

Authority Agenda

Wednesday 25 January 2012

To be held at

Etc Venues, Bonhill House, 1-3 Bonhill Street, London. EC2A 4BX

Lunch 12.15pm

Meeting starts 1.00pm

1. **Welcome, Apologies and Declaration of Interests**
2. **Minutes of 7 December 2011**
[HFEA (25/01/2012) 626]
3. **Chair's Report**
(verbal)
4. **Multiple Births Year 4 Target**
[HFEA (25/01/2012) 629] & Presentation
Decision
5. **Chief Executive's Report**
(verbal)
6. **Directors' Reports**
[HFEA (25/01/2012) 627]
Information
7. **P2010 Evaluation Report**
Presentation
Information
8. **Update on Authority Banking Arrangements**
[HFEA (25/01/2012) 628] & Presentation
Decision
9. **Mitochondria – Public Dialogue Review**
Presentation
Information
10. **Donation Review Update**
Presentation
Information
11. **Update from Committee Chairs**
Information
12. **Any Other Business**

Close 3.30pm

Next meeting: Wednesday 21 March, 2011 London

Venue

etc.venues

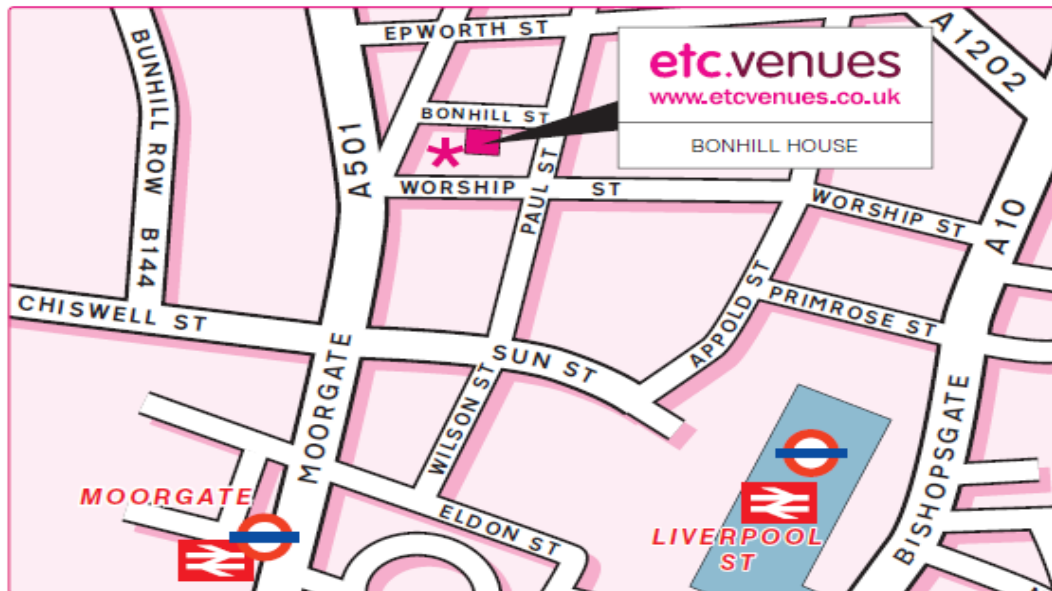
www.etcvenues.co.uk

Bonhill House, 1-3 Bonhill Street, London, EC2A 4BX

Tel: 020 7588 2334 Fax: 020 7588 2326

Email: bonhill@etcvenues.co.uk

Sat nav: 51.522684, -0.086065



Authority Paper

Paper Title	Minutes of Authority meeting 07 December 2011
Agenda Item	2
Paper Number	[HFEA (25/01/2012) 626]
Meeting Date	25 January 2012
Author	Terence Dourado, Committee Secretary
For information or decision?	Decision
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting.

Minutes of the Authority meeting held on 07 December 2011 at ETC Venues, London

Members

There were 18 members at the meeting, 11 lay members and 7 professional members.

Members present

Lisa Jardine (Chair)	Rebekah Dundas	Emily Jackson
Hossam Abdalla	Jane Dibblin	Ermal Kirby
David Archard	Ruth Fasht	Lillian Neville
Debbie Barber	Andy Greenfield	Lesley Regan
Sally Cheshire	Neva Haites	Susan Price
Mair Crouch	Gemma Hobcraft	Alan Thornhill

Apologies

Anna Carragher

Observers

Ted Webb (DH)
Bill Ledger

Staff in attendance

Alan Doran	Rachel Hopkins	Siobhain Kelly
Peter Thompson	Chris O'Toole	Diane Malcolm
Mark Bennett	Emer O'Toole	Nick Spears
Nick Jones	Paula Robinson	

1. Register Research Panel – Report to the Oversight Committee (Authority sitting as the Oversight Committee)

- 1.1. Members agreed to sit as the Register Research Oversight Committee for this item, as set out in Annex A of Section 7 to the Standing Orders.
- 1.2. Peter Thompson, Chair of the Register Research Panel (RRP), presented the paper and reported that following the HFE Act 2008 it was possible for the HFEA, under particular conditions, to share identifiable information with researchers. Members were informed that annually, as Chair to the RRP, he was required to report on the activities and research which the Panel had approved.
- 1.3. Members were reminded that the Panel was formally constituted by The Director of Strategy and Information (Chair), Head of IT and the Head of Business Intelligence (Caldicott Guardian).
- 1.4. The Panel's work had been conducted in coordination with the National Information Governance Board (NIGB) because all requests tended to concern data linkages between the HFEA's data and data-sets overseen by the NIGB. The RRP had processed one application to date but spent more of its time in less formal correspondence with researchers about possible projects on which it might collaborate.
- 1.5. The RRP had approved two studies in the first year of operation: A study about cancer risk in children born after IVF and ICSI, which the Chair confirmed was now active; and a study about cancer risk and mortality in women after IVF, which had made slightly slower progress. The studies approved in 2011 aimed to explore the wider risks of mortality for IVF-conceived children to determine whether linkage via birth registry data was feasible.
- 1.6. The Chair was aware of the fairly protracted consideration of whether, in addition to the anonymised data, the Panel could issue an enhanced data set. Members queried when this might be issued. The Chair confirmed that the full process for the enhanced data set would be presented to the Authority at its meeting in March 2012.
- 1.7. Members queried whether any safeguards were in place to avoid the enhanced data set being breached. The Chair acknowledged that while this type of data could not be treated in precisely the same way as the anonymised data set, a simple application process would be designed by which persons wishing to use the enhanced data would be required to specify the reasons for use and sign an agreement that other data sets would not be linked to.
- 1.8. The Chair informed members that the RRP had shared data with the National Institute for Health and Clinical Excellence (NICE) whose intention it was to develop a prediction model for which patients are most likely to get pregnant using IVF. Furthermore, NICE, as part of its review of fertility treatment, had also used HFEA's data to build their knowledge of the health economics of single versus double embryo transfers. The Chair informed members that the NICE study was due to emerge in 2012 and could potentially make some important observation about the commissioning of services around health economics in this area.

Information

- 1.9. The Authority noted the RRP's report of activities and its decisions during the previous 12 months.

2. Welcome, Apologies and Declaration of Interests

- 2.1. The Chair opened the full Authority meeting, welcoming Authority members, HFEA staff, Bill Ledger as observer and Terence Dourado as Committee Secretary. The Chair thanked members and staff who had participated in the morning workshop session.
- 2.2. Apologies were received from:
 - Anna Carragher
- 2.3. Declarations of interest were made by:
 - Hossam Abdalla (Clinical Director at a licensed clinic)
 - Debbie Barber (part-time Nurse Specialist at a licensed clinic); and
 - Alan Thornhill (Scientific Director at a licensed clinic).

3. Authority Minutes of 19 October 2011

- 3.1. Members agreed the minutes subject to three amendments:
 - In paragraph 2.21 ‘...cases, a larger proportion involved donation by friends or relatives than donation on a purely altruistic basis by women who were not known to the recipients of the eggs’ should be replaced by ‘donors, a significant proportion are known donors, who donate to one person only. Egg sharers provide a very significant proportion of the eggs available to women who do not use a known donor’
 - In paragraph 2.26 ‘members noted that in 2005 the Authority had taken into account the lack of funding for NHS treatment, and that a lack of funding continued to be an issue for some patients.’
 - In paragraph 2.48 ‘none opposed the recommendation, and there was a clear recommendation in favour’ should be replaced by ‘There was a clear majority in favour of the motion, and no one voted against it.’
- 3.2. The Chair agreed to sign the minutes as amended.

4. Chair's Report

- 4.1. The Chair reported that she and the Chief Executive met with Anne Milton, Parliamentary Under Secretary of State (Public Health), on 31 October 2011 to discuss a range of issues including the Donation Review and the Arm's Length Bodies (ALB) review. On 10 November the Chair met with Stephen Dorrell, Chair of the Health Select Committee, to discuss concerns about whether the HFEA being folded into the Care Quality Commission (CQC) would result in the sector being regulated as well as it was now. The Chair informed members that on 1 December 2011 she had attended an ALB Chairs meeting with Earl Howe.
- 4.2. The Chair reported that Professor David Archard had been appointed Chair of Philosophy at Queen's University, Belfast, to commence in June 2012. Members congratulated Professor Archard on his appointment.
- 4.3. The Chair reported on recent changes to committee membership. Rebekah Dundas would join the Compliance Committee, and Sally Cheshire would move from the Licence Committee to the Research Licence Committee in December 2011.

5. Chief Executive's Report

- 5.1. The Chief Executive, Alan Doran, reported that on his behalf, Peter Thompson, Director of Strategy & Information, had attended the ALB Chief Executives' meeting on 2 December 2011.
- 5.2. The Chief Executive reported that the HFEA had received some excellent press coverage following the Donation Review and the decision on donor compensation taken by the Authority on 19 October 2011. The Chair had appeared on BBC Breakfast News, BBC Radio 4's Today programme and the Jeremy Vine show on BBC Radio 2. Subsequently, the HFEA received a greater number of enquiries as did licensed centres.
- 5.3. The Chief Executive reported that he had had an opportunity to communicate with the HFEA's equivalent organisation in Quebec, Canada in October 2011. Like the HFEA they had been debating the issue of fees for donation alongside their own multiple births strategy. The Chief Executive also reported that he had attended a chimera workshop at Harvard University, Boston where he received very positive feedback about the HFEA from the workshop delegates.
- 5.4. The Chief Executive reported on media coverage in other related areas. An Australian report had shown that assisted reproduction had increased by nearly 50% in the last five years in Australia and New Zealand; a study in Holland had found that women receiving IVF treatment faced an increased risk of ovarian cancer – the relative risk was high but the absolute risk remained low. The study nonetheless added to the increasing body of knowledge in this area. Following a full inspection report made to the Licence Committee, the Mail on Sunday had reported on incidents which had taken place at IVF Wales.
- 5.5. The Chief Executive reported that Nick Spears, HFEA Press Officer, would be moving on to the Medicines and Healthcare products Regulatory Agency (MHRA). Mr Spears was thanked for his valuable contribution to the HFEA and members congratulated him on his new appointment.

6. HR Update

- 6.1. Rachel Hopkins, Head of Human Resources, informed members that a short survey had been circulated to all HFEA staff to seek views on key areas of operational matters and to review the new ways of working at the new office. The outcome of the survey indicated that most staff were proud to work for the HFEA but were still getting used to new ways of working; that they felt appreciated for their contribution to the HFEA but less so by line-managers; and that they had felt well informed about the ALB review.
- 6.2. The Head of Human Resources reported that an Away Day followed the survey. Four key themes were discussed throughout the day including - morale, communication, the home-based/office-based working arrangement and workload. Feedback from the Away Day was positive and members of the Senior Management Team (SMT), each with support from one Departmental Head, would lead on exploring a key theme and the related action points arising from the Away Day.
- 6.3. The Head of Human Resources informed members that there was an on-going review of the organisational structure in order to continue to make the required savings; two posts were currently deemed 'at risk' but it was acknowledged that staff had been working well to deliver despite continued pressure as a result of reduced staffing resources.

