Reproductive rights, new reproductive technologies and the European fertility market

19-20 November 2015 Santander, Spain

Social egg freezing: a rational market choice?

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'An exploratory study of egg freezing for non medical reasons'

 Media analysis of newspaper articles on the topic of egg freezing-Content and Critical Discourse Analysis

Interviews with 31 female users of egg freezing technology

'Non medical', 'elective', 'social', 'lifestyle' reasons



Introducing Neoliberalism

- Neoliberalism is currently the dominant social, political and economic ideology shaping our world today (Saad-Filho and Johnson, 2005)
- Promoting individualism, consumerism and the transferring of state power and responsibility to the individual, neoliberalism renders the political subject free, empowered and positively encouraged to construct their lives through their own choosing (McGregor, 2001; Brown and Baker, 2012)
- Under neoliberalism individuals are cast as responsible for managing social risks and life in society and, as such, the consequences of their actions, or inactions, are understood as solely their own, regardless of the constraints on their behaviour or choices (Rose, 1989; Gill 2007).



- Participant investment in a particular motherhood experience
- Motherhood at the wrong time, in the wrong circumstances seen as a threat to their ontological security and sense of self
- Participants were on average ** years of age at time of egg freezing (Range**-**)



- Participants accounts reflected a strong subscription to neoliberal values of responsibilisation self-actualisation and self-determined action
- 'Go getters' women who did not 'lead their lives as witnesses' (Sofia)
- Participants drew on egg freezing technology as a resource to manage and mitigate against the risk they perceived their ageing body posed to the furtherance of their biographical project.
- Reflective of neoliberal values which prioritises individual responsibility and action in the face of 'risk knowledge'



Declining ovarian reserve, options:

- To have a child in circumstances which they deemed unsuitable
- To choose to remain child free whilst looking for a suitable partner
- To engage with egg freezing technology in an attempt to preserve reproductive potential for future use.
- The highly rational strategy of using of egg freezing in this way can frame the consumer of such technology as a strategic, choice making, responsibilised individual



- '..taking matters in to my own hands' (Anne)
- Making an 'active decision' (Helena)
- 'Taking control of the situation rather than just let it ride' by doing 'something constructive...something proactive' (Johanna)
- Doing 'something responsible, cutting edge and proactive'.
 (Mabel)



 Krolokke and Pant (2012) developed the concept of the reproductive entrepreneur; the 'reproprenur'

 Such a characterisation also reflects how medicalised fertility treatment is constitutive of the neoliberal ethos

 Becomes a further means by which individuals can transform themselves through consumption (Mamo, 2010).



- This notion of egg freezing as a form of consumption is reflected in the language used in its discussion which is laden with market-based and economic references and metaphors (Romain, 2011).
- For me egg freezing was the perfect solution because I knew I wanted to have kids. I was 37 at the time, I still felt hopeful that I would find a partner in the coming years but I felt like, ok, I'm just buying myself an extra 5 years of security in terms of being able to do it on my own. (Jen)
- I wanted to use it purely as an **insurance** policy...its like some sort of comfort to think well if it doesn't work the traditional way there is this that I can try. So it's just something to try and make me think that I would have one other chance if it didn't work naturally really. (Johanna)



- What egg freezing offered these women was an assumedly greater, more optimistic, orientation towards the future where options regarding motherhood and a family remained intact and within reach.
- Therefore, similar to other forms of autologous tissue banking such as cord blood banking (Waldby and Mitchell, 2006, Martin et al, 2010) what egg freezing offers women was hope.
- Specifically the hope they could partake in the broader social traditions of the family and pursue what the participants saw as the normal route to motherhood.



Is understanding women as 'reproprenuers' a useful means to theorise their use of egg freezing?

- Is useful as it helps explain the desire felt by women to take action in the face of declining fertility
- However whilst it is possible to understand women's use of egg freezing through the discourse of individual choice, such an individualistic approach 'atomizes' women (O' Riordan, 2009:194) by presenting her choices in a social vacuum
- Thereby obscures the wider structural gender inequalities, national politics and collective preoccupations which affect such decision making (Gerodetti and Mittier, 2009; O' Riordan, 2009).



The atomised woman?

- The problem with understanding women's use of egg freezing as a rational market choice is that it continues to obscures how choice is highly constrained
- Boutique medicine (Hannerz 1996)
- Neoliberal governmentality converts gender inequality from a structural problem in to an individual concern
- Such an orientation arguably contributes to, and helps sustain the notion that female users of egg freezing are highly rational consumers of medical technology in the pursuit of highly individualistic goals.



- There is a need to move away from hyper individualised notions of egg freezing as simply the outcome of a rational market choice
- Does not account for why some women do not engage with egg freezing technology
- Characterised as a market choice-such a highly individualistic characterisation is likely to result in a reductionist and unrealistic reflection of the complex web of social relations which actually inform such decisions.
- An illusion of reproductive control (Earle and Letherby, 2002)



The importance of recognising Neoliberalism in action

We cannot fight neoliberalism and neoliberal ideology

- It is nevertheless important to recognise how it structures and shapes our decision making and actions
- Must not allow it to obscure the often unequal social relations which it masks by promoting seemingly attractive neoliberal values individualism, consumption and freedom of choice.



Reproductive control as the outcome of a constellation of different factors

Economic

Need for dual income household

Cost of living

Market instability

Consumer confidence

Cost of childcare

Welfare cuts i.e Child Benefit

Structural

Gendered division of labour in the family

Parental leave

Flexible working policies

Geographical dispersal of family

Need for geographic mobility

Longer periods of time in education

Relational

Perceived lack of procreative desire among men

Disjuncture between expectations and reality in women's expectations of men

Men's lack of awareness about age related fertility decline

Unequal power relations in intimate partnerships

Ideological

Motherhood imperative

Intensive mothering

New fatherhood

Hegemonic femininity

Neoliberal governmentality

Reproductive responsibility

Normative family forms

Individualism

Physical

Age related fertility decline in women and men

Other risks to fertility: weight, other health related behaviours

Risks of older motherhood to mother and child



Thank you-Questions?

References:

• To add.....



Embryo's rights and FMI in Italy and in the UE legislation



Annarita Caramico
University of Salerno





The children in the womb feel every emotion of the mother from anger to fear from happiness to sadness The modern diagnostic tools have allowed us to investigate the "lost paradise" that unites us all We are all trying to solve the most ancient question ever:

There is life before the birth?



Law n. 40 of 2004

- 1)The heterologous FMI was forbidden
- 2) The preimplementation analysis was forbidden
- 3) Was mandatory the implementation of at least three embryos at the same time





After 33 sentences of the Italian's Court the law about FMI and all the violation of human rights in it are almost over...but the law stand still.



- The sentence of 2009 n. 151 by the Constitutional Court ha eliminated the implant of minum three embryos
- The sentence of 2014 n. 162 by the Constitutional Court (after a sentence of the Court of Human Rights of 2012 which condemned Italy because of the violation of the fondumental human right of building a family as in the art. 8 of CEDU) was allowed to make researches on embryos for medical purposes and the denial of the consent by the father before the implementation
- ✓ The sentence of 9 april 2015 has allowed the heterologous FMI also in Italy
- There was a sentence few days ago always by t he Constitutional Court about FMI
- It has been established a National Registry of donors but it is still needed an entire regulatory framework that regulates the PMA and the condition of the so-called abandoned embryos

International and EU law about FMI

Art. 1 of the Universal Declaration of Human Rights adopted by the UN on December ensure dignity and a series of inalienable rights

Art. 25 provide care and assistance to mothers and their child

Art. 1 of the European Convention On Human Rights it is entitled "Obligation to respect human rights

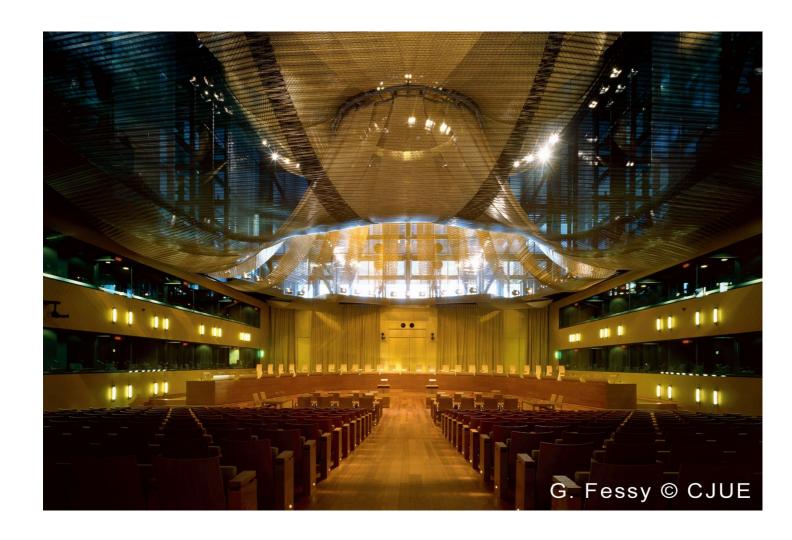
An interpratation made by the EU Commission itself affirmed in the 80s that the art. 1 and 2 couldn't refers to a right of life of the fetus especially in cotrast to that of the mother.

Art. 1 of the Oviedo Convention commits to protect "the dignity and the identity of all human beings and to ensure every individual, without discrimination, respect for their integrity and the other rights and fundamental freedoms against the application of Biology and medecine.

Art. 13 of the Oviedo Convention ban the use of thecniques of medically assisted procreation for the unique purpose of knowing the sex of the child except the one in order to avoid a serious hereditary disease linked to sex (Art. 14)

The Cart of Fundamental Rights of The EU signed in Nice in 2001 establish the principle of human dignity and at art. 2 establishes that "everyone has right to life" while art. 3 statues the importance human integrity

Cases Brustle Vs Green Peace 18 October 2011



Regulates the uses of human embryos for industrial or commercial purposes. The thecniques of Parthenogesis and therapeutic cloning are important but even more important it's to guarantee the Principle of life.

International Stem Cell Corporation Vs

Comptroller General of Patents



The production of pluripotent stem cells has to be combined with the inviolable rights of man

"Although the parthenote, according to our current knowledge, not possible in humans, they initially through the same stages of development of a fertilized egg, in particular the division and differentiation cell, and thus consitute human embryo"

"The right to life should be protected by law" and the Court recognize "merely to european states a wide margin of appreciation with regardTo legislative policy choises"

So the choice it's totally left to the States.

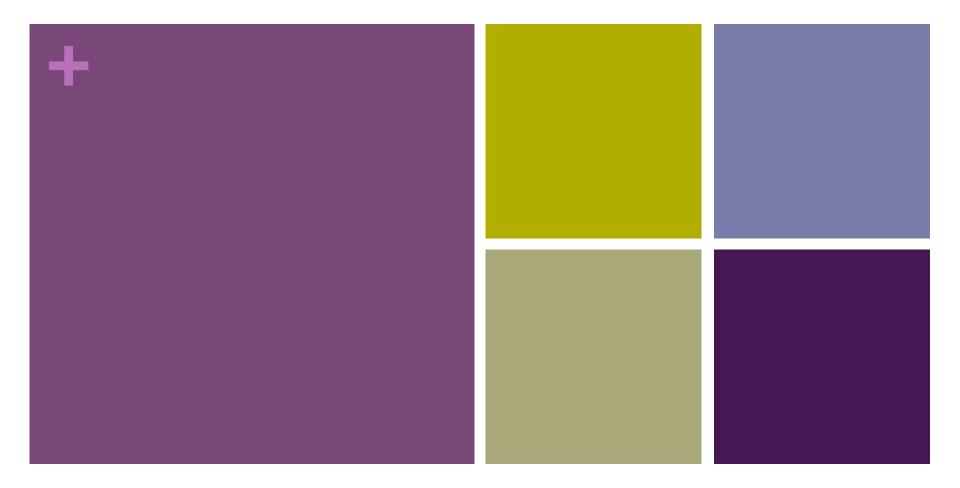
Muchas gracias



Danke je

EUXUPICTÚ

Annarita



International Commercial Surrogacy: Are Artificial Wombs the Answer?

