Care of poor responders: Ethical aspects...or...when is treatment “futile”?

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No conflict of interest

- commercial relationships : none
- activities that might be perceived as a potential conflict of interest : none

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Setting the scene

Poor responders may be older than average

Poor responders may have prejudiced (« reduced ») ovarian reserve compared to aged matched fertile women

Poor responders may have **more specific knowledge** of their status in view of their experience (« at least one cycle »)

National

Tenfold rise in fertility treatment for over-40s

Steady increase in overall success rate

Watchdog's warning on delaying children

James Randerson
Science correspondent

The number of women undergoing fertility treatment in their 40s has increased tenfold in the last 15 years, according to figures released yesterday by the government's fertility watchdog. In 1991, fewer than 600 women were being treated to help them conceive, but by 2006 the number had risen to 6,000.

The statistics, published by the Human Fertilisation and Embryology Authority, show that although treatments for older women are less successful, the overall success rate has risen steadily from 14% in 1991 to 21% in 2004. Between 1991 and 2006, the number of women over 40 seeking treatment jumped from 9% of the total seeking treatment to more than 15%. In the same period, the proportion of women aged 35 or below undergoing treatment dropped from 58% to 40%.

Sam Abdalla, director of the assisted conception unit at the Lister hospital in west London, said that the reasons for the shift were social rather than medical. Angela McNabb, chief executive of the HFEA, said women needed to be aware that their chances of conceiving drop as they get older. "It's a matter, I think, of concern," she said. According to data collected from all 85 fertility clinics in the country, a woman aged under 35 who embarks on IVF has a 26% chance of having a healthy baby at her first attempt. The same figure for a woman aged 40 to 42 is 9% and by 44 or older it drops to 1%.

"Some women are waiting longer for various reasons to have a family," said Sheena Young, head of business development at Infertility Network UK, a support organisation for IVF patients. "But you should keep in mind that many people are not having access to treatment at the optimum age." Access to fertility treatment on the NHS is patchy around the country and even if it is available, couples may have to wait for treatment.

In an apparent riposte to comments made in the Guardian last week by the fertility expert Lord Winston, Shirley Harrison, the HFEA's chair, said: "I don't subscribe to the view that we have large numbers of clinics run by the greedy or the corrupt."

Lord Winston had said: "It's very easy to exploit people by the fact that they're desperate and you've got the technology which they want, which may not work."

Ms Harrison conceded that patients approach the HFEA with concerns over the cost of treatment. "The cost of treatment is the single biggest issue for patients and more than a third of private patients pay more for their treatment than they expected," she said. One IVF cycle typically costs £4,000-£8,000. She said the HFEA favoured the introduction of costed treatment plans which lay out what fertility procedures will cost from the start.

SocietyGuardian.co.uk/health »

A few words about bioethics: 4 principles

- **Autonomy:** consent for investigations and treatment; information is “**key**”

- **Beneficence V maleficence**: safety: “innovative therapy” eg cytoplasmic transfer; addiction to treatment syndrome, psy aspects (W of C Taskforce)

- **Justice** and access to healthcare

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ART specific ethical aspects

- **Welfare of the child**: minimal v max threshold eg parental health (TF13, H R 22: 2585-88 (2007))
- **new techniques** ...(adopted). without the necessary evaluation of their efficacy, effectiveness, safety and social and economic consequences.
- Their use without **safeguards** re health of the children= premature introduction of drugs without proper research
- **Genetic counselling** may be necessary (+ Down's); min discuss risk for that pregnancy (often older woman)

ART ethico-political aspects: “macro” ethics

- **Justice and access**: single women, women in lesbian couples : new rights under HFE Act but….no funding by PCTs; same if >40 (43 France)
- Access **barriers** to treatment: in UK all care > 40 is in private sector; other criteria BMI, FSH levels
- Conversely, care should not be provided (***merely***) for “financial benefit” (ARSM Ethics committee)

Justice, funding, caring: ...What is futility?

- **Most literature comes from "end of life" care** (Sokol)
- **Goal** specific (futile for what aim?): a child
- **Quantitativ**e: highly unlikely, futile v very poor
- **Qualitative**: would achieved such a poor outcome that deemed best not to attempt it
- Function (**values** of patient); may help couple to come to terms with outlook ("tried everything")

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Definitions ASRM ethics committee

- Futility: < 1% live birth chance; Very poor: 1% to 5%
- Clinicians may refuse in both cases, and should refer...if appropriate
- Decisions should be **patient centred**, not for protecting centres' success rates
- Conclude: Provision of **futile** treatment is not ethically justifiable v inform clear risks v benefits and alternatives when **very poor success rate**

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Success rates and league tables

- HFE A policy decision v not in France (results are amalgamated)
- Headlines not always representative of reality: Abdalla HI, Battacharya S and Khalaf Y. Is meaningful reporting of national data outcome data possible? Human Rep , 25: 9-13 (2010)
- UK LBR per cycle started v Live birth events per 100 E transferred (account of X)
- Inducement to refuse poor outlook, or to channel via other treatment (IUI)

Financial aspects (ASRM)

- Conversely, care should not be provided for “financial benefit”
- Solution is transparency, proper information to the prospective patient re evidence based chance
- Conclusion (FS): If “research” (eg cytoplasmic transfer), should not be paying

How much information is enough?..

Thorough discussions in futile and very poor prognosis cases...