7. Directors' Reports

- 7.1. The Director of Compliance, Nick Jones, briefly reported on patient feedback and the proxy for speaking to patients and donors about how they might better inform the inspection process. Furthermore, it was reported that a review of interim themes had been deferred by the Compliance team to allow it to consider unannounced inspections, mindful of the available resources and the impact that might have on the Compliance Committee.
- 7.2. The Director of Finance and Facilities, Mark Bennett, reported that the HFEA had recorded 60,000 cycles in a 12 month span for the first time which indicated that the sector remained buoyant. The resulting fee income remained buoyant too and so a decision had been taken that the Authority would not claim £600K of the grant-in-aid it was due from the Department of Health.

8. Implementing and Monitoring the HFEA Policy on Family Limit

- 8.1. Dr Chris O'Toole, Head of Research Regulation, reminded the Authority that it had made various decisions relating to the Donation Review and that the implementation of most of those decisions had been delegated to the Compliance Committee. However, at that time, members requested that the Executive review the HFEA's policy on family limit for the Authority to reconsider at a later date.
- 8.2. Members were reminded they had agreed two decisions about family limit:
 - That the donor family limit should remain at ten or fewer subject to the scope of the donor's consent, and;
 - That donors should optimise, where possible, the use of donor gametes to ensure that they were used to create the number of families that had been intended by the donor's consent.
- 8.3. On donor optimisation, the Head of Research Regulation informed members that failure to optimise the number of families created using a donor's gametes would be against the HFEA's guidance but should not result in a breach by the centre concerned.
- 8.4. On donor family limit, the Head of Research Regulation informed members that the Executive proposed to enhance the donor-usage report by sharing information with all centres about the UK-wide usage of an individual donor's gametes. On the basis that steps would be taken to ensure that donor anonymity was protected where appropriate, there was agreement that sharing information in this way was an essential aspect of making the proposed policy work well. The report, if utilised as intended, should serve to help centres in making best use of donor gametes within the terms of the donor consent given.
- 8.5. While the HFEA would work to ensure centres were fully informed about the usage of an individual donor's gametes, the Centre would ultimately need to satisfy itself that gametes were used within the terms of the consent provided by the donor, and that it was not in breach of the family limit consented to by the donor. Should it come to light that a donor's gametes had been used to create more than ten families it would be incumbent upon the centre to inform the donor and families concerned.
- 8.6. In response to members' concerns on how a non-compliant centre would be determined in such cases, it was noted that a full investigation, following the terms of the Compliance and Enforcement Policy, would be conducted by the Inspectorate and any non-compliance would be a matter for the Licence Committee to consider.
- 8.7. Members noted a discrepancy between the wording of the recommendation in the paper and the corresponding presentation and some inconsistencies within the case studies. The Head of Research Regulation confirmed that the paper's recommendation was the correct version.

- 8.8. Members were informed that the decisions would be implemented by way of an update to Code of Practice guidance notes and a Chair's letter informing all centres about the policy.

Decision

- 8.9. The Authority agreed the following recommendations, as amended::
- That donor usage reports should be enhanced;
 - That the report should include information on the use of a donor's gametes at all centres;
 - That information be shared with all centres;
 - That a register flag should be developed to alert the HFEA register and governance teams where a donor appeared to have been approaching the family limit to which they had consented;
 - Note the potential for regulatory action and sanctions applied by a Licence Committee to be taken where non-compliance with HFEA policies on family limit has taken place.

9. Opening the Register Update

- 9.1. Emer O'Toole, Information Manager, informed members that a similar paper was previously presented to the Authority in October 2010. That paper covered Opening the Register (OTR) information requests since the change in access rights came into force in October 2009. It was reported that since 1 October 2010 there had been 181 requests for register information which represented a 30% increase from the previous year.
- 9.2. Following that Authority meeting, the Register team had published an online survey to seek applicants' views on the OTR process. The feedback, albeit from a small pool of respondents, indicated that the application form and content were clear, the process worked well, and that a drive to promote information about Donor Sibling Link (DSL) would be welcomed.
- 9.3. A member expressed concern that the legislation, which did not allow children brought up by a donor to have any rights to the information held on the register, was an anomaly in the law. Although it was not strictly within the HFEA's remit, the member suggested that the Chief Executive might wish to write to the Department of Health to make them aware of the issue.
- 9.4. The Information Manager reported that on occasion the information held by the HFEA did not correspond with the information held by recruiting centres. Members were reassured that a further step in the process had since been introduced for the registry team to cross-check the register information with recruiting centres prior to release.
- 9.5. Members were informed that since Donor Sibling Link (DSL) had been introduced in October 2009, twelve registered donor-conceived people were now of age to share their contact details with their donor-conceived genetic siblings. There had been no confirmed DSL matches to date. However, as more donors, parents and the donor-conceived became eligible to apply, the Registry team anticipated an increase in information requests. It was noted that all the protocols were in place and any impact on staff workload would be monitored.
- 9.6. A member reminded the Authority that it had previously discussed that a working group be set up to consider family relations in similar contexts and that these issues may fit within the remit of that group.
- 9.7. Another member queried whether the HFEA may have capacity for an information campaign to promote re-registration of donors. It was noted that this might be explored further if a cross-organisation group on donation was established.

- 9.8. It was noted that paragraph 5.3 of the paper stated 'we are dealing with donor conceived.' which should be reworded as appropriate.

Information

- 9.9. Members noted the update, that DSL was a specialised and useful service, and that the survey helped the HFEA obtain a fresh perspective on the patient voice. The Information Manager confirmed that the survey could still be accessed via the HFEA website.

10. High Level Risk Register

- 10.1. Paula Robinson, Head of Business Planning, informed members that the Authority had previously seen the risk register in May 2011, and that regular reviews of the register served to ensure the document was kept up-to-date and reflected on-going developments and controls.
- 10.2. Members were informed about each risk and recent amendments made by the Corporate Management Group. The Executive was mindful that attendance by Authority members would need to be closely monitored to ensure all committees remained quorate. Similarly, internal recruitment chains would be monitored since this carried its own capacity risk; the concern was that as the HFEA recruited internally, more vacancies would arise in other areas of the organisation.
- 10.3. Members were informed that the Executive had considered the possibility of raising the tolerance levels on some risks but had decided against this for the time being.
- 10.4. Members were informed that the re-licensing project and Donation Review had been completed and that major projects such as RBAT (the Risk Tool) and Epicentre were becoming usable. The development of these tools would help to lower the risk of an internal process failure.

Information

- 10.5. The Authority noted the current high level risks and controls and that the High Level Risk Register was kept under review by the Audit and Governance Committee. A member noted that certain aspects of the Risk Register were outside the HFEA's control but that these were being managed, and that there was a level of stability given the environment the HFEA was operating in.

11. Six-month Review of the Business Plan

- 11.1. The Head of Business Planning informed members that the most recent business plan was published at the end of September 2011, and that as a result, the HFEA was not required to publish an update because the content had not changed since that time.
- 11.2. Members were updated on the delivery of the first objective, which focused on core functions and regulatory improvements, and heard that regulation and information functions were on track (i.e. Inspection programmes, responding to Opening the Register requests and Freedom of Information requests), and that the HFEA's statutory role was being delivered.
- 11.3. Progress on the second objective, evidence based policies included a multiple births condition update to the Code of Practice, implemented in October as planned. Further Code of Practice updates, following the outcome of the Donation Review, had been planned for April 2012.
- 11.4. Members were informed about the plan for managing change and preparing for the future (objective 3). The office move had been completed, the embedding of records management project was on-going and collaborative working with other organisations was being developed.

Information

- 11.5. The Authority noted the Six-month Review and that since no changes to the text were required, it was not necessary to re-publish the Business Plan for 2011/12.

12. Draft Business Plan 2012/13

- 12.1. The Head of Business Planning informed members of the draft Business Plan for 2012/13 and briefly stated its objectives. It was noted that the content would be updated in April 2012 because the document would need to include information about delivery in 2011/12. The eSET discount was included in the plan because it was due to be implemented on 1 April 2012 and would need to be monitored. The Business Plan also included information about shared services and efficiency savings. The Department of Health would not be able to sign-off the final version until April 2012.
- 12.2. Members were informed that the Executive met on 9 September 2011 to scope forthcoming projects and to get a sense of what capacity might be required to deliver the projects, whilst mindful of the resourcing implications of their implementation.
- 12.3. Members noted that the Authority had previously discussed the potential for creating a National Strategy Group to improve awareness of donor services, possibly via a website which could be modelled on One At a Time. Members were informed that this proposal would be put to the Department of Health for approval as one possible use for the HFEA's £3 million cash balance.
- 12.4. A member noted that the Quality of Care section should include something about the 'effectiveness and outcomes' for areas such as Multiple Births Strategy, and the 'Corporate Enablers' section might better express how the Authority is supported if a diagram was included.

Information

- 12.5. The Authority approved the draft business plan for 2012-2013 in its current state with the amendments listed at paragraph 12.4. However, it noted that the draft may change prior to submission to the Department of Health as a result of the scoping and capacity planning work being conducted and that if any substantive changes were made, an updated draft would be circulated to Authority members by email.

13. Standing Orders Review

- 13.1. Mark Bennett, Director of Finance and Facilities, explained that the Executive had sought views from the Committee Chairs on what they considered should be updated in the Standing Orders. This was developed through the Corporate Management Group (CMG) and Audit and Governance Committee.
- 13.2. Members were informed that the sections on committee membership and frequency of meetings of some committees had been updated; that paragraph 1.6 on page 115 of the proposed Standing Orders explained how the Executive proposed to generate scope for any future review, and that some definitions had been tidied up at paragraph 7.24 on page 132.
- 13.3. The Executive had considered how the Licence Committee, Research Licence Committee and the Executive Licensing Panel might assess trends in their respective work and how it might better share this information, and would propose a way forward for the Authority to consider.

Decision

- 13.4. The motion required two-thirds of the Authority to be present and required at least half of the Authority to be in favour of the proposed changes to the Standing Orders. This requirement was met; members unanimously approved the Standing Orders and the Director of Finance and Facilities confirmed that the document would be circulated in due course as finalised and active.

14. eSET Reduction in Fees

- 14.1. The Director of Finance informed members that following a decision made by the Authority in May 2010, the Executive had conducted a piece of work on the reduction in fees for centres carrying out Elective Single Embryo Transfer (eSET).
- 14.2. Members were informed that the Executive wished to keep the process simple to avoid chasing what would amount to a small number (approximately 3000-5000) of overall treatments each year. The Executive considered that exclusion cases would be complex and warranted the extra fee. One member queried whether it would be simpler to include the proposed excluded 'embryo donation cycle', and 'cycles where embryos are transferred from another centre or from abroad between the first and subsequent transfer', which amounted to a few hundred cycles per year, to save on administrative costs to centres and the HFEA. The Director of Finance and Facilities confirmed this would be followed up via the Compliance Committee.
- 14.3. The Director of Finance and Facilities informed members that the proposal required that eSET occurred in a first transfer to have taken place after 1 April 2008 and that qualifying treatments would fall after 1 April 2012 (ie. a patient who had eSET after April 2008 and a further treatment after 1 April 2012 would qualify for the reduction in fees). Treatment cycles that would not qualify for the reduction in fees included: cycles where the initial transfer had taken place pre 1 April 2008; cycles that had used donated embryos; where embryos were transferred from another centre or from abroad between the first and subsequent transfer, and FET cycles where the initial transfer was not SET.
- 14.4. Members heard that the Executive had updated centres on developments on eSET fees via the Licenced Centres Panel and would further communicate to centres how the proposal would work, how the proposed billing logic would be implemented, and how and when the HFEA would instate a billing system to reflect that logic.

