Ethical and societal acceptability of a clinical trial (the EVERREST trial) of a highly experimental treatment in complex pregnancies with high risk of still birth

Maria Sheppard, Rebecca Spencer, Anna L David, Richard Ashcroft on behalf of the EVERREST consortium

Supported by the EC under the FP7 Programme

EVERREST

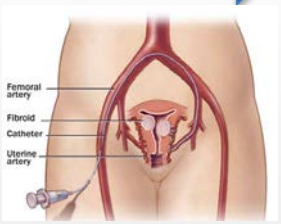
SEVENTH FRAMEWORK PROGRAMME

original idea

ethical & regulatory approval

Phase I/IIa safety/efficacy study

2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019



bioethics

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A review of the ethical, legal and regulatory literature on prenatal gene therapy

Interview study with stakeholder groups

Bioethics

Interview study with patients

Independent advisory ethical review panel

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A review of the ethical, legal and regulatory literature on prenatal gene therapy

2 critical questions

Is it ethical to conduct a clinical trial in a pregnant woman with a potentially risky treatment when she herself has no benefit from the treatment?

Is it ethical to conduct a clinical trial in this condition of the fetus not only because as an early phase trial benefit to the fetus cannot be guaranteed but, if the intervention proved to be effective, the child may be born with a serious disability when without treatment they would have died?

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Literature Review of ethical, legal and regulatory literature on prenatal gene therapy

- Fetus-regarding clinical trials with pregnant women
  - Who is the patient?
- Early phase trials posing no more than minimal additional risks
  - Medicine for Human Use (clinical Trials) Regulation 2004 and Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use
- Prenatal gene therapy
- Therapeutic misconception
  - Hybrid phase I/II trials
- No benefit to woman but psychologically burdensome
    - Vulnerability of pregnant women in fetus-regarding clinical trials
- 'Informed consent'
  - *Montgomery v Lanarkshire Health Board [2011]* UKSC 11, GMC guidelines

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Literature Review of ethical, legal and regulatory literature on prenatal gene therapy

- Clinical trials are experiments and not treatments
- If clinical trial effective to extend pregnancy leading potentially to a child with serious disability
  - Link of length of gestation with severity of disability (EPICure 2 study)
- Non-identity problem (Parfit)?
- Can existence (!) ever be so demonstrably awful that non-existence would be preferable?
  - Right to life (article 2 ECHR)
  - *Re B (a minor) [1990]* 3 All ER 921
  - Legal standing of fetus
- Disability studies

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Empirical ethics

- Debate about whether descriptive research in social sciences contributes to normative aspects of bioethics
  - Ethical theory is based in experience (Parker)
  - Reasoning from inside out rather than outside in (R. Dworkin)
  - Practice informing theory just as theory informs practice/symbiotic empirical ethics (Frith)
    - 'doing bioethics' contributing to a greater understanding of ethics in practice
- EU Commission

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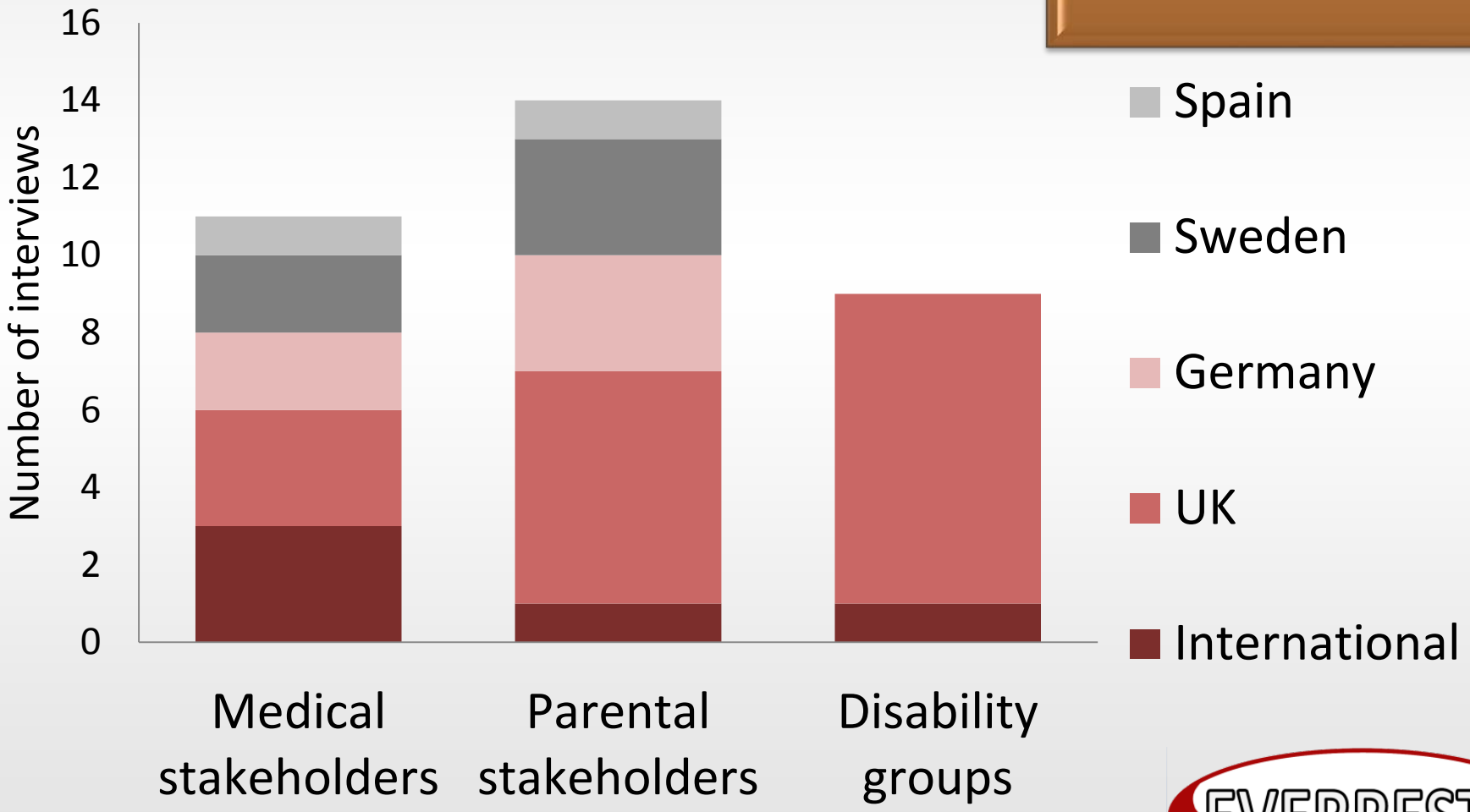
Interview study with stakeholder groups

- 34 semi-structured stakeholder interviews
- 30-40 minutes conducted by native language speakers (Spain and Germany) or in English (UK and Sweden)



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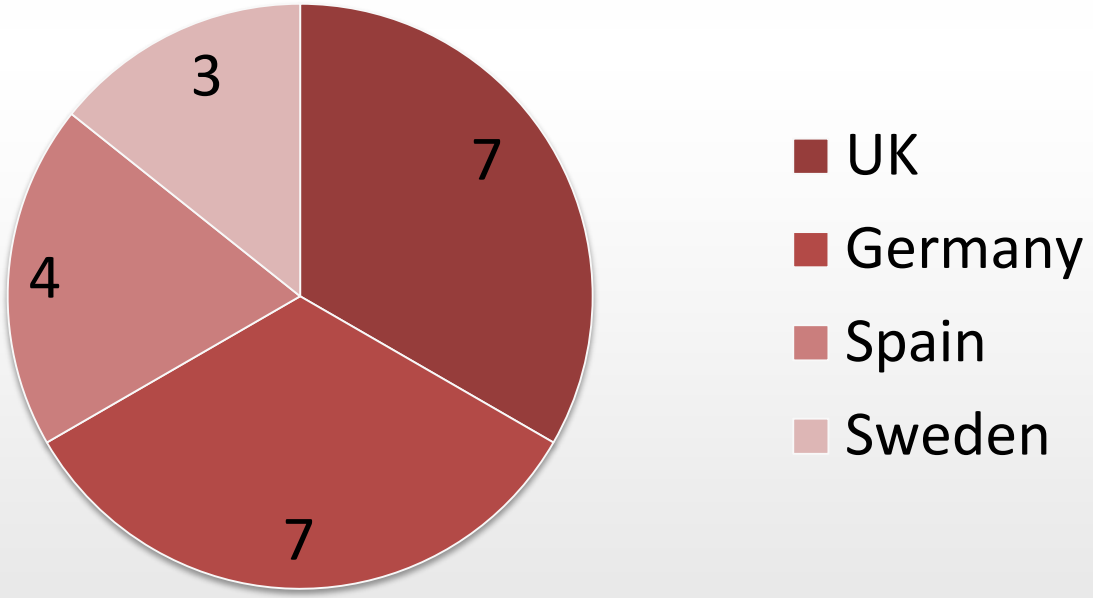
- Ethical approval in 4 EU countries
- Women with a pregnancy affected by severe early onset fetal growth restriction that ended less than 3 months ago or more than 5 years ago
- Semi-structured interview 1-1.5 hours conducted in native language and interpreted by social scientist/qualitative interviewer

Number of women interviewed



Interview study with patients

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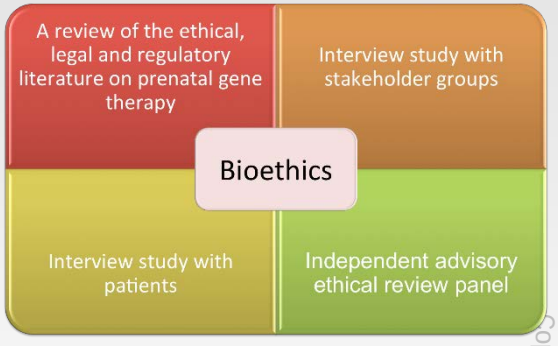
Issues	Stakeholders	Patients
Who is the patient?	Broad range of attitudes: “the fetus has no legal status” “the fetus has a moral status”	For most patients the fetus was a person. My “baby”.
Maternal treatment for fetal benefit	Treatment should be permissible, after careful consideration of the balance of risks and benefits.	Mother and baby’s life are intertwined. Decision to take part depends on the risk of the treatment.
Making a decision in an FGR pregnancy about trial participation	Concerned about psychological stress put on the mother. Ethics Advisory Committee disagreed: having a choice “may reduce this stress”.	Most women felt able to make decision at time of diagnosis Discussed with family members and healthcare team. Need time to make rational decision.
Survival of fetus with disability	Not a new concept and applicable to most prenatal interventions.	Acceptable as long as disability not due to the treatment itself.
Challenges of informed consent	Need for independent advice for participants.	Almost all would involve their partner.
Acceptability of gene therapy	The novelty of gene therapy was not a concern. The exception were stakeholders from Germany, where there is a negative societal view of gene therapy.	Most had a spontaneous positive reaction to a trial of a novel treatment. No concerns about gene therapy.

Conclusions



- Maternal gene therapy in pregnancy not a concern
- Safety and independent advice are key
- Decision-making in pregnancy affected by severe FGR difficult
- Women could arrive at a decision if given time
- The potential for disability of the child due to prematurity was not a contraindication to a trial
- Women welcomed an option of treatment for severe early onset FGR

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Acknowledgments

Professor Richard Ashcroft

Dr Anna David

Dr Rebecca Spencer

EVERREST consortium members

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EVERREST consortium

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NHS Foundation Trust

LUND UNIVERSITY

UCL

Queen Mary University of London

EURAM LIMITED

FinVector Vision - Therapies

Universitätsklinikum Hamburg-Eppendorf

IDIBAPS
Institut D'Investigacions Biomèdiques August Pi i Sunyer

UNIVERSITY OF EASTERN FINLAND

MAGNUS LIFE SCIENCE

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EVERREST

The influence of Catholicism in political and legislative decisions regarding reproductive technologies: similarities between Argentina and Poland

Laura F. Belli - University of Buenos Aires
Andrzej Girdwoyń - University of Warsaw

- On March 1987 the Vatican published a document called **“Instruction on Respect for Human Life in Its Origin and on the Dignity of Procreation”**.

- It was a **highly influential document** that shaped legislative decisions regarding human reproduction technologies in many catholic countries like Argentina and Poland.

- We will try to present an overview on how political and legislative decisions regarding reproductive rights and technologies are constrained by historical **relations of power between the Church and the State** both in Argentina and Poland.

ARGENTINA

- Argentina is a secular country (as stated in the Constitution) but supports the Roman Catholic Church.

- **Rare exceptions in Argentina**: Law on Sexual Health and Responsible Parenthood / National Sex Education Law / Same Sex Marriage / Gender Identity Law / Medically Assisted Reproduction Law.

- A comprehensive study (2011) showed that **3 out of** 4 lawmakers reported that **the views of the Catholic Church affects (at least partially) the decision of the Congress** with regard to the processing of bills on sexual and reproductive rights.

ARGENTINA

- **Abortion is considered a crime** (only legal when the life or the health of the woman is in danger and in the case of rape of a mentally ill woman).

- An estimated **500.000 clandestine and unsafe abortions** take place every year (many women hospitalized and around a 100 die each year)

- This is due to the **lack of political w**ill of the government and the **resistance and opposition of the religious sectors.**

ARGENTINA

- Faith-based social values into the political vision reflected in Argentina's Civil Code reform in 2015

- The **article 19** on the beginning of existence states: "The existence of the human being begins at conception" (inside or outside the womb)

- This causes a **huge impact on reproductive technologies** (mainly because some reproductive techniques involve the loss of human embryos) and also on the possibility of achieving the **legalization of abortion**

- In such cases, it is argued, **the right to life is affected**

POLAND

- The Polish Constitution from 1997 guarantees the principle of secular state

- Some influential representatives of the doctrine differentiate “impartial” from “neutral” declaring that it is **impossible to separate the Constitution and the values it is based on**.

