medical care

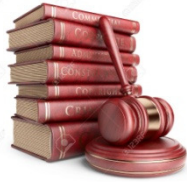
Let's stop rushing to find husbands
and start rushing to freeze our eggs.



someecards

Conclusions

**As scientific progress develops and
the law confronts itself
with new biotechnologies**



**Human rights obligations
can provide a useful tool
to avoid misuse,
unjustified restrictions on
access to ARTs/OoC or
address critical issues**



- **Safety and efficacy of OoC**
- **The notion of “medical condition”**
- **The quality and comprehensiveness of information to be provided**
- **The prevention of infertility**

Conclusions

Since there is no competence of the EU to call for harmonization in this field

Practices and legal frameworks are jeopardized across Europe

The use of “soft law” mechanisms

- monitoring practices
- measuring reproductive health indicators
- exchanging best practices
- increasing education and awareness
- Organising debates/consensus conference



may promote the use of a common set of principles or standards

with a more comprehensive approach including

- issues related to techniques (OoC)
- fertility (childbearing) as a whole

Conclusions

Main objectives/key



role

Principle of
beneficence non-
maleficence

A high level of
human
health protection
shall be ensured

The equality and
non-discrimination
of the European
citizens

Principle of
respect of person
(autonomy/self-
determination)

The primacy of the
interests and welfare
of the human being
over the sole interest
of society or science

Principle
of justice





EUROPEAN ASSOCIATION of HEALTH LAW

7th Conference

Innovation and healthcare: new challenges for Europe



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Toulouse, 2019

*Thank
you*



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