

Online Submission by the Association of Women Solicitors

Human Fertilization and Embryology Authority

“The Best Possible Start to Life”

A Consultation document on multiple births after IVF

4 July 2007

1. What is your interest in multiple births after IVF?

Elizabeth Todd/Tilly Rubens, solicitors: We represent an organisation with a key interest in the issues covered by the consultation: The Association of Women Solicitors (National Executive Committee and Law Reform Group).

2. Do you think there is generally too much or not enough emphasis on the health risks for twins and their mothers?

Too much emphasis

X Not enough emphasis

The right degree of emphasis

Why? Please give your reasons below.

The AWS is of the view that there is insufficient emphasis on - and insufficient education about - the health risks of multiple embryo transfer for twins and their mothers. This is especially the case in view of the fact that studies in this area have been ongoing. The risks and failure/success rates of all IVF transfer techniques continue to be scoped and researched. It is now common cause that it has recently been shown by the independent expert group, which produced the report “One Child at a Time”, that being born as part of a set of multiples is the biggest known risk to the health and welfare of children born as a result of IVF.

The risks to the health of the mother and life and health of the children in multiple embryo transfer – including difficult pregnancy, miscarriage, pre-term birth, disability, stillbirth, death within the first week after birth, high incidence of cerebral palsy in IVF children - must remain paramount in guidance/rules of the HFEA. With such high risks, multiple embryo transfer might not be in the best interests of either the mother or the IVF child/children.

It is in the public interest that as much information as possible be given to prospective parents considering IVF treatment; these are life issues, and they will be living the

consequences of any such risks realised after IVF treatment of the woman – in the mother and the child. In accordance with the principles of (i) transparency and (ii) a woman’s “right to know”, the AWS believes that as much information as possible on the risks should be conveyed to the mother and prospective parents. There should be a firm and comprehensive, positive legal obligation on IVF practitioners in this regard. In addition, comprehensive information about life and health risks is about good patient care.

It should also be stated to prospective parents that IVF remains an area where the medical/scientific profession is still identifying the extent of all risks relating to IVF, and scoping their impact. Thus, prospective parents should be enabled to take as informed a decision as possible on these matters.

The HFEA will be aware that recent studies at Guy’s Hospital in London have shown that single embryo transfer has equal success rates to multiple embryo transfer (worst case), and could even have better success rates than multiple embryo transfer (best case). The results of such studies should be emphasised to prospective parents, and especially to women undergoing IVF treatment. This is especially true for an older woman undergoing IVF treatment, if in fact single embryo transfer will be less risky to her health and has success rates equal to or better than multiple embryo transfer. In addition, single blastocyst transfer should be considered as an alternative to multiple embryo transfer.

It should also be noted that where women are given insufficient information of the risks of multiple embryo transfer, this may have malpractice implications for medical professionals. Lack of sufficient information may well ground an action in law, including tort law, in an area where litigation is not in the public interest. This would lead to an impact on the costs of medical practitioner's indemnity and malpractice insurance.

3. Who do you think should decide which women should have just one embryo transferred during IVF?

The HFEA through guidance to fertility centres

Professional bodies (organisations that represent fertility practitioners) through recommendations to fertility practitioners

Only the clinician in discussions with the patient

X Other (please specify below).

Those decision-makers having the most objective approach with the public interest and “best practice” healthcare considerations in mind should most appropriately be empowered to regulate this issue. On the other hand, those with the most self-interest, or vested interests, should not be permitted to decide this question exclusively, though as stakeholders, should be permitted to contribute to the formation of policy based on objective standards, including ethical standards, and information.

The AWS has noted that the IVF industry has been reported to have become over-commercialised. Profitability should never be the prime motivator in such an industry. Accordingly, the clinician in discussion with the patient should not be allowed to decide the matter of embryo transfer exclusively, and the vulnerability of the patient must always be taken into account with regard to her own decision-making.

While it may be appropriate for the HFEA to specify guidance to fertility centres, certain abusive, high-risk procedures should be prohibited. In any guidance documents, IVF practitioners should be required to give women a full range of fertility care options, though it is recognised that commercially, it may not be in the interests of such practitioners to do so. As the HFEA may be aware, Professor Robert Winston has stated that more than 50% of the women referred to IVF Clinics ‘would be better treated by alternatives’ (Professor Robert Winston, “*The IVF Revolution*”).