- Issues such as a full legalization of abortion or providing homosexual couples the same rights as heterosexual couples **cannot be considered without a reference to Christian values**

POLAND

- Abortion is permitted in a number of exceptional cases:
1) when the woman's life or health is seriously threatened;

2) when the fetus is irreparably damaged; and

3) when the pregnancy appeared as a result of rape or incest.

- Those conditions are an object of a **constant criticism from the Catholic Church** and pro-life organizations

- In the past 22 years, numerous projects of bills **providing a total ban of abortion** were voted by the Parliament

POLAND

- Legal conditions and refund of *in vitro* fertilization were an object of an intensive debate. In 2015 a bill on infertility treatment was passed and **it has been widely criticized** by polish bioethical experts

- Polish law (unlike argentinean) **does not provide a full legal protection of human life from conception** until birth.

- The state guarantees each person a protection of life but a *nasciturus* is not considered as a “natural person”

POLAND

- In 2014 a group of catholic doctors and medicine students published *A Declaration of Faith of Polish Doctors and Medicine Students Concerning Human Sex and Reproduction*

- The document consists of 6 articles that **condemns acts like abortion, contraception, *in vitro* fertilization and euthanasia**, states that God created men and women (and human sex is determined by nature) and that **conscientious objection should prevail even when confronted to the law**.

POLAND

- Since March 2014, almost 4.000 doctors and medicine students (including 59 professors of medicine) have signed the Declaration.

- It has been approved as an “act of courage” by the polish Episcopate and by the political party “Law and Justice” that won the elections in October 2015

- In October 2015 polish Constitutional Tribunal **ruled that the law obliging physicians to refer a person to another doctor or clinic in case the required services are against their personal beliefs is unconstitutional**

CONCLUSIONS

- Despite legal separation between Church and State, the **Catholic Church has successfully spread its influence over sexual and reproductive rights** (at different levels of policy and practice)

- **Religious catholic symbols** (like crucifixes or the Holy Virgin) are often **displayed in public facilities** like courthouses, hospitals or police precincts.

- **John Paul II** and **Pope Francis** are usually invoked as moral figures in political speeches and during the legislative sessions while discussing the laws.

CONCLUSIONS

- Both in Argentina and Poland the **Catholic Church still plays a significant role in reproductive health and rights decision-making** at all levels of society, from policy-making to the reproductive decisions made by individuals.

THANK YOU

ADOPTION V. DONOR REPRODUCTION AND SURROGATES

Some reflexions

presented by
Mariana Karadjova

DONOR REPRODUCTION AND SURROGACY FOR HAVING CHILDREN ON OUR OWN

- The purpose of Donor reproduction and reproduction through Surrogates is to help people to have children on their own.

- For achieving this purpose people mix more and more their genes (donor reproduction) or use a foreign uterus (surrogates).

- Is there a contradiction between the (big) efforts to satisfy the desire to have children on our own and the result to have children with foreign genes or through another woman (mother)?

ENLARGED CICLE OF ART BENEFICIARIES

- The Assisted reproductive technology was initially developed to help infertile heterosexual couples to procreate and have children on their own. The purpose was to remediate to a problem seen as medical one.

- Later we assisted to the enlargement of ART beneficiaries (especially through donor conception or surrogacy): singles, homosexual couples or post-menopausal women.

- For beneficiaries the purpose remains almost the same: to have children on their own.

NEW ART FOR SATISFYING AN OLD DESIRE

- If the use of artificial insemination had already opened the door to foreign genes, nowadays donor reproduction and surrogacy become an almost normal way to have children on our own.

- In fact new Assisted reproductive technologies maintain the old historical desire to have “our own children” and to see them as our own prolongation.

- We can underline here an interesting controversial phenomenon: in order to procreate and have their own children, people accept to include foreign gametes or foreign uterus into their reproductive process

MOVING GENETIC MATERIAL TO ANOTHER COUNTRY

- Beneficiaries of donor reproduction or surrogacy accept moving gametes from one to another country or moving babies themselves from one to another country.

- Are these practices innocent? Can we admit that when genetic material is moved from one country to another before birth there should not be consequences for future children?

- Can we find similarities and learn some lessons from another process of creating legal parentage on non-biological basis, the adoption?
- Can we talk about protection of children best interests in new Assisted reproduction technologies?

FUTURE V. EXISTING CHILDREN

- Several philosophers (e.g. J. Glover) argue for a difference between parents' and children' rights in adoption and in assisted reproduction. For them adoption concern already existing children whose best interest should be strongly protected while Assisted reproduction concern future children whose best interest is to exist, so parents' rights to have a child should be stronger protected than future children' rights.

- However can the best interest to exist be taken as an excuse to not completely protect the best interest of future children?

- Is the right of future parents to have children on their own a sufficient argument for including third parties into the reproductive process and imposing to their children situations where they could not completely know their origins?

RIGHT TO A CHILD AND ART

- No international convention at the moment grants the right to have a child. The European Convention of Human Rights (art. 12) guarantees only the right to found a family.

- The European Court of Human Rights gives to States a large margin of appreciation regarding reproductive rights regulation and recognizes only the right to respect for a couple's decision to become genetic parents.

- In this lack of international regulation the Hague Convention on Intercountry Adoption (1993) is seen as the fundamental source of reference for a future international regulation on children' and parents' rights in assisted reproduction, especially in donor conception and surrogacy.

ACTING *EX POST FACTO*

- Does it mean that best interest of child should be granted in assisted reproduction at the same level as in adoption? Is there a substantial difference between a new-born baby's rights and a future child's rights?

- We assist to a situation of accomplished facts, a situation where children are created and later, when they already exist, taken as argument to legalize a family project

- Thus parents trough donors or through surrogacy avoid legal checks introduced for legal parentage, especially in an international context.

IMPOSSIBILITY FOR LEGAL CHECKS BEFORE BIRTH

- In International adoption transfer of children to another country is permitted only on a principle of subsidiarity in which domestic options are the priority in order to preserving biological, cultural and ethnic origins of the child.

- In International transfer of gamete or surrogacy put State authorities in a situation where they can execute legal checks only *ex post facto* and, importantly, *once a child already exists*.

- This is an especially difficult issue in surrogacy cases. Recognition of legal parentage without prior legal checks, even in international level (several judgments of the ECHR) may encourage more parents to undertake surrogacy in circumstances where other safeguards are not in place for all parties

CHILD LAUNDERING

- Probably it is difficult to think that ART could be linked to child laundering or sale of children.

- The definition of The CRC Optional Protocol on Sale of Children concerns:

- “any act or transaction whereby a child is transferred by any person or group of persons to another for remuneration or any other consideration’ (Art 2.a). What about international surrogacy in the light of this rule?

TRANSFER OF GAMETES AND ETHNICITY

- What about international transfer of gametes in the light of organ trafficking regulations?
- Could we consider that transferring gametes we don't transfer ethnic and epigenetic specificities?

ADOPTION EXPERIENCES ON ATTACHMENT

- Could we ignore the experience of adoptive parents and specialists underlining that attachment with birth mother starts its development before birth and that separation of the baby and his birth mother creates a wound for life?

- The breach in the psychological continuity of link between baby and birth mother is not just seen in abandonment and adoption. Babies separated during the war or other disasters, may suffer from the interruption of the continuity of the original relationship with the mother.

OPEN QUESTIONS

- **Could we go on in this no man's land between variety of state regulations, desire of future parents and interests of business oriented intermediaries?**

- **Could we continue to underestimate all these points in the quest for children on our own?**

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ROPA

"CUANDO MADRE NO HAY MAS QUE DOS"

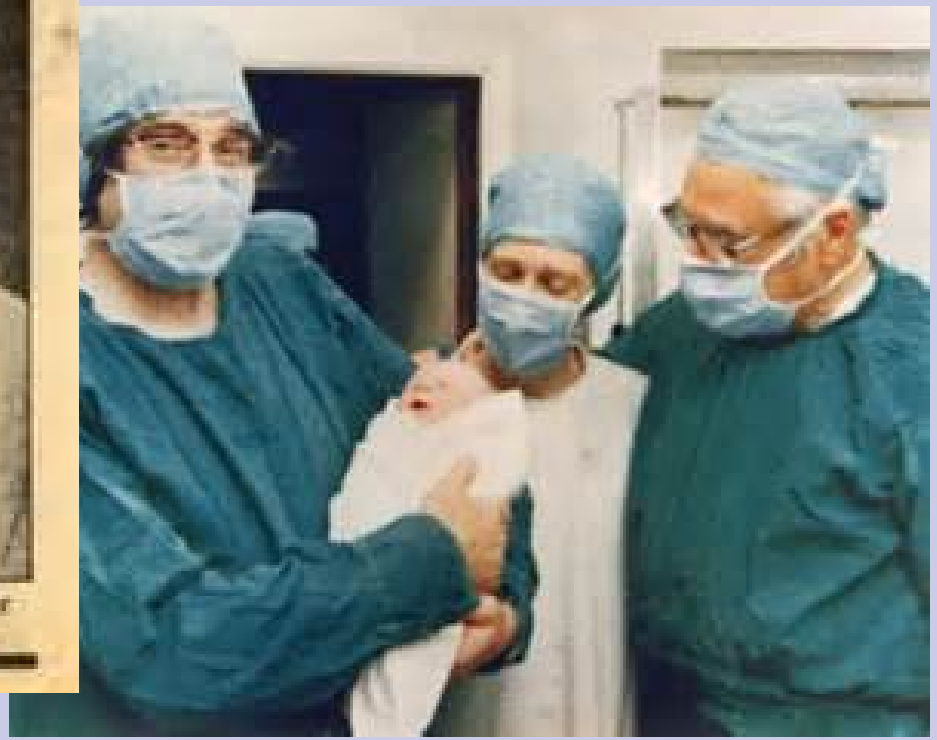
M. Reguera Cabezas. Embrióloga. Unidad de Reproducción Asistida

Evening News

Meet Louise, the world's first test-tube arrival

SUPERBABE

Wide-eyed Louise Brown pictured in hospital 18 hours after she was born. Today she's doing well. See Page Three



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6 mill/ niños

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EOC

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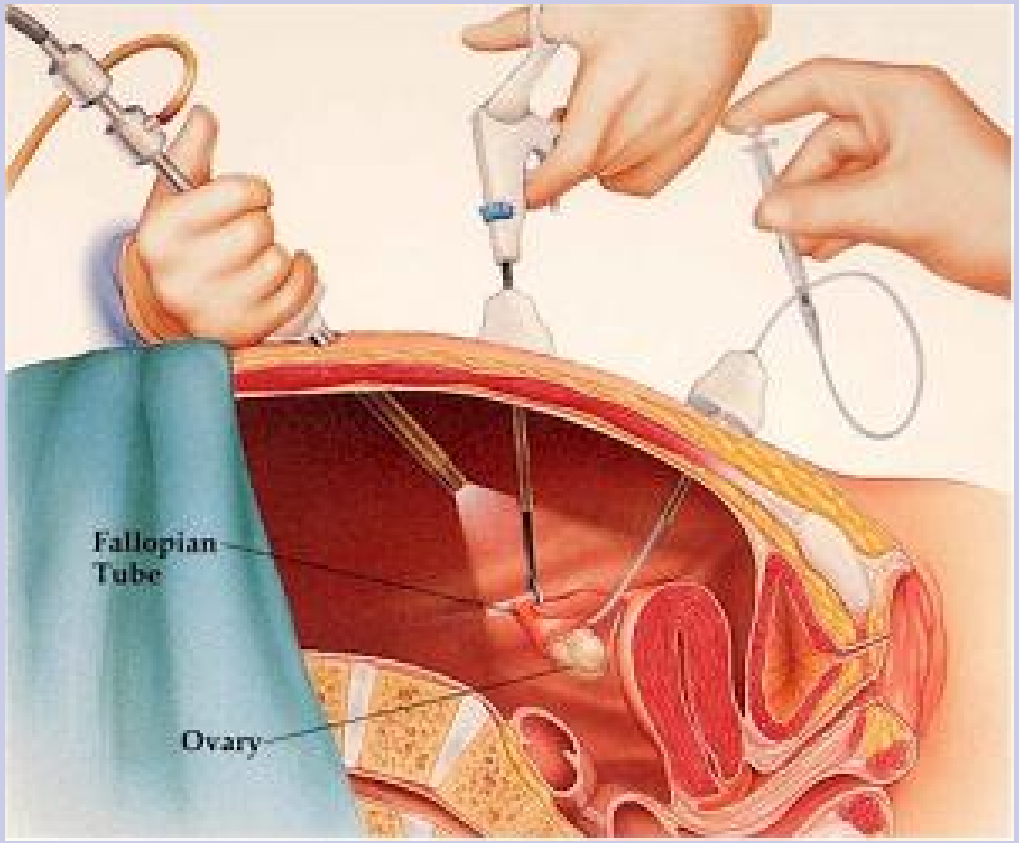