Dr Natasha Hammond-Browning Southampton Law School, UK





Surrogacy and Ectogenesis (Artificial Wombs)

- Ectogenesis the growth and development of a being outside it's mother's womb during the period when it would normally be inside the womb Singer and Wells
- Total ectogenesis the gestation of a human being entirely outside the body of a human female Leslie Cannold
- Ectogenesis The term is commonly used to refer to any device or process that would allow a foetus to develop to maturity without having to spend any time inside the body of a woman Stephen Coleman
- Surrogacy is the practice by whereby one woman carries a child for another with the intention that the child should be handed over after birth. Warnock Report, para 8.1

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Surrogacy

- Baby Cotton (1985)
- Exact numbers of surrogacy arrangements (UK & abroad) difficult to determine Blyth, Crawhaw and Fronek/A comparative study on the regime of surrogacy in EU Member States
- UK Surrogacy Act 1985 and Human Fertilisation and Embryology Act 2008
- Birth mother = legal mother regardless of any agreement/ other national laws to the contrary
- Increasing reproductive tourism circumvent national laws?
- Hague Convention on Private International Law



Problems with international commercial surrogacy

- Enforcement and recognition of surrogacy arrangements problems with legal parenthood and nationality
- Surrogacy exploits women
- Reproduction should not be a commodity
- Control over the surrogate's behaviour
- Harm to the children?



Enforcement and recognition of international arrangements

- UK surrogacy arrangements are unenforceable
- Parental order transfer legal parenthood welfare of the child is the court's paramount concern permits commercial surrogacy?
- Re (X and Y) [2008] EWHC 3030 (Fam)

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Do artificial wombs solve the legal issues?

- Artificial womb negates need for a 'middle woman'
- Intended parents concerns eased child would be handed over
- No concerns for surrogate that she will be left with a child she has not intended to raise
- No longer have legally parentless or stateless children
- Reform of law legal parenthood first time would have children with no gestational or legal mother
- Reform nationality laws?
- Contractual issues with womb provider?



Artificial wombs – the end of international commercial surrogacy?

- If artificial wombs become a safe and acceptable method of reproduction, could end the need for international commercial surrogacy
- Overcome problems with legally parentless and stateless children
- Risk of exploitation of (surrogate) women is completely removed
- Are they a desirable method of human reproduction? Harm to the child?
- Preferable to recognise intended parents as legal parents from birth and to promote autonomy of women who act as surrogates

+ Thank you for listening

- Dr Natasha Hammond-Browning
- Southampton Law School, University of Southampton



The Organisation and Negotiation of Commercial Gestational Surrogacy in Russia

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Outline

- Methodology and research participants
- Research site and sociocultural context: Surrogacy in Russia
- Legal Framework
- Options to arrange surrogacy
- Organizing the surrogacy pregnancy

Methodology and Research Participants

- Ethnographic fieldwork in Saint Petersburg (August 2014 - May 2015)
- In-depth interviews
- (Participant) observations and online observations
- Informal conversations
- Writing ethnographic fieldnotes

Participants: 26 Surrogacy workers

6 Intending parents

8 IVF specialists

13 Staff of surrogacy agencies

5 Staff in maternity wards

1 Doctor in women's clinic

3 Staff in civil registry/embassy

Research Site and Sociocultural Context

- "The Russian woman is a fruitful, fertile woman." (Doctor in maternity ward)
 - Hostility towards infertility and chosen childlessness
- Gestational surrogacy practised since 1995
- Opinions on surrogacy
 - Public survey (WCIOM 2013):
 - 26% 'surrogacy is morally intolerable'
 - 51% 'surrogate mothers are doing something necessary and useful'
 - 16% 'surrogacy is completely acceptable'
 - "Mutiny against God" Patriarch Kirill
 - Opportunity to resolve childlessness: chance should be taken
- High secrecy among intending parents and surrogacy workers

Legal Framework

- Russia: "a reproductive paradise" (Svitnev 2011)
- Family Code, 1995
 - married couple eligible to purchase surrogacy service
 - surrogacy worker is legal mother -> until she signs consent to hand over parental rights to intending parents
- Federal Law No. 323, 2011
 - married or unmarried heterosexual couple and single women allowed
 - homosexual men -> precedents exit; right to fatherhood enforceable but costly
 - certified infertility of intending mother
 - posthumous surrogacy allowed
 - sex selection for social reasons prohibited
- Medical Order No. 107
 - list of reasons for infertility of intending mother
 - criteria for surrogacy workers (20-35 yrs.; healthy; at least 1 healthy child, vaginal delivery; if married, husband's written consent)

Gaps in Legal Framework

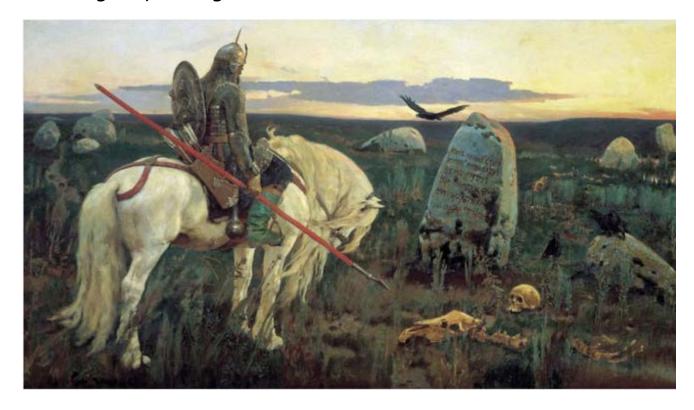
- "Those few provisions on surrogate motherhood that exist in the Russian law hardly correspond to the meaning that we associate with the word 'regulation'". (Khazova, 2013:311)
- Are surrogacy contracts binding under the Russian law?
 - Neither legal nor court guidance exists
- Unregulated: Decision making
 - Embryo transfer: quantity of embryos, quantity of attempts, spacing of attempts
 - Eventualities and responsibilities during pregnancy (miscarriage, pathologies of surrogacy worker or child, illness, wish for reduction or termination)
 - Birth: What to do in case of two or more surrogacy workers?

Opinions on Regulation

- Alexander, director of surrogacy agency
- Gabriella, surrogacy worker

Surrogacy Arrangement Options

- (1) Private arrangements ['napryamuyu']
- (2) Agency arrangements



"Death to the left, swamps to the right, unknown what lies ahead..."

Direct Arrangement

"Surrogate mother

with experience..."

Cities in Russia

Объявлен	ния «Суррогатное материнство»	/	Город
21.10.15 (18:06)	Ищем суррогатную маму.		СПетербург
21.10.15 (17:45)	Выношу Вашего малыша		Москва
21.10.15 (17:30)	Ищу Био !		Украина
21.10.15 (17:10)	могу быть суррогатной матерью		Москва
21.10.15 (17:04)	Приглашаем суррогатных мамочек		Иркутск
21.10.15 (16:43)	СМ с опытом		киржач
21.10.15 (16:05)	Для твёрдо настроенных Био. ИИ		пфо
21.10.15 (16:03)	Сурмама		Уфа
21.10.15 (15:14)	Сур мама с опытом		Краснодар , Кра
21.10.15 (14:36)	Ищу сурмаму, протокол в Санкт-Петербурге		СПетербург
21.10.15 (14:02)	стану СМ		Ставрополь
21.10.15 (13:13)	Ищу Био, Красноярск.Крио.		Красноярск
21.10.15 (13:05)	Ищу суррогатную маму		Краснодар
21.10.15 (12:55)	стану донором		Краснодар , Кра
21.10.15 (12:20)	Ищу био из Ростова. Анализы.		Ростов-на-Дону
21.10.15 (11:50)	Стану вашей суррогатной мамой		Краснодар
21.10.15 (11:21)	нужна СМ, протокол в Спб, 900/200/150/20		СПетербург
21.10.15 (11:11)	см с опытом		Тверь
21.10.15 (10:54)	Срочно для Био		Другой
21.10.15 (10:36)	ищу сурмаму 650/100/100/15		Н.Новгород
Indication	of offer:		

Saint Petersburg

Nizhniy Novgorod

900 000 ₽ - final compensation

"Searching surrogate

mother."

200 000 ₽ - additional in case of twins

150 000 ₱ - additional in case of Caesarean section

20 000 ₽ - monthly allowance

Apparent price gap between the centres and periphery

Direct Arrangement – Risks

- No third party to mediate in conflicts
- Risks of black-mailing
- Risks of 'disappearing' and other interruptions

Search experience of intending mother Yana

- 1st, Ukrainian woman (claimed experience in Ukraine and Moscow), came without any analysis; paid extra, delay, faulty results)
- 2nd : Tajik woman, migrant worker in Saint Petersburg, all analysis paid for, again faulty results)
- 3rd: Uzbek woman, migrant worker in Saint Petersburg, positive examination, but 'illegal' residence; deported by police before embryo transfer

Agency Arrangement



Приглашаем суррогатных мам!

Российская сеть <u>клиник «Центр ЭКО»</u> и <u>компания «Свитчайлд»</u> приглашает женщин в возрасте до 35 лет стать суррогатными мамами для бездетных семей.

Благородная работа суррогатной мамы гарантирует самое высокое в России вознаграждение до **1** 500 000 рублей!

Пожалуйста, заполните анкету и наш менеджер свяжется с Вами в удобное для вас время.

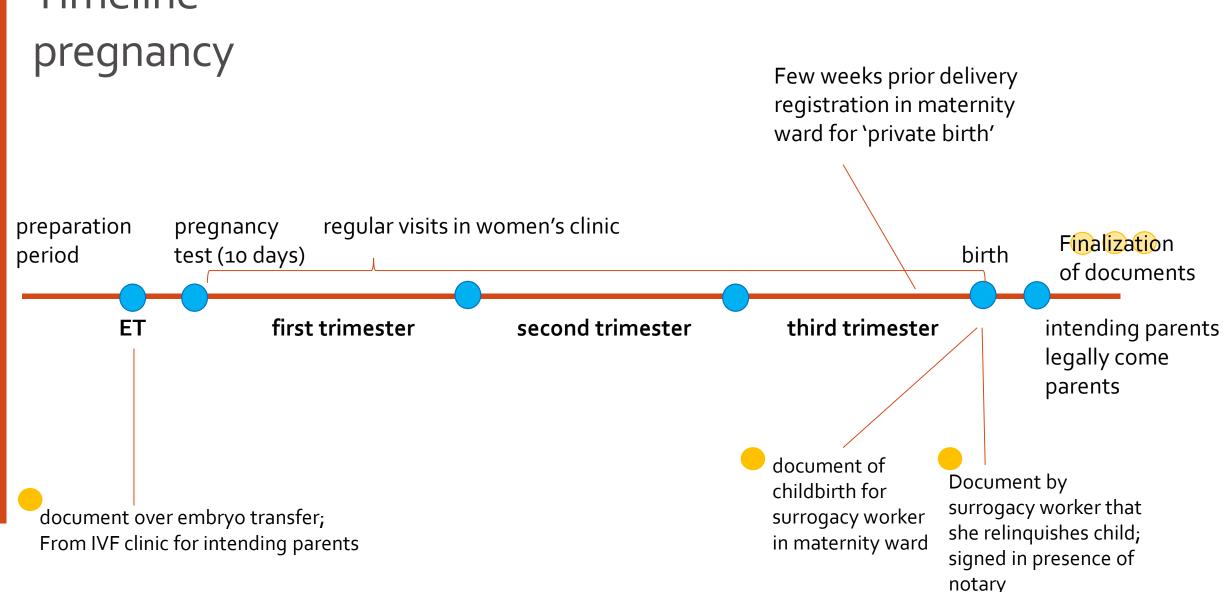
Inviting surrogate mothers!