Information

- 14.5. The Authority noted the update and confirmed that the Compliance Committee would consider the possibility of simplifying the reduction in eSET fees by including the patient cycles which the paper had proposed to exclude, namely:
- Embryo donation cycles
 - Cycles where embryos were transferred from another centre or from abroad between the first and any subsequent transfers.

15. Update on Equality Act Work

- 15.1. Peter Thompson, Director of Strategy and Information, informed members that a paper was presented to the Authority in December 2010 setting out where the HFEA stood in terms of compliance to the Equalities Act and that, like all public bodies, the HFEA was required to comply with it. Although members were of the view that the HFEA was broadly compliant, the Executive considered some areas which the Authority might wish to focus on going forward:
- The Patient Experience: As the regulator the HFEA could try to assist clinics with guidance in respect of the treatment they provide to people with 'protected characteristics'. Also, as requested by members, it could be mindful of other factors such as Article 14 of the European Conventions Act (ie. Right to private and family life), and more research could be done around the patient journey to learn more about the barriers to donation;
 - Monitoring the equalities consequences of key policy decisions: ie. the recent decision on donation might mean that the donor population changes over time;
 - Moving beyond standard socio-economic categories in policy work – e.g. although Impact Assessments were sophisticated in their identification of differing impacts, given some of the issues the HFEA was responsible for, religion and belief may contain more meaningful differences;

- Executive staff and members – e.g. to what extent does the composition of the HFEA's staffing complement compare with similar public sector bodies.
- 15.2. Jane Dibblin, Equalities Champion, informed members of other areas it might wish to explore and act upon such as why barriers to donation occur for certain groups, and raising questions around who was receiving NHS funding for their treatment. The Equalities Champion noted that it would be useful to raise the profile of Equal Opportunities on the HFEA website so that patients might feel more able to approach the HFEA with any related concerns.
- 15.3. Members noted that the HFEA's Welfare of The Child guidance had given an indicative list for clinics including 'mental and physical health problems' which might be vulnerable to an equalities challenge. Similarly, going forward the HFEA may also wish to form a view on how parenthood provisions would apply to trans-gender people as the likelihood of new family configurations increased.

Information

- 15.4. The Authority noted the update and the Director of Strategy and Information welcomed the Authority's comments and agreed to explore the possibilities further.

16. Update from Committee Chairs

- 16.1. Lisa Jardine reported that she had chaired a Remuneration Committee and that Anna Carragher, Licence Committee Deputy Chair, had chaired a Representations Hearing in November 2011.
- 16.2. Emily Jackson reported for the Research Licence Committee (RLC), informing members that the committee had dealt with an on-going renewal application and had been ably assisted by the Compliance team who provided a thorough report for the committee to consider.
- 16.3. Ruth Fasht reported for the Compliance Committee, informing members that the committee had met on 26 October and 23 November 2011. At both meetings the Director of Compliance reported on the work of the compliance team and compliance activity.
- 16.4. The Compliance Committee looked at the Donation workload and how that would be processed, noting that it would not revisit policy decisions but would look at how the Code of Practice should be amended in relation to the Authority's decisions in October 2011 and would review related operational issues. In November the Compliance Committee agreed Code of Practice updates on three areas: upper age limit for sperm donation, conditional donation and family donation. In December it would look at the definition of a clinic visit, would agree a mechanism to allow donors to claim additional expenses, and would agree how compliance with the policies could be monitored and fed back to Authority.
- 16.5. There had been a full discussion on Special Directions, consideration of which is delegated to the Compliance Committee. The Executive was reviewing the current process and exploring how consistency in applications might be promoted, since at present the Committee was noticing gaps in information and differences in interpretation between centres.
- 16.6. The Committee had a long discussion on unannounced inspections and concluded that some form of observational visit would be a positive thing.
- 16.7. The Head of Research Regulation had presented a paper on registration of donors in respect of an audit carried out at all centres which store and/or use donor gametes in the provision of donor services. This was to verify that all donors whose gametes have been used in treatment services after 1 April 2006 were registered with the HFEA as identifiable. The Committee were reassured by the results of the audit which found that, with the exception of one, all centres were compliant with the HF&E Act.

17. Any Other Business

- 17.1. A member raised a matter related to the clinical studies about cancer risk discussed during the RRP item, before members formally convened as the Authority. It was reported that since cancer risk following fertility treatment affected a small percentage of people, and there was a growing literature showing that fertility treatment conveyed a serious risk of cardiovascular disease later in life, whether the Authority might consider funding future studies in this area. The Director of Strategy and Information noted that the HFEA was currently considering whether it ought to be funding or encouraging research in different areas; a list of possible topics for consideration had been assembled and this could form part of that list.
- 17.2. The Chair and Chief Executive thanked Ermal Kirby for his invaluable contribution to the Authority's work, for his compassion and wisdom since joining as an Authority member in 2009, and congratulated him on his new appointment in Cape Town, South Africa.

18. Date of Next Meeting

- 18.1. The Chair confirmed that the next Authority meeting would be held on Wednesday 25 January 2012 in London, and reminded members that it was imperative that they attended all meetings they had committed to attend.

I confirm this to be a true and accurate record of the meeting.

Chair

Date

Authority Paper

Paper Title	Directorates Report
Agenda Item	5
Paper Number	[HFEA (25/01/2012) 627]
Meeting Date	25 January 2012
Author	Paula Robinson
For information or decision?	Information

1. Introduction

1.1. Directorates Report Summary

- 1.2. The attached paper summarises the main performance indicators, with commentary from the most recent CMG review of the document. On this occasion, this was done at the December meeting, and is therefore based on November data; any additional comments (relating to the newer December data) from the CMG meeting on 19 January will be reported to the Authority verbally at the meeting.

1.3. Recommendation

- 1.4. The Authority is invited to note the summarised Directorates Report.

Paula Robinson
Head of Business Planning
January 2012

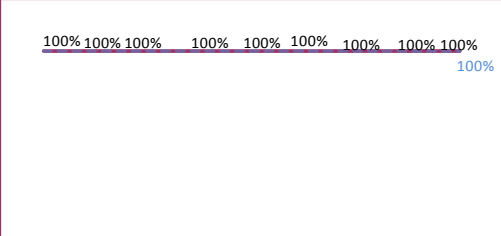

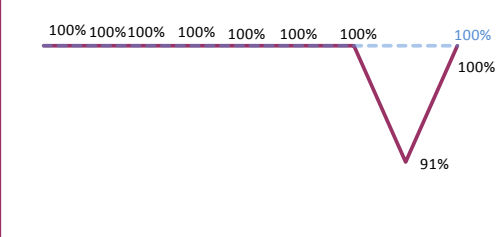

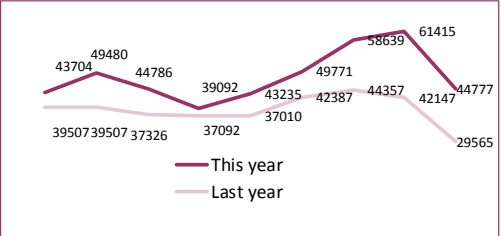
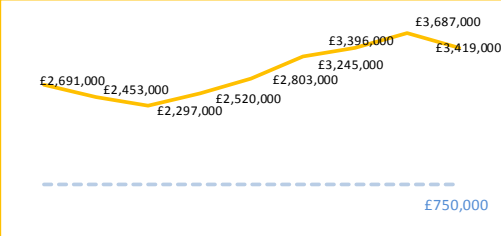
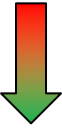
HFEA Performance Scorecard

Key Performance and Volume Indicators: December Performance Data

Indicator	Performance	RAG	Trend since April ¹	Aim ²	Notes
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being communicated to the centre.	65			 Decrease to 60wd or less	KPI: Less than or equal to 60 working days. (New, stretching, target – we need to track this for a few months to see if this is the right target).
Licensing decisions made: - By ELP - By Licence Committees	14 0			No KPI – tracked for workload monitoring purposes	Volume indicator (no KPI target). ELP handling majority of decisions, as intended.
Percentage of PGD applications processed within 4 months (88 working days).	66%			 Maintain at 90% or more	KPI: 90% processed (i.e. considered by LC/ELP) within 4 months (88 working days) of receipt of completed application. (See below for commentary).
Staff sickness absence rate (%) per month.	0.7%			 Maintain 3% or less	KPI: Absence rate of ≤ 3%. Public sector sickness absence rate average is 8 days lost per person per year (3.5%).

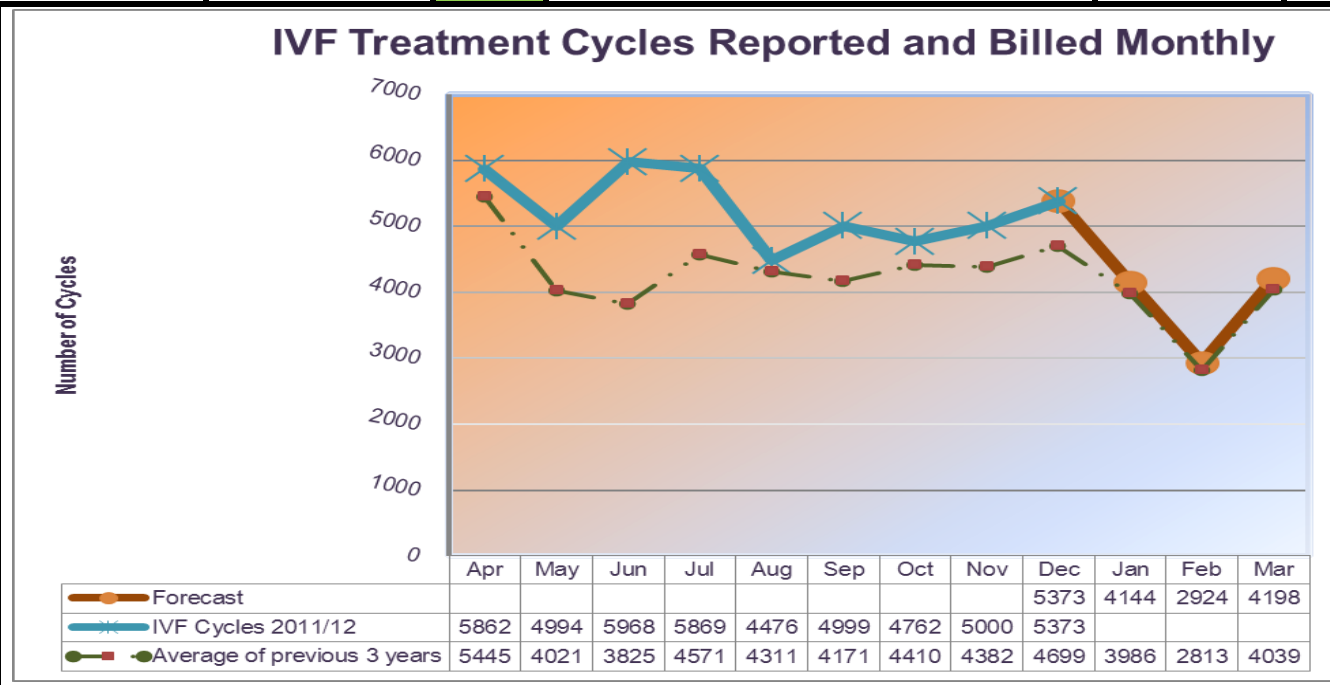
¹ Blue dashed line in all graphs = KPI target level. This line may be invisible when performance and target are identical (e.g. 100%).

