The Human Fertilisation and Embryology Authority: Regulatory Challenges and the Future of Regulation in the UK

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Timeline:

Edwards RG, Bavister BD and Steptoe PC (1969) 

25\textsuperscript{th} July 1978: Louise Brown born
1982: Warnock Committee appointed
Legislative timeline

1985: Unborn Children (Protection Bill) 238 MPs voted in favour, 66 MPs voted against
1986: Unborn Children (Protection) Bill 229 MPs in favour, 129 against.

**Human Fertilisation and Embryology Act 1990**
Amended by Human Fertilisation and Embryology (Research Purposes) Regulations 2001 and Human Fertilisation and Embryology Act 2008
Regulatory challenges

1. Multiple births
2. Storage time limits
3. Avoidance of regulation
4. Abolition
1. Multiple births

Used to be high level of both twin and triplets following IVF.

First policy change 2004: 6th Code of Practice

8.20 (i) Women aged under 40 receive no more than two embryos.

(ii) Women aged 40 or over receive no more than three embryos.
This policy brought down the triplet rate:
• from 3.5% of all IVF births in 1991 to 0.3% in 2006

But the twin rate fell only very slightly:
• from 25.1% in 1991 to 22.3% in 2006.
• the vast majority of these twins were born after two embryo transfer to women under 40 years.
Risks to mothers of twin pregnancies

• Higher rates of miscarriage.
• 20% of women pregnant with twins suffer from hypertension (1–5% if singleton).
• 30% risk of pre-eclampsia (2–10% if singleton).
• 12% risk of gestational diabetes (4% singleton).
• Doubles risk of maternal mortality.
Risks to babies in twin pregnancies

- 48.4% of twins have low or very low birth weight (8.2% of singletons)
- 40-60% of IVF twins are transferred to neonatal care units
- twins are 4 - 6 times more likely to suffer from cerebral palsy than singletons
- twins are 6 times more likely to die in the first year of life than singletons.
Obstacles to single embryo transfer:

• hard to persuade patients that twins are not a good, or even an ideal outcome
• treatment is expensive (NHS funding is scarce, most treatment is privately funded) and stressful
• twins = ready made family
• Some clinicians favour double embryo transfer because it increases success rates (if calculation is live birth per cycle started)
HFEA 2007 multiple birth policy

• Overall aim to reduce the UK IVF multiple birth rate to 10% in stages over a period of years.
• The HFEA will set a maximum multiple birth rate that clinics should not exceed, which will be lowered each year.
• All centres will devise their own ‘multiple births minimisation strategy’ setting out how they will not exceed the maximum multiple birth rate
Maximum multiple birth rate:

Year 1 (2009) → 24% maximum multiple rate
Year 2 (2010) → 20% maximum multiple rate
Year 3 (2011) → 15% maximum multiple rate

2011 also introduced Licence Condition (breach can lead to regulatory sanctions): *The centre shall not exceed the maximum multiple birth rate specified by Directions.*
What is a multiple birth reduction strategy?

- Sets out who should receive elective single embryo transfer (eSET) - younger women (<35 or <37) and women on their first cycle of treatment.
- In 2009, 87.3%, of women receiving eSET were aged 37 or under.
- In 2009 67.3% of women receiving eSET were on their first cycle, 17.1% were on their second
Figure 11: Multiple births, as a proportion of all live births, January 2008 to June 2009.
2. Time limits for storage of gametes and embryos

→ not because of clinical limit on safe storage
→ clinics do not want to have to store indefinitely
→ patients often do not want to make a decision about embryo destruction
→ limit used to be 10 years for gametes, 5 years for embryos, with possibility of extension if ‘prematurely infertile’ or ‘significantly impaired fertility’, until age 55.
Impact of limits?

• Right to export gametes (*R v Blood*) and embryos.
• When nearing end of statutory storage period, possible to apply to export gametes or embryos for use in a country with different rules.
• Human rights considerations favour permitting export.
• Encourage people to have treatment abroad?
Human Fertilisation and Embryology Act 2008: extension of storage period

Now 10 years for both gametes and embryos but possible to extend for 10 years at a time (renewable subject to medical certification) with an absolute maximum of 55 years in total.

→ new issue: intergenerational donation

→ parents storing gametes or embryos for their children (eg girls with Turner’s syndrome)
Does this raise any issues?

Welfare of the child? – in the UK clinics are legally obliged to take account of the welfare of any child to be born before offering treatment services

Consent? – an issue in interfamily donation?

Family roles? – if store embryos for child, daughter give birth to her genetic sister.
3. Avoiding regulation?

Seeking treatment abroad. Why?