(...)

The grateful work of a surrogate mother guarantees the highest compensation in Russia, up to 1 500 000 Roubles [£17 000].

(...)

Timeline



Maternity Wards









Conclusion





- Commercial gestational surrogacy in Russia evolves in the minimally regulated private sphere.
- The legal framing represents a neoliberal approach.

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- Svitnev, K. (2011). Legal control of surrogacy—international perspectives. http://claradoc.gpa.free.fr/doc/441.pdf (accessed 29/10/2015)
- WCIOM (2013) [http://wciom.ru/index.php?id=236&uid=114646, accessed o8/10/2015].
- Photographs from maternity wards (1) + (2): http://your-photography.com/russia/russian-maternity-hospital/ (accessed 29/10/2015)

Bypassing regulation: DIY assisted conception and cross-border reproduction

Emily Jackson

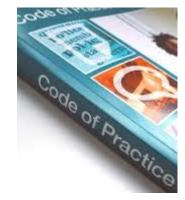


UK regulation is supposed to be comprehensive

- Treatment must be provided in licensed centres
- Centres are regulated by the HFEA and inspected regularly
- Centres must comply with the Human Fertilisation and Embryology Act 1990 and the Code of Practice



HFEA Code of Practice



- Set progressively lower upper multiple birth limit: 24% 10%
- Each centre must have a 'multiple birth reduction strategy'
- Sets out which patients should receive elective single embryo transfer (eSET).



What lies outside the HFEA's reach?

■ The costs of treatment.





- DI if sperm is not 'procured'
- 'Introduction websites'
- Treatment carried out overseas
- Surrogacy

comprehensive?



Cross-border reproductive care

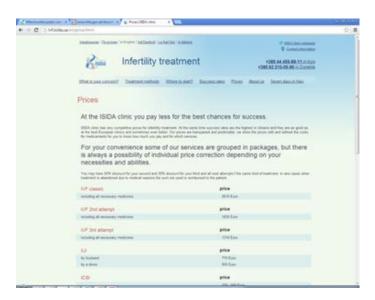
Why do people seek treatment abroad?

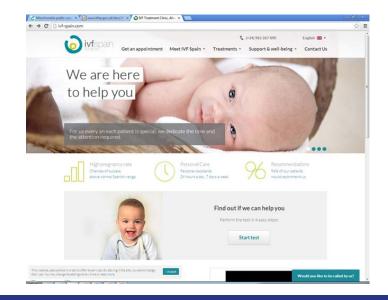
- Cheaper
- Treatment is illegal at home
- To avoid waiting lists
- Access ethnically matched donors
- Perception that treatment may be 'better'







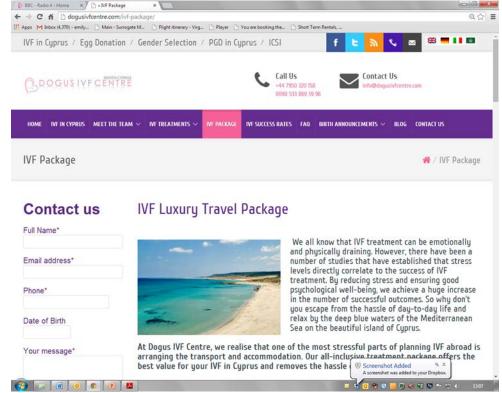








Reproductive tourism? or reproductive exile?





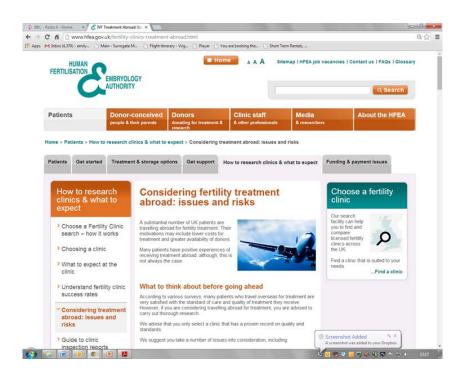
Risks of treatment abroad?

- Traceability? Record keeping?
- Increased risk of multiple pregnancy
- Costs to NHS neonatal services
- Only available to the wealthy
- 'Safety valve' which 'enables' restrictive rules? Eg SH v Austria



What role is there for regulation?

Warnings for patients?





Turkey has attempted to prohibit travel for treatment with donated gametes



- Unintended consequences?
- Deter clinics from offering advice and support?



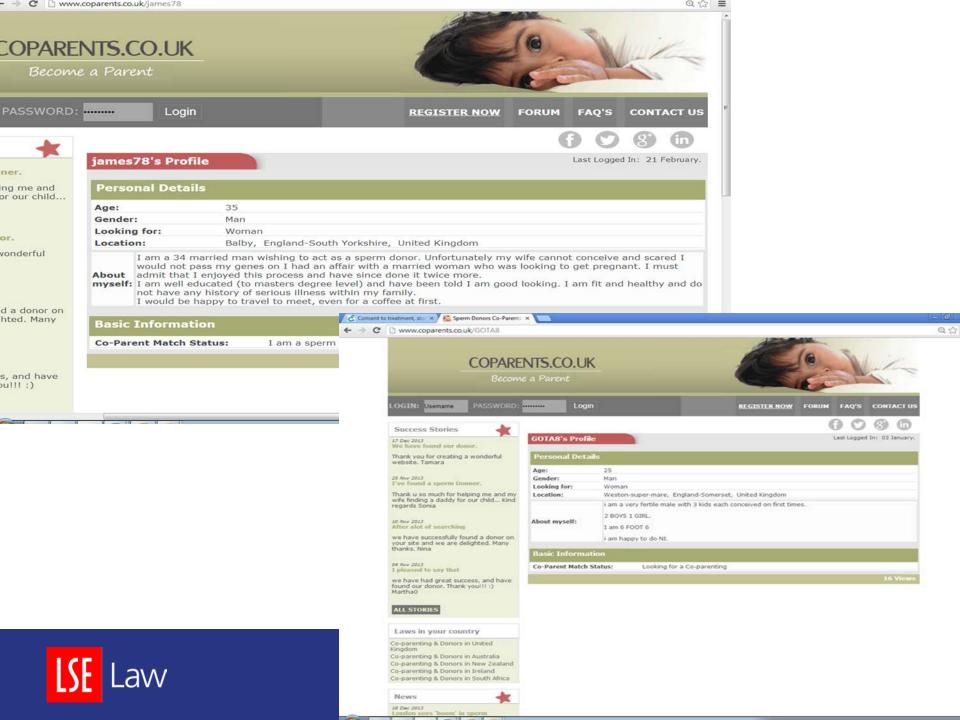
Internet-assisted conception

- No testing of sperm
- Risk of infection
- Risk of passing on genetic disease
- Risk that donor is azoospermic
- No age limit
- No traceability...



- Child has no right to information
- No restrictions on how many times a man can donate
- No way for children to find out if they are related
- Scope for arrangements to break down...





Perceived advantages?

- Motivations were 'Wanting the child to know both biological parents' and 'Wanting to know the person who provides the sperm/egg to create the child'....
- 'A particular concern arising from these findings is the length of time prospective co-parents planned to be in contact with each other prior to attempting conception. Most expected to be in contact for a few months which raises the question of whether this allows sufficient time to establish a sustainable coparenting relationship.'

V. Jadva et al 'Friendly allies in raising a child': a survey of men and women seeking elective co-parenting arrangements via an online connection website' (2015) 30 Human Reproduction 1896-1906.



Cases are now reaching UK courts:

M v F [2013] EWHC 1901 (Fam)

- F had fathered 30+ children through Al and sexual intercourse
- He had once 'advertised himself in graphic terms as willing to participate in a "breeding party", i.e. a male-dominated orgy designed to get a woman pregnant'.



Peter Jackson J

- If conception was via sex, HFE Act provisions do not apply and the donor is the legal father.
- Question of fact, but '[M and F] are ... untruthful, devious and manipulative... they both lied extensively..., and one of them was of course lying about the central issue of the child's conception...'

"...regulation is broadly successful in protecting participants from exploitation and from health risks, while providing some certainty about legal relationships... In comparison, participants in informal arrangements have to judge all risks for themselves. They may not be in a good position to do so. Those seeking to conceive may be in a vulnerable state and not all donors are motivated by altruism.



Neuroscientist who claims he's fathered 58 children while running a 'one-stop shop' insemination service avoids jail for molesting woman who used his 'breeding programme'

- Professor Gennadij Raivich appeared to be the embodiment of respectability
- · But he set up a donor service to 'exploit' women 'desperate to conceive'
- · He advertised services online under a false name and carried out home visits
- 52-year-old, from North London, convicted of sexually abusing Claire Long
- He has been given a nine-month jail term, suspended for two years

By STEPH COCKROFT FOR MAILONLINE

PUBLISHED: 18:03, 30 September 2014 | UPDATED: 19:11, 30 September 2014













969View comments

A neuroscientist who claims to have fathered 58 children while running a 'one-stop shop' sperm donor programme has walked free from court after being convicted of molesting one of his clients.

Professor Gennadij Raivich, 52, from North London, set up a 'breeding programme' on the internet to artificially inseminate women who were desperate to start a family.

The academic - who has three children of his own - visited the women at home and pretended he was trying to help them.

But a court heard how Raivich 'exploited' women



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▶ Giddy Cara Delevingne and supermodel BFF Kendall Jenner enjoy a huge cuddle as they reunite at Karl Lagerfeld's Chanel cruise



Steven and Alex
Gerrard to live in the lap
of luxury in sprawling
£16.8m Malibu home
with an ocean view as
they prepare to relocate
to Los Angeles



Re TT (Surrogacy) [2011] EWHC 33 (fam) Baker J

I am concerned that [the mother] is at risk of exposing herself to malign and possibly dangerous influences via the internet which could in turn affect the children. For the sake of her children, I advise her to adopt greater restraint in the use of the internet.



I am concerned about the dangerous and murky waters into which they, and particularly Mrs. W, have strayed via the internet... It cannot be said too strongly that it is extremely unwise to invite someone into your home whom you have only met over the internet.

