

SECOND MEETING OF THE HFEA

MULTIPLE BIRTHS AND SINGLE EMBRYO TRANSFER ADVISORY GROUP

THURSDAY 22 DECEMBER 2005, 10.30AM

ROOM LG09, 21 BLOOMSBURY STREET, LONDON WC1

PRESENT

ADVISORY GROUP MEMBERS

Peter Braude (Chair)	Jan Gerris
Sam Abdalla	Helen Kendrew
David Barlow	Brian Lieberman
Kate Brian	Dave Morroll
Clare Brown	Karl Nygren
Jane Denton	Claire O'Donnell

HFEA STAFF

Juliet Tizzard
Cathleen Schulte
Stephanie Croker
Tim Whitaker
Neelam Sood
James Healy

Also present were Lena Gimbergsson and Didi Braat (presenting) and Richard Kennedy (observing).

1 Apologies and welcome to the meeting

1.1 Apologies were received from Siladitya Bhattacharya, Dave Morroll and Bill Ledger.

1.2 Peter Braude welcomed the two guests, Lena Gimbergsson and Didi Braat, who came to give presentations to the meeting. He also informed the group that two new members have been recruited (although they were not able to attend this meeting): Dr Patricia Hamilton, incoming President of the Royal College of Paediatrics and Child Health, and Dr Alun Elias-Jones, consultant paediatrician at Leicester Royal Infirmary.

2 Minutes of the last meeting

2.1 Members suggested that there may not be evidence to back up the last sentence of paragraph 6.1.

Action: Juliet Tizzard to check this with Siladitya Bhattacharya

2.2 Members suggested that paragraph 6.3 lacked clarity.

Action: Peter Braude to re-draft the paragraph

2.3 Juliet Tizzard updated the group on progress on certain tasks since the last meeting. The report on the incidence and impact of multiple births has been drafted, but is being checked by Siladitya Bhattacharya. It will be available for members to review soon. The Balen abstract (paragraph 6.4 of the minutes) has been reviewed, but more information is needed. Jane

Denton is to meet someone from the NW Thames neonatal network data collection committee to discuss this. Two paediatricians (paragraph 6.5) have agreed to join the group (see 1.2 above).

2.4 Regarding paragraph 8.2, Clare Brown will do a presentation about the funding of treatment in the UK at a later meeting.

3 Tackling multiple births in the Nordic countries: Professor Karl Nygren

3.1 The presentation will be summarised in a separate report.

4 Patient reactions to SET in Sweden: Lena Gimbergsson

4.1 The presentation will be summarised in a separate report.

5 Questions

5.1 Members asked about patients' reactions to the introduction of SET in Sweden. Initially, many were angry and called IRIS, the patient support group, for help. However, IRIS gave the same advice as the doctors, which reassured patients and made them more accepting of the policy.

5.2 When asked whether the success rates in Sweden following eSET are cumulative (i.e. they include frozen embryo transfers), Karl Nygren said they are not. Data on frozen embryo transfers (FETs) will be added soon, meaning that the success rates are likely to increase. The time cut-off for including FETs will be within five years from the fresh cycle (five years is the maximum storage period), although this is still under discussion.

5.3 Members wondered whether the impact of a lower multiple birth rate on ART children has been measured in Sweden. The data has been collected, but findings have not yet been reported. Comparing outcomes for singletons born following eSET with singletons born following double embryo transfer would be a good way of measuring this.

5.4 The social criteria for access to treatment in the Nordic countries were discussed. Approximately half of the clinics in Sweden are under reimbursement from the state and half are privately funded. Privately funded centres do not have social criteria limiting access to treatment. However, centres which are publicly funded do restrict access to women under 38 years old without any children or social problems (though there is a trend towards wider access on this latter criteria).

5.5 The group discussed whether they should be looking at individual clinic data or national data, and it was suggested that because of fluctuation between clinics, national data should be the goal.

5.6 The visiting speakers were asked about the criteria relating to duration of infertility before treatment is offered. The National Institute for Clinical Excellence (NICE) fertility guideline recommends three years after the diagnosis of unexplained fertility, but centres are expected to use their one

discretion. In Holland indications for IVF are after approximately three years, up to the age of 36 and two years for those over 36. In Sweden it is left to the discretion of the clinician.

5.7 The commercial factors were also discussed, as competition among UK clinics is very high. In Denmark there are a high number of commercial clinics and competition does exist, whereas in Sweden it is not an issue.