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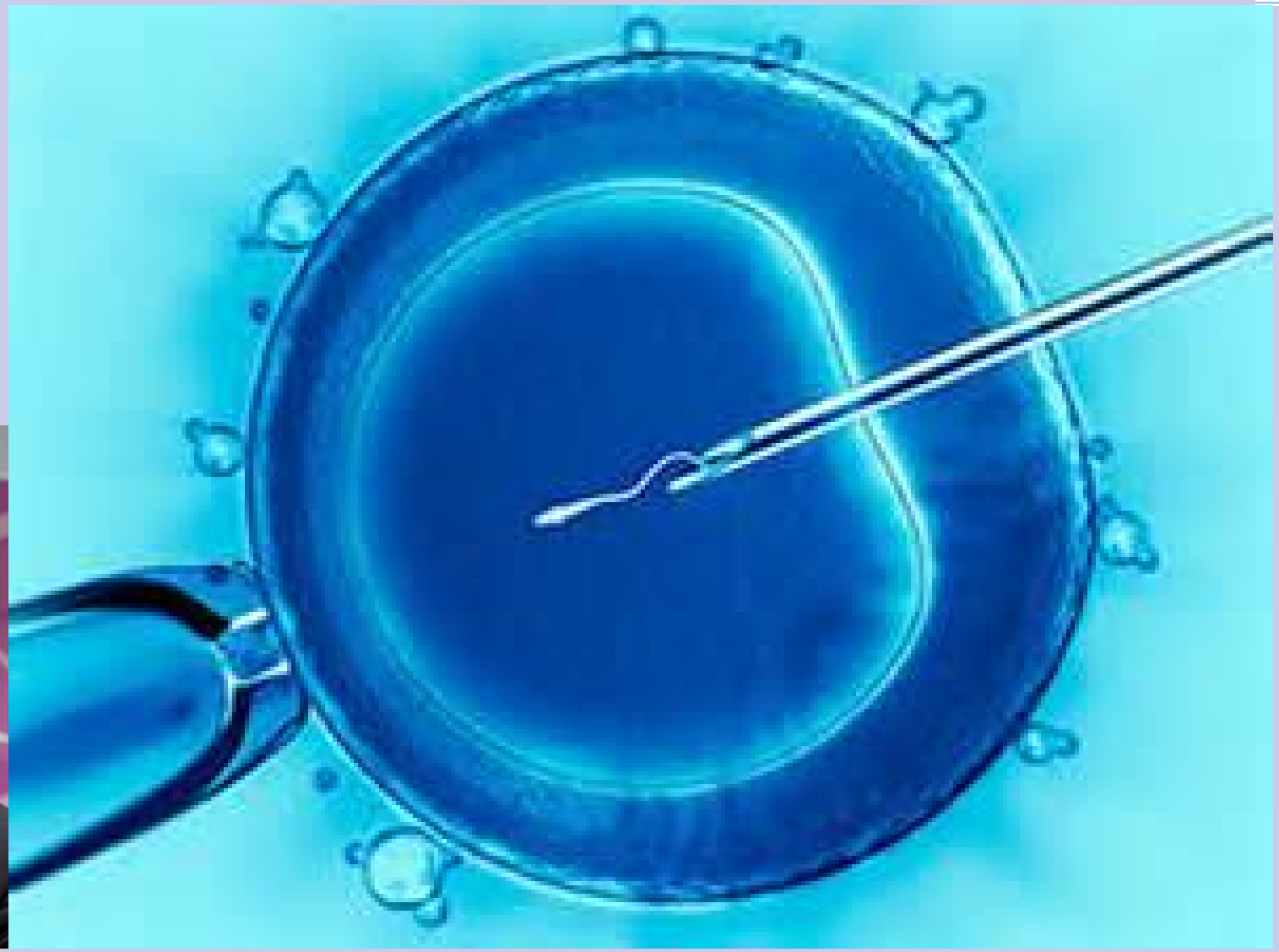

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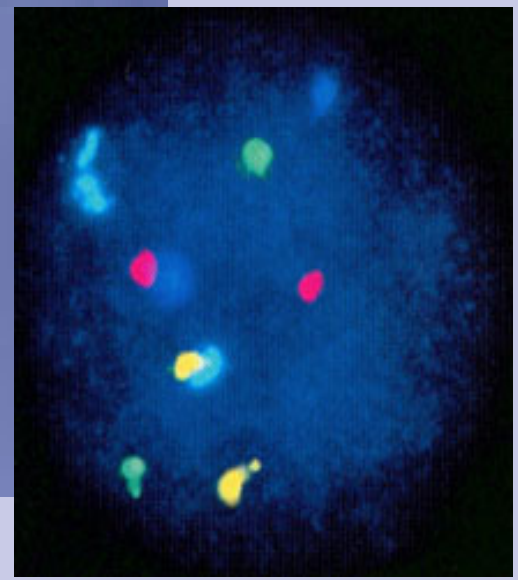

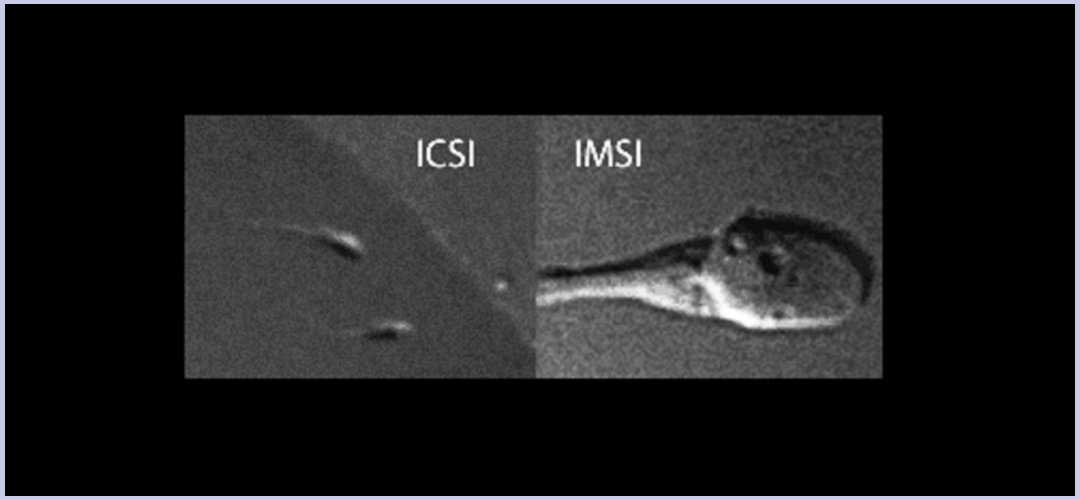

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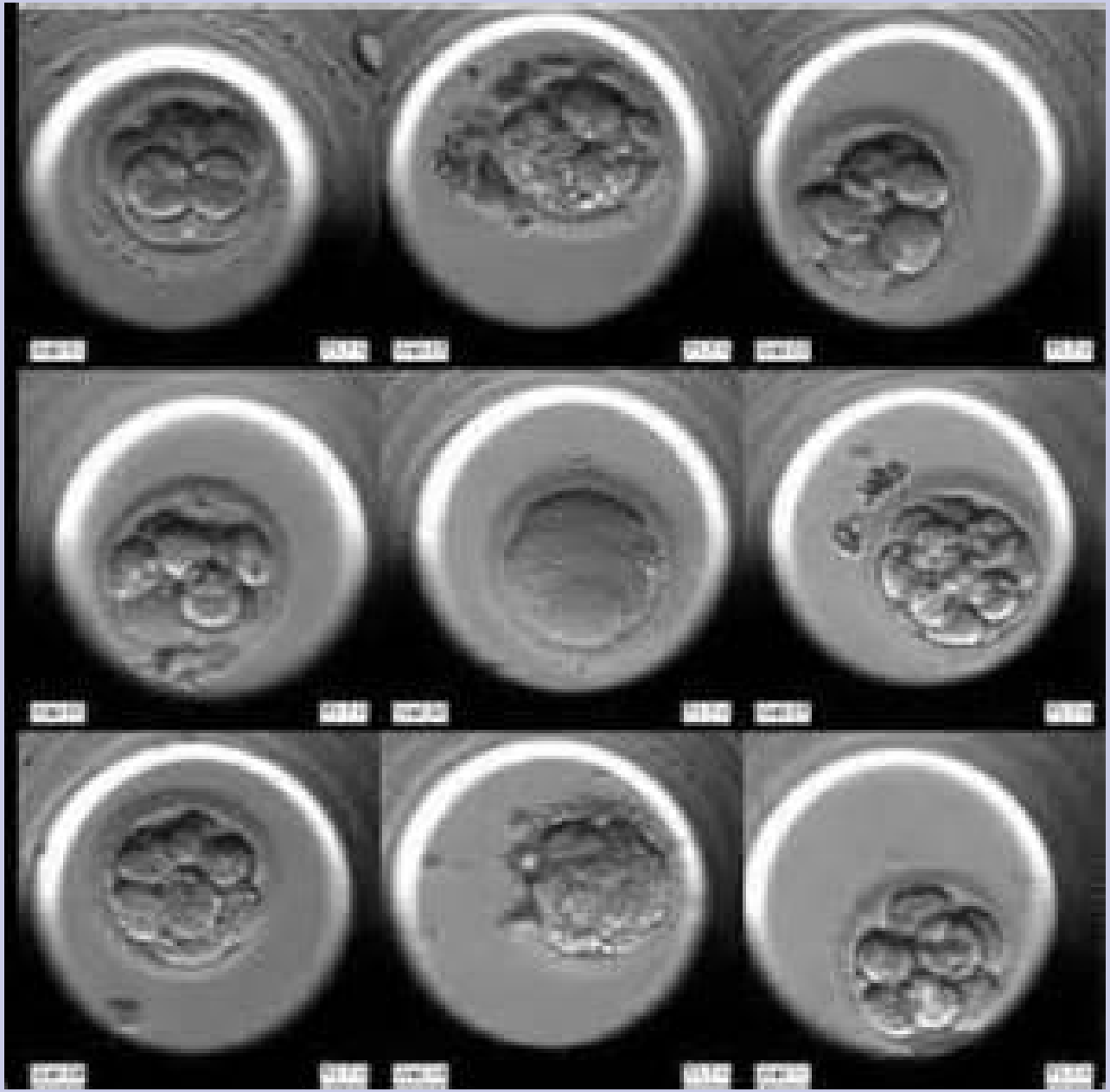

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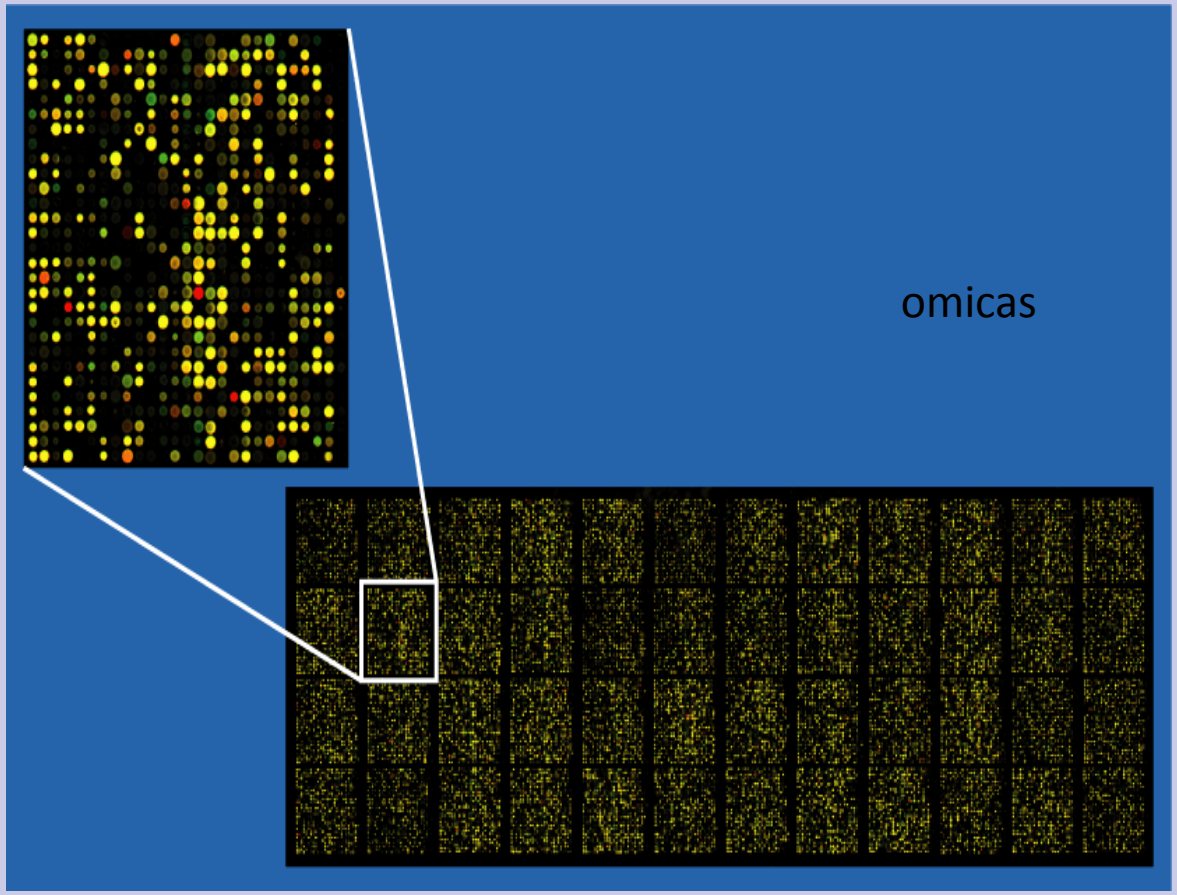

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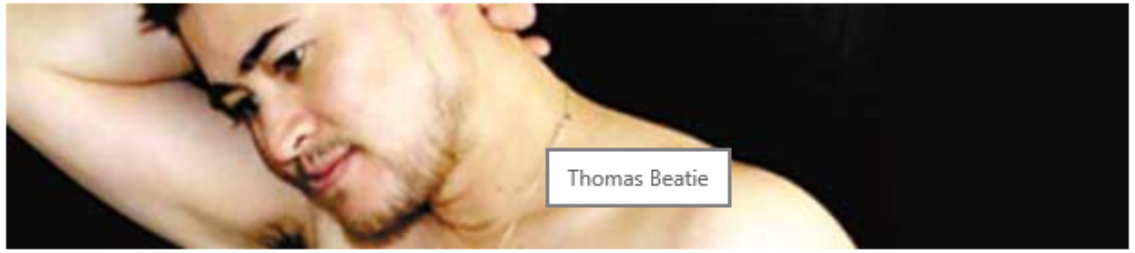
2008: Primer Transexual embarazado

Thomas Beatie, el 'primer hombre embarazado', espera su tercer hijo



Thomas Beatie posa en la portada de 'The Advocate'. (The Advocate)

- Beatie nació con órganos reproductivos femeninos.
- En 2008 tuvo una niña y en 2009, un niño.
- El transexual mostró su primer embarazado hace dos años en la portada 'The Advocate', lo que generó una gran polémica.