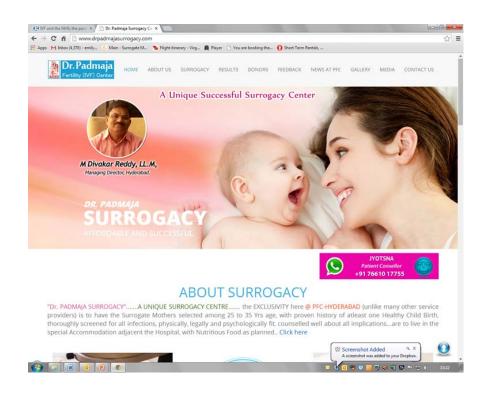


Re A (A Child) [2014] EWFC 55

This case represents a tragedy for all concerned but most particularly for the child at its centre. It is a cautionary tale as to what can go wrong in unregulated surrogacy. mature, balanced and sensitive handling.



Surrogacy overseas









Re W [2013] EWHC 3570 (Fam)

This case is another timely reminder of the importance for intended parents embarking on surrogacy arrangements abroad to ensure they have appropriate legal advice in the jurisdiction where the surrogacy arrangement is entered into.



JP v LP [2014] EWHC 595 (Fam).

the facts of this case stand as a valuable cautionary tale of the serious legal and practical difficulties which can arise where men or women, desperate for a child of their own, enter into informal surrogacy arrangements, often in the absence of any counselling or any specialist legal advice.







MAIN ABOUTUS ADVANTAGES BRANCHES DATABASE BLOG CON

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CAUCASIAN EGG DONORS

WELCOME TO NEW LIFE INDIA FERTILITY CLINIC!

New Life India is a part of New Life Global Network Group that successfully operate in Georg Estonia, Armenia, Israel and India.

New life India is the only European owned clinic in India with a world-renowned team

Does unregulated assisted conception matter?

- le normal conception is not regulated, so does the lack of regulation simply equalise the position of those who do and do not need help with conception?
- People increasingly meet sexual partners online, why not reproductive partners too?



What are the purposes of regulation?

- Safety
- Record keeping
- Facilitate epidemiological research
- Rules governing parentage

do people need information about benefits of regulation? Or incentives?



Importance of education?

- Sex and relationships education in schools?
- Public education function for regulator?
- Significance of google as source of health information and advice?



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Gamete Donation Across International Borders: The Challenge of Ensuring Donor Contact in Europe

Dr. Andrea Mulligan, LLB, LLM(Harv.)

Barrister-at-Law

Adjunct Associate Professor, School of Law, Trinity College Dublin

Reproductive Rights, New Reproductive Technologies, and the European Fertility Market. Santander, 19-20 November 2015



Anonymous Gamete Donation in Europe

- Divisive ethical issue in regulation of assisted reproduction.
- Divergent laws across Europe.
- Circumvention of domestic law Cross Border Reproductive Care
- Imported gametes.

Imported Gametes and the Child's Right to Identity

- What problems arise in ensuring the rights of the child?
- What problems arise for donors?
- Whether effective regulation is possible in absence of international cooperation.

Human Rights Aspects of Anonymous Donation

- The United Nations Convention on the Rights of the Child
- Article 7: "the right to know and be cared for by his or her parents."
- Article 8: "the right to preserve his or her identity, including nationality, name and family relations...without unlawful interference."
- Article 9: right not to be separated from his or her parents.

Human Rights Aspects of Anonymous Donation

- ♦ The European Convention on Human Rights
- Article 8: Right to respect for private and family life
- ♦ Eg: Mikulic v Croatia
 - "Respect for private life requires that everyone should be able to establish details of their identity as individual human beings and that an individual's entitlement to such information is of importance because of its formative implications for his or her personality"

Human Rights Aspects of Anonymous Donation

- ♦ Odievre v France Right not absolute
- SH v Austria
 - ▶ That the Austrian legislator could also find an appropriate and properly balanced solution between competing interests of donors requesting anonymity and any legitimate interest in obtaining information of a child conceived through artificial procreation with donated ova or sperm.

Case Study: Gamete Donation in Ireland

- Assisted Reproduction in Ireland
- Legislative vacuum
- No domestic gamete donation
- Sperm from Denmark
- Eggs from Ukraine and Czech Republic

The Children and Family Relationships Act 2015

♦ (1) The operator of a DAHR facility shall not acquire for use in a DAHR procedure a gamete provided by a donor unless, at the time of such acquisition, he or she also acquires the information specified in subsection (3) in respect of the donor.

•

- ♦ (3) The information referred to in subsections (1) and (2), in relation to the donor concerned, is:
 - (a) his or her name;
 - (b) his or her date and place of birth;
 - (c) his or her nationality;
 - (d) the date on which, and the place at which, he or she provided the gamete;
 - (e) his or her contact details.

The Children and Family Relationships Act 2015

- National Donor Conceived Person Registry
- Minister for Health limited jurisdiction to deny access to details
- Entry on Register of Births
- Clear policy objective: Donor contact and child's right to identity

Effective Vindication of the Right to Identity?

- Practical difficulties
- Substantive vindication of the right
- Protection of donor interests
- What's the alternative?

- Questions and comments welcome
- Dr Andrea Mulligan
 - <u>anmullig@tcd.ie</u>
 - School of Law, House 39, Trinity College Dublin, Dublin 2, Ireland.



SEVERAL LEGAL PROBLEMS OF THE PROCEDURES FOR REPRODUCTIVE HEALTH CONCERNING LEGISLATION THE

REPUBLIC OF BULGARIA

Antonia Ilieva

-Over the past decade, the reproductive health issues have caused more and more debates worldwide, as well as in our country. The topicality of the questions and legal alternatives, associated with the medical practice and theory, place a serious accent on the ensuing rights, obligations and legal consequences which are relevant to various forms of assisted reproduction including the issues of the surrogate mother and the sponsor.

-The legal organization of some of the aspects of reproductive health causes serious difficulties and gaps in the practical enforcing of legislation. Some legal regulations relevant to the considered issues have been included in the Health Act, the Family Code and the Transplantation of Organs, Tissues and Cells Act.

-A legal debate is due to the so called contract settling the affairs between the surrogate mother, the donor of the genetic material and the guardianship over the newborn child. In the present article we will pay attention to the problems relevant to the secret of donation of genetic material and the issue of legal consequences for the participants in the procedure "surrogate motherhood".

- -The issues involving reproductive health as a human right and the medical opportunity of patients with generative disfunction problems are widely covered in the health policy of several governments.
- -Realizing the importance and actuality of the subject, the legislators have made it their aim to create an adequate and flexible legal organization, settling some of the problems. So, how successful the existing legal regulation is itself, has to be a point of valuation from both the medical and legal point of view.
- -The assisted reproduction, as a part of this common definition makes the impression of a lack of concreteness.
- -The legal basis accepted is also a question of social will because this issue penetrates deeply into the moral and ethical views of Bulgarians who are still quite conservative

-As an initial step in the organization, the Bulgarian legislators have postulated partial definitions for the subjects who take part in the procedures - art. article 60, par. Paragraph 2 of the Family Code, where it is said that the mother of the child is the woman who gives birth of the child, including in assisted reproduction.

-Including assisted reproduction, as a part of this common definition gives the impression of a lack of preciseness. Furthermore, the law text says that the motherhood of the woman who gives birth to the child in assisted reproduction cannot be disputed for this reason – art. 60, par. 5 of the FC. - Their will has to be expressed by a General Declaration to the treating doctor /par.1 point 20/.

-Thus, the legal regulation gives rise to a series of questions, concerning the future development of a live newborn child. Because, although at the present moment, the surrogate motherhood in Bulgaria has not been legalized, it does not mean it is not practiced.

-What is more - not being a part of the legal regulation, there are a lot of preconditions for dangerous and illegal actions on the part of the sponsors, medical experts and the surrogate mother, exactly because of the lack of legislation and control.

-In order to clarify the range of the legal consequences ensuing from a reproductive procedure, from the point of view of origin, parental guardianship and inheritance, different medical forms of this kind of conceiving and the legal consequences as a result of that have to be considered.

-An assisted reproduction is needed when the state of the man and the woman does not permit the realization of their reproductive functions in a natural way- art.129 –the Health Act, after getting a written agreement from the people who want to have children- art.130, par. 1 –Health Act. Their will has to be expressed by a General Declaration to the treating doctor/par.1 point 20/.

-Although, not demanded by law, it is preferable to have this declaration in a written form. The existing legal forms of donation find expression in a partnership donation /it is when the partners know each other and have a relation but due to a medical problem, one of them could not fulfil their reproduction functions leading to conception, / and a non-partnership donation – in this situation the donors have no relation between each other and it is possible not to know each other, but after anonymous donorship of genetic material the woman manages to conceive.

- -The procedure of donating male genetic material, and ova and the zygote/fertilized ova/ is coniderably well-regulated by law -After the successful procedure accomplishment and the child's birth the question is: "Who is the baby's real mother?" concerning biological and of moral and ethical aspect as well.
 - -In donorship of zygote the subjects of donorship are separate spermatozoa and the ova. Implanting the zygote into woman's body as a recipient is called Embryo transfer in which the zygote is implanted into the uterus.

-Another procedure is implanting the zygote into the uterine tubes during laparoscopy, as well as implanting a mixture of spermatozoa and ova into the uterine tubes during the process itself – art.18, Regulation №20/2007.

- -Donating a zygote poses the question of the moral and ethical aspects of the procedure. This relates to the so called embryo reduction. The method is to reduce the number of the embryos, implanted into the uterus in order to decrease the risk attending the multifetal pregnancy.
- -In the case of non-partnership donorship it is very important to protect the secret of the male donor legally as well as from a medical point of view because of probable serious problems with a number of serious legal and moral-ethical consequences after its revealing.

-A different kind of the human reproduction is the surrogate motherhood. This is a method in which a woman is carrying another woman's baby and after the child is born she delivers the baby to the biological parents . It is practically known as "a womb for rent", in which a donor zygote is implanted in a woman's womb . In this case numerous legal issues arise because this kind of relationship could not be legally arranged via rent contract.

-The form of legal terms contract which has to be set up is very specific and causes numerous legal and moral-ethical issues. Up to now the legislator has not provided any practical decision or solution of the problem. There are also plenty of issues to what extent such a procedure and interpersonal arrangement could lead to pregnancy via "womb for rent" and what the mechanisms will be to guarantee delivering the newborn baby to the sponsor –parents.

-In the Republic of Bulgaria "surrogate motherhood" is not settled as an operating legal regulation for reproduction. However, this does not mean it is not practiced outside the law. This risk exists because of the unsettled statute of this reproduction activity. Although there's lack of regulation, the practice shows that the possibility for the mother who agreed to bear another woman's child, to disclaim at any moment the undertaken engagement and demand to keep the newborn child, despite the contract agreement with the sponsor

-This possibility, given by the Family Code of the Republic of Bulgaria, contributes in addition to making this form of reproduction harder. According to Bulgarian legislation the fatherhood of a child, born after in vitro fertilization is determined by conception. But this causes numerous hard-to-determine facts which are contestable. In this case the legislator has chosen to apply the presumption for fatherhood – the mother's husband is considered to be the father of the child, born during the time of marriage or 300 days before its ceasing - art.61, par.1 of the FC.

CONCLUSIONS:

- 1. After this partial review it is obvious that our society and legal organization are not still "prepared" to accept and legalize the surrogacy. The lack of specific legal texts, creates some preconditions for illegal actions, in which not only the surrogate mother and the sponsor parents but also the medical experts are involved in some cases, when a physical contact between the man/as a member of the couple/ and the surrogate mother, does not exist.
- 2. Regulation of the in vitro fertilization procedure in the Republic of Bulgaria creates some analogical preconditions for misinterpreting the legal regulation concerning the "surrogate motherhood", which at the present moment has no legal statute in legislature.