² In what direction are we trying to drive performance on this indicator? Are we aiming to exceed, equal, or stay beneath this particular KPI target?

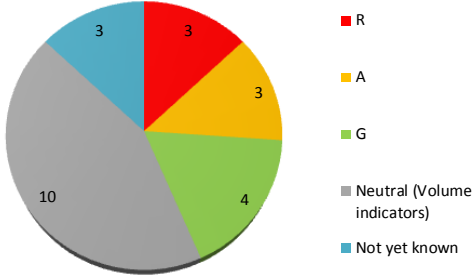
Indicator	Performance	RAG	Trend since April ¹	Aim ²	Notes
<p>Percentage of Opening the Register requests responded to within 20 working days</p>	<p>100%</p>	<p>Green</p>	 <p>A line chart showing performance from April to October. The y-axis represents the percentage of requests responded to within 20 working days. The data points are: April (100%), May (100%), June (100%), July (100%), August (100%), September (100%), and October (100%). A horizontal dashed line is drawn at the 100% mark.</p>	<p>Maintain at 100%</p> 	<p>KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)</p>
<p>Percentage of requests for contributions to Parliamentary Questions answered within Department of Health deadlines</p>	<p>100%</p>	<p>Green</p>	 <p>A line chart showing performance from April to October. The y-axis represents the percentage of requests answered within deadlines. The data points are: April (100%), May (100%), June (100%), July (100%), August (100%), September (100%), October (100%), and November (91%). A horizontal dashed line is drawn at the 100% mark.</p>	<p>Maintain at 100%</p> 	<p>KPI: 100% of PQs to be answered within deadlines set by the Department of Health. In November, one PQ was sent with a 4 hour deadline when all staff were out of the office at an away day. However this was still picked up in time to meet the Ministerial deadline.</p>
<p>Number of visits to the HFEA website (cw previous year)</p>	<p>44,777 (29,565)</p>	<p>Grey</p>	 <p>A line chart comparing website visits between 'This year' (dark purple line) and 'Last year' (light purple line) from April to October. The y-axis represents the number of visits. The data points for 'This year' are: April (43704), May (49480), June (44786), July (39092), August (43235), September (49771), October (58639), and November (61415). The data points for 'Last year' are: April (39507), May (39507), June (37326), July (37092), August (37010), September (42387), October (44357), and November (42147). A legend indicates 'This year' and 'Last year'.</p>	<p>No KPI – tracked for general monitoring purposes</p>	<p>Volume indicator showing general website traffic compared with same period in previous year.</p>
<p>Cash & Bank Balance</p>	<p>£3,419k</p>	<p>Red</p>	 <p>A line chart showing the cash and bank balance from April to October. The y-axis represents the balance in pounds. The data points are: April (£2,691,000), May (£2,453,000), June (£2,297,000), July (£2,520,000), August (£2,803,000), September (£3,245,000), October (£3,396,000), and November (£3,687,000). A horizontal dashed line is drawn at the £750,000 mark.</p>	<p>Decrease to £750k or less</p> 	<p>KPI: Balance not to exceed DH limit of £750k. Fee reduction of 28% implemented 1 October; effective from November invoices; this has stopped it growing.</p>

Indicator	Performance	RAG	Trend since April ¹	Aim ²	Notes
Percentage of invoices paid within 30 calendar days	99%			Maintain at 95% or more ↑	KPI: 95% of invoices to be paid within 30 calendar days
Debts collected within 60 calendar days	93%			Maintain at 85% or more ↑	KPI: 85% of debts to be collected within 60 calendar days from billing

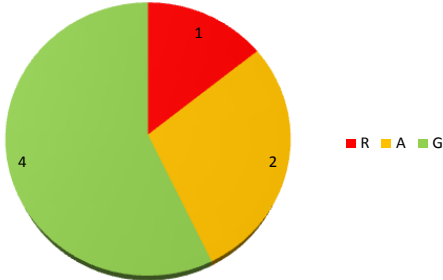
IVF Treatment Cycles Report & Billed



Summary Table:

Scorecard area	KPIs / RAG Status	Red Indicators and Management Comments on Controls
<p>General Note: ‘Grey’ indicators below are volume, rather than performance, indicators. Over time, as we establish baseline performance for new indicators, it will be possible to set appropriate performance targets for some of these. Others will always remain as volume indicators, providing ongoing operational context and management information about capacity and pinch-points.</p>		
<p>Regulatory Operational Performance</p>	 <p>A pie chart illustrating the distribution of KPIs across different RAG (Red, Amber, Green) statuses. The chart is divided into five segments: a large grey segment representing 10 'Neutral (Volume indicators)', a green segment representing 4 'G' (Green) indicators, a red segment representing 3 'R' (Red) indicators, a yellow segment representing 3 'A' (Amber) indicators, and a blue segment representing 3 'Not yet known' indicators. A legend to the right of the chart identifies each color with its corresponding RAG status.</p>	<p>The 3 red indicators are:</p> <ul style="list-style-type: none"> - Average number of working days between ELP/LC date and minutes being finalised: <ul style="list-style-type: none"> o The Christmas period, staff transition and handover following internal recruitment, and representations hearings, one occurring one day after another Licence Committee meeting, all contributed to some delays in finalising minutes. (Meetings in December have to be fitted into the earlier part of the month and therefore there is less time between meetings for minute-writing.) o The ELP and Compliance Committee Secretary also had meetings close together with a large number of items, with certain minutes requiring expediting. o We will look at busy periods like this in the coming year and to try to ensure, insofar as is possible, that this overload of competing priorities does not recur. However Representations Hearings are ad hoc by nature and will always create additional pressure. - Percentage of PGD applications processed within 4 months: <ul style="list-style-type: none"> o Although all applications were considered by Licence Committee within 88 days, two were not completed (i.e. minutes signed off) until the 89th and 93rd day respectively, thus missing the overall KPI. This was due in both cases to a two month delay in obtaining a Peer Reviewer, earlier in the process. - PGD – Percentage of applications for HLA processed within 6 weeks of receipt <ul style="list-style-type: none"> o The target for this has been missed in 3 successive months, for several different reasons. o Centres were asked not to submit applications through the clinic portal during September, since we were upgrading the system. One centre did in fact attempt to submit portal applications during this period, and the HFEA therefore did not receive them (until much

Scorecard area	KPIs / RAG Status	Red Indicators and Management Comments on Controls
		<p>later).</p> <ul style="list-style-type: none"> ○ In one case, a centre was asked to provide additional information before the application could be progressed. This was not provided in time for the KPI (and has still not been provided). ○ One application could not be prepared in time for the ELP meeting on 20 December, owing to workload pressures on the staff member preparing the documentation.
Capacity		<p>The red indicator relates to capacity. Turnover is currently at 26% (compared to a target of 16%). See detailed comments on this below.</p>
Corporate Governance		<p>There are currently no red indicators. All the amber indicators relate to projects in progress. The risks are being managed, and mainly reflect pressure of work and tight timelines.</p>
Information Provision		<p>No red or amber indicators at present.</p>

Scorecard area	KPIs / RAG Status	Red Indicators and Management Comments on Controls
<p>Financial Performance</p>		<p>The red indicator relates to our bank balance, currently at £3,419k. There has been a fall of £268k in the cash balance from November, following the fees reduction and our voluntary suspension of grant in aid. Discussions continue with the Department on proposals to reduce the balance with valuable projects. In the meantime, a proposal is being developed to transfer most of the surplus funds to an account with the Government Banking Service.</p>

CMG Commentary:

- CMG will discuss the December updates at its meeting on 19 January (just after Authority papers are posted out to Members). Therefore the comments below relate to November data, which was considered at CMG in December.
- Overall, performance remains satisfactory and has not shown a dip.
- The recent successful conclusion of two major projects is notable – EpiCentre and the Donation Review.
- All red indicators are explained above. The indicator for the whole licensing process is still being assessed, since this has only been measured since April. It may later prove necessary to amend the KPI. Meanwhile we continue to monitor this from month to month and ensure we understand the contributory factors if the KPI is not reached.
- There has been approximately an 8% increase in treatments.
- Although there has been some staff ‘churn’, turnover would still be considered reasonable. The staff turnover rate (i.e. staff leaving the organisation) increased slightly to 18% in November, and then to 25.67% in December. This is due to a combination of retirements (3 in December), normal resignations, and also people leaving as result of organisational changes and reconfigurations necessary to make efficiencies and budget savings, as required by government. Although the percentage turnover rate has risen, it is worth nothing that it is still below the 27% figure of January 2010, and which prevailed throughout that quarter of 2009/10 – before the general election, budget/recruitment restrictions, and the announcement that the HFEA was to be abolished. However, there is a certain amount of ‘internal churn’, which arises because the recruitment controls require that we look to fill roles internally in the first instance, thus producing a knock-on need for ‘back fill’. This can lead to a prolonged situation of uncertainty while the ‘churn’ is worked through.

Authority Paper

Paper Title	Update on Authority Banking Arrangements
Agenda Item	7
Paper Number	[HFEA (25/01/2012) 628]
Meeting Date	25 January 2012
Author	Rachael Henry, Head of Finance
For information or decision?	Decision
Recommendation	The Authority is requested to review the report and to agree to continue operations banking with Barclays; and to transfer HFEA surplus cash funds to a new account with the Government Banking Service (GBS.)
Resource Implications	Potential maximum loss of interest of c.£3,000 and additional charges of c.£300 per year; some finance team preparation and management time required.
Implementation	February 2012, ongoing management thereafter
Communication	Existing bank (Barclays)
Organisational Risk	A principal objective is to lessen HFEA financial risk attached to the unusually large current surplus being outside GBS. On the basis proper controls are applied, the operational risk of the move is anticipated to be low.
Evaluation	The National Audit Office (NAO) will audit our banking records for finance year 2011/12.

1. Report

Review of Current Banking Arrangements

- 1.1. In accordance with the Authority's Management Statement (Financial Memorandum) the Authority is required to comply with HM Treasury's (HMT's) *Managing Public Money* in respect of its banking arrangements and, specifically, to keep these arrangements under review.
- 1.2. The Authority has held accounts with Barclays for over 10 years and, in general, the service has been good. All receipts and payments are processed through these accounts, and a significant level of integrated standing data has been built up in our accounting and online banking records.
- 1.3. At present the Authority holds cash funds of c.£3.4m. This sum is significantly in excess of the limit set under the Financial Memorandum (£0.75m) and discussions are underway with DH to agree how these funds can be utilised in support of the Authority's work. Nevertheless, HFEA bank balances are likely to remain high for the next two to three years.
- 1.4. We reviewed our banking arrangements with particular regard to the developments in the banking sector since 2008 and their associated risks; the establishment of the Government Banking Service (GBS); the significantly increased pressure on government cash borrowing requirements; and material falls in interest rates (interest received has fallen by 80% to below £4,000 pa.)
- 1.5. In accordance with section 6.1.2 of HFEA Standing Financial Instructions, Authority approval is required for our banking arrangements.