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….actualidad

FERTILIDAD | En el hospital turco de la Universidad de Akdeniz

La receptora del primer trasplante de útero está embarazada

- **Derya Sert está embarazada de su primer hijo**
- **Fue fecundada con sus óvulos y los espermatozoides de su marido**
- **Padecía agenesia congénita úterovaginal o síndrome de Rokitansky**

Ainhoa Iriberri |
Actualizado sábado 13/04/2013 **11:47 horas**

COMPARTIR

Recomendar 57

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Enviar a un amigo
Valorar
Imprimir
En tu móvil
Rectificar

Además

¿Sería posible en España?

Por fin los médicos han confirmado la noticia. Derya Sert, la receptora del primer trasplante de útero del mundo, llevado a cabo en agosto de 2011 en el hospital de la Universidad de Akdeniz (Turquía), está embarazada de su primer hijo, fruto de la fecundación in vitro (FIV) de sus propios óvulos con los espermatozoides de su marido.

El domingo 31 de marzo, un equipo de médicos de la Universidad de Akdeniz (Turquía) transfirió un embrión a la joven Derya. **Si su embarazo llega a término, será el primer caso de éxito de la técnica de reproducción asistida más novedosa** y también la más polémica: el trasplante de útero.

Derya Sert | Afp

En el comunicado de prensa que ha distribuido uno de sus médicos, Mustafa Unal, no se daban demasiados detalles del estado de la paciente de la que solo se dijo que, por el momento, se encontraba "bien".

La comunidad científica involucrada en este tipo de trasplantes sabía que este anuncio iba a producirse en cualquier momento. Así se lo adelantó a ELMUNDO.es Antonio Pellicer, jefe de

Nace el primer niño tras un trasplante de útero

- La madre, que nació sin el órgano, recibió el de una amiga de la familia el año pasado
- **César Díaz : "Hicimos 9 trasplantes. Es previsible que haya más partos pronto"**

JAIME PRATS | Valencia | 4 OCT 2014 - 09:39 CEST 7

Archivado en: Trasplantes Suecia Cirugía Escandinavia Tratamiento médico Investigación científica Europa Medicina Salud Ciencia


Imagen del equipo responsable del nacimiento realizando un trasplante de útero en abril. / JOHAN WINGBORG (AP)

10.548
1.297
4
92

Enviar
Imprimir
Guardar

Una mujer sueca de 36 años de edad se ha convertido en la primera del mundo en dar a luz tras un trasplante de útero, según una información que ha adelantado hoy la revista médica *The Lancet*.

La mujer, que no ha sido identificada, sufre un trastorno genético por el que nació sin útero. Fue una de las nueve mujeres suecas que recibieron un trasplante de este órgano tras una donación en 2013. El útero trasplantado, en el caso de esta nueva madre, fue el de una amiga de la familia de 61 años de edad, que había llegado a la menopausia siete años antes.

Uterus Transplants May Soon Help Some Infertile Women in the U.S. Become Pregnant

By DENISE GRADY NOV. 12, 2015 606 COMMENTS


The doctors leading the uterus transplant team at the Cleveland Clinic, from left: Andreas G. Tzakis, Uma Perni, Rebecca Flyckt and Tommaso Falcone. Michael F. McElroy for The New York Times

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CLEVELAND — Six doctors swarmed around the body of the deceased organ donor and quickly started to operate.

The kidneys came out first. Then the team began another delicate dissection, to remove an organ that is rarely, if ever, taken from a donor. Ninety minutes later they had it, resting in the palm of a surgeon's hand: the uterus.

www.eleconomista.es/europa/noticias/6131466/10/14 http://elpais.com/elpais/2014/10/04/ciencia/1412406310_537420.html
http://www.nytimes.com/2015/11/13/health/uterus-transplants-may-soon-help-some-infertile-women-in-the-us-become-pregnant.html?ref=health&_r=0


They Started a Joke
Amy Poehler, Seth Meyers, Ed Helms...
The Murder Capital of NY
Jonathan Chait on Fed-Bashing
Against Bipartisanship, by Frank Rich
NEW YORK
Is She Just Too Old For This?
By Lisa Miller

España, Ley 14/2006 del 26 mayo de 2006, TRA

9292 *LEY 14/2006, de 26 de mayo, sobre técnicas de reproducción humana asistida.*

JUAN CARLOS I

REY DE ESPAÑA

A todos los que la presente vieren y entendieren.

Sabed: Que las Cortes Generales han aprobado y Yo vengo en sancionar la siguiente ley.

EXPOSICIÓN DE MOTIVOS

I

La aparición de las técnicas de reproducción asistida en la década de los 70 supuso la apertura de nuevas posibilidades de solución del problema de la esterilidad para un amplio número de parejas aquejadas por esta patolo-

necesidad de acometer con prontitud la reforma de la legislación vigente, con el fin de corregir las deficiencias advertidas y de acomodarla a la realidad actual. Para ello, en sus últimas reuniones ha ido definiendo las líneas directrices que debería seguir la nueva regulación y que esta Ley incorpora.

II

Esta Ley se enmarca precisamente en esa línea e introduce importantes novedades. En primer lugar, define claramente, con efectos exclusivamente circunscritos a su ámbito propio de aplicación, el concepto de preembrión, entendiendo por tal al embrión in vitro constituido por el grupo de células resultantes de la división progresiva del ovocito desde que es fecundado hasta 14 días más tarde. Además, en línea con lo que dispone la Constitución Europea, prohíbe la clonación en seres humanos con fines reproductivos.

Las técnicas de reproducción asistida que pueden practicarse también son objeto de nueva regulación. Debido a que la Ley 35/1988, de 22 de noviembre, siguió el método de enumerar, mediante una lista cerrada, cuantas posibili-

	España	Francia	Inglaterra	Alemania	Italia
Donación semen	SI	SI	SI	SI	NO
Donación Óvulos	SI	SI	SI	NO	NO
Anonimato en la donación	SI	SI	NO	NO	NO
PGD	SI	SI	SI	NO	NO
Donación de embriones	SI	SI	SI	NO	NO
Criopreservacion embriones	SI	SI	SI	SI	SI
Selección de sexo	SI*	NO	SI*	NO	SI*
Tratamiento a mujeres solas	SI	NO	NO	NO	NO
Tratamiento a parejas Homosexuales	SI	NO	NO	NO	NO
Fecundación post mortem**	SI	NO	NO	NO	NO
Subrogación uterina	NO	NO	NO	NO	NO

*Sólo para evitar transmitir a la descendencia, una enfermedad ligada al sexo, presente en los progenitores.

** Previo documento notarial de últimas voluntades y en un plazo Max de 1 año desde fallecimiento

BOE nº 126 del 27 de mayo de 2006, pag19947

España, Ley 13/2005 del 1 de julio

Artículo único. Modificación del Código Civil en materia de derecho a contraer matrimonio.

El Código Civil se modifica en los siguientes términos: Uno. Se añade un segundo párrafo al artículo 44, con la siguiente redacción:

«El matrimonio tendrá los mismos requisitos y efectos cuando ambos contrayentes sean del mismo o de diferente sexo.»

Dos. El artículo 66 queda redactado en los siguientes términos:

«Artículo 66.

Los cónyuges son iguales en derechos y deberes.»

Tres. El artículo 67 queda redactado en los siguientes términos:

«Artículo 67.

Los cónyuges deben respetarse y ayudarse mutuamente y actuar en interés de la familia.»

Cuatro. El primer párrafo del artículo 154 queda redactado en los siguientes términos:

«Los hijos no emancipados están bajo la potestad de sus progenitores.»

Cinco. El primer párrafo del artículo 160 queda redactado en los siguientes términos:

«Los progenitores, aunque no ejerzan la patria potestad, tienen el derecho de relacionarse con sus hijos menores, excepto con los adoptados por otro o conforme a lo dispuesto en resolución judicial.»

Seis. El párrafo 2.º del artículo 164 queda redactado en los siguientes términos:

«2.º Los adquiridos por sucesión en que uno o ambos de los que ejerzan la patria potestad hubieran sido justamente desheredados o no hubieran podido heredar por causa de indignidad, que serán administrados por la persona designada por el causante y, en su defecto y sucesivamente, por el otro progenitor o por un administrador judicial especialmente nombrado.»

Siete. El apartado 4 del artículo 175 queda redactado en los siguientes términos:

«4. Nadie puede ser adoptado por más de una persona, salvo que la adopción se realice conjunta o sucesivamente por ambos cónyuges. El matrimonio celebrado con posterioridad a la adopción permite al cónyuge la adopción de los hijos de su consorte. En caso de muerte del adoptante, o cuando el adoptante sufra la exclusión prevista en el artículo 179, es posible una nueva adopción del adoptado.»

Ocho. El apartado 2 del artículo 178 queda redactado en los siguientes términos:

«2. Por excepción subsistirán los vínculos jurídicos con la familia del progenitor que, según el caso, corresponda: 1.º Cuando el adoptado sea hijo del cónyuge del adoptante, aunque el consorte hubiere fallecido. 2.º Cuando sólo uno de los progenitores haya sido legalmente determinado, siempre que tal efecto hubiere sido solicitado por el adoptante, el adoptado mayor de doce años y el progenitor cuyo vínculo haya de persistir.»

Nueve. El párrafo segundo del artículo 637 queda redactado en los siguientes términos:

«Se exceptúan de esta disposición las donaciones hechas conjuntamente a ambos cónyuges, entre los cuales tendrá lugar aquel derecho, si el donante no hubiese dispuesto lo contrario.»

Diez. El artículo 1.323 queda redactado en los siguientes términos:

BOE nº 157 del 2 de julio de 2005, pag23632

[Bloque 16: #dfquinta]

Disposición final quinta. Modificación de la Ley 14/2006, de 26 de mayo, sobre técnicas de reproducción humana asistida.

Se modifica la Ley 14/2006, de 26 de mayo, sobre técnicas de reproducción humana asistida, en los siguientes términos:

Uno. Se modifica el apartado 3 del artículo 7, que queda redactado del siguiente modo:

«3. Cuando la mujer estuviere casada, y no separada legalmente o de hecho, con otra mujer, esta última podrá manifesta conforme a lo dispuesto en la Ley del Registro Civil que consiente en que se determine a su favor la filiación respecto al hij nacido de su cónyuge.»

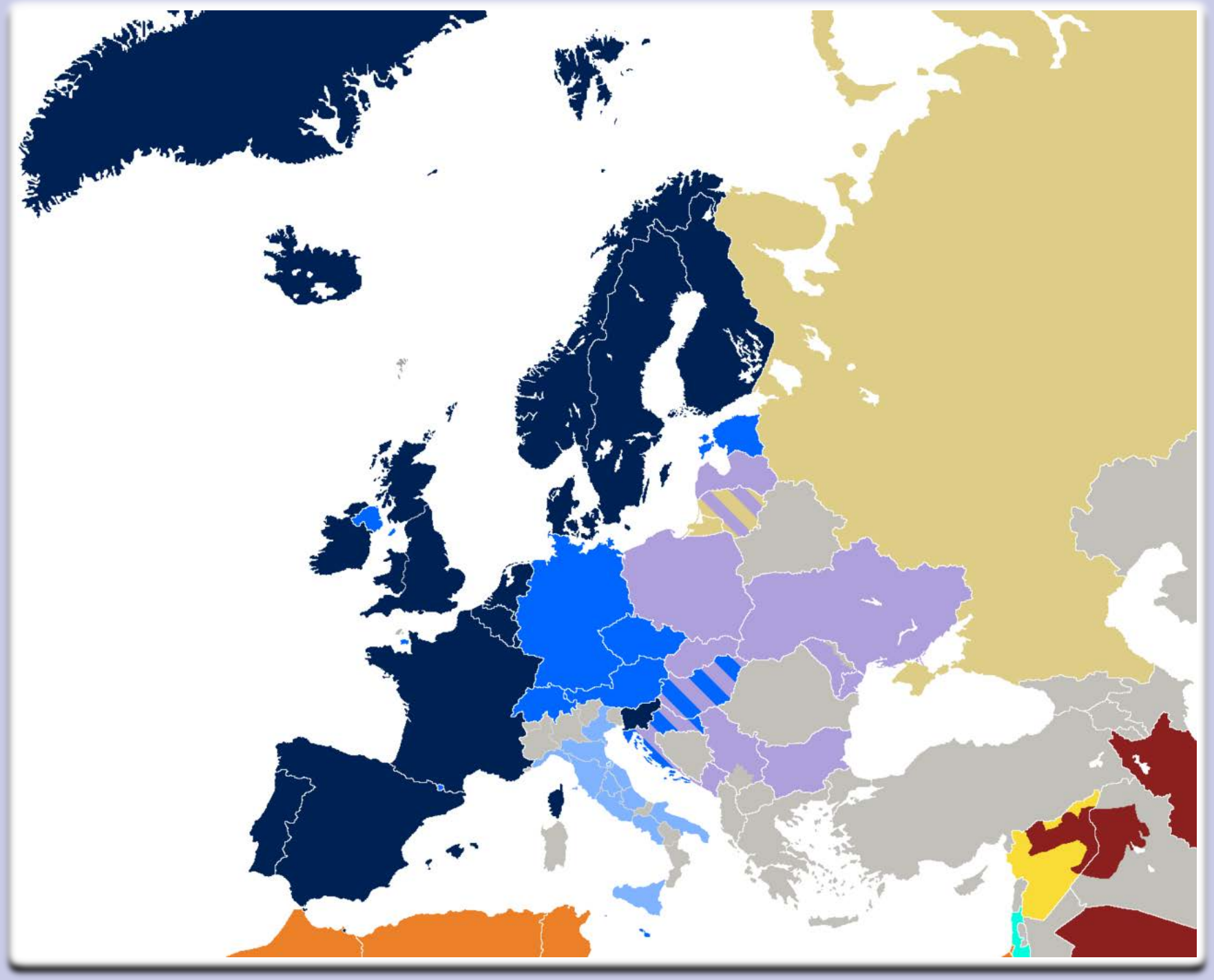
Dos. Se modifica el apartado 2 del artículo 8, que queda redactado del siguiente modo:

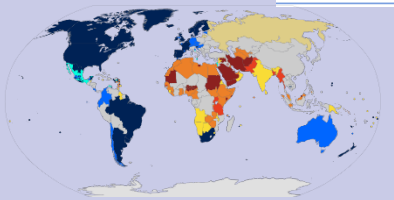
«2. Se considera escrito indubitado a los efectos previstos en el apartado 8 del artículo 44 de la Ley 20/2011, de 21 de julio, del Registro Civil el documento extendido ante el centro o servicio autorizado en el que se refleje el consentimiento a la fecundación con contribución de donante prestado por varón no casado con anterioridad a la utilización de las técnicas. Queda a salvo la reclamación judicial de paternidad.»