6 Tackling multiple births in the Netherlands: Professor Didi Braat

6.1 The presentation will be summarised in a separate report.

7 Tackling multiple births in Belgium: Dr Jan Gerris

7.1 The presentation will be summarised in a separate report.

Action: Juliet Tizzard to produce reports

8 Questions

8.1 The use of IUI was discussed among the group, and the difficulties of controlling the multiple birth rates were acknowledged. It was suggested to the group that the only way to avoid high numbers of multiple pregnancies was to perform unstimulated IUI and, if that failed, to offer IVF with elective SET.

8.2 It was acknowledged that funding arrangements differ between the respective countries. Access to publicly funded treatment has been extended in Belgium, but restricted in the Netherlands. In Sweden, reimbursement varies according to region. It was agreed that access to publicly funded treatment is an important factor in making eSET policies a success.

9 Discussion

9.1 Peter Braude outlined some of the findings from the morning presentations and discussion:

- The high incidence of multiple births resulting from infertility treatment is a problem;
- There is evidence from other countries to show that elective use of SET can reduce the incidence of multiple births;
- The morphology of embryos affects the outcome of SET;
- The age of the patient affects the outcome of SET;
- There is insufficient data to show how the use of frozen embryo transfers might increase the success rate of eSET;
- Whether or not patients opt for eSET is more dependent upon advice from their doctor than upon funding or their understanding of the risks of multiple births.

9.2 However, there are a number of factors in the UK IVF sector which may make uptake of eSET slow:

- patients may not see twins as a risky treatment outcome, even after the risks of multiple births have been explained;
- because cumulative success rates are not reported in the UK, eSET would make the success rates of a clinic appear lower, thus undermining clinical support for eSET;
- there is a wide variation in NHS funding policies, which has an impact upon the ability of patients to access services.

9.3 The importance of educating patients is a key factor in the success of a SET policy. In countries that have a SET policy in place, the patients are fully supportive and understand the reasons behind it. In Sweden, wider public awareness of the risks of multiple births and better available of state-funded IVF are contributory factors. However, Swedish research has shown that these factors are not key in a patients' decision to opt for SET. The advice of the professionals is likely to have a greater influence. Funding was seen to be an important issue, especially in the UK as there are discrepancies between funding of treatment between different PCT's.

9.4 It is not only the patients which need educating about the need to reduce twin and multiple pregnancies, but also the clinicians, clinic staff and GPs. There is currently a lack of support for SET, which may prevent patient uptake.

9.5 There is a high level of competition between centres in the UK and the importance of a good position in the 'league' tables for not only attracting patients, but also PCT funding, is key. The introduction of SET may cause success rates to fall, particularly if frozen embryo transfers are not factored in. It was suggested to the group that if the reporting of outcome data changed so that a low multiple birth rate appears as a positive indicator, clinicians will be more enthusiastic about SET.

9.6 There is currently no linkage in the reporting of fresh and frozen cycles. The group identified the need to look at the cumulative pregnancy rate to get accurate figures.

Action: JT to look into the availability of this data

9.7 The presentation, by Jan Gerris, of the Belgium data highlighted the relationship between the morphology of the embryo and the success of the treatment. It also set out the factors which are the most important to take into account when selecting the best embryos for transfer. There is little UK data in this area, and there are a range of factors which are taken into account between different laboratories.

9.8 One solution suggested to the group was for centres to be set a target multiple birth rate which should be met by a certain date. For example, clinics could aim to reduce the twin rate to 20% (the national average is currently ~23%) by 2008, and this percentage will be lowered as clinics reach the target. The group were supportive of this suggestion, however it raised questions about the difficulties of setting the percentage and the need for a strong evidence base to back this up.

9.9 Additional information about the legalities of this approach and the appropriate sanctions would be needed.

Action: JT to invite the HFEA legal advisor to the next meeting

9.10 It was suggested that in circumstances where clinics had not lowered their twin and multiple pregnancy rates, PCT's should raise a levy on clinics which generate twin and multiple pregnancies. However, it is not clear what the mechanism for this kind of charging would be for private clinics and how it could be enforced.

9.11 The group also identified the need for data setting out the costs to the NHS as a result of multiple births caused by infertility treatment.

9.12 The issues of multiple births in IUI were also raised, but it was pointed out that this is outside the remit of the HFEA. The use of hyper-stimulatory drugs in IUI should be discouraged, as this is a major cause of multiple births. There is no way of tracking the number of multiple births which are as a result of IUI.

10 Next meeting

10.1 The next meeting will be held on 9 February 2006, 12-3pm and the following meeting will provisionally be held on 10 April.

11 Communicating the Advisory Group's work

11.1 Juliet Tizzard informed the group that a page on the HFEA's website about the MBSET group will soon be established. She asked for members to send short biographies for this purpose.