The Government Banking Service

- 1.6. GBS was established in 2008 to provide a modern banking service for the public sector through EU-tendered contracts with Citi and Royal Bank of Scotland Group (RBSG.) GBS holds the working balances of Government Departments and other public bodies in high-level accounts at the Bank of England. These are made available overnight to the National Loans Fund to reduce government borrowing costs and are released daily into the operational accounts of departments and bodies to meet requirements.
- 1.7. *Managing Public Money* sets out a requirement for public sector bodies to use GBS as far as possible, whilst the NAO have also supported this principle on the grounds of good cash management in government and the minimisation of risk.
- 1.8. There is also the possibility that a GBS account could facilitate HFEA participation in finance shared business services.
- 1.9. Applications to open an account with GBS require HMT approval. The minimum cost of running an account is c.£300 p.a. with further charges on a per transaction basis. A full suite of banking services is available, and there is the possibility – subject to HMT agreement – that interest could be paid, albeit at a very low rate.
- 1.10. Based on information from GBS, the bank account that would be most appropriate to the Authority is offered by Citi. With any new account, HFEA finance would seek to obtain the same high standard of operational and management controls as apply to the existing accounts.

Review Conclusions

- 1.11.** The current operation and service from Barclays is good, has worked well for several years and HFEA finance know and trust the operations and management of the account. It is not proposed to change the use of Barclays in respect of clinic and current transactions particularly as, given finance team workload and potential major changes to systems and functions during 2012, it is impractical to close and transfer our current account arrangements due to the disruption internally and for clinics that would ensue.
- 1.12.** Given the unusual size of the surplus funds the HFEA now has; the risks set out in the foregoing report and the opportunity identified to mitigate them; and the HMT requirements set out in *Managing Public Money*, it is not possible to propose to 'do nothing' with the surplus.

2. Recommendation

- 2.1.** The Authority is requested to review the report. The Director of Finance & Facilities recommends Members agree to continuing arrangements with Barclays and to apply to open an account with GBS in order to transfer the existing surplus, estimated at £2.9m, to its management. A working balance of c.£0.5m would be retained at Barclays to fund day to day transactions.

Authority Paper

Paper Title	Multiple Births Year 4 Target
Agenda Item	8
Paper Number	[HFEA (25/01/2012) 629]
Meeting Date	25 January 2012
Author	Hannah Darby, Senior Policy Manager (with contributions from Suzanne Hodgson, Richard Baranowski and Debra Bloor)
For information or decision?	Decision
Recommendation	<p>Members are asked to agree the following recommendations:</p> <ul style="list-style-type: none"> - the Year 4 maximum multiple birth rate is lowered to 10%, to come into effect in October 2012 (with advance warning given immediately), - the Multiple Births Directions 0003 is updated to reflect the Year 4 maximum multiple birth rate, to come into effect in October 2012
Resource Implications	Accounted for in business plan
Implementation	Revised Directions will be issued to centres in July 2012, to come into effect in October 2012.
Communication	Decisions will be communicated to centres via a Chief Executive's letter in January/February and revised Directions in July 2012.
Organisational Risk	High
Evaluation	The policy is evaluated on an annual basis for the Authority to set the next multiple births target.
Annexes	Annex A – Consensus statement on multiple births Annex B – Register data analysis: (i) Twin births by age

	<p>and cycle (ii) The negative correlation between eSET rate and multiple births.</p> <p>Annex C(i) - Funnel plot graphs of centres' year 2 and year 3 performance</p> <p>Annex C(ii) – Explanation of funnel plot graphs</p> <p>Annex D(i) – Centres' performance against Year 2 target</p> <p>Annex D(ii) – Centres' performance against Year 3 and proposed Year 4 target</p>
--	--

1. Introduction

- 1.1.** Multiple births is the single biggest risk to the health and welfare of mothers and children born after IVF. Crucially it is a risk that can be avoided, by transferring one embryo in those women most likely to get pregnant and therefore most at risk of having twins. Twenty-one parties, made up of professional bodies, patient groups and the HFEA, agreed this in a consensus statement in 2007, which was reviewed and re-published in 2011 (Annex A).
- 1.2.** The Authority decided, in 2007, to adopt an outcome-based policy, which allows centres the flexibility to develop their own eSET strategy that is appropriate for them and the patients they treat. A very recent study has confirmed the appropriateness of this approach¹.
- 1.3.** The overall aim of this policy is to reduce the UK IVF multiple birth rate to 10% in stages over a period of years. The Authority decided to set a maximum multiple birth rate that clinics should not exceed, which will be lowered each year and require centres to devise their own 'multiple births minimisation strategy' setting out how they will not exceed the maximum multiple birth rate.
- 1.4.** Since Year 1 of the policy was introduced in January 2009, centres have carried out more eSETs and the multiple pregnancy rate has decreased. The overall pregnancy rate initially increased and is now remaining steady.
- 1.5.** The Authority recognised that the policy would only be successful if it was part of a national strategy to reduce multiple births, supported by the fertility and wider sector. The Multiple Births Stakeholder Group leads this national strategy. It has provided centres with the tools to change clinical practice and share their experiences by developing professional guidelines, the One at a Time website and factsheets, and by holding workshops.
- 1.6.** In September 2011 the Authority had a preliminary discussion about the Year 4 target. Members were reminded that it had always been known that the 15% target rate would prove more stretching for clinics and it seemed possible that a number of clinics would not meet this target. As the target rate came down, clinics would need time to modify their strategies and monitor the effects.
- 1.7.** Members recognised this, but agreed that it was important not to lose the momentum gained thus far. Members were presented with the following options for introducing a Year 4 target:
 - introducing a fourth target in April 2012
 - extending the third target period for a further 6 to 12 months, or
 - extending the third target whilst at the same time setting the fourth target so that clinics could begin to prepare themselves.

¹ Lawlor D & Nelson S. Effect of age on decisions about the numbers of embryos to transfer in assisted conception: a prospective study. The Lancet, January 12, 2012 DOI:10.1016/S0140-6736(11)61267-1.

- 1.8. Members indicated that their view at this time was to take a steady approach to the implementation of the next target and to understand how the sector had responded so far - and what challenges it faced - before making a decision about when to set the fourth year target. The information outlined in section 2 of this paper addresses this and the Authority is now tasked with making this decision.

2. Current situation

- 2.1. This section of the paper provides an overview both of the performance of the sector as a whole (both data trends and national data per target year) and of how centres have performed individually. It then looks at how eSET impacts upon individual patients and presents feedback from a patient questionnaire. Finally it summarises the recent literature regarding eSET.

National data trends

- 2.2. In November 2011 we published an overview of information about patients, treatments and results from 2009 and 2010². The report outlined trends and figures regarding eSET, blastocyst transfers, pregnancy and live birth rates, which are summarised below.

- The proportion of transfers performed which are eSET has increased: from 4.8% of embryo transfers in 2008 to 14.9% in 2010. This increase has been greatest in younger women, particularly those aged 18–34, though the rate of increase in this group has tailed off since mid-2010.
- Since 2008 there has been a steady increase in the percentage of embryos transferred at the blastocyst stage: from 8.6% of all embryo transfers in January 2008 to 31.7%, in December 2010. The proportion of these which are eSET has increased.
- The multiple pregnancy rate has decreased between 2008 and the end of 2010. The decrease is most pronounced in women aged 18–34, who saw the greatest increase in eSET. Although there is variability from month to month, the overall the trend is downwards: from 26.7% overall in 2008, to 21.8% overall in 2010. The multiple birth rate closely follows the multiple pregnancy rate, showing a continuing decline between 2009 and 2010, again most notably in the women aged 18–34.
- The pregnancy rate has remained broadly steady between 2009 and 2010. Between 2008 and 2009 the overall live birth rate per cycle started declined very slightly (25.8% to 25.2% for all ages, using fresh own eggs). The live birth rate has shown a decline year on year before; for instance between 2003 and 2004 it dropped one percentage point. However, it recovered the next year and continued to increase to the levels we see today. This is something we will continue to monitor.

² 'Fertility treatment in 2010 - trends and figures': <http://www.hfea.gov.uk/6771.html>

Overview of national data

- 2.3.** Since the introduction of the policy in January 2009, the proportion of eSET and blastocyst transfers has increased, the multiple pregnancy rate has decreased and, from the data currently available, the overall pregnancy rate has increased, then remained steady. Table 1 provides the key figures. The national average data shows the sector as a whole was well under the Year 1 maximum multiple birth rate of 24%, was under the Year 2 maximum multiple birth rate of 20% and is predicted to be close to the Year 3 maximum multiple birth rate of 15%.

Table 1. Overview of embryo transfers, multiple pregnancies and overall pregnancies³

		Pre-policy (2008 calendar year)	Year 1 ⁴ (Jan 2009 – March 2010)	Year 2 ⁵ (April 2010- March 2011)	Year 3 (April- October 2011)
Proportion of transfers that are eSET (%)	↑	4.8	11.1	15.1	16.3
Proportion of transfers that are blastocyst transfers (%)	↑	13.0	20.6	30.3	35.1 ⁶
Multiple pregnancy rate (%)	↓	26.7	24.1	21.6 ⁷	19.9 ⁸
Multiple birth rate (%)	↓	23.6	21.3	18.6	No data
Overall pregnancy rate (%)	—	29.0	31.4	30.1	No reliable data

Has eSET impacted upon pregnancy rates?

- 2.4.** A common concern is that carrying out more eSET will impact on overall pregnancy rates. Looking at the Year 2 data in Table 2 below, we can see that the overall pregnancy rates for eSET and double embryo transfer (DET) are very similar for all age groups. In fact for younger patients (37 or under) the pregnancy rate is higher for eSET. This may be due to the fact that the majority of eSETs are blastocyst transfers (55-60%). DET has a slightly higher pregnancy rate as patients increase in age. However the

³ Due to data submissions and verification, many of the figures for previous years are slightly different from the figures published in the paper presented to the Authority in December 2010.

⁴ Births data has been verified until the end of 2009; pregnancy data has been verified until the end of 2010

⁵ Pregnancy data from 01/01/2011 unverified

⁶ These blastocyst and eSET rates are not affected by missing outcomes data.

⁷ Data from the risk tool extracted in October 2011

⁸ Data from the risk tool extracted in October 2011

number of patients having eSET in the slightly older age groups is small, so we cannot draw firm conclusions from this.

- 2.5. It is important to remember that there are still 3 to 4 times more DETs than eSETs, the majority of which are cleavage stage transfers (~70-80%). Centres will be focusing primarily on younger women having eSET, as these are the women who are most at risk of a multiple pregnancy. Crucially, Table 2 also shows the high multiple pregnancy rates from DET. It is not just a question of weighing up the success rates; we are also trying to minimise the risk to patients and children born of multiple pregnancies.

Table 2. Overall pregnancy rates (per embryo transfer) and multiple pregnancy rates in Year 2 of the policy from April 2010 – March 2011

Patient age	eSET preg. Rate	<i>eSET multiple preg. Rate</i>	DET preg. Rate	<i>DET multiple preg. rate</i>
Under 35	38.7%	1.7%	37.7%	34.7%
35 – 37	36.1%	1.8%	33.7%	28.6%
38 – 39	27.0%	2.9%	28.5%	22.3%
All ages	36.2%	1.8%	32.2%	29.8%

- 2.6. The pregnancy rates from blastocyst transfers are higher. The average pregnancy rates for younger patients are comparable for blastocyst eSET and blastocyst DET (Table 3). We can see that the multiple pregnancy rates from double blastocyst transfers are unacceptably high.