CONCLUSIONS:

- 3. The anonymity existing in some forms of in vitro fertilization raises some moral and ethical points, to which the legal theory now does not have adequate answers. The related international practice in this area in addition puts some legal limits and confines regarding the right of information of the newborn baby grown into an adult about its origin. There are different opinions in the practice which put some borders on the legislator's ability to introduce definite liberality to the issue.
- 4. Bearing in mind the importance of the surrogate motherhood issue and the legal obstacles, resulting from it, we think that it is more than necessary for the Legistator to take special notice, regarding some explanatory campaigns, legal consultations for the couples willing to use this kind of reproduction after it is legally regulated, in order to prevent the illegal and vicious practice, concerning this issue.

Thank you for your attention!





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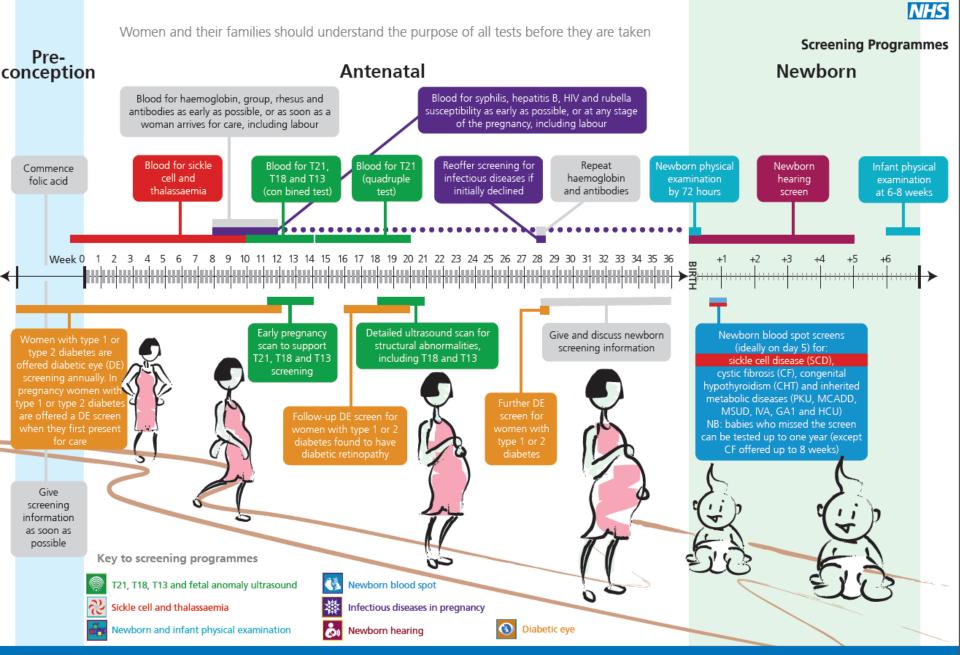
The Ethics of Reproductive Screening: Conceptual and Ethical Challenges





Contents

- 1. Screening for Reproductive Choice
- 2. The Original Paradigm: Prevention
- 3. Moral Objections to PNS2
- 4. The Alternative Paradigm: Meaningful Reproductive Choice
- 5. The Scope of PNS2: Familiar Ethical Issues



Antenatal and Newborn Screening Timeline - optimum times for testing



1. Screening for Reproductive Choice

- ➤ PNT1: Testing for infectious diseases/clinical conditions
 - E.g. Infectious diseases: HIV, Hepatitis B, and Syphilis
 - E.g. Clinical conditions: Anemia, pre-eclampsia, gestational diabetes

- PNT2: Testing for heritable and congenital conditions
 - Chromosomal abnormalities (e.g. T21, T18, T13)
 - Fetal malformations (e.g. Neural tube defects)
 - Recessive autosomal disorders (e.g. thalassemia, sickle cell disease)



2. The Original Paradigm: Prevention

The original (prevention) paradigm for population screening was articulated by Wilson & Junger in 1968

"Improve the health of the population by the early detection and treatment of illness ... " (to avoid suffering)

"... to lengthen the productive life of the population at risk, and in this way to improve the over-all economy" (for social utility)

(Wilson & Junger: 1968)

- Screening programmes evaluated according to overall reductions in mortality, morbidity, and disability
- Physicians may recommend participation (a directive screening offer)

Acceptable for PNT1...

... but not for PNT2!



3. Moral Objections to PNS2

The fetal rights perspective

- ... trivialization of abortion decisions
- Screening services should take into account the presumed interests of the fetus;
 abortion should not become a means of achieving public health goals

(Marquis: 1989)

The feminist rights perspective

- ... pressure or coercion of women
- Reproductive decision making should remain a highly personal and voluntary process; women's reproductive rights and freedoms should not be compromised, even for very serious cases

(Lippman: 1991; Wertz & Fletcher: 1993)

The disability rights perspective

- ... bias in the provision of health services
- Society should be inclusive of people living with disabilities; health services should not offer screening in a way that disadvantages people with disabilities

(Holm: 2008; Parens & Asch: 2003)

A 'preferred choice' should not be implied!



4. The Alternative Paradigm: Meaningful reproductive choice

➤ PNS2 is justified primarily for 'enhancing reproductive autonomy' through the provision of opportunities for reproductive choice:

"... to provide meaningful options for reproductive choice to pregnant women and their partners"

However, the scope of conditions for which it may be offered is limited by the principle of 'avoiding suffering' of future children and prospective parents

"... only if understood as allowing prospective parents to avoid suffering related to living with (a child with) serious disorder or handicaps ... " (de Jong & de Wert: 2015, p46)

... but is this really true in practice?



5. The Scope of PNS2: Familiar Ethical Issues

- > If justified for avoiding suffering...
 - Avoid suffering of future children where life may not be worth living ... only very severe cases (extremely rare)
 - Avoid suffering of prospective parents where there is a high expectation of significant suffering associated with parenthood

... highly personal (no limits to scope)

- If justified for social utility...
 - Mainly serious disorders or disabilities where the cost of medical care and social support is high

Is preferred choice still implied by the scope?



5. The Scope of PNS2: Familiar Ethical Issues

Avoiding suffering Vs.
Social utility
...?

- The importance of the social context
 - 1. Access to non-medical/minor PNT2 outside of the health system?
 - 2. Use of public funds to ensure equitable access to these options?
 - 3. Equitable access to follow-up options:
 - Health care and social support for families affected by disability?
 - ii. Abortion services?



Questions, comments ... or answers?



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The Wilson & Junger Criteria

- The condition sought should be an important health problem
- 2. There should be an accepted treatment for patients with recognized disease
- 3. Facilities for diagnosis and treatment should be available
- 4. There should be a recognizable latent or early symptomatic stage
- 5. There should be a suitability test or examination
- 6. The test should be acceptable to the population
- 7. The natural history of the condition, including development from latent to declared disease, should be adequately understood
- 8. There should be an agreed policy on whom to treat as patients
- The cost of case finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole
- 10. Case finding should be a continuing process and not a "once and for all" project

Wilson & Junger (1968)



The Concept of Screening

- > (1) It is a process of selection with the purpose of identifying those individuals who are at a sufficiently high risk of a specific disorder to warrant further investigation or sometimes direct preventive action. It is usually a preliminary process to offering a diagnostic test and, if required, preventive action.
- (2) It is systematically offered to a population who have not sought medical attention on account of symptoms of the disease for which screening is being conducted. It is normally initiated by medical authorities and not by a patient's request for help on account of a specific complaint.
- ➤ (3) Its purpose is to benefit the individuals being screened. On this basis, mass testing activities such as surveillance for HIV-infection or pre-employment examinations to test fitness for work would not be classified as medical screening.

"... initiated by medical authorities and not by a patient's request for help"

(Wald: 2008, p50)





European Journal of Human Genetics (2015) 23, 1438-1450 © 2015 Macmillan Publishers Limited All rights reserved 1018-4813/15 ^{EJHG}Open

Non-invasive prenatal testing for an uploidy and beyond: challenges of responsible innovation in prenatal screening

This paper has been amended since online publication and a corrigendum also appears in this issue

Wybo Dondorp*, Guido de Wert, Yvonne Bombard, Diana W Bianchi, Carsten Bergmann, Pascal Borry, Lyn S Chitty⁷, Florence Fellmann⁸, Francesca Forzano⁹, Alison Hall¹⁰, Lidewij Henneman¹¹, Heidi C Howard¹², Anneke Lucassen13, Kelly Ormond14, Borut Peterlin15, Dragica Radojkovic16, Wolf Rogowski17, Maria Soller18, Aad Tibben¹⁹, Lisbeth Tranebjærg^{20,21,22}, Carla G van El¹¹ and Martina C Cornel¹¹ on behalf of the European Society of Human Genetics (ESHG) and the American Society of Human Genetics (ASHG)

This paper contains a joint ESHG/ASHG position document with recommendations regarding responsible innovation in prenatal screening with non-invasive prenatal testing (NIPT). By virtue of its greater accuracy and safety with respect to prenatal screening for common autosomal aneuploidies, NIPT has the potential of helping the practice better achieve its aim of facilitating autonomous reproductive choices, provided that balanced pretest information and non-directive counseling are available as part of the screening offer. Depending on the health-care setting, different scenarios for NIPT-based screening for common autosomal aneuploidies are possible. The trade-offs involved in these scenarios should be assessed in light of the aim of screening, the balance of benefits and burdens for pregnant women and their partners and considerations of cost-effectiveness and justice. With improving screening technologies and decreasing costs of sequencing and analysis, it will become possible in the near future to significantly expand the scope of prenatal screening beyond common autosomal aneuploidies. Commercial providers have already begun expanding their tests to include sex-chromosomal abnormalities and microdeletions. However, multiple false positives may undermine the main achievement of NIPT in the context of prenatal screening: the significant reduction of the invasive testing rate. This document argues for a cautious expansion of the scope of prenatal screening to serious congenital and childhood disorders, only following sound validation studies and a comprehensive evaluation of all relevant aspects. A further core message of this document is that in countries where prenatal screening is offered as a public health programme, governments and public health authorities should adopt an active role to ensure the responsible innovation of prenatal screening on the basis of ethical principles. Crucial elements are the quality of the screening process as a whole (including non-laboratory aspects such as information and counseling), education of professionals, systematic evaluation of all aspects of prenatal screening, development of better evaluation tools in the light of the aim of the practice, accountability to all stakeholders including children born from screened pregnancies and persons living with the conditions targeted in prenatal screening and promotion of equity of access.

European Journal of Human Genetics (2015) 23, 1438-1450; doi:10.1038/ejhg.2015.57; published online 18 March 2015

INTRODUCTION

(trisomy 21) and other common autosomal aneuploidies (trisomy level of evidence for the clinical validity of NIPT-based testing for

18 and 13), based on sequencing of cell-free DNA (cfDNA) in In the past few years, several professional societies have issued position maternal plasma. 1-5 The focus of these position statements was on statements on non-invasive testing (NIPT) for Down syndrome NIPT as a promising novel approach to fetal aneuploidy screening, the

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"This document argues for a cautious expansion of the scope of prenatal screening to serious congenital and childhood disorders, only following sound validation studies and a comprehensive evaluation of all relevant aspects."