• treatment may be cheaper (surrogacy in India; egg donation in the Ukraine)
• avoid waiting lists (egg donation in Spain)
• access treatment that is illegal or unavailable in the UK (sex selection in the US)
Destination Spain: the rise and rise of fertility tourism

UK’s waiting list for donors pushes couples abroad, where thanks to payments for donations there is no shortage

Denis Campbell, health correspondent
 guardian.co.uk, Sunday 22 August 2010 22:00 BST
 Article history
Relax

Get the state-of-the art Treatment while vacationing

Our Accommodations

Location: Petra Health Retreat, home of the International IVF and PGD Centre, is situated in the idyllic location of total tranquility, between Larnaca and Limassol on Southern shores of the Island of Cyprus. Larnaca International Airport is 18 miles and Paphos Airport - 50 miles away. Just drive into village of Zyggi, at the sea front turn left and follow the road along the coast. The Retreat is surrounded by its own organic orchards and fields. Numerous small taverns in nearby fishing villages are famous for their sea food mezes and of course for their warm hospitality.
Ten Egg Guarantee

Due to increased demand from our patients for greater reassurance prior to treatment, Dogus IVF Centre have now introduced a 10 egg guarantee. During every egg donation treatment, we aim to get between 20 and 30 eggs from our donors and so, although it is likely that you will get more than 10 eggs, we are now providing you with the guarantee of at least 10 eggs from your chosen donor to be used solely for your egg donation cycle. This is intended to provide you with the peace of mind that you need to feel comfortable about the treatment you are undertaking. If 10 eggs can not be provided then Dogus IVF Centre will provide a full fresh cycle free of charge. In the entire time that Dogus IVF Centre has been open, we have never collected less than 10 eggs from one of our donor women and so we are confident in providing you with this guarantee.

Whenever possible, we will try and culture your embryos to 5 day blastocyst stage, free of charge, to give you the best possible chances of successful pregnancy.
Avoiding regulation in the UK via web based matching services

HFEA Gamete Donation Consultation 2010

We are concerned about the safety of patients and the quality of care if donation does not take place within a licensed clinic. There are real risks that:

- the sperm sample received is not safe
- the donor is not who they say they are
- women in a vulnerable situation are exploited
- the safeguards that the law offers to parents, to donors and to those who are born do not apply.

There have also been media reports of donors being paid directly by the recipient for their donation.
Co-parents.net

Welcome to Co-Parents.net - Find Your Sperm Donor Or Co-Parent

Ever wondered how you can have a child independently? Meet others who wondered the same! A brand new website which has been created to help anyone who is looking for sperm donation or wants to find a sperm donor, a surrogate or a co-parent to have a child.

Co-Parents.net is a dating site for co-parenting and sperm donors. We are an introduction and social networking website aimed at connecting and introducing men, women and couples who would like to have a baby but haven’t found the right person to have one with yet. You can also communicate with other people directly on our sperm donor forum from all over the world such as USA, UK, Australia and many other regions. If you’re in need of a sperm donor, join our sperm donation forum today! Here at Co-parents.net, we have more than 8500 sperm donors.
Personal Details

Username: dave
Age: 36
Gender: Man
Looking for: Woman
Location: peterborough, England, United Kingdom
About myself:

I'm a genuine self employed gent who can travel most anywhere UK and just wants to help girls who want to get pregnant, don't even mind if you not want me involved after (i prefer that anyway) I'm a clean DRUG & STD free person and will only meet girls who are the same. If interested then mail me some contact details and we can talk about what you want. Yours dave

Physical Appearance

Co-Parent Match Status: Offering donation
Marital Status: Single
Impact of web based donation matching sites

- Enable people to decide on level of contact, perhaps during childhood too.
- Enable people to avoid regulation.
- Lack of information for donor conceived people.
- Unregulated.
- Difficult to enforce rules like 10 family limit if donors donate informally.
Role of national regulator in relation to activities outside its legal remit?

• Information provider? Eg surrogacy, issues around parenthood and nationality

• Warn patients of dangers or risks of unregulated treatment?

• Try to remove barriers to accessing regulated treatments? Eg recent increase in payments to donors in the UK
4. Future challenges

Government announced a ‘bonfire of the quangos’.

192 public bodies to be axed. Including the HFEA.
What is the government’s plan?

Initially to split the HFEA’s functions 3 ways:

- The Register → NHS Information Service
- Fertility treatment → Care Quality Commission
- Embryo research → new single research regulator

Now two way split:

- treatment → CQC
- research → research regulator
Baroness Thornton:

‘The public have learnt to trust the HFEA... UK legislation on these matters is the envy and the blueprint for the world.’

Baroness Deech:

‘The risks will be too great and the gains from the government proposal nil, and our international reputation will suffer.’
Splitting the regulation of fertility treatment and embryo research?

• Embryos used in research are created for use in treatment.
• Consent to donation to research takes place at the same time as consent to fertility treatment.
• Duplicate regulation and inspection/licensing?
• Issues which exist at the intersection of treatment and research may be missed (e.g., freezing policy).
Public support for IVF and embryo research?

→ contingent upon its strict regulation
→ cell nuclear replacement
  hybrid embryos
  saviour siblings
  all relatively accepted in the UK.

But existence of regulator is crucial