Thus, the AWS is of the view that the HFEA, as an independent regulator and watchdog of fertility healthcare, should ensure a more holistic and neutral approach be taken to the treatment of infertility of women. IVF treatments should be considered along with alternative fertility-promoting treatments, such as NaProtechnology and the Creighton Model. Treatments and options restoring women to full reproductive health should be encouraged rather than exclusively focusing on the manufacturing of pregnancy via IVF procedures which treat the symptoms of infertility i.e., childlessness.

4. Do you think the current guidance on embryo transfer by the HFEA is about right?

Yes, it is essentially okay

No, it is too strict and limits women’s chances to conceive

X No, it is not strict enough and allows the high number of twin pregnancies to continue

5. Part 4 of this consultation contains regulatory options for the HFEA – which one do you prefer?

X Option 1: HFEA to work with clinics, patients and professional bodies to encourage increased use of single embryo transfer

Option 2: HFEA to set a maximum twin rate for fertility centres

Option 3: HFEA to develop new guidance for the Code of Practice that defines which group of patients should only be offered one embryo for transfer

Option 4: A combination of 2 and 3 above, i.e. clinics could be given an overall set maximum twin birth rate.

If they fail to achieve it or don’t seem to try, they have more detailed guidance imposed on them by the HFEA

None of the above (Please specify what would you like to see happening instead below)

Option 1, however, as stated elsewhere in this response, the AWS believes that women should be given advice on the full range of fertility care and treatment options, including NaProtechnology which has been shown to have higher success rates for pregnancy carried to full term, especially for older women.

It should be recognised that women professionals such as solicitors may often delay pregnancy due to the intense time demands of the legal profession, and, as IVF treatment has been shown to have low success rates, such women should be encouraged to explore alternatives such as NaProtechnology, which are also less costly financially, are non-invasive, which focus on restoring women to full reproductive health, and treat the woman's fertility holistically. Thus, alternative treatments may be especially relevant to professional women who may have delayed child-bearing due to the constraints of careers, or simply because they meet their husbands or partners later in life.

6. The Expert Group investigating the question of multiple births after IVF and the HFEA have discussed some possible obstacles to change. Do you think that any of the factors listed below make it harder to effectively reduce the proportion of twin pregnancies after IVF? (You can tick more than one box)

- The lack and inconsistency of NHS funding for fertility treatments
- The lack of understanding of the risks involved in multiple pregnancies by patients and/or fertility practitioners
- A desire for twin pregnancies by some patients and fertility practitioners
- The way the HFEA produces and presents outcome data for fertility clinics (pregnancy rate per fresh cycle started)
- Competition between fertility centres
- The absence of professional guidance on using single embryo transfer for some groups of patients (guidance developed by the relevant professional bodies like ACE, the BFS and the RCOG)
- Lack of UK data on the use of only one embryo during IVF
- Uncertainty whether the international experience can be applied in the UK
- Lack of understanding of the issue by NHS commissioners
- Inconsistency of embryo grading and selection between fertility clinics
- Inconsistency or freezing protocols and problems with the availability of embryo freezing
- Lack of follow-up of health outcomes for IVF children

Other possible obstacles:

The AWS believes that the following factors should be taken into account and addressed in order effectively to reduce the number of multiple/twin pregnancies following IVF treatment:

1. The lack and inconsistency of NHS funding for fertility treatments

It is reported to be a postcode lottery as to whether some patients may receive only one cycle of treatment, if that, and others are permitted more. There is often uncertainty about future funding and a patient may think that if she can only expect to receive a single cycle of treatment from the NHS, there will be only one chance to become pregnant. Thus, she will want as many embryos implanted into the womb as may be permitted under legislation (i.e., currently 4 embryos) in order to increase her chance of becoming pregnant.

2. **The lack of understanding of the risks involved in multiple pregnancies**

The AWS believes that many patients may not be aware of the nature and extent of the risks to both mother and child/children involved in multiple-births. There is a need for greater educational/health programmes regarding this in appropriate forums and websites.

3. **A desire for twin pregnancies by some patients and fertility practitioners**

See answer to above in relation to fertility practitioners.

In relation to patients, both the financial cost involved per cycle of treatment as well as the emotional uncertainty and discomfort may mean that patients would prefer to complete their family in “one go” by just having twins, however this may be a false understanding due to recent studies which show (1) that single embryo transfer has an equal if not better success rate for pregnancy than multiple embryo transfer, and (2) fewer health risks to the mother and child that are involved with single embryo transfer than with multiple embryo transfer.