Tres. Se modifica el apartado 3 del artículo 9, que queda redactado del siguiente modo:

«3. El varón no unido por vínculo matrimonial podrá hacer uso de la posibilidad prevista en el apartado anterior; dicho consentimiento servirá como título para iniciar el expediente del apartado 8 del artículo 44 de la Ley 20/2011, de 21 de julio, del Registro Civil, sin perjuicio de la acción judicial de reclamación de paternidad.»

[Bloque 17: #dfsexta]





ESHRE 2010, Roma:

“CROSS-BORDER REPRODUCTIVE CARE”

El primer bebé nacido en Francia en 2013 es hijo de una pareja de lesbianas

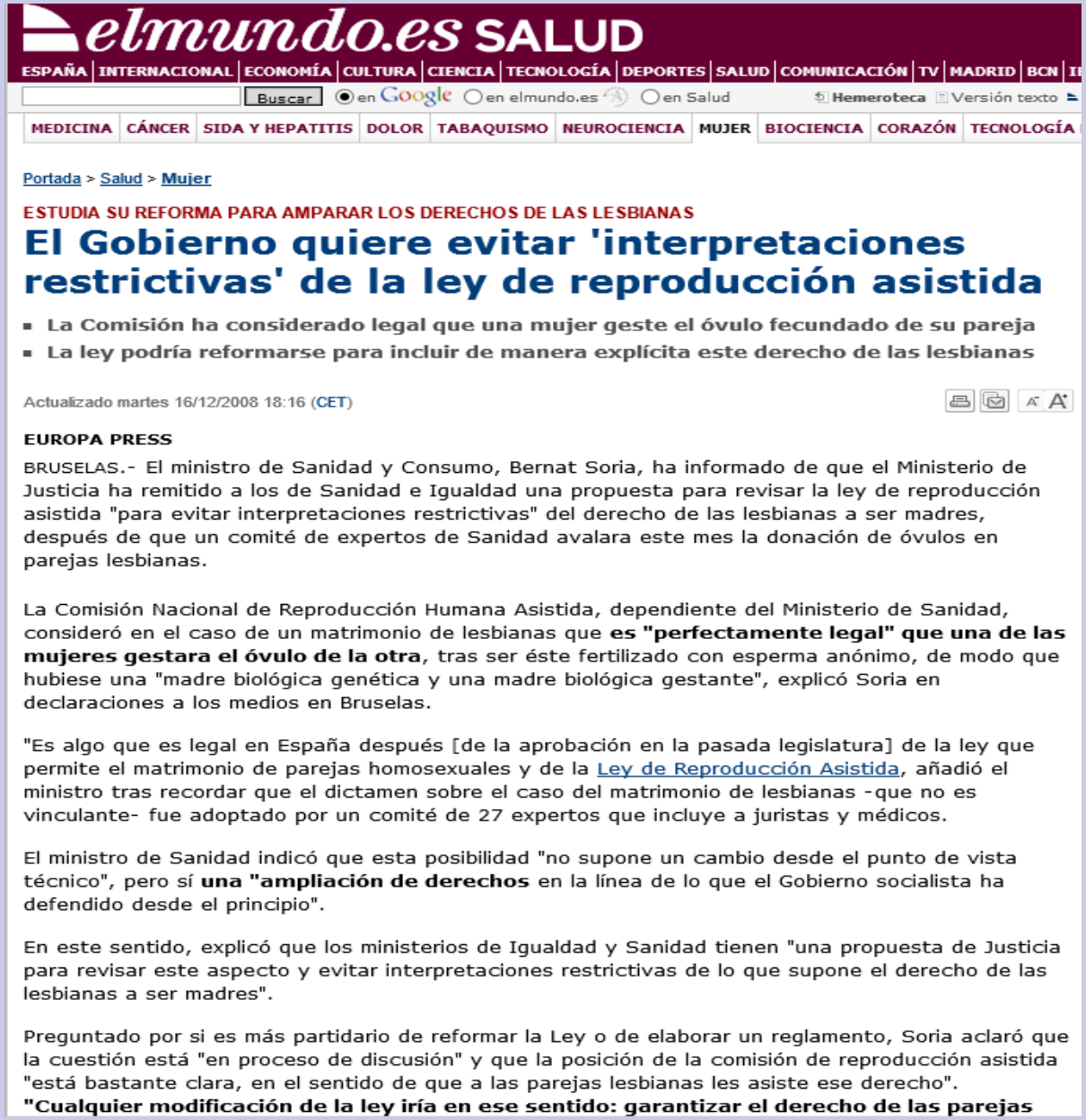
MIÉRCOLES, 02 DE ENERO DE 2013 POR REDACCIÓN GAYGUATEMALA

15 Me gusta Tweet G+1 1

Es un varón, se llama Sacha y tiene dos mamás. Es el primer bebé nacido en Francia en el año que se estrena. La noticia ha avivado la polémica acerca de la pertinencia de la enmienda sobre reproducción asistida al proyecto de ley de matrimonio igualitario.

Todos los medios de comunicación franceses se han hecho eco de la noticia del primer bebé nacido en 2013, algo habitual en estas fechas. El matiz distinto es que Sacha tiene dos mamás, Maude y Delphine. El nacimiento tuvo lugar en Moulin, apenas un minuto después del comienzo del año. Sacha tuvo que ser concebido en otro país, Bélgica, porque en Francia aún no está permitida la reproducción asistida para parejas de lesbianas. Maude fue quien se sometió a las técnicas de fertilización y quien gestó al bebé, y por ello es reconocida como madre por la vigente legislación francesa. Delphine, a día de hoy, no tiene ningún vínculo legal con el pequeño, a pesar de que la pareja está registrada como tal desde el año 2010 a través del PACS (Pacte Civil de Solidarité, un tipo de unión civil abierta a las parejas del mismo sexo que concede algunos derechos, pero no los de parentalidad).

www.**france**24.com/fr/20121116-homosexualite-**lesbiennes-couple**...
www.lefigaro.fr › Société
www.lexpress.fr/actualite/societe/**le-premier-bebe**-de-l-annee-a...



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Portada > Salud > Mujer

ESTUDIA SU REFORMA PARA AMPARAR LOS DERECHOS DE LAS LESBIANAS

El Gobierno quiere evitar 'interpretaciones restrictivas' de la ley de reproducción asistida

- La Comisión ha considerado legal que una mujer geste el óvulo fecundado de su pareja
- La ley podría reformarse para incluir de manera explícita este derecho de las lesbianas

Actualizado martes 16/12/2008 18:16 (CET)

EUROPA PRESS

BRUSELAS.- El ministro de Sanidad y Consumo, Bernat Soria, ha informado de que el Ministerio de Justicia ha remitido a los de Sanidad e Igualdad una propuesta para revisar la ley de reproducción asistida "para evitar interpretaciones restrictivas" del derecho de las lesbianas a ser madres, después de que un comité de expertos de Sanidad avalara este mes la donación de óvulos en parejas lesbianas.

La Comisión Nacional de Reproducción Humana Asistida, dependiente del Ministerio de Sanidad, consideró en el caso de un matrimonio de lesbianas que **es "perfectamente legal" que una de las mujeres gestara el óvulo de la otra**, tras ser éste fertilizado con esperma anónimo, de modo que hubiese una "madre biológica genética y una madre biológica gestante", explicó Soria en declaraciones a los medios en Bruselas.

"Es algo que es legal en España después [de la aprobación en la pasada legislatura] de la ley que permite el matrimonio de parejas homosexuales y de la Ley de Reproducción Asistida, añadió el ministro tras recordar que el dictamen sobre el caso del matrimonio de lesbianas -que no es vinculante- fue adoptado por un comité de 27 expertos que incluye a juristas y médicos.

El ministro de Sanidad indicó que esta posibilidad "no supone un cambio desde el punto de vista técnico", pero sí **una "ampliación de derechos** en la línea de lo que el Gobierno socialista ha defendido desde el principio".

En este sentido, explicó que los ministerios de Igualdad y Sanidad tienen "una propuesta de Justicia para revisar este aspecto y evitar interpretaciones restrictivas de lo que supone el derecho de las lesbianas a ser madres".

Preguntado por si es más partidario de reformar la Ley o de elaborar un reglamento, Soria aclaró que la cuestión está "en proceso de discusión" y que la posición de la comisión de reproducción asistida "está bastante clara, en el sentido de que a las parejas lesbianas les asiste ese derecho".
"Cualquier modificación de la ley iría en ese sentido: garantizar el derecho de las parejas

Recepción de Óvulos de Pareja

ó

Maternidad compartida

http://www.elmundo.es/elmundosalud/2008/12/16/mujer/1229447791.html

ROPA

REPRODUCCIÓN | Cesión de gametos

Embarazada de mi mujer

Celeste y Paloma empiezan en febrero con el método ROPA. | Antonio M. Xoubanova

- El método ROPA consiste en que una de las mujeres gesta un óvulo de la otra
- En nuestro país, esta opción reproductiva está en un 'limbo legal'

Cristina de Martos | Madrid

Comentarios 61

Actualizado lunes 21/02/2011 **08:21 horas**

La ciencia aún no es capaz de que dos óvulos formen un embrión, pero ofrece alternativas a las parejas de lesbianas que desean tener hijos. La cesión de gametos, en la que una de ellas gesta el óvulo de la otra, es una opción poco extendida aún, que brinda a estas mujeres la posibilidad de ser ambas madres biológicas del bebé. Sin embargo, muchas encuentran dificultades a la hora de realizar su sueño.

"La mujer podrá ser usuaria o receptora de las técnicas reguladas en esta Ley **con independencia de su estado civil y orientación sexual**",

actualidad

Viernes, 18.9.2009. 03:02 h siguiente >

La primera niña española con dos madres biológicas

donación de óvulos, homosexualidad y reproducción asistida ★★★★★ (3 votos)

Se llama Lluna y nació en la Clínica Quirón de Valencia el pasado mes de agosto fruto de la donación de óvulos entre sus madres progenitoras.

Por fin Mònica y Verònica, una pareja de lesbianas valencianas, han visto el sueño cumplido de ser madres tras haber nacido Lluna, la primera niña nacida en España con dos madres biológicas.

Esta feliz pareja de Valencia se ha convertido en la primera pareja homosexual que logra dar a luz a un bebé con estas características, ya que las dos son consideradas madres legal y biológicamente de la niña, gracias a que una de ellas aportó su óvulo, fecundado con semen de donante, mientras que la otra lo recibió en su útero.

La directora científica de la unidad de reproducción de la clínica Quirón de Valencia y ginecóloga de la pareja, Elena Pau, señaló que la pareja ya había intentado previamente conseguir un embarazo a través de varias inseminaciones o tratamientos de fecundación in vitro pero que no lograron buenos resultados. El éxito llegó cuando Mònica y Verònica se acogieron a un tratamiento de donación de óvulos.

La doctora Pau reveló que esta misma pareja tiene más embriones congelados, lo cual deja abierta la posibilidad que estas madres repitan el proceso y ambas puedan ser madres por segunda vez. Elena Pau también anunció que ya hay otras parejas que han solicitado la maternidad compartida y donar así ovocitos a la otra.

Ante esta situación, cabe destacar que éste es un paso más hacia la igualdad de derechos entre las parejas heterosexuales y las homosexuales.

URL corta http://invitrotv.com/1174

Me gusta 17 Twittear 0 G+1 0

Artículos relacionados

- Preservar los óvulos para retrasar la maternidad 20.10.2009
- Análisis genéticos exhaustivos para los donantes de semen y óvulos 25.11.2009
- Las donaciones de óvulos se duplican en Zaragoza 16.12.2009
- Los donantes de óvulos y semen podrían ser mejor recompensados 27.01.2010
- La donación de óvulos aumenta con la crisis 02.02.2010

TÉCNICA PIONERA

Los tres primeros bebés del mundo con dos madres biológicas nacerán en verano

El Instituto de Reproducción asistida **Cefer** ha confirmado el nacimiento este verano de **tres bebés** con dos madres biológicas, fruto de la gestación del **óvulo de una de ellas en el útero de la otra**.

Me gusta 5 Twittear 0 G+1 0 Compartir 0 Comentarios

Bebés con dos madres biológicas

antena3.com | Barcelona | Actualizado el 14/03/2009 a las 00:00 horas

El director de Laboratorio de Cefer, Fernando Marina, ha asegurado que en pocos meses nacerán los tres bebés, de tres parejas de lesbianas distintas.

Marina ha explicado que "hasta ahora los óvulos debían provenir de un donante anónimo en el caso de parejas no casadas, pero la **equiparación de derechos**, entre ellos el de matrimonio, de las parejas homosexuales con las heterosexuales ha abierto la posibilidad de que las lesbianas puedan intercambiar sus óvulos de forma artificial", y de esta forma ambas mujeres serían madres biológicas de los bebés.

El doctor ha añadido que "el número de peticiones de este tipo está creciendo" y ha indicado que "la mayoría de lesbianas que nos visitan desconocen esta posibilidad, pero cuando se informan no dudan en realizar el tratamiento".