Table 3. Overall pregnancy rates (per blastocyst transfer) and multiple pregnancy rates from blastocyst transfers in Year 2 of the policy from April 2010 – March 2011⁹

Patient age	eSET blastocyst preg. Rate	<i>eSET multiple preg. Rate</i>	DET blastocyst preg. Rate	<i>DET multiple preg. rate</i>
Under 35	46.0%	1.7%	43.3%	43.0%
35 – 37	42.6%	1.6%	41.3%	39.9%
38 – 39	32.3%	2.0%	37.5%	32.1%
All ages	43.4%	1.7%	39.8%	38.5%

⁹ Table 3 is a subset of table 2 data; the results in table 2 are likely to be being pulled up by the blastocyst results themselves

- 2.7. It is also worth noting that about 70% of pregnancies and multiple pregnancies following transfer of a single embryo are from eSBTs. This indicates that there may be a higher rate of monozygotic twinning following blastocyst transfer, although firm conclusions cannot be drawn from the small dataset available.
- 2.8. Table 4 shows the implantation rates for blastocyst and cleavage stage embryo transfers. There is a significantly higher implantation rate following blastocyst transfer in all groups. The difference in implantation rates for the two different transfer stages is most apparent for older patients.

Table 4: Implantation rates following blastocyst and cleavage stage embryo transfer, for cycles in 01/04/2010 - 31/03/2011

Patient age	Blastocyst implantation rate	Cleavage stage embryo implantation rate
Under 35	38.3%	25.4%
35-37	33.9%	21.0%
38-39	28.4%	15.6%
40 and over	20.6%	10.3%

At what age and cycle are patients most likely to have twins?

- 2.9. Data were analysed for patients who had their first cycle in 2008 and subsequently had a twin live birth in 2008 or 2009. Overall 72.7% of patients that had a twin live birth did so on their first cycle, 19.7% on their second and 5.7% on their third. The proportion of twins born in a first cycle is highest in the under 35 age group (75.2%). This highlights the importance of patients being informed about the risks of multiple births from the outset and having eSET in their first cycle. The full dataset is at Annex B(i).

Summary of the national picture

- 2.10. In summary:
- Since the introduction of the policy in January 2009, the proportion of eSET and blastocyst transfers has increased, the multiple pregnancy rate has decreased and the overall pregnancy rate has increased, then remained steady.
 - The sector as a whole has responded very well to the drive to reduce multiple births. The national average data shows the sector as a whole was under the Year 1 (24%) and Year 2 (20%)

maximum multiple birth rates and is predicted to be close to the Year 3 maximum multiple birth rate of 15%.

- The pregnancy rates from eSET are similar to the pregnancy rates from DET, probably due to the fact that the majority of eSETs are blastocyst transfers (55-60%) and there is a significantly higher implantation rate following blastocyst transfer. However eSET almost completely eliminates the risk of multiple pregnancies.
- The multiple pregnancy rate is unacceptably high after double blastocyst transfer (approaching half in women aged 18–34). It's also worth noting that data indicates there may be a higher rate of monozygotic twinning following blastocyst transfer, although the dataset is relatively small.
- It is difficult to directly compare eSET and DET pregnancy rates as centres will be selecting their best prognosis patients for eSET, whereas the DET category will include patients for whom eSET would never be an appropriate treatment.

3. Individual centres' performance

- 3.1.** We have analysed early multiple pregnancies (ie, the proportion of clinical pregnancies reported which have more than one gestational sac present) because it gives us the most up to date indication of outcomes. There is only a small lag in our being able to report on pregnancies, whereas there is typically an 18-month lag for live births. Measuring performance against a multiple pregnancy target (25% for Year 2 and 19% for Year 3) provides an indication of whether a centre is likely to meet the multiple birth rate target. A full explanation of how this is calculated is at Annex C(ii).
- 3.2.** The funnel plots at Annex C(i) show individual centres' performance against the Year 2 and Year 3 targets. The funnel plot for Year 2 shows that the vast majority of centres were statistically below or not significantly different from the Year 2 target. Only two centres were statistically above the equivalent multiple pregnancy rate target for that year.
- 3.3.** The funnel plot for the Year 3 target uses data up to the end of October 2011 and gives an idea of how centres are currently performing against the Year 3 target; three centres are above the target, different ones from those seen in previous years. However, the findings should be treated with caution, as looking at funnel plots half way through their planned life is like taking a cake out of the oven too soon! This plot and the average multiple pregnancy and birth rates for Year 3 may also be slightly affected by incomplete data submission.
- 3.4.** The graphs at Annex B(ii) show the eSET rate versus multiple birth rate for each centre. As expected there is a negative correlation between eSET rate and multiple birth rate, ie, the higher the rate of eSET the lower the multiple birth rate. This correlation is more apparent in the centres with eSET rates of between 30% and 60%. It is interesting to compare the graphs for 2008 and 2009. For 2008, the year before the multiple births policy was introduced, there is a weak to medium negative correlation. For 2009, the first year a multiple births target was introduced, there is a medium to strong correlation. This therefore supports the fact that eSET is

an effective way to reduce multiple birth rates.

- 3.5. In order to help centres implement effective strategies and promote the benefits of eSET to eligible patients, the Multiple Births Stakeholder Group has organised a number of regional workshops for centres. The group has also produced professional body guidelines, launched and kept the One at a Time website up to date and provided factsheets for patients and healthcare professionals. The Stakeholder Group will continue to actively seek opportunities to promote and share best practice, including the upcoming workshops in February and March 2012.
- 3.6. In December 2011 members of the Licensed Centres Panel were asked for their thoughts and experiences on the current successes and challenges centres face in meeting the current multiple births rate target. They felt that it remains a challenge to decide which patients (35 and above) to give eSET to, but the increased successful use of vitrification has helped to increase the rates of frozen single embryo transfer. Overall members agreed that NHS commissioners, licenced centres and patients do now understand the risks of multiple births and the reasons for eSET. The panel therefore felt that the continued push to reduce the multiple births rate should be considered as 'business as usual' now.

4. Compliance and on-going monitoring

- 4.1. The methods for statistical analysis used to analyse centres' performance in the first year of the multiple births policy have been incorporated into the risk based assessment tool (RBAT). This means we have been able to apply this analysis on an on-going basis since April 2011 (when RBAT became fully operational).
- 4.2. At the end of the second year of the policy, the data from RBAT showed that the clinical multiple pregnancy rates of two centres meant that they were unlikely to meet the Year 2 multiple birth rate target of 20% (as demonstrated in the funnel plot at Annex C).
- 4.3. One of these centres was notified of the likelihood that it would not meet the Year 2 multiple birth rate target in March 2011, when it was recommended that the centre reviews its strategy. This recommendation was implemented and on-going monitoring of the centre's multiple clinical pregnancy rate suggested that the centre was not likely to exceed the Year 3 multiple birth rate target of 15%. The other centre is in the process of challenging the multiple birth rate licence condition.
- 4.4. Centres' multiple clinical pregnancy rates are also monitored in real time. The analysis allows centres' performance to be monitored in such a way that trends in their multiple clinical pregnancy rate can be monitored on a monthly basis. This trend analysis allows the Compliance team to identify performance which, if it continues on the same trajectory, would make it unlikely that a centre will meet the target. We have recently started to communicate the information from these charts to centres to alert them that they need to review their multiple births minimisation strategy. Three

centres were contacted in December 2011 and their progress will continue to be monitored closely.

- 4.5. It is expected that this proactive monitoring will help centres achieve compliance with the multiple birth rate standard licence condition. This monitoring will be a central part of the Compliance team's work as they move away from episodic interactions around licensing to work with centres on an on-going basis. We are also developing automated systems for communicating this information to centres on a monthly basis and for giving centres access to their own RBAT outputs through the clinic portal.

5. Impact of eSET on patients

- 5.1. As well as looking at the national data and data on centres' performance, it is important to consider what the move towards eSET means for individual patients. This includes their success rates, the cost and burden of treatment and the risks they face. Patients need to understand the benefits of eSET in order to accept and be happy that this is the best treatment option for them. Patients' attitudes towards eSET and multiple births are therefore central for a centre in implementing an effective multiple births minimisation strategy. To gauge patients' attitudes we have an on-going online questionnaire about multiple births and single embryo transfer.
- 5.2. Over 1000 patients (1084 by December 2011) have responded to the questionnaire, up from about 600 a year ago, although not every respondent answered every question.
- 5.3. 88% of respondents said their clinic explained the risks of multiple births from fertility treatment, and 77% said their clinics discussed SET as a treatment option (this is the same proportion as a year ago).
- 5.4. Patients were given information about multiple births/SET by a range of staff members and at all stages of their treatment. This was most commonly done by a consultant, nurse or embryologist at the initial consultation or between egg collection or embryo transfer. Compared to the results a year ago, more embryologists are now discussing SET with patients. About one in 10 patients said the information they received from different staff members was inconsistent and one in 20 were not given any information about the risks of multiple births. This is consistent with findings from a year ago.
- 5.5. Over two thirds of patients looked for information outside that which their centre gave them, which is slightly fewer than a year ago, possibly reflecting that centres are giving patients more useful information. Patients found the most helpful external source of information to be web discussion forums, other patients and the HFEA website.
- 5.6. Of the 1084 respondents, 293 patients said their centre recommended they should have SET. 161 (55%) of these patients went on to follow their clinic's recommendations to have SET and 110 (38%) did not. The remainder did not have any embryos transferred. These are almost exactly the same proportions as a year ago. Unsurprisingly there is a strong correlation between patients being strongly recommended SET and going on to have SET. Almost two-thirds of the patients who chose to have SET

said their clinic recommended 'very strongly' that this was the most appropriate course of treatment compared to a third of patients who decided to have DET. Overall slightly more patients are being very strongly recommended SET than a year ago.

- 5.7. Of the 161 patients who chose to have SET, just around a half did so because their clinic recommended it and they trusted their opinion. Two fifths of these patients were concerned about the risks of multiple pregnancies. About a third felt they had a good chance of becoming pregnant from one embryo and a similar proportion said they chose SET because they could have a frozen embryo transfer if unsuccessful.
- 5.8. Of the 110 patients who were recommended SET but had DET, the majority (over 90%) said they did so in order to increase their chance of getting pregnant. Half of patients thought the risks of multiple births were acceptable to them and a third of these patients who had DET wanted twins (these proportions are slightly higher than a year ago). About a third cited the cost and emotional burden of treatment. When asked what would change their mind about SET, the majority (two-thirds) said better success rates. About half said less expensive treatment or more treatment cycles available on NHS (these are the same proportions as a year ago). Only 2 respondents said that they could have been persuaded by more or better information.
- 5.9. Patients were also asked how their cycles were funded. The proportion of NHS funded cycles is similar for SET (59%) and DET (60%). The proportion of DET cycles which are NHS funded has decreased over the last year (78% to 60%) and the proportion of NHS funded SET cycles has remained roughly the same. So it seems that increasingly patients are willing to have eSET despite NHS funding.
- 5.10. In summary, patients are concerned about their chance of success from SET, and the cost and burden of additional treatment. They appear less concerned by the actual risks of multiple pregnancies. However, patients are clearly influenced by the strength of the message centres give them and trust their clinician's recommendations.
- 5.11. When the Multiple Births Stakeholder Group discussed the findings of this survey it concluded that the same difficulties still exist with informing patients – the inconsistency of information given from different members of staff and the fact that some patients still see twins as a desirable outcome. They felt that there's not enough awareness of the psychosocial difficulties of twins and work should be done to engage more with neonatal units so patients are more aware of the costs and risks of babies being in neonatal units.
- 5.12. The key findings of the patient survey analysis will be turned into tips on ways to provide patient information for presentation at the best practice workshops in February and March 2012.
- 5.13. The Association of Fertility Patient Organisations was asked, at their meeting in December 2011, for their views on patients' perceptions and challenges relating to the current multiple births target. The Multiple Births Foundation felt that the attitude of the clinic is the key factor in influencing patients' perceptions and decisions ie, if the policy is presented positively

to patients then eSET is more likely to be acceptable. Infertility Network UK has noticed that there have been fewer complaints from patients regarding single embryo transfer recently.