Potential Harms of PNS2

- Burden of choice (to participate in PNS)
- Anticipation anxiety (PNS)
- False positives, false negatives, unsolicited findings
- Burden of choice (to participate in PND)
- Test related anxiety and anticipation anxiety (PND)
- False positives, false negatives, unsolicited findings, and findings of UCS
- Burden of reproductive choice
- Regret



New Technologies in ART How should they be validated?

Prof Joyce Harper

Genetics, Embryology and IVF Group

Institute for Womens Health University College London











Formerly known as: The Assisted Conception Unit



Disclosure

Partner in:



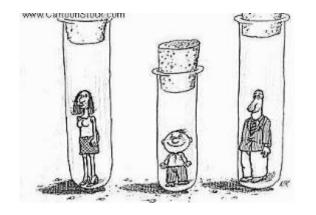
And CEO and Founder of:





Overview

- Techniques old and new
- How should we validate?
- Some examples
- Take home messages





Human Reproduction, Vol.0, No.0 pp. 1-11, 2011

doi:10.1093/humrep/der414

human reproduction

OPINION

When and how should new technology be introduced into the IVF laboratory?

Joyce Harper^{1,*}, M. Cristina Magli², Kersti Lundin³, Christopher L.R. Barratt⁴, and Daniel Brison⁵



REVIEW

The clinical benefit and safety of current and future assisted reproductive technology

Rachel Brown a,*, Joyce Harper b

^a Division of Medicine, University College London, Gower Street, UK; ^b UCL Centre for PG and D, Institute for Women's Health, University College London, UK and The Centre for Reproductive and Genetic Health, UCLH, London, UK ** Corresponding author. E-mail address: rmjbreb@ucl.ac.uk (R Brown).



In vitro fertilisation











The Nobel Prize in Physiology or Medicine 2010 Robert Edwards



UCL

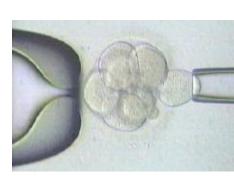
Over 37 years How has technology changed...



- SUZI, ICSI, IMSI, TESA, PESA, MESA
- Slow freezing, vitrification: eggs/embryos
 - Freeze all
- Culture media
 - What is in it?
- Day of transfer
 - Blastocyst
- PGD
- Assisted hatching
- Time lapse



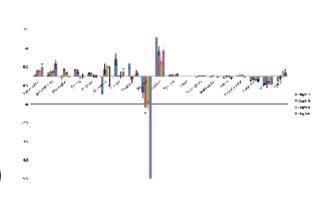






Techniques being developed

- PGS all chromosomes
- Oocyte activation
- In vitro maturation for sperm and eggs
- Amino acid profiling
- Mitochondria donation
- Augment
- In vivo culture (Anecova AneVivo)
- Ovarian stem cells
- Measuring mitochondrial DNA





And some that did not work....

- Ooplasm donation
- Culture media with no serum

- Metabolomics
- PGS using FISH and cleavage stage biopsy



Some future technologies....

Introdución de la contraction de la contraction

- Gonadal tissue transplantation
- Reproductive cloning
- Artificial gametes from ESC or iPS
- Artificial womb
- Gene therapy for infertility







Research and Development

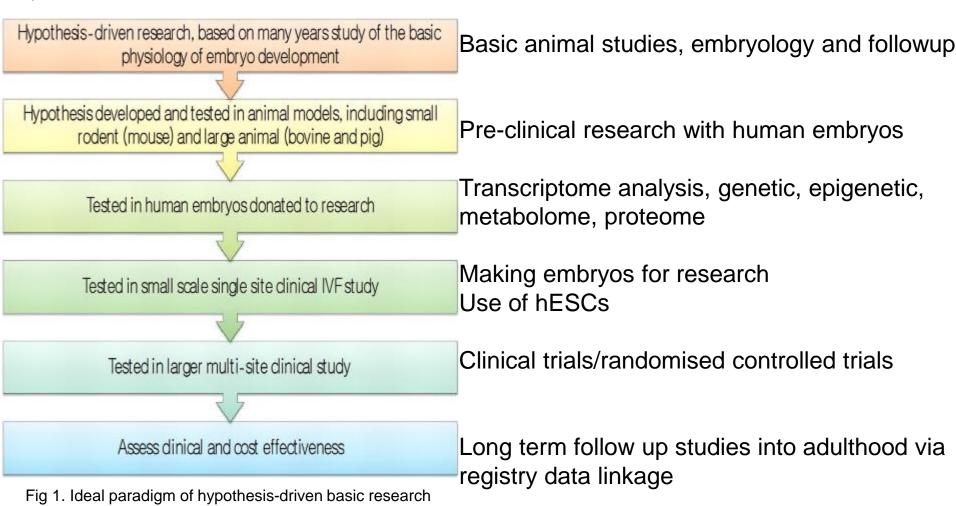
- Why develop a new technology?
- Will it be of benefit to the patient?
- Has it been tested?
- Does it work?
- Is it safe?
- Is it cost effective?

"Every procedure involving application to the human body should be defined as experimental until adequate scientific evidence is provided regarding its safety and efficacy"



Pathway for assessing new technologies?

Harper, 2012





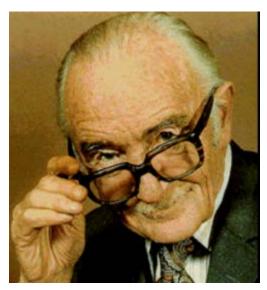
Publish

- Experiments must be published
- But need effective reviewers and editors
- Critical evaluation of paper
- Once published we must all still critically evaluate
- Control group, methods, data, statistics, type of study, significance?



RCT Gold standard

- Blinding
- Randomization
 - Method must be reported
- Control group
- Statistics
- End point in ART should be delivery rate





- Grandfather of evidence based medicine Archie Cochrane
- Meta-analyses

Evid Based Med 2014;19:e13 doi:10.1136/eb-2013-101571

Therapeutics

Systematic review

Current evidence for ART practice: the Cochrane of Cochranes on optimising outcomes



Some Examples

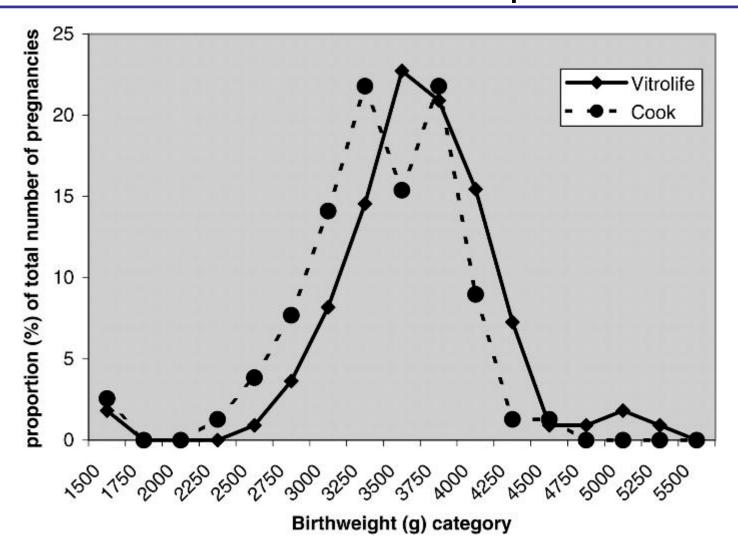


Culture Media

- How did it develop?
- How does it get tested?
- Who decides what new things get added?
- How is it tested to ensure it is safe?
- Do we really know that it improves success rates?
- Developed in mouse embryos not ideal for human



Birthweight distributions of live born singletons resulting from embryo culture in either Vitrolife or Cook sequential media



Dumoulin, J. C. et al. Hum. Reprod. 2010 25:605-612; doi:10.1093/humrep/dep456; Nelissen E.C. et al. Hum. Reprod. 2012 27:1966-1976.





Barker Hypothesis



- Barker, 1994:
- Birth weight is linked to an increased risk of early onset of adult diseases including diabetes, hypertension and cardiovascular disease
- Developmental origins of health and disease:
 DoHaD
- Long term problems with low birth weight babies

UCL

GM-CSF

- Promotes blastocyst development (Sjoblom et al)
- Origio ESHRE 2011 (Ziebe et al, 2013)
 - Increase size inner cell mass
 - Decrease apoptosis
 - Increase metabolism (opposite to Leese)

- Elaimi, Gardner, Kistnareddy and Harper, HR, 2012
 - Dose response curve no positive effect on development
 - No difference in aneuploidy



Regulation of media



HFEA

- Horizon Scanning
- Scientific and Clinical Advances Advisory Committee (SCAAC)



MHRA

- IVF media now class III medical devices, CE marked
 - disclosure of media composition
 - safety assessment, post market surveillance programme
 - register of expert advisors



ESHRE

- Culture media working group
- Expert meeting on IVF Culture Media and Epigenetics
- Meetings with companies



EpiHealth

- EU FP7-funded €3M consortium
- ART child health outcomes epigenetics, imprinting, DOHaD

human reproduction update

IVF culture media: past, present and future

Elpiniki Chronopoulou 1,* and Joyce C. Harper^{2,3}

Human Reproduction Update Advance Access published July 17, 2014

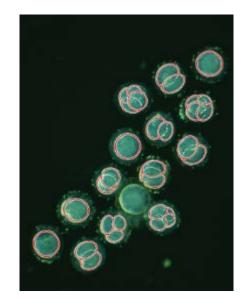
Human Reproduction Update, Vol.0, No.0 pp. 1-17, 2014



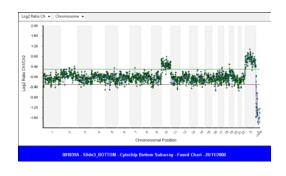
Embryo Selection

- Invasive
 - PGS
 - Mitochondria





- Non invasive
 - Metabolomics
 - Time lapse imaging
 - Morphology







Preimplantation Genetic Screening

TYPE OF PATIENTS – infertile or subfertile



AIMS

- selecting embryo to transfer on chromosome status to (hopefully) improve IVF delivery rate

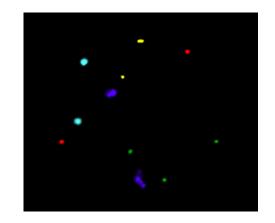
Need to have evidence to show it improves delivery rates

Controversial technique (Harper et al, 2008, 2010a) and many others



Indications for PGS

Advanced maternal age (>35/38)



Recurrent IVF failure (2 or more)

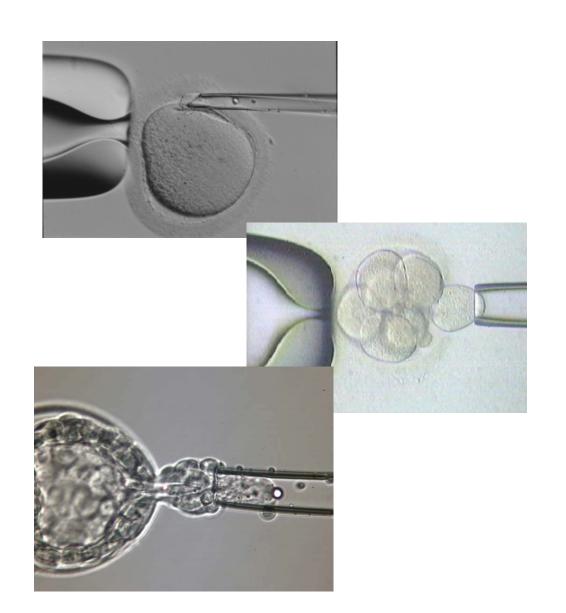
Recurrent miscarriage (karyotypes normal)

