Les recherches sur l’embryon humain in vitro: aspects scientifiques et éthiques
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EVOLUTION of FRENCH LAW REGARDING RESEARCH ON HUMAN EMBRYOS

• 1994 : research is strictly forbidden

• 2004 -2011: prohibition is maintained but derogations are possible under strict control

• 2013 : research is now authorized whereas still being strictly controlled
WHICH EMBRYOS CAN BE USED FOR RESEARCH IN FRANCE?

• Cryopreserved embryos devoided of parental project (need confirmed consent from parents)

• Embryos used for PGD analysis (and showing genetic defect)

• Embryos discarded (no transferred nor frozen because of poor quality)
WHAT ARE THE CONDITIONS FOR RESEARCH ON HUMAN EMBRYOS?

• Authorization of the protocole by the « Agence de la biomédecine »

• Creation of embryos for research is forbidden

• An embryo cannot be transferred if it has been subjected to experimentation
THE SITUATION of EMBRYO RESEARCH IN THE WORLD:
4 CATEGORIES OF LEGISLATION

- Permissive: Belgian, UK, Sweden… (for Europe), Russian, Japan, South Corea,…
- Permissive with restrictions: Denmark, Spain, Greece, Netherland, Portugal, Swiss… (for Europe), Australia, Canada, India,…
- Restrictive: Germany, Italy… (for Europe), USA
- Strict prohibition: Austria, Poland…
- France: evolution of law regimen (prohibition ➔ permissive with restrictions)
A FEW COMMENTS…

• OVIEDO International convention on human beings rights, prohibits the creation of embryos dedicated to research; it has been signed by many European countries.

• Some countries make a distinction between embryos within 14 days of development (sometimes called « pre-embryos » as in UK), where research is widely permitted, and beyond (where it is forbidden).
### ASSISTED REPRODUCTIVE TECHNOLOGY
### FRENCH IVF/ICSI RESULTS (2013)

<table>
<thead>
<tr>
<th>Cycles*</th>
<th>Deliveries (%)</th>
<th>Newborns (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>88 182</td>
<td>15 963 (18.1%)</td>
<td>17 919 (20.3%)</td>
</tr>
</tbody>
</table>

*IVF, ICSI and FET; donor or non-donor cycles

<table>
<thead>
<tr>
<th>Oocytes*</th>
<th>Embryos (%)</th>
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<tbody>
<tr>
<td>540 090</td>
<td>286 384 (53.0%)</td>
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</table>

<table>
<thead>
<tr>
<th>Transferred</th>
<th>Cryopreserved</th>
<th>Discarded</th>
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</thead>
<tbody>
<tr>
<td>85 467</td>
<td>57 492</td>
<td>143 425</td>
</tr>
<tr>
<td>(29.8%)</td>
<td>(20.1%)</td>
<td>(50.1%)</td>
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*IVF, ICSI; autologous gametes

14 262 newborns
17.5% implantation rate
FUTURE of CRYOPRESERVED EMBRYOS

- French legislation (Guide des Bonnes Pratiques en AMP, 2010)
- Request once a year
- Two possibilities:
  - Maintain
  - Or no maintain of the parental project (to be confirmed 3 months later)
    - STOP cryopreservation (➔ destruction)
    - Donation to an infertile couple
    - Donation for research
FUTURE of CRYOPRESERVED EMBRYOS

• Results (31.12.2013, Biomedecine Agency)

• Embryos used for research since 2007: 1428 (S. Arrabal, Biomedecine Agency)
  • 2007 - 2010: ~ 150 à 200 per year (peak in 2009 : 487)
  • From 2011 : ~ 50 per year
AUTHORIZATIONS DELIVERED by BIOMÉDECINE AGENCY since 2007 (31.12.2013)

235 decisions
210 authorizations (36 teams)

<table>
<thead>
<tr>
<th>Authorization Type</th>
<th>Count</th>
</tr>
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<tbody>
<tr>
<td>Authorizations for research</td>
<td>73</td>
</tr>
<tr>
<td>Authorizations for importation</td>
<td>56</td>
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<tr>
<td>Authorizations for conservation</td>
<td>34</td>
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<tr>
<td>Substantial modifications</td>
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<tr>
<td>Research renewals</td>
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<tr>
<td>Ended researchs</td>
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<tr>
<td>Rejections</td>
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<td>Authorization revocations</td>
<td>17</td>
</tr>
<tr>
<td>Prorogations</td>
<td>2</td>
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WHICH TYPES of RESEARCH PROJECTS?

• For the embryo itself
  – Improve ART
  – Identify markers of embryos with the best chances of evolution

• For our knowledge of embryo development (cellular differentiation, gene expression, …)

• “Embryo genome editing”: to correct a defect (Liang et al., Protein Cell, 2015)

WHICH EMBRYOS FOR RESEARCH?  
ETHICAL CONCERNS

• “Spare” cryopreserved embryos and donated for research
  • Could a woman be ‘intentionally’ over-stimulated so as to ensure a good number of ‘spare’ embryos?
  • Would it be fair to subject embryos for research from couples who have been unable to cryopreserve their embryos for financial constraints?

• “Poor quality” discarded embryos?
  • When to make the choice? day 2? day 3? blastocyst stage?
  11.8 – 19.7% of poor quality embryos were frozen at day 5/6 with a delivery rate of ~ 15-17% (Poulain et al., RBM, 2014; Kaartinen et al., RBM, 2015)
  • What to do with these discarded embryos?

• Embryos created for research?
  Forbidden in France and many EU countries
WHY SO FEW EMBRYOS ARE ACTUALLY USED FOR RESEARCH?

- Is it specific to France? Ethical concerns?
- How to promote a better link between IVF centers and scientists?
- Is it realistic to set up “platforms” for human embryo research?
- Difficulties of funding (prohibition of the use of EU funds for research which results in destruction of human embryos (except hESC).
CONCLUSION

- There is a high heterogeneity between European countries, regarding research on human embryos.
- French legislation has progressively moved from a prohibited to an authorized – but still strictly controlled - regimen.
- However, the number of experiments using embryos given for research, remains surprisingly low.