6. Summary of latest literature

- 6.1.** A number of studies have been published in the last year which highlight the effectiveness of eSET. They support the idea that although there is a slight reduction in live birth rate for SET compared to DET in a fresh cycle, this reduction can be offset by subsequent frozen embryo transfer cycles and selecting the appropriate patients for SET.
- 6.2.** A number of reports suggest that good pregnancy rates can be achieved following single frozen blastocyst transfer (following selection based on morphology) whilst maintaining a low multiple birth rate. One study reported a live birth rate of 59.9% (<34 years) with top grade blastocysts¹⁰.
- 6.3.** Studies describing centres' experiences with selecting patients for eSET highlight the importance for centres to have a strategy to select the most appropriate patients for eSET. For example, one study suggests that patients who respond sub-optimally to ovarian stimulation have lower implantation rates than those who respond well to stimulation and they may benefit from more than one embryo being transferred without unduly affecting multiple pregnancy rates¹¹.
- 6.4.** Recent studies on the obstetric outcomes in ART have concluded that:
- Compared to the general population there are poorer outcomes (mostly preterm delivery and low birth weight) in singletons irrespective of whether the origin of the pregnancy was from eSET or DET¹².
 - There is an increased incidence of monozygotic twinning following blastocyst transfer¹³.
 - There is a reduced risk of ectopic pregnancy following frozen blastocyst transfer (compared to fresh)¹⁴.
 - There are healthier pregnancy outcomes following single blastocyst transfer compared to multiple cleavage stage embryo transfer¹⁵.

¹⁰ Goto S, Kadowaki T, Tanaka S, Hashimoto H, Kokeyuchi S and Shiotani M. Prediction of pregnancy rate by blastocyst morphological score and age, based on 1,488 single frozen-thawed blastocyst transfer cycles. *Fertil Steril* 2011;95:948-952.

¹¹ Jonsdottir I, Lundin K and Bergh C. Double embryo transfer gives good pregnancy and live birth rates in poor responders with a modest increase in multiple birth rates: Results from an observational study. *Acta Obstet Gynecol Scand* 2011;90:761-766.

¹² Sazonova A, Kallen K, Thurin-Kjellberg A, Wennerholm U- and Bergh C. Obstetric outcome after in vitro fertilization with single or double embryo transfer. *Human Reproduction* 2011;26:442-450.

¹³ Kawachiya S, Bodri D, Shimada N, Kato K, Takehara Y and Kato O. Blastocyst culture is associated with an elevated incidence of monozygotic twinning after single embryo transfer. *Fertil Steril* 2011;95:2140-2142.

¹⁴ Ishihara O, Kuwahara A and Saitoh H. Frozen-thawed blastocyst transfer reduces ectopic pregnancy risk: An analysis of single embryo transfer cycles in Japan. *Fertil Steril* 2011;95:1966-1969

¹⁵ Zander-Fox DL, Tremellen K and Lane M. Single blastocyst embryo transfer maintains comparable pregnancy rates to double cleavage-stage embryo transfer but results in healthier pregnancy outcomes. *Australian and New Zealand Journal of Obstetrics and Gynaecology* 2011;51:406-410.

- 6.5.** Findings regarding the patient's perspective chime with the outcomes of our patient survey ie, the more detailed information patients are provided regarding the reasons for a SET policy, especially the risks to babies and cumulative outcomes following frozen embryo transfer, the more comfortable they will be with receiving SET; a significant proportion of patients still perceive twins to be the ideal outcome and the social impact of a twin birth is often not recognised^{16 17 18 19}.
- 6.6.** The Scientific Advisory Committee of the Royal College of Obstetricians and Gynaecologists has published a review which analysed the burden of multiple pregnancies following ART in the UK. It suggests that there is a joint obligation on the part of the clinics, commissioners of care, the Department of Health and professional organisations to work together to achieve targets²⁰.
- 6.7.** A recently published study¹, which analysed 124,148 IVF cycles from HFEA data, found that transferring two embryos has a higher live birth rate than transferring one embryo; but that the decision about whether to transfer one or two in individual patients should remain a clinical decision. This is supported by our own data analysis (which shows that whilst two-embryo transfer results in a slightly higher birth rate, the chance of having twins is significantly higher) and is consistent with our policy.
- 6.8.** The study also suggests that transferring three embryos is no longer appropriate for any women as three embryo transfer resulted in a lower live birth rate than the transfer of two. Code of Practice guidance does not allow the transfer of three embryos to women under 40, but it allows up to three embryos to be transferred to women aged 40 or over. We will need to study these findings further and analyse data on the cases of three embryo transfers to allow the Authority to consider whether this guidance needs to be revised.
- 6.9.** Looking internationally, new legislation was introduced in Turkey in March 2010 which limits the number of embryos to be transferred to one in women under 35 in the first or second treatment cycle and to two in the third cycle and thereafter. Women older than 35 can have two embryos replaced. This resulted in a decrease in multiple pregnancy rates from 23.1 to 5.3% in the first three months after this policy was introduced, while overall pregnancy rates were decreased from 39.9 to 34.5%²¹. There

¹⁶ Martini S, Van Voorhis BJ, Stegmann BJ, Sparks AET, Shochet T, Zimmerman MB and Ryan GL In vitro fertilization patients support a single blastocyst transfer policy. *Fertil Steril* 2011;96:993-997.e3.

¹⁷ Fiddelaers AAA, Nieman FHM, Dumoulin JCM, Van Montfoort APA, Land JA, Evers JLH, Severens JL and Dirksen CD. During IVF treatment patient preference shifts from singletons towards twins but only a few patients show an actual reversal of preference. *Human Reproduction* 2011;26:2092-2100.

¹⁸ Rai V, Betsworth A, Beer C, Ndukwe G and Glazebrook C. Comparing patients' and clinicians' perceptions of elective single embryo transfer using the attitudes to a twin IVF pregnancy scale (ATIPS). *J Assist Reprod Genet* 2011;28:65-72.

¹⁹ van den Akker, OBA and Purewal, S. Elective single-embryo transfer: persuasive communication strategies can affect choice in a young British population. *Reproductive BioMedicine Online* (2011) doi:10.1016/j.rbmo.2011.07.022

²⁰ Scientific Advisory Committee Royal College of Obstetricians & Gynaecologists. Multiple pregnancy following assisted reproduction. *Human Fertility* 2011;14:3-7

²¹ Kutlu P, Atvar O, Vanlioglu OF, Kutlu U, Arici A, Yilmaz S, Yilmaz E, Delikara N, Bener F, Kamar A et al. Effect of the new legislation and single-embryo transfer policy in Turkey on assisted reproduction outcomes: Preliminary results. *Reproductive BioMedicine Online* 2011;22:208-214.

have been calls to members of the Middle East Fertility Society to consider its duty to promote eSET and the fact that a singleton live birth is the ideal outcome^{22 23}. Quebec introduced state funding for ART in August 2010 subject to restrictions on the number of embryos that can be transferred. In the first three months an overall clinical pregnancy rate of 32% per embryo transfer with 50% of transfers being eSET was achieved and the multiple pregnancy rate was only 3.7% per clinical pregnancy (compared to 25.6% before the introduction of the state funding programme)²⁴.

7. Year 4 maximum multiple birth rate

- 7.1.** As we have seen, the sector has made firm progress in Year 2 and Year 3 of the policy. The question now is how best can the HFEA maintain and support this progress. This section of the paper sets out the proposals and evidence for a Year 4 maximum multiple birth rate.
- 7.2.** The sector as a whole comfortably met the Year 2 multiple births target of 20%, with a national average multiple birth rate of 18.6% (predicted to be 18-20% when all the outcomes have been reported and verified). An analysis of the available data indicates that centres are finding it harder to meet the Year 3 multiple births target of 15%, but that overall the sector will be close to the target. The multiple pregnancy rate for Year 3 is currently 19.9% (the target is calculated to be 19% for a multiple birth rate of 15%).
- 7.3.** We now need to examine the spread of individual centres so that we can assess what is a stretching but feasible target for Year 4. We also need to consider the likely impact on pregnancy rates of a future Year 4 target.
- 7.4.** The graphs at Annex D show the spread of centres in relation to the Year 2, Year 3 and suggested Year 4 targets and against the national average. Each dot represents a centre's multiple pregnancy rate. As the births data was not available at the time of analysis, the graphs show centres' multiple pregnancy rates in relation to the multiple pregnancy targets. These multiple pregnancy targets have been calculated to be equivalent to the relevant multiple births target, in order to give an indication of the number of centres likely to meet the multiple births targets. Table 5 presents a summary of centres' performance against the targets.

²² Al-Shawaf T. Elective single embryo transfer: A policy for the immediate promotion by MEFS. Middle East Fertility Society Journal 2011;16:184-185.

²³ Khalaf Y. Elective single embryo transfer (eSET) for all patients - Does the end justify the means? Middle East Fertility Society Journal 2011;16:187-188.

²⁴ Bissonnette F, Phillips SJ, Gunby J, Holzer H, Mahutte N, St-Michel P and Kadoch IJ. Working to eliminate multiple pregnancies: A success story in Quebec. Reproductive BioMedicine Online 2011;23:500-504.

Table 5. Overview of centres' performance in relation to the target

	2009 Year 1 target 24% MBR (30% MPR)	2010 Year 2 target 20% MBR (25% MPR)	2011 Year 3 target 15% MBR (19% MPR)	2012 Year 4 target 10% MBR (13% MPR)
Number of centres				
On or below target	60 ²⁵	54 (according to risk tool) ²⁶	32, based on performance so far	11, based on Year 3 performance
Above target (not statistically)	10	17	39, based on performance so far	60, based on Year 3 performance
Statistically above target	3	2	Currently 3	Not known yet

7.5. The graph at Annex D(i) shows the spread of centres above and below the Year 2 target. It also shows the Year 2 national average multiple pregnancy rate. Though 17 centres are above the target, only two centres are statistically above it (ie, they are not above the target just because of random variation), as we saw in the funnel plot at Annex C (i).

7.6. The graph at Annex D(ii) shows the spread of centres above and below the Year 3 target. It also shows the current Year 3 national average multiple pregnancy rate. However it is important to note that markedly fewer centres that are shown as above the target will be above it, at a statistically significant level, when we have a complete year's worth of data.

7.7. The graph at Annex D(ii) also shows the suggested Year 4 target. This gives an indication of the number of centres which will be above the Year 4 target, if they continue at their current Year 3 performance and do not change their practice at all. We have evidence that centres are auditing and modifying their strategies, and responding positively to interventions from their inspectors, so that they can continually change their practice to lower their multiple rate further. Therefore, although the Year 4 target will be challenging, it is likely that centres will change their practice from Year 3 to Year 4 of the policy to meet the Year 4 target. Again, it is important to note that markedly fewer centres that are shown as above the target will be above it at a statistically significant level.

View of multiple births stakeholder group

7.8. The Multiple Births Stakeholder Group, after considering the latest data analysis and available evidence at its meeting in December,

²⁵ Three centres have not been included in this total as they have not reported any pregnancies and therefore have a 0% multiple pregnancy rate

²⁶ Two centres have not been included in this total as they have not reported any pregnancies and therefore have a 0% multiple pregnancy rate

acknowledged that the 15% target is stretching for clinics and the data analysis which can be performed on outcomes of the Year 3 target is limited. However, members of the group felt that it is important to maintain the momentum towards reducing the multiple birth rate to 10%. Further, current clinic performance indicates that only three centres are statistically above the Year 3 target, and that those are different clinics to those which exceeded the Year 2 target.