Técnica poco conocida

El doctor Marina ha afirmado que "existe mucho desconocimiento entre el público y entre las propias clínicas de reproducción asistida de la existencia de esta posibilidad", y ha asegurado ignorar la existencia de casos similares en otros países en los que el matrimonio homosexual esté permitido.

NUEVAS FORMAS DE FAMILIA

Los primeros bebés de España con dos madres biológicas nacerán este año

Tres matrimonios de lesbianas esperan hijos que una parte de la pareja gesta con el óvulo de la otra

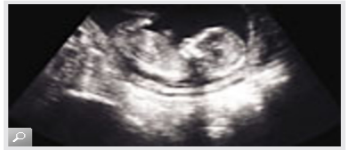
La ley de bodas homosexuales evita el requisito de que el intercambio de ovocitos sea anónimo

Viernes, 13 de marzo del 2009 AAA

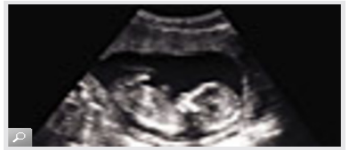
ÀNGELS GALLARDO
BARCELONA

Comentarios 0 Votos: +0 -0

Los espermatozoides que un hombre casado transfiere a su esposa en un encuentro sexual no son una donación, y tampoco lo será el gameto que surja cuando ese esperma fecunde un óvulo de la mujer. Esta consideración, que la ley española reserva en exclusiva para los matrimonios, ha permitido que una decena de parejas de mujeres lesbianas casadas utilicen los recursos técnicos de la fecundación artificial para intentar tener unos hijos que serán por completo, y biológicamente, de ambas a la vez. Tres de esos matrimonios --dos en Catalunya y uno en Valencia-- han iniciado la gestación.



Ecografía de un feto de 14 semanas de gestación. INSTITUTO CEFER



Ecografía de un feto de 14 semanas de gestación generado en el Instituto Cefer de Barcelona tras la donación a la mujer gestante de un óvulo de su pareja.

En esos tres embarazos el óvulo del que surgió el embrión en desarrollo le fue extraído a la mujer que no ejerce de gestante. A su pareja se le transfirió dicho embrión, generado en probeta inyectando en el óvulo un espermatozoide de donante anónimo. Los médicos que propiciaron las gestaciones, conseguidas en el Instituto Cefer de Barcelona, escogieron el esperma en los ficheros de su banco de semen. "Intentamos que el perfil del participante masculino en la gestación sea de una raza, peso, talla, color de cabello y ojos coherentes con los de las dos futuras ma-

más", explica el doctor Simón Marina, director de Cefer.

EN BUSCA DEL SEGUNDO

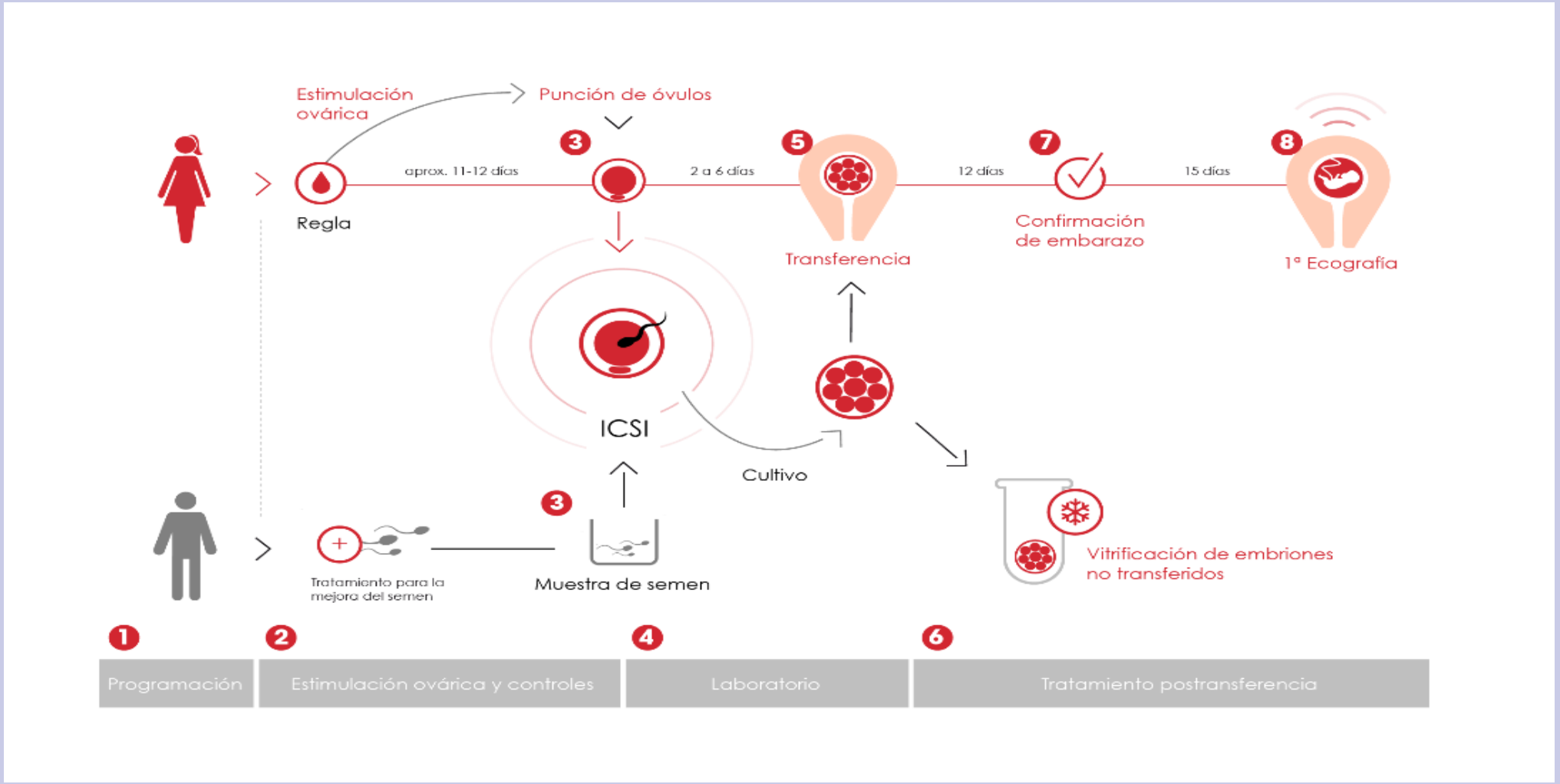
Alguna de estas parejas prevén tener un segundo hijo que se generará de la misma forma pero a la inversa: la embarazada será quien ahora ha sido donante del

http://www.antena3.com/noticias/ciencia/los-tres-primeros-bebes-mundo-dos-madres-biologicas-naceran-verano_2009031300082.html

http://www.elperiodico.com/es/noticias/sociedad/20090313/los-primeros-bebes-espana-con-dos-madres-biologicas-naceran-este-ano/33108.shtml

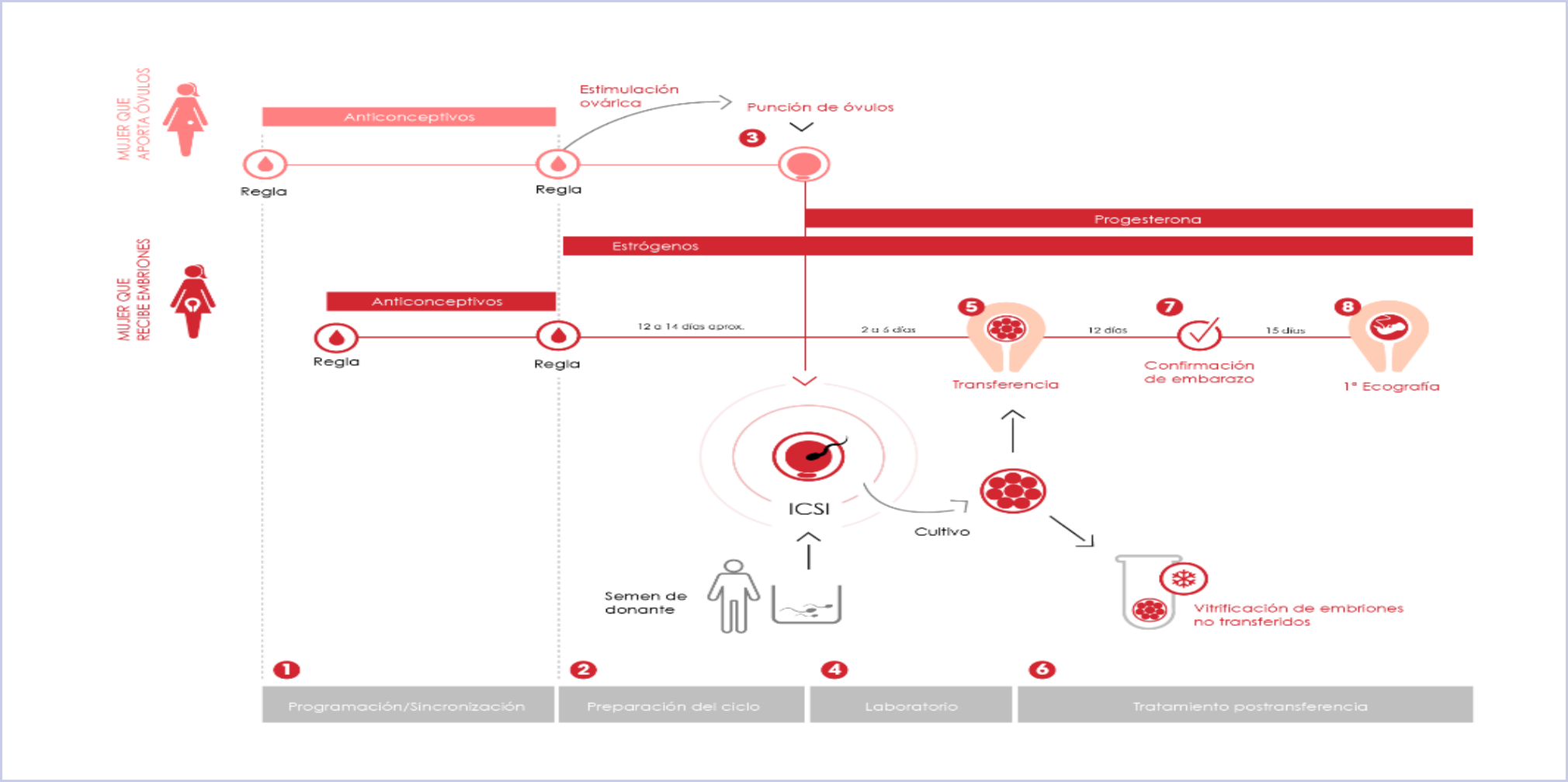
http://www.invitrotv.com/noticia/1174/la-primera-nina-espanola-con-dos-madres-biologicas

Ciclo de fecundación in vitro



Imágenes de https://www.ginemed.es/

Ciclo Recepción de óvulos de la pareja: ROPA



Imágenes de https://www.ginemed.es/

Valdecilla
Hospital Universitario Marqués de Valdecilla

BOLETÍN OFICIAL DEL ESTADO

Núm. 269 Jueves 6 de noviembre de 2014 Sec. I. Pág. 91369

I. DISPOSICIONES GENERALES

MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

11444 *Orden SSI/2065/2014, de 31 de octubre, por la que se modifican los anexos I, II y III del Real Decreto 1030/2006, de 15 de septiembre, por el que se establece la cartera de servicios comunes del Sistema Nacional de Salud y el procedimiento para su actualización.*

El Real Decreto 1030/2006, de 15 de septiembre, por el que se establece la cartera de servicios comunes del Sistema Nacional de Salud y el procedimiento para su actualización, regula en sus anexos el contenido de cada una de las carteras de servicios

3. Se modifica el apartado 5.3.8 que queda redactado de la siguiente manera:

«5.3.8 Los tratamientos de reproducción humana asistida (RHA) se realizarán con fin terapéutico o preventivo y en determinadas situaciones especiales.

5.3.8.1 Los tratamientos de reproducción humana asistida tendrán la finalidad de ayudar a lograr la gestación en aquellas personas con imposibilidad de conseguirlo de forma natural, no susceptibles a tratamientos exclusivamente farmacológicos, o tras el fracaso de los mismos. También se podrá recurrir a estos procedimientos a fin de evitar enfermedades o trastornos genéticos graves en la descendencia y cuando se precise de un embrión con características inmunológicas idénticas a las de un hermano afecto de un proceso patológico grave, que no sea susceptible de otro recurso terapéutico. Para su realización en el ámbito del Sistema Nacional de Salud deberán cumplir los criterios generales de acceso a los tratamientos de RHA que se recogen en el apartado 5.3.8.2 y en su caso, los criterios específicos de cada técnica.

a) Tratamientos de RHA con fin terapéutico: Se aplicarán a las personas que se hayan sometido a un estudio de esterilidad y que se encuentren en alguna de las siguientes situaciones:

1.º Existencia de un trastorno documentado de la capacidad reproductiva, constatada tras el correspondiente protocolo diagnóstico y no susceptible de

2.º Ausencia de consecución de embarazo tras un mínimo 12 meses de relaciones sexuales con coito vaginal sin empleo de métodos anticonceptivos.

transmisión de enfermedades o trastornos de base genética graves, o la transmisión o generación de enfermedades de otro origen graves, de aparición precoz, no susceptibles de tratamiento curativo posnatal con arreglo a los conocimientos científicos actuales, y que sean evitables mediante la aplicación de estas técnicas.