4. **Competition between Fertility Clinics**

See comments under paragraph (1) in the answer to Question 7 below regarding competition in the fertility care.

This must particularly be the case where patients are paying privately. The costs involved in fertility treatment per cycle are so high that, clearly, would-be patients will want to know what the success rates are per clinic. If multiple births increase the success rates of a particular clinic then, clearly, this will be a factor such a clinic will wish to advertise in marketing material and on its website.

5. **Lack of UK data on the use of only one embryo during IVF**

The AWS maintains that funding should be made available for further research to be carried out on IVF treatments, as well as for data collection regarding the use of single embryo during IVF research. Recent studies

show this to be a more successful, less risky IVF treatment, and it is accordingly in the public interest to fund further research in this regard.

6. Lack of follow-up health Outcomes for IVF Children

Same answer as immediately above.

7. Is there anything else you want to tell the HFEA about the issues raised in the consultation document?

Yes.

- (1) The AWS notes that it has been reported that a number of academics and practitioners in obstetrics and gynaecology have observed that the IVF industry in the UK is increasingly becoming over-commercialised and corrupt (Lord Winston, *The Times*, 11 June 2007). If this is the case, the best interests of children and women will not be considered paramount, and will be sidelined for the pursuit of profit. IVF is an expensive and invasive procedure, involving embryo destruction, and can have devastating impact upon women undergoing the IVF procedures. A number of women seeking to become pregnant via IVF are emotionally vulnerable, and liable to exploitation. This should be monitored and discouraged, both in relation to single embryo and multiple embryo transfer. Fertility care, like other healthcare sectors, should not be regarded as a commercial industry subject to competition and cost-cutting with “a race to the bottom” by practitioners eager for the “business”. Subjecting the industry to competition is inappropriate, whoosh could lead to the commoditization of the embryo and IVF treatments, and the treatment of patients as “consumers”. Bringing in competition to the fertility industry or allowing commercial issues and the race to profitability to predominate over the best interests of the patient and the child/children to be born, involves assigning economic value to something which has traditionally not been considered in economic terms, creating a market for it with competition over price and quality standards. This is undignified since IVF treatments concerns the creation of new life.
- (2) The AWS has noted the issue of exploitation in egg-harvesting practices: there have been reports of over-harvesting of eggs in some women with devastating consequences. This is not in the public interest, and can further lead to exploitation of women. There are also ethical concerns over the practice of paying women for ova donations – which can lead to the exploitation of women who come from economically deprived backgrounds in the UK and other countries.
- (3) There are a number of ethical issues which remain within the IVF industry - such as the fact that IVF involves the egg donation, the creation of new life, and embryo destruction. Fertility care practices should be constantly and monitored and re-evaluated to guard against abuses.

- (4) Professor William Leger, Professor of Obstetrics and Gynaecology at the University of Sheffield has recently commented in *The Times* (June 2007) that more women are turning to IVF as a lifestyle choice, as a convenience. This may be as a result of the way that the IVF industry is being positioned in the UK. Greater access to education and workplace equality means women are delaying pregnancy, often with unhappy consequences. It may be that professional and older women will need to have more realistic options following the very low success rates of IVF treatment – whether via single or multiple embryo transfer. Professor Ledger has also commented that where possible women should be encouraged to have a child by natural biological means (*Daily Telegraph*, 6 June 2006). Dr David Dunson, National Institute of Environmental Health Sciences in North Carolina has commented that many couples embark on IVF treatment when they could conceive a child by natural means with patience and persistence (*The Times*, 4 July 2006).
- (5) As an independent watchdog and in order to be truly representative of all approaches to fertility treatments, the HFEA should equally promote education of alternative methods to IVF, especially where these have good success rates. They may be more appropriate for women who lead a stressful professional life. These methods will also not introduce unnecessary risks to the health of the IVF child after birth (e.g., higher incidence of cerebral palsy in IVF children). The HFEA should be inclusive and diverse of such approaches to fertility treatments, promoting natural options and not exclusively those falling under the Assisted Reproduction Technology (ART) umbrella. IVF should be viewed as a “last resort” method of conception: patients should be encouraged – with comprehensive information via the NHS – to be treated more holistically – such as is offered with NaProtechnology methods. NaProtechnology methods minimize the health risks to the mother and child as well as the financial burden. Acknowledgment of such considerations remain in the public interest, and the interests of all women.

Elizabeth Todd and Tilly Rubens
On behalf of the National Executive Committee, and Law Reform Group
Association of Women Solicitors
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