Good prognosis



Biopsy

- 1. Polar Body
- 2. Cleavage Stage
- 3. Blastocyst





Diagnosis

(FISH)

Analyse chromosomes

Polymerase chain reaction (PCR)

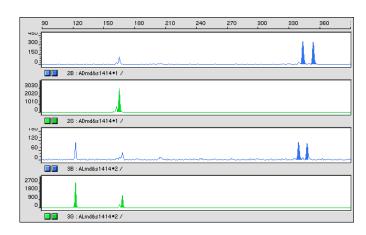
Analyse specific mutation

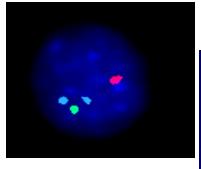
Arrays

Analyse chromosomes and/or genes Array CGH SNP arrays

Sequencing

Sequence the genome









PGS version 1 FISH and cleavage biopsy



Mainly advanced maternal age

Eleven randomised controlled trials showing no benefit

Cleavage stage biopsy maybe not the right time

FISH also has limitations as cannot look at all of the chromosomes

Need RCTs using polar body or trophectoderm biopsy and arrays

What next for preimplantation genetic screening (PGS)? A position statement from the ESHRE PGD Consortium steering committee[†]

Joyce Harper^{1,12}, Edith Coonen², Martine De Rycke³, Francesco Fiorentino⁴, Joep Geraedts², Veerle Goossens⁵, Gary Harton⁶, Celine Moutou⁷, Tugce Pehlivan Budak⁸, Pam Renwick⁹, Sioban SenGupta¹, Joanne Traeger-Synodinos¹⁰, and Katerina Vesela¹¹

approaches. Until results of RCTs using a different biopsy stage and arrays can demonstrate a significant increase in delivery rates, there is no evidence that routine PGS is beneficial for patients with AMA.



PGS version 2



- Good and poor prognosis patients
- Assumes version 1 failed
 - FISH and biopsy stage
- Comprehensive chromosome analysis
- Polar body biopsy
- Blastocyst biopsy
- Freeze all



ESHRE – PGS v2 with polar bodies

uman eproduction ORIGINAL ARTICLE Reproductive genetics

Polar body array CGH for prediction of the status of the corresponding oocyte. Part I: clinical results

Joep Geraedts^{1,*}, Markus Montag², M. Cristina Magli³, Sjoerd Repping⁴, Alan Handyside⁵, Catherine Staessen⁶, Joyce Harper^{7,8}, Andreas Schmutzler⁹, John Collins¹⁰, Veerle Goossens¹¹, Hans van der Ven², Katerina Vesela¹², and Luca Gianaroli³

human reproduction **TECHNICAL NOTE Reproductive genetics**

Polar body array CGH for prediction of the status of the corresponding oocyte. Part II: technical aspects

M. Cristina Magli^{1,*,†}, Markus Montag^{2,†}, Maria Köster², Luigi Muzi¹, Joep Geraedts³, John Collins⁴, Veerle Goossens⁵, Alan H. Handyside^{6,7}, Joyce Harper^{8,9}, Sjoerd Repping¹⁰, Andreas Schmutzler¹¹, Katerina Vesela¹², and Luca Gianaroli¹



Multiple meiotic errors caused by predivision of chromatids in women of advanced maternal age undergoing in vitro fertilisation



ESTEEM centres



- Dept. of Medical Genetics, Athens University, Greece
- Institut Universitari Dexeus, Barcelona, Spain
- S.I.S.Me.R., Reproductive Medicine Unit, Bologna, Italy
- Department of Gynecological Endocrinology and Reproductive Medicine, University of Bonn, Bonn, Germany and Department of Gynaecological Endocrinology and Fertility Disorders, University of Heidelberg, Germany
- Center for Reproductive Medicine, University Women's Hospital, Christian Albrechts-University Kiel, Germany
- Centre for Reproductive Medicine BRUSSELSIVF, Vrije Universiteit Brussel
- Medical Genetics Institute, Shaare Zedek Medical Center, Jerusalem, Israel



PGS v 2 - blastocyst biopsy – good prognosis

Selection of single blastocysts for fresh transfer via standard morphology assessment alone and with array CGH for good prognosis IVF patients: results from a randomized pilot study

45 patients
Control rate low PR 40%

Zhihong Yang¹, Jiaen Liu², Gary S Collins³, Shala A Salem¹, Xiaohong Liu², Sarah S Lyle¹, Alison C Peck¹, E Scott Sills^{1*} and Rifaat D Salem¹

In vitro fertilization with single euploid blastocyst transfer: a randomized controlled trial

Eric J. Forman, M.D., ** Kathleen H. Hong, M.D., ** Kathleen M. Ferry, B.Sc., ** Xin Tao, M.Sc., ** Deanne Taylor, Ph.D., ** Brynn Levy, Ph.D., ** Nathan R. Treff, Ph.D., ** and Richard T. Scott Jr., M.D. ** A.D. ** (A.D. **).

89 patients
Ongoing PR similar both groups
No multiples in study group

Fertil Steril. 2013 Sep;100(3):697-703. doi: 10.1016/j.fertnstert.2013.04.035. Epub 2013 Jun 1.

Blastocyst biopsy with comprehensive chromosome screening and fresh embryo transfer significantly increases

in vitro fertilization implantation and delivery rates: a randomized controlled trial.

Scott RT Jr, Upham KM, Forman EJ, Hong KH, Scott KL, Taylor D, Tao X, Treff NR.

72 patients, including egg donors

Randomised on day 5

At least 2 blastocysts

Controls transferred on day 5

PGS on day 6



Criticisms of RCTs version 2

- Sample size too small
- Comparing apples and lemons
- Not designed with intent-to-treat (only ET)
- Lack of blinding
- Suitable controls
- Power calculations
- End point live birth per egg collection
- BlueGnome web site 2014
 - over 250,000 cycles PGS



PGS version 3 Next Generation Sequencing



The impact of next-generation sequencing technology on preimplantation genetic diagnosis and screening

Julio Martin, Ph.D., "Ana Cervero, Ph.D.," Pere Mir, Ph.D., "Jose Antonio Conejero Martinez, Ph.D., "Antonio Pellicer, M.D., and Carlos Simón, M.D., "

Antonio Pellicer, M.D., and Carlos Simón, M.D., and M.D., a

Evaluation of targeted next-generation sequencing—based preimplantation genetic diagnosis of monogenic disease

Nathan R. Treff, Ph.D., a.b.c Anastasia Fedick, B.S., a.b Xin Tao, M.S., a. Batsal Devkota, Ph.D., a. Deanne Taylor, Ph.D., a.c and Richard T. Scott Jr., M.D. a.c

8 July 2013 Last updated at 00:02

Baby born using new IVF screening technique

By James Gallagher
Health and science reporter, BBC News



Connor Levy's parents had been trying to conceive naturally for four years.

A baby has been born in the US using a new method for screening embryos during IVF which could dramatically reduce costs, researchers report.





^a Iviomics, and ^b Instituto Valenciano de Infertilidad, University of Valencia, Valencia, Spain

^{*} Reproductive Medicine Associates of New Jersey, Morristown, New Jersey; b Molecular Genetics, Microbiology and Immunology, and Cobstetrics, Gynecology, and Reproductive Sciences, University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School, New Brunswick, New Jersey



ESHRE PGD Consortium

Human Reproduction Update, Vol.18, No.3 pp. 234-247, 2012

Advanced Access publication on February 16, 2012 doi:10.1093/humupd/dmr052

human reproduction update

The ESHRE PGD Consortium: 10 years of data collection

J.C. Harper^{1,2,*}, L. Wilton³, J. Traeger-Synodinos⁴, V. Goossens⁵, C. Moutou⁶, S.B. SenGupta¹, T. Pehlivan Budak⁷, P. Renwick⁸, M. De Rycke⁹, J.P.M. Geraedts¹⁰, and G. Harton¹¹

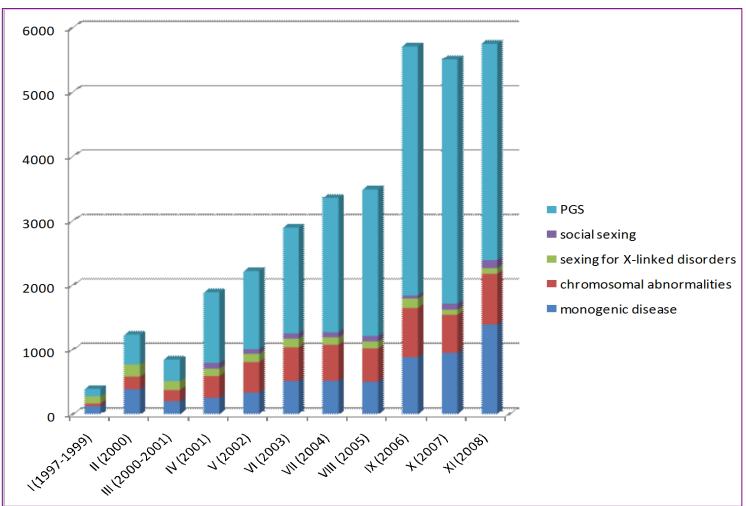






Evolution of cycle data





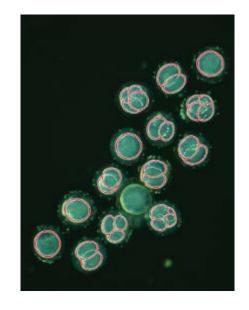
Harper et al, HR, 2010



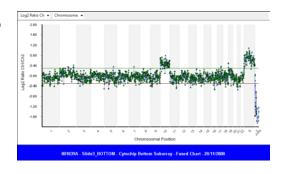
Embryo Selection

- Invasive
 - PGS?
 - Mitochondria ?





- Non invasive
 - Metabolomics ?
 - Time lapse imaging ?
 - Morphology ?







FERTILITY

TREATMENTS

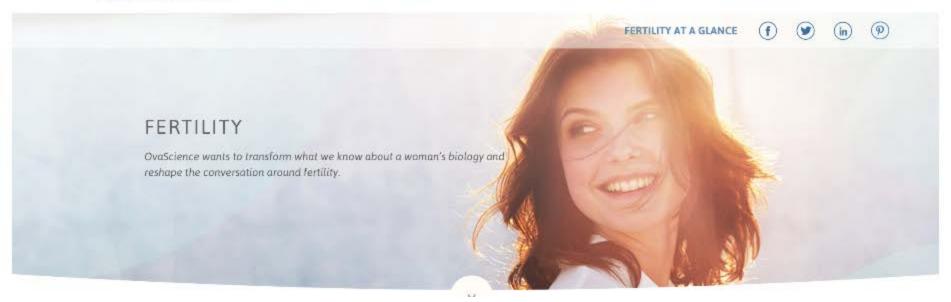
TECHNOLOGY

PATIENTS

NEWS

ABOUT US

INVESTORS







[Myth #1]

"Women are born with a set number of eggs that die over time."