Cristina Cifuentes anuncia que Madrid dará reproducción asistida a todas las mujeres

Cristina Cifuentes, delfín de esta propuesta. EFE

MARCHA ATRÁS A LOS RECORTES DEL 2012

La reproducción asistida gratuita vuelve para lesbianas y solteras

A partir del lunes la sanidad pública dará cobertura al tratamiento

Condenan a la Comunidad de Madrid y a un hospital por discriminar a unas lesbianas en reproducción asistida

- El centro paró temporalmente el tratamiento por la orden ministerial 2065/2014
- Esta norma limita el acceso a la reproducción asistida a mujeres estériles
- La juez: la ley no permite esta discriminación y es de rango superior que la orden
- El colectivo LGTB celebra la sentencia mientras el hospital recurre la sentencia

05.10.2015 | actualización 21h41

RTVE.es / AGENCIAS

El Juzgado de lo Social número 18 de Madrid ha condenado al Hospital Fundación Jiménez Díaz y a la Consejería de Sanidad de la Comunidad a indemnizar con casi 5.000 euros a una pareja de lesbianas por haber sido discriminadas por su orientación sexual en el acceso a un tratamiento de reproducción asistida.

El centro sanitario suspendió el tratamiento que seguía una de ellas, una vez iniciado, entre el 28 de noviembre de 2014 y el 13 de mayo de este año, momento en el que se retomó a iniciativa del propio hospital, que ya ha recurrido la sentencia.

Las demandantes fueron excluidas temporalmente ante la entrada en vigor de la orden ministerial, aprobada cuando Ana Mato era ministra de Sanidad y que limitaba el acceso a estos tratamientos a las mujeres con problemas de infertilidad.

Cantabria reconoce por ley el acceso de las lesbianas a la reproducción asistida

Imagen de una embarazada sosteniendo su vientre. (GONZOO)

- Es una propuesta para reconocer el derecho a una atención sanitaria sin discriminación por razón de "orientación sexual, expresión o identidad de género.
- Específicamente, el sistema sanitario público facilitará el acceso a estos tratamientos a las mujeres lesbianas y bisexuales.

Reproducción asistida pública para lesbianas y mujeres solas en Navarra

Cristina Mestre Ferrer

El parlamento de Navarra ha aprobado una resolución en la que exige al Ejecutivo Foral que las **mujeres homosexuales** puedan acceder a la reproducción asistida en la seguridad social navarra.

Esta resolución permite que las **mujeres solas que deciden tener un hijo**, también puedan acceder a este servicio tras declarar que no tienen pareja. En la reforma de Bildu consta "El Ejecutivo Foral cebe establecer, como requisitos para poder acceder al servicio de reproducción humana asistida, el diagnóstico de infertilidad, la prescripción clínica o la mera imposibilidad. Para ello, será suficiente el informe médico expreso, estar inscrita en el registro de parejas de hecho o estar casadas y, en el caso de mujeres solteras, la declaración de no tener pareja".

Sanidad pública y Ropa

Necesidad de revisar la normativa común del SNS:

- En respuesta a la motivación de compartir la maternidad
- Para evitar discriminaciones en el acceso al sistema sanitario
- Para dotar de seguridad jurídica la práctica de los profesionales

Gracias por su atención

Egg donation: compensation, rights and donors registers.

Authors:

Francisco Amo Setién, María Paz-Zulueta, Susana Gómez-Ullate Rasines, Tamara Silio García, Paula Parás Bravo, Raquel Sarabia-Lavín, Jaime Zabala Blanco.

Nursing Department, University of Cantabria.

We have no commercial disclosure

INTERNATIONAL CONFERENCE ON
"REPRODUCTIVE RIGHTS, NEW REPRODUCTIVE TECHNOLOGIES AND THE EUROPEAN FERTILITY MARKET"

Santander (Spain), 19-20 November 2015

Background

Reproductive rights must be guaranteed as human rights.

Background

- Ley 35/1988, de 22 de noviembre, sobre Técnicas de Reproducción Asistida. Boletín Oficial del Estado, núm. 282, (24-11-1988).

- Ley 45/2003, de 21 de noviembre, por la que se modifica la Ley 35/1988, de 22 de noviembre, sobre Técnicas de Reproducción Asistida. Boletín Oficial del Estado, núm. 280, (22-11-2003).

- Ley 14/2006, de 26 mayo, sobre Técnicas de Reproducción Humana Asistida. Boletín Oficial del Estado, núm. 126, (27-5-2006).

Background

Women with fertility problems need other women to donate their eggs so that they are implanted once they are fertilized.

This right includes not only recipients but also, and in the same way, donors.

Objective

Critical reflection on the legislation regulating egg donation in Spain today.

Law 35/1988

Spain is pioneer adressing the legislative regulation of assisted reproduction techniques.

One important improvement point.

Ley 35/1988, de 22 de noviembre, sobre Técnicas de Reproducción Asistida.
Boletín Oficial del Estado, núm. 282, (24-11-1988).

Law 45/2003

The destination of cryopreserved human preembryos was adressed by this law.

It delimited to three the maximum number of fertilized eggs and also the number of preembryos implanted.

Restrictive.

Ley 45/2003, de 21 de noviembre, por la que se modifica la Ley 35/1988, de 22 de noviembre, sobre Técnicas de Reproducción Asistida. Boletín Oficial del Estado, núm. 280, (22-11-2003).

Law 14/2006

Today, Assisted Human Reproduction is regulated by this law in Spain.

Wide law:

-It defines “Preembryon”

-National Gamete and Preembryon Donors Register

-Assisted Reproduction Center Activity Register

-Article 5: Donors and contracts.

Ley 14/2006, de 26 de mayo, sobre técnicas de reproducción humana asistida. Boletín Oficial del Estado, nº 126, (27-5-2006).

Lack of regulation on the number of eggs extracted

It is a healthcare procedure for donors.

It is not explicitly mentioned the number of donations allowed.

It does not regulate the number of eggs extracted allowed.

Infractions.

Ley 14/2006, de 26 de mayo, sobre técnicas de reproducción humana asistida. Boletín Oficial del Estado, nº 126, (27-5-2006).

Financial compensation

According to the law, it is a gratuitous, formal, and confidencial contract.

There is a financial compensation (≈1200€) in Spain.

Lack of regulation + financial compentation = RISK

Ley 14/2006, de 26 de mayo, sobre técnicas de reproducción humana asistida. Boletín Oficial del Estado, nº 126, (27-5-2006).

Lack of National Register

Since 1988 law, the maximum number of children born using the gametes of one donor is 6.

A National Donors Register is necessary to guarantee this point.

This register is regulated by the three laws (1988, 2003, 2006), but it has not been created yet.

Ley 14/2006, de 26 de mayo, sobre técnicas de reproducción humana asistida. Boletín Oficial del Estado, nº 126, (27-5-2006).

Conclusion

The sum of these issues lead to a potential risk of violation of rights.

Conclusion

- 1. Donors go through treatments, not free of risk, with the objective of obtaining plenty of eggs that can be used in more than one receptor. She accept a gratuitous, formal, and confidencial contract that should not lessen the respect for the mínimum ethics, this is, the non-malificence and justice principles.

Conclusion

- 2. The financial compensation established by the article 5.3 of the law of 2006 could be hiding the altruistic nature of the regulation, particularly in the current times of crisis

Conclusion

- 3. The law which limits to 6 the maximum number of children born using gametes from the same donor cannot go into effect in Spain due to the lack of a national donors register.

Egg donation: compensation, rights and donors registers.

Corresponding author:

franciscojose.amo@unican.es

INTERNATIONAL CONFERENCE ON
"REPRODUCTIVE RIGHTS, NEW REPRODUCTIVE
TECHNOLOGIES AND THE EUROPEAN FERTILITY MARKET"

Santander (Spain), 19-20 November 2015

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE
Council of Europe
Conseil de l'Europe

Human rights and ethical issues related to surrogacy

Tanja E. J. Kleinsorge
Head of the Secretariat
Committee on Social Affairs, Health and Sustainable Development
Parliamentary Assembly of the COE

Council of Europe
Conseil de l'Europe

Human rights and ethical issues related to surrogacy

Background:

- The Council of Europe and its Parliamentary Assembly (PACE)
- The Committee on Social Affairs, Health and Sustainable Development
- Procedure in Committee and in PACE
- Role of the report and the Rapporteur

Council of Europe headquarters
Strasbourg, France
founded 1949
47 member states

Parliamentary Assembly
over 300 MPs and as many substitutes from 47 national parliaments

Rapporteur: Petra De Sutter (Green Party)
Belgian Senator, Professor Gent University,
Head of Reproductive Health Department of Gent University Hospital

Background and context

- an estimated 1 in 10 to 1 in 6 couples struggles with infertility
- surrogacy – having someone carry the baby to term for you – is often the last resort for these couples, as well as for gay couples who could otherwise not naturally procreate
- divisive issue because of the human rights and ethical issues involved

Questions

1. Should a woman be allowed to “rent out her womb“ (for altruistic motives or even for financial gain)?
2. Who is the mother of a baby born by a surrogate: the genetic or the birth mother, or (in the case of surrogacy cum egg donation) the “intending“ mother?
3. Does surrogacy reduce babies to commodities to be ordered and delivered at the whim of those who can afford to do so (including ordering a termination of the pregnancy if the baby is not healthy or the couple has separated)?
4. Is surrogacy by definition exploitative, outsourcing physical and psychological risks linked to pregnancy and childbirth to poorer, uneducated women?

"Surrogacy-friendly jurisdictions"	"Anti-surrogacy jurisdictions"	"Surrogacy-neutral jurisdictions"
• for-profit surrogacy is legal • performed on a large scale • legal measures allowing intended parent(s) to obtain legal parentage • no nationality, domicile or habitual residence prerequisite for the intended parents	• outlaw surrogacy in all its forms	Two subtypes: • regulated but only an altruistic form is permitted (prohibition of for-profit surrogacy arrangements) • all forms of surrogacy remain unregulated, neither expressly banned nor expressly permitted
Russia, Ukraine, India, Uganda	France, Germany, China	1. Greece, UK, Australia, Israel, New Zealand, South Africa 2. Belgium, the Czech Republic, Hungary, Ireland, the Netherlands, Spain, Argentina, Brazil, Guatemala, Japan, Venezuela

Katarina Trimmings and Paul Beaumont, "General Report on Surrogacy", Chapter 28, in: Katarina Trimmings and Paul Beaumont (eds) "International Surrogacy Arrangements", May 2013

- **no international legal instrument currently regulates surrogacy**
- relevant European Court of Human Rights judgments:
- June 2014: *Mennesson & Labassee v. France*, in which the Court, availing itself of the "best interests of the child"-principle, clarified that France had violated Article 8 of the European Convention on Human Rights in refusing to recognise the legal parent-child relationship of a genetic father with his surrogate-born children
- January 2015: *Paradiso & Campanelli v. Italy* (no genetic link between the intending parents and the child), where the ECtHR also spelled out that it is necessary that a child should not be disadvantaged by the fact that he was born by a surrogate mother (this judgment was appealed by the Italian government, and will be judged by the Grand Chamber)
- the Hague Conference on Private International Law (HCCH) has been working on the feasibility of drawing up a multilateral instrument in the field of parentage / surrogacy for several years now:
- currently forming an Expert Group, which is to meet for the first time in the first half of 2016, to explore the feasibility of advancing work in the area of "private international law issues surrounding the status of children" – i.e., cross-border problems arising in relation to legal parentage, including those resulting from ISAs

Vulnerabilities: the surrogate mother

- runs all the risks of a medically-induced pregnancy and childbirth
- bound to give up the child shortly after birth – usually, (full) payment will depend on it
- psychological risks, compounded in cases where:
  - the surrogate mother is also the genetic mother of the child
  - the surrogate receives no proper counselling and/or
  - cannot stay in contact with the child.
- risk that the intending parents will interfere with the pregnancy (placing limitations on the decision-making of surrogate mothers regarding their health or even the continuation of the pregnancy)
- risk that the intending parents refuse to accept and thus abandon a child which is not healthy or otherwise not wanted anymore.
- most international, for-profit surrogacy arrangements involve surrogate mothers who are relatively poor and uneducated, the validity of whose consent can be questioned due to the “life-changing“ amount of money they receive as compensation (risk of exploitation)

Vulnerabilities: the child(ren)

- it is clear that the child cannot be blamed for being born of a surrogacy arrangement
- thus, the European Court of Human Rights has ruled that the rights of the child cannot be curtailed simply because the intending parents flouted national law (when it forbids surrogacy), as the best interests of the child prevail
- **what is in the best interests of the child?**.
- United Nations Convention on the Rights of the Child (UNCRC) guarantees the right to children to be registered immediately after birth and the right from birth to a name, the right to acquire a nationality and as far as possible, the right to know and be cared for by his or her parents (Article 7) - but the definition of who is a child's parent depends on the legal definition in national law
- **what is not in the best interests of the child?**
  - being abandoned by the intending parents (in particular, if the surrogate mother refuses to care for the child, as well) because the child is not healthy or otherwise not wanted anymore,
  - theoretical concerns that a child may also run psychological risks due to the lack of maternal attachment of the surrogate mother during pregnancy, and the "abandonment" straight after birth, as well as psychological risks later in life if the child is unable to trace his/her genetic and/or birth origins.

Vulnerabilities: intending parents

- usually relatively well-off and educated, but vulnerable because of their desire to have a child
- risk of the surrogate mother changing her mind (in particular, in traditional surrogacy arrangements), since even in surrogacy-friendly jurisdictions, surrogacy arrangements are rarely enforceable, i.e. a surrogate mother can seldom be forced to give up the child she has born to the intending parents, even if the child is not genetically related to her
- vulnerable to blackmail by surrogate mothers or other parties involved in the arrangement
- may fear that the surrogate mother harms the baby through her behaviour during the pregnancy.