... The lesser the chance, the more information is needed : **proportionality** (in this case "**inverse proportionality**", FS)

Refusal of care

- Refusal to initiate treatment
- Refusal to continue treatment
- Conflict of interest between patients/physicians over “the utility of treatment” (v futility)
- Solution : seek another opinion, counselling; other option (OD)

Clinician autonomy

1. Duty of care may be terminated if no danger to patient , and continuing may cause more harm than discontinuing
2. Lack of “impermissible” discrimination must be shown (ethnic, gender if the law states so as new HFE Act 2008)
3. Then discuss OD, access, source of oocytes; adoption; giving up

2005: identifiable donors

- The Regulations at: http://www.opsi.gov.uk/si/si2004/20041511.htm
- http://www.hfea.gov.uk (all HFEA publications)
- HFEA (Disclosure of donor informatiion regulations) 2004: affects new donors from 1 April 2005, with transition period till 1st April 2006 for old donors (except)

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Egg donation/egg sharing

- To share or not to share? CONSENT
- ? Coercition: Devroey and Pennings, RBM Aug 2006, “subsidised IVF and the effect on the number of egg sharers”
- Offer “irresistible” ?
- When a donation “selling”: proportionality principle

Operating profit

have undermined this trend.

However, globe-trotting patients o
ever occupied a niche. What is getting p
ple excited today is the promise of a bo
in mass medical tourism, as a much big

Table 1: Percentage of patients crossing borders to the six treating countries first 4 countries (where questionnaires number is >100, and next 3 (Q1>50))

	Country of treatment							
Country of Residence	Be	CZ	DK	SLO	SPA	SWZ	TOTAL	
	%	%	%	%	%	%	N	%
Italy	13.0	2.6	0.3	1.0	31.7	51.4	391	31.8
Germany	10.2	67.2	11.9	0.0	10.7	0.0	177	14.4
Netherlands	96.6	0.0	0.0	0.0	3.4	0.0	149	12.1
France	85.0	7.5	0.0	0.0	7.5	0.0	107	8.7
Norway	0.0	1.5	98.5	0.0	0.0	0.0	67	5.5
UK	7.6	52.8	11.3	0.0	28.3	0.0	53	4.3
Sweden	0.0	5.7	92.4	0.0	1.9	0.0	53	4.3
Total n	365	252	154	65	193	201	**1230**	---
%	29.7	20.5	12.5	5.3	15.7	16.3	100.0	---

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Crossing borders, in search of eggs

- ? Responsibility of referring agent
- ? Local “pressure” on donors (disproportionate compensation)
- Worse case: women coerced into donating
- US **oocyte paradox**: paid for “donation”, but not “appropriate” for research
- Spain : highest OD number in Europe (EIM figures), fair “compensation”?

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Mc Kelvey, David, Jauniaux and Shenfield , BROG

How IVF tourists and their multiple babies overload the NHS

By Jenny Hope

Last updated at 12:35 AM on 20th September 2008

Doctors have revealed for the first time the burden on the Health Service caused by women who have multiple births after going abroad for fertility treatment.

New evidence shows that one in four women having triplets or more as a result of IVF treatment had conceived outside the UK.

They travel overseas for IVF because it is cheaper and they are likely to get a higher number of embryos used in treatment, according to fertility specialists who carried out a study at a leading London hospital.

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POLÉMIQUE AUX ÉTATS-UNIS :
DES FEMMES FONT CONGELER LEURS OVULES

UN BÉBÉ POUR PLUS TARD ?

Parce qu'elles se consacrent à leur carrière ou qu'elles n'ont pas trouvé le père idéal, des Américaines font congeler leurs ovules pour différer leur grossesse. Des entreprises ont flairé la bonne affaire. ENQUÊTE ISABELLE DURIEZ

A la terrasse d'un café californien, elle sirote son thé glacé l'air de rien. Pourtant, cette jeune femme à l'allure de poupée Barbie vient de lancer une petite bombe sur le marché de la fertilité aux Etats-Unis. Elle est en train d'investir des millions de dollars dans une nouvelle technologie qu'elle estime « aussi révolutionnaire que la pilule » : la congélation des ovules. « Nos mères ont passé leur vie à essayer de ne pas tomber enceintes. Notre génération, elle, n'arrive pas à faire des bébés. Eh bien, promet-elle, finie la tyrannie de l'horloge biologique. » Selon Christy Jones, fondatrice d'Extend Fertility, les femmes peuvent avoir un enfant quand elles le souhaitent, même après 40 ans, à condition de faire congeler leurs ovules tant qu'elles sont jeunes. Et de préférence dans l'une des sept banques d'ovules qu'elle vient d'ouvrir aux quatre coins des Etats-Unis.

Christy Jones n'est ni médecin ni chercheur, mais une redoutable femme d'affaires qui sait à qui elle s'adresse : aux milliers de trentenaires célibataires qui, comme elle, ont peur de rencontrer trop tard l'homme de leur vie. « Quand j'avais 20 ans, raconte-t-elle, j'imaginais que j'allais faire des études, rencontrer l'homme de ma vie, me marier et avoir des

Conclusions

- What is common in the clinic?
- **Patients**: need evidenced based information, truth about unknowns
- Practitioner: **patients**' interest , Welfare of the child ??? Success rate (private sector> subsidised…?)
- **Patients** centred approach: Success, access and justice
- ? Prevention: ? Vitrification for all, on the NHS or profit making

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Justice and access

- **<u>Equity of access to assisted reproductive technology</u>**

- Medical interventions, both to have a child and to avoid a genetically affected child, should be **funded at least partially** in relatively affluent societies.

- Funding of medically assisted reproduction should be considered in a structured way including **efficiency**, safety and equity to **avoid unjustified discrimination.**

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