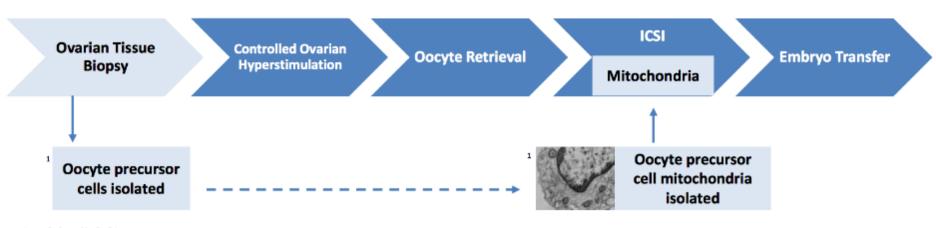
+ REVEAL TRUTH

Egg precursor (EggPCSM) cells – immature egg cells

Potential to form healthy, young eggs







Performed by OvaScience

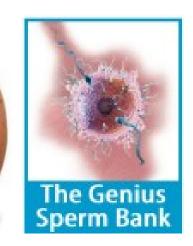
UCL

The future Food for thought...









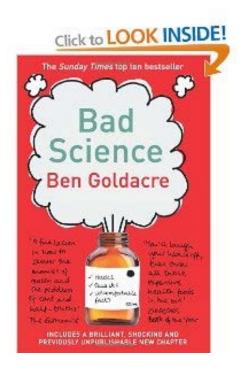




Take home messages

- Cross border treatments
- IVF in developing world
- Well designed R and D
- RCTs
- Follow up of children
- Publish in peer review journals with same results from different clinics or multi-centre studies

Ben Goldacre – Bad Science



Dynamics and ethics of comprehensive preimplantation genetic testing: a review of the challenges

Kristien Hens^{1,2,3,*}, Wybo Dondorp^{1,2}, Alan H. Handyside^{4,5}, Joyce Harper^{6,7}, Ainsley J. Newson⁸, Guido Pennings⁹, Christoph Rehmann-Sutter¹⁰, and Guido de Wert^{1,2,3}

European Journal of Human Genetics

POLICY

Current issues in medically assisted reproduction and genetics in Europe: research, clinical practice, ethics, legal issues and policy

European Society of Human Genetics and European Society of Human Reproduction and Embryology

Joyce Harper*,1, Joep Geraedts², Pascal Borry³, Martina C Cornel⁴, Wybo J Dondorp⁵, Luca Gianaroli⁶, Gary Harton⁻, Tanya Milachich⁶, Helena Kääriäinen⁶, Inge Liebaers¹⁰, Michael Morris¹¹, Jorge Sequeiros¹², Karen Sermon¹³, Françoise Shenfield¹⁴, Heather Skirton¹⁵, Sirpa Soini¹⁶, Claudia Spits¹³, Anna Veiga¹⁷, Joris Robert Vermeesch¹⁶, Stéphane Viville¹⁶, Guido de Wert⁵ and Milan Macek Jr²⁰ on behalf of ESHG, ESHRE and EuroGentest²

HUMAN EMBRYOS: RESEARCH & LEGAL GUARANTEES





JUAN IGNACIO OCHAGAVÍAS COLÁS



SUMMARY

INTRODUCTION

IVF - DONATION

BIOMEDICAL RESEARCH & LEGAL GUARANTEES

ARE WE CLONING HUMAN EMBRYOS?

HUMAN EMBRYOS COULD BE PATENTED?

INTRODUCTION

IN VITRO FERTILIZATION (IVF) TREATMENTS STAND OUT AS A BENCHMARK FOR EMBRYONIC AND BIOMEDICAL RESEARCH

BIRTH OF LOUISE BROWN IN 1978

THIS EVENT WAS A REAL REPRODUCTIVE REVOLUTION, STARTING NEW ETHICAL AND LEGAL CONFLICTS

EUROPEAN SPECIALIZED COMMITTEES

MULTIDISCIPLINARY PERSPECTIVE AND A LEGAL PURPOSE ("BENDA REPORT" IN GERMANY, "WARNOCK REPORT" IN UK AND "PALACIOS REPORT" IN SPAIN)



1ST "CRITICAL" STEP - DONOR ANONYMITY VS CHILDREN'S RIGHT TO KNOW "BIOLOGICAL PARENTAGE"

IVF DONATION

BIOETHIC & LEGAL DEBATE (DIVERSE EXPERIENCES IN EUROPE):

- COMPLETE RECOGNITION OF THE RIGHT TO KNOW "BIOLOGICAL PARENTAGE" (SWEDEN 1984: DONATIONS DECREASED)
- LIMITED RECOGNITION: AUSTRIA
- DONOR ANONYMITY: SPAIN, UK, FRANCE, DENMARK, GREECE, PORTUGAL.
- DOUBLE TRACK SYSTEM: BELGIUM
- MAIN RESULT: REPRODUCTIVE TOURISM
- LEGAL CHANGES (<u>EUROPEAN TRENDS</u>): AIMED TO RECOGNIZE RIGHT TO KNOW BIOLOGICAL ORIGIN → SINCE 2005 IN UK

SPANISH LEGAL SYSTEM

DONOR ANONYMITY: PROTECTED SINCE 1988 (1ST HUMAN ASSISTED REPRODUCTION ACT)

IT KEEPS IN FORCE LAW (2006), BUT THERE IS AN EXCEPTIONAL CHANGE → DONOR IDENTITY MAY BE UNVEILED IN CASE OF:

1- MOTHER'S LIFE IN DANGER
2- BABY OR MINOR'S HEALTH REASONS
3- PENAL PROSECUTION

2ND "CRITICAL" STEP: BIOMEDICAL RESEARCH

VALUES & PRINCIPLES

- (OVIEDO CONVENTION) CONVENTION FOR THE PROTECTION OF HUMAN RIGHTS AND DIGNITY OF THE HUMAN BEING WITH REGARD TO THE APPLICATION OF BIOLOGY AND MEDICINE: CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE COUNCIL OF EUROPE
- ADDITIONAL PROTOCOLS: SUCH AS ON THE PROHIBITION OF CLONING HUMAN BEINGS & CONCERNING BIOMEDICAL RESEARCH

SPECIFIC FIELD OF BIOMEDICAL RESEARCH WITH SURPLUS EMBRYOS FROM IVF (ALSO KNOWN AS SUPERNUMERARY EMBRYOS), THERE IS A RELEVANT DIVERSITY IN LEGAL SYSTEM EU MEMBERS:

ALLOWED: UK, FINLAND, THE NETHERLANDS, BELGIUM, HUNGARY, GREECE, PORTUGAL, SWEDEN, FRANCE, DENMARK, SPAIN AND BULGARIA (IN CHRONOLOGICAL ORDER OF REGULATORY APPROVAL)

NOT ALLOWED: GERMANY, AUSTRIA AND ITALY

EUROPEAN TREND: HEADING LEGAL ACCEPTANCE OF SUCH RESEARCH PRACTICE (THERAPEUTIC PERSPECTIVES)

ANOTHER INFLUENCES

UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS

INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA

UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS

SPANISH CONSTITUTIONAL COURT

HUMAN EMBRYO - LEVEL PROTECTION

GRADUALIST CONCEPTION

IN VITRO EMBRYOS VS TRANSFERRED EMBRYOS TO WOMB: NOT SAME PROTECTION

IT DEPENDS ON BIOLOGICAL DEVELOPMENT

CONSEQUENCE: PREEMBRYO & EMBRYO (LEGAL DIFFERENCES)

2006 ASSISTED HUMAN REPRODUCTION LAW

CASE: SURPLUS EMBRYOS IVF NOT TRANSFERRED TO WOMB

LEGAL OPTION FOR CRYOPRESERVATION IN AUTHORISED ASSISTED REPRODUCTION CENTRES

SPANISH CONSTITUTIONAL COURT (SENTENCE 116/1999) ON CRYOPRESERVATION:

- NOT IMPLANTED PREEMBRYOS ARE NOT HUMAN BEINGS
- IT IS NOT AGAINST HUMAN DIGNITY
- NOT WITHOUT LIMITS OR WITHOUT LEGAL GUARANTEES

WHAT IS NEEDED?

SPECIALIZED ANALYSIS & DISABLE ORIGINAL FUNCIONALITY -> SEVERAL DESTINATIONS (ONE OF THEM IS BIOMEDICAL RESEARCH)

REQUIREMENTS

- ANONYMITY
- CONFIDENTIALITY
- GRATUITY
- NON PROFIT
- INFORMED CONSENT (PREVIOUS TO GENERATE PREEMBRYOS): IT COULD BE MODIFIED BY THOSE INTERESTED

INFORMED CONSENT

WRITTEN, SIGNED BY WOMAN OR COUPLE, DETAILED PURPOSE & LEGAL PROJECT, CONFIDENTIALITY FOR PROGENITOR, RESIGNATION TO RIGHTS LINKED TO RESEARCH

RENOVATION OR MODIFICATION WILL BE REQUIRED AT LEAST EVERY 2 YEARS

IF TO KEEP IN TOUCH WITH INTERESTED IS NOT LIKELY ->
BIOLOGICAL MATERIAL IS <u>AVAILABLE FOR CRYOPRESERVATION</u>
<u>CENTRES</u>

TIME LIMIT: 14 DAYS SINCE FERTILIZATION (DISCOUNTING TIME OF CRYOPRESERVATION)

BIOMEDICAL RESEARCH ACT (2007)

(VALUES) FULL RESPECT TO DIGNITY & HUMAN IDENTITY

(CONDITIONS) DONATION TO RESEARCH WITH EMBRIONIC STEM CELLS:

- LACK OF CAPACITY ON BIOLOGICAL DEVELOPMENT

- NOT POSSIBLE IN CASE OF ABORTION

REQUIREMENTS

EXPRESSED INFORMED CONSENT

TARGET (PROJECT)

CONSEQUENCES (RESEARCH)

MEDICAL INTERVENTION NEDEED TO EXTRACT BIOLOGICAL MATERIAL

NON PROFIT

LIMIT TO BIOMEDICAL RESEARCH WITH EMBRIONIC STEM CELLS

CONSTITUTION OF PREEMBRYOS OR EMBRYOS WITH AN EXPERIMENTAL PURPOSE ->
FORDIDDEN

THERAPEUTIC CLONING

- ETHICAL & LEGAL DEBATE ABOUT <u>CLONING AS A NEW THERAPY</u> USING A NEW TYPE OF EMBRIONIC STEM CELLS (CALLED "CLONING")

- RESEARCHING ON CELULAR THERAPY

VS

REPRODUCTIVE CLONING

(FORBIDDEN IN NATIONAL & INTERNATIONAL LAWS)

- <u>UK PARLIAMENT (2001)</u>: 1ST APPROVING POSSIBILITY OF RESEARCH PROJECTS ON THERAPEUTIC CLONING

BIOMEDICAL PATENTS

HUMAN EMBRYOS PROTECTION AGAINST INDUSTRIAL ACTIVITY:

- 1.- EUROPEAN DIRECTIVE (98/44/CE) & SPANISH PATENT'S LAW (1986): FORBIDDEN PATENTS ON PROCESS OF CLONING HUMAN BEINGS & USING HUMAN EMBRYOS WITH A TRADE OR AN INDUSTRIAL PURPOSE
- 2.- RELEVANT CASE-LAW FROM EUROPEAN COURT OF JUSTICE: HUMAN EMBRYOS ARE PROTECTED FROM INDUSTRIAL ACTIVITY

 (C-377/98 & C-34/10)