Other vulnerabilities: egg donors in particular

Rapporteur's proposal:

- recognise the right of Council of Europe member states to regulate or prohibit surrogacy at the national level as they see fit
- in view of the vulnerabilities and risks described above which are particularly prevalent in for-profit and – to a lesser degree – in traditional surrogacy arrangements, and which may result in grave violations of the human rights in particular of surrogate mothers and children born of surrogacy arrangements:

  - **strongly discourage for-profit surrogacy arrangements**

  - **caution against traditional surrogacy arrangements.**

Rapporteur's proposal:

Where surrogacy arrangements of any sort are permitted, regulation should be clear, transparent, and robust:

- Clinics, associations, agencies and other intermediaries should be licensed, and their adherence to the country's regulations should be monitored.
- Appropriate official records (such as birth certificates) should be established and maintained to give participants in surrogacy arrangements the option of acquiring information on their origins and/or future contact should the mutual desire or need for it arise.
- A basic screening of both the intending parents and the surrogate mother should be carried out *ex-ante* to reduce risks of abandonment or abuse of children born via surrogacy, and the risk of harm to the surrogate mother.
- Evidence-based information about known and potential risks, living conditions and outcomes for surrogate mothers, gamete providers and intending parents should be provided to the parties before they enter into an agreement. Agreements to be signed by the parties *ex-ante* covering the different eventualities which could occur should be mandatory (whether or not they are enforceable). It should be possible for intending parents to apply for parental orders *ex-ante*.

Rapporteur's proposal:

- Where surrogacy arrangements are not permitted, care should be taken not to violate children's rights when taking measures to uphold public order and discourage recourse to surrogacy arrangements.
- Both Council of Europe member states and the Committee of Ministers should be encouraged to collaborate with the Hague Conference on Private International Law (HCCH) with a view to human rights and ethical issues related to surrogacy being taken into account in any multilateral instrument that may result from its work.
- The Committee of Ministers should draw up European guidelines on the matter.
- Council of Europe member states make adoption more of a viable alternative to surrogacy.

Watch this space: on Monday you will know which recommendations found a majority in Committee, in January you will know which ones were adopted by the Assembly... Thank you!

Vilhjálmur Árnason, University of Iceland

Reproductive Autonomy:
Some Moral and Social Challenges

Reproductive Rights, New Reproductive Technologies
And The European Fertility Market

Santander, Spain, 19–20. November 2015

Overview

- Reproductive rights and autonomy
- The liberal emphasis and its limitations
- Alternatives to liberal autonomy
- Different rationalities
- Collective autonomy
- The special case of reproduction
- Example: Icelandic bill on surrogacy
- Final remarks

Reproductive rights

- The basic idea is to secure freedom from coercion in reproduction
- A negative right: Not to have one‘s resproductive capacities interfered with against one‘s will
- Example: forced sterilisation
- Places obligations of non-interference upon others

Reproductive choice

- The central idea is that individuals should be permitted to control their fertility, i.e. the timing and amount of reproduction.
- Example: access to contraception to solve the problem of unwanted fertility
- Giving women increased liberty
- Controversial issue
  - The right to choose abortion (limited by the right to life of another human being)

Reproductive autonomy

- Using reproductive technology to solve the problem of unwanted infertility
- Can arguments that have been used to support negative reproductive rights and to facilitate reproductive choice be used as reasons for the claim not to restrict the use of a wide range of fertility treatments?
  - Use of eggs, sperm and gestation provided by others, incorporating genetic aims

The liberal position

- The ideal of a liberal society is the value of personal autonomy: “that, to the greatest degree possible people should be free to make their own life choices and decisions for themselves ... And the state should as far as possible opt out of the province of personal morality”
    - (Max Charlesworth *Bioethics in a liberal society,* 1993: 16).
- “It is not the business of the state ... to enforce personal morality, or to establish a common morality” (16).

Extensive procreative liberty

- Spokesmen (e.g. Harris, Robertson, Dworkin) argue that "the sorts of choices that are at stake in human reproduction are not mere choices, but that they are peculiarly intimately bound up with our deepest individual nature, and that they are central to individual autonomy, robustly construed".

  » Onora O'Neill, *Autonomy and Trust in Bioethics* (2002), 60

- Analogy with freedom of expression and religion.

Instrumental rationality

- The prevailing liberal notion of autonomy is often fleshed out in terms of instrumental rationality where goals are determined by individual preferences within the limits of no harm
  - This leads to controversial conclusions, not least in relation to human genetics and reproduction:
  - Pre-natal diagnosis, genetic enhancement, surrogacy, etc.
  - Various forces affect individual preferences

Interrelations

- “We live in a world with other people, in networks of relationships, families, and ‘communities’, and this means that to live an autonomous life is necessarily to engage in and to take seriously the social dimensions of and limitations on, one’s choices and actions”
  - Michael Parker, “Public deliberation and private choices in human genetics”

Setting limits

- How can we sensibly argue about limits to individual autonomy to shape morally legitimate policies in a liberal pluralistic society?
- In the area of reproduction, there are strong moral reasons not to leave the matters to the "private sphere"
  - to defend the vulnerable from exploitation
  - to protect the best interests of children
  - to secure conditions for everyone to project their lives

A Communitarian response

- Reject the appeal to personal autonomy as a misguided ideal in bioethics
- Substantive reasons
  - The end of medicine and its professional ethos
  - Notions of giftedness and the mystery of life
  - Notions of human nature and flourishing
- In the language of Charlesworth, this implies that “personal autonomy is subordinated to ‘objective’ moral values”

Value rationality

- This can be characterized as value rationality which monologically determines the outcomes of public policy and legislation
- Although it may be morally appealing, this is not justified unless agreed to in public debate
- Charlesworth: “there is no such thing as ‘the community view’ which has some kind of special normative status and which provides a basis for public morality” (27)

A need for public deliberation

- Both the communitarian and the liberal views lose sight of important options for collective autonomy
- The liberal view makes a too strict distinction between the personal and the political which is reduced to the “sphere of the law”
- The communitarian perspective refers to the authority of cultural values that are not tested in an open public debate

Communicative rationality

- A need to maintain and strengthen the conditions for human agency and deliberation
  - the capacity of citizens to act freely, make decisions and assume responsibility for them
- Both personal, institutional and political
  - conditions for “encouraging continuing discussions of fundamental values in all phases of the democratic process … and encouraging public-spirited perspectives on public issues”
    - Gutmann & Thompson, “Deliberating about bioethics”, 39–40.

A key question

- Are we to "to proceed *autonomously* according to the standards governing the normative deliberations that enter into democratic will formation, or to proceed *arbitrarily* according to the subjective preferences whose satisfaction depend on the market".
  - Habermas, *The Future of Human Nature*, p. 12

Collective autonomy

- Meaningful autonomy needs to be exercised collectively in the public sphere
  - No sharp separation between bioethics and biopolitics
- Main tasks
  - Critical analysis of arguments and reasons brought to defend policies – accountability
  - Strengthening conditions for public spirited perspectives to feed into policy
  - Resolving ethical disagreements in a respectful way

Dealing with disputes

- The goal of both ethical and political argument is not just to reach a conclusion supported by the majority, but a solution or a fair compromise which ideally everyone can agree on, and is supported by sound ethical reasons
- This is particularly important in areas, like human reproduction, where there are deep disagreements that are unlikely to be settled

Critical analysis of an argument

- O'Neill argues that the liberal transition from the right of noninterference and choice into a right to procreative autonomy is unconvincing
  - "Reproduction is unlike both contraception and abortion, in that it aims to bring a third person − a child − into existence. … [R]eproductive decisions are irresponsible unless those who make them can reasonably offer adequate and lasting care and support to the hoped for child" (61, 62)
    - The harm principle is necessary but not sufficient in this sphere of life which has distinct characteristics

Not a positive right

- This implies that it is defensible to place various restrictions on the use of NRT‘s which a couple may need in order to reproduce
  - (A couple? “Reproduction is intrinsically not an individual project“, 65)
- In “ordinary“ cases, people are protected by the right to non-interference in their private sphere, until after a child is born and is abused or seriously neglected

An Icelandic example

- A bill has been proposed in the Icelandic parliament legalizing altruistic surrogacy
- It will be the first Nordic country to do so
- The main aims of the legislative proposal are, in this order:
  - Protecting the best interests of the child
  - Respect the autonomy and welfare of the surrogate mother
  - Accomodating the prospective parent‘s wishes

The context

- Response to problems raised by cross-border surrogacy that may involve exploitation of women in a vulnerable position and attempts to reduce its moral hazards
  - The current ART act is very liberal and allows both single sex women and single women access to fertility treatment
  - Current practices have not been guided primarily by the best interests of the child, but have rather accomodated the prospective parents‘ wishes

Several restrictions

- The primary interests of the child guide the entire propsal in order to provide a good, nurturing environment for the child and a fair basis for its life opportunities (a liberal ideal).
- Conditions that the surrogate must meet
  - Residency, age, health, reproductive history, spouse, consent, counselling, commitment, payment
- Conditions that intended parents must meet
  - Residency, age, health, reproductive history, spouse, consent, counselling, commitment, payment

Additional requirements

- To serve the interests of the child
  - Gametes must originate from at least one of the parents, but the surrogate‘s ova must not be used. Close family of either is excluded from supplying gametes.
    - In order to prevent “confused and ambiguous family relationships” (O’Neill, 67)
  - The child has a right to know its origin
  - Forbidden to make use of surrogacy abroad which does not meet conditions of the Icelandic law

Final remarks

- My aim has been to show the need for rational debate to guide policy and place reasonable limits on the liberal agenda in the realm of reproduction
- I have argued that individual choices are legitimately limited by decisions that are taken collectively through democratic venues
- Such decisions need to be based on principles and justified by reasons that could be accepted by all
- An additional challenge to work this out in a cross-border context which calls for harmonious regulation

Thank you!

universität wien

eif Institute for European Integration Research

Transparency and information on medical devices and in-vitro diagnostic devices: Key elements of the EU legislative reform

Dr. Maria Eva Földes

Santander, 20 November 2015

Medical devices

Any instrument, apparatus, appliance, software, implant, reagent, material etc., intended for:

– Diagnosis, prevention, monitoring, treatment or alleviation of disease, injury, disability;

– Investigation, replacement or modification of the anatomy or of a physiological process or state;

– Control or support of conception

In vitro diagnostic devices

Any medical device intended to be used *in vitro* for the examination of specimens derived from the human body, to provide information on:

– A physiological or pathological state;

– A congenital abnormality;

– The predisposition to a medical condition;

– The safety & compatibility with potential recipients;

– Determining treatment response or reactions;

– Defining / monitoring therapeutic measures

Objectives of EU action in the field of medical devices

- **Free movement** of medical devices as goods in the internal market
- Protecting **public health & safety**
- Fostering **innovation & competitiveness**

Harmonization - limited so far to technical standards concerning essential **safety & performance** requirements

- Risk-based classification of devices
- Conformity assessment carried out by notified bodies

Information to the public on medical devices – current situation

The EU Directives on medical devices emphasize confidentiality of regulatory data:

- **Clinical investigations** on safety, performance & effects of devices on patients
- **Claims** submitted by manufacturers to notified bodies
- **Conformity assessment reports** issued by notified bodies
- **Vigilance & market surveillance data** – i.e., malfunctions & related measures

Such data are treated as commercially sensitive information and are not accessible to health care practitioners and patients

EUDAMED
EUROPEAN DATABANK ON MEDICAL DEVICES

Since May 2011 - mandatory for Member States' authorities to report data to Eudamed

Transparency issues & restricted access to information:

- Eudamed currently **NOT open to public,** only to governments & the Commission
- **NO publicly available registry** of medical devices available on the EU market
- Emphasis on **confidentiality** of commercially sensitive information

At the same time, current EU rules allow for direct-to-consumer advertising of medical devices

Information to the public on medical devices: background

PIP (breast implant) incident (Dec 2011) ⇨ "Patient empowerment" rhetoric:

Photo: WILL WINTERCROSS

European Commission (Feb 2012):

- Better information to the public
- Greater patient involvement in reporting adverse effects
- Traceability and long-term monitoring of high-risk devices

European Parliament (June 2012):

- Better information about the quality & potential risks of devices
- Empower patients to report adverse effects
- A single, publicly accessible European database

Eudamed - Commission proposal

Develop Eudamed into a comprehensive information system and opening up some of its parts to the public

Data entered by state authorities, conformity assessment bodies, economic operators

Source: http://www.chemgineering.com/de

EUDAMED – current systems & changes proposed by EU institutions

Comm.	Comm.	Comm.	Comm.	Comm.	Comm.	Parliament	Council
Electronic system on **Registration** Devices & Economic operators 	Electronic system on **Conformity assessm. certificates** Issued by notified bodies 	Electronic system on **Clinical investig.** Safety, Perform., Effects on patients	Electronic system on **Vigilance** Serious incidents, Field safety corrective actions	Electronic system on **Market surveillance** Risk to health & safety Formal non-compliance Preventive health protection measures 	Electronic system **Unique Device Identific. (UDI)**  	Electronic system on **Marketing authoriz.** Granting, Suspension Revocation of applic.  	Electronic system on **Notified bodies** Assessm. Designation Notification Monitoring  

Eudamed – Commission proposal: only partial access to the public

- **Clinical investigations data** – ***no public access*** to data on serious adverse events, device deficiencies in case of a single application, and information exchanged between Member States' authorities and the Commission

- **Vigilance data** - ***appropriate levels of access*** to the public as determined by the Commission

- **Market surveillance data** – ***only open*** to the Commission and Member States' authorities

Eudamed – Parliament amendments

Goal: a 'comprehensive right to information on medical devices'

- **For medical professionals** – **full access to the whole database**
- **For the public** - a possibility to **obtain information upon request** within 15 days

Obligation to **consult patient and consumer organizations** to ensure a user-friendly format of Eudamed

Marketing authorization for the highest risk devices and a publicly accessible electronic system on marketing authorization data

Increase transparency on the structure, operation and activities of notified bodies

New rules on information – do they serve the interest of patients?

Unclear terms – e.g., ***appropriate levels of access***

How will access to Eudamed data help patients?

We need to know more about:

- The type of information that patients need - with focus on high risk devices
- How patients use this information - its effect on patients' knowledge about safety & performance issues and their involvement in vigilance efforts

How about access to comparative information? – Council proposal to include in Eudamed the summaries of safety & clinical performance of devices with information on the place of the device in the context of alternative diagnostic or therapeutic options

THANK YOU FOR YOUR ATTENTION!

Dr Maria Eva Földes

eva.foeldes@univie.ac.at