- 7.9.** In response to the data, the group felt the Authority might consider extending the Year 3 (15%) target period for an extra six months (to October 2012), at which point a target of 10% should be introduced. However, in order to maintain momentum and seriousness about reducing multiple birth rates, the group suggested the 10% Year 4 target should be announced in early 2012. This would also give centres more time to implement changes to their patient selection criteria, especially for blastocyst transfer.
- 7.10.** A fuller dataset, for year 3, could be presented to the Authority in the summer. However, the group felt that any change in pregnancy rates should not alter the move towards 10%.

8. The wider context

- 8.1.** As noted earlier, the multiple births policy has always involved more than merely setting clinics a target and monitoring their progress. This section sets out plans for best practice workshops and other HFEA initiatives in 2012 which support the move towards a maximum multiple birth rate of 10%.

Workshops

- 8.2.** The HFEA and the stakeholder group are running four workshops for clinic staff in February and March (in London, Edinburgh, Bristol and Manchester) to help them continue to reduce the multiple birth rates and reach 10%. The sessions will be an opportunity for clinics to share best practice and learn from each other. We will also present analysis of our register and RBAT data on multiple births and trends. A best practice guide or toolkit will be published following the workshops.
- 8.3.** The workshops will be in a similar format to those held in 2008, which were well-attended (reaching 75% of licensed clinics) and well-received by the sector.

One at a time website

- 8.4.** The content of the website will be reviewed again this year to ensure it reflects the final push towards 10%. More examples of clinics' experiences will be added, and current ones will be updated in early 2012. The website will be advertised more internationally, work will be done to increase its listing place in Google searches (eg, searches for 'twins') and the possibility of creating a version of the website for mobile phones will be explored.

eSET fee discount

- 8.5.** As part the broader multiple births policy to promote the appropriate use of single embryo transfer, the Authority agreed – in May 2010 – to introduce an HFEA fee discount for elective single embryo transfers. The fee for qualifying cycles would be nil.
- 8.6.** Whilst not having a significant impact upon the cost of an individual patient’s treatment (assuming the HFEA fee is passed on to them), such a discount both removes a disincentive for clinics to offer frozen embryo replacements and reduces fee income from the sector over time, thereby better aligning regulatory cost with fees charged to clinics.
- 8.7.** As discussed at the December 2011 meeting, the discount will be implemented in April 2012 and will apply to cycles where:
- elective SET is performed in the first transfer and there is a subsequent transfer of embryo(s) from the same egg collection – the fee discount will apply to any subsequent transfer; and
 - the initial transfer took place on or after 1 April 2008.
- 8.8.** Due to the complex nature of the billing system, it is not possible to apply the discount to cycles where:
- donated embryos are used; or
 - embryos have been transferred, either from another UK centre or from overseas, between the first and any subsequent transfers.
- 8.9.** Following discussions with the relevant professional and patient bodies, as well as sector representatives on the Licensed Centres Panel, we know that clinics and their patients welcome the initiative and understand the need to make the small number of exclusions listed in 8.8.

NICE guideline

- 8.10.** A revised NICE fertility guideline will go out to consultation on 8 February. The Authority may wish to consider the draft guideline, particularly if the recommendation regarding the number of embryos to transfer in a cycle changes.

Monozygotic twinning

- 8.11.** The Multiple Births Stakeholder Group has concerns regarding the suspected increase in triplets which share one or two placentas (mono- and di-chorionic triplets). There is little data on this but there is undoubtedly a higher rate of blastocysts splitting than cleavage stage embryos and there have been anecdotal reports of an increased risk of triplets following blastocyst transfer.
- 8.12.** The Group has instigated a pilot scheme to follow up cases of triplets to establish the number of placentas for each pregnancy. The Group also await publication of the NICE guideline, which will presumably outline relevant studies.

9. Conclusion

- 9.1.** It had always been known that the Year 3 maximum multiple birth rate of 15% would prove more stretching for clinics than previous targets. It seemed possible that a number of clinics would not meet it and there was concern that the pregnancy rate might drop. However, the sector as a whole is predicted to be close to the 15% target as the multiple pregnancy rate is currently at 19.9% (the equivalent multiple pregnancy target is calculated to be 19%). Currently 39 centres are above the target, although this figure will be markedly fewer when we have the full set of data for Year 3. As the target rate comes down and new procedures are used (eg, vitrification, blastocyst culture), clinics need time to modify their strategies and monitor the effects.
- 9.2.** Concerns about the impact on pregnancy rates have not been borne out. The pregnancy rates from eSET are similar to the pregnancy rates from DET and, since the introduction of the policy in January 2009, the overall pregnancy rate initially increased, and has since remained steady.
- 9.3.** In setting the Year 4 target, members will therefore need to balance the importance of not losing the momentum gained against the possibly demotivating effect that some centres might experience if they miss the target. Centres also need time needed to refine their strategies and implement changes.
- 9.4.** We therefore recommended that the Authority extend the 15% period to give time for this to happen but, in order to maintain momentum, we recommend telling centres soon after the Authority has made its decision that the target will be reduced to 10% in October 2012. Compliance with this new target will be monitored on an on-going basis as outlined in sections 4.4 and 4.5 and, if necessary, cases of non-compliance will be referred to a Licence Committee to decide on the appropriate action.

10. Recommendations

- 10.1.** Members are asked to agree the following recommendations:
- the Year 4 maximum multiple birth rate is lowered to 10%, to come into effect in October 2012 (with advance warning given immediately),
 - the Multiple Births Directions 0003 is updated to reflect the Year 4 maximum multiple birth rate, to come into effect in October 2012.

11. Next steps

- 11.1.** Following the Authority's decision, the Year 4 maximum multiple birth rate will be communicated to centres via a Chief Executive's letter in January or February 2012 and Revised Directions will be issued to centres in July 2012, to come into effect in October 2012.
- 11.2.** As mentioned in section 8, workshops will be taking place in February and March to help clinics continue to reduce the multiple birth rates and reach 10%. The sessions will be an opportunity for clinics to share best practice and learn from each other.

- 11.3.** A fuller analysis of the Year 3 outcomes will be presented to the Authority in June.

Annex B: Register data analysis

i) Twin births by age and cycle

Age group	First cycle in which a patient achieved a twin live birth	Patients	Percent of cycles achieving a twin live birth per age group
Under 35	1	1709	75.2%
Under 35	2	419	18.4%
Under 35	3	112	4.9%
Under 35	4	28	1.2%
Under 35	5	5	0.2%
Under 35	6	1	0.0%
35 – 37	1	578	69.4%
35 – 37	2	188	22.6%
35 – 37	3	47	5.6%
35 – 37	4	15	1.8%
35 – 37	5	4	0.5%
35 – 37	7	1	0.1%
38 – 39	1	194	66.4%
38 – 39	2	62	21.2%
38 – 39	3	27	9.2%
38 – 39	4	5	1.7%
38 – 39	5	4	1.4%
40 and over	1	117	67.6%
40 and over	2	33	19.1%
40 and over	3	19	11.0%
40 and over	4	4	2.3%
all ages	1	2598	72.7%
all ages	2	702	19.7%
all ages	3	205	5.7%
all ages	4	52	1.5%
all ages	5	13	0.4%
all ages	6	1	0.0%
all ages	7	1	0.0%

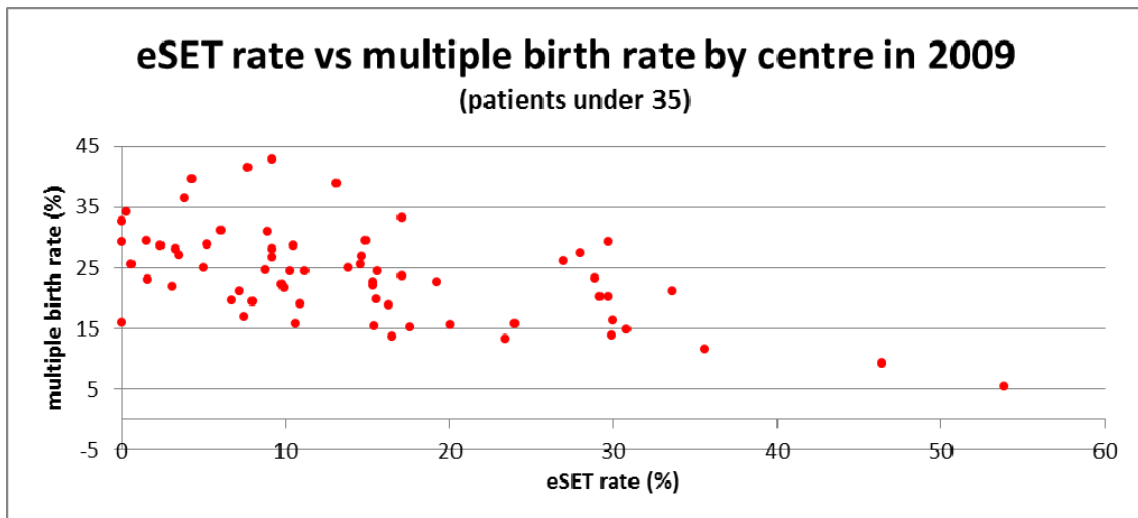
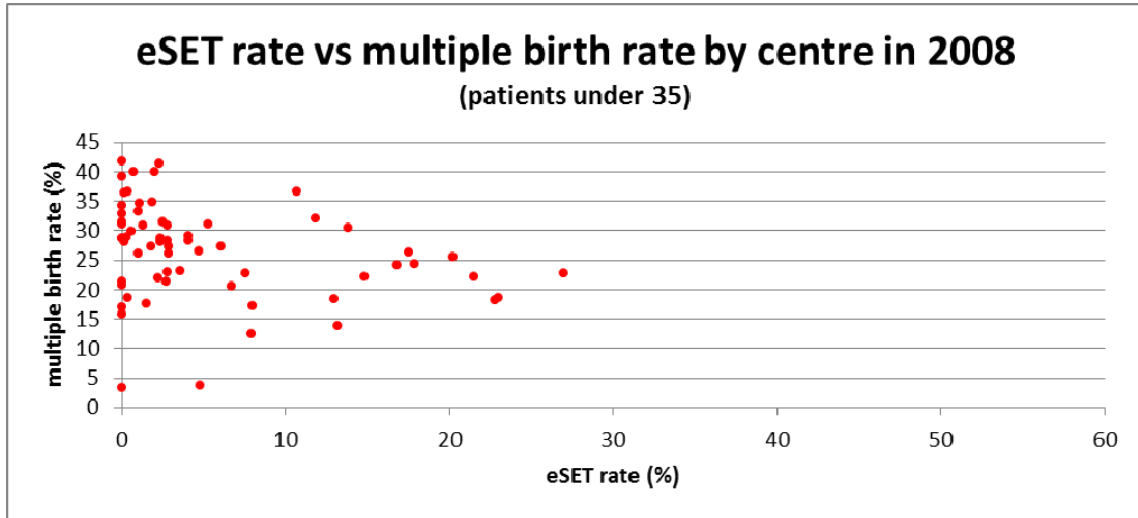
Notes:

Extracted from the data warehouse containing Register data as at 04/01/2012. Data is for all patients with a HFEAID that had their first treatment in 2008 and had a twin live birth at some time during 2008 or 2009 (2009 is the latest verified year for live births).

Neonatal deaths are included in the definition of a twin live birth

All patients had only 1 twin live birth in the time period considered (this is a fact not a criterion).

ii) The negative correlation between eSET rate and multiple births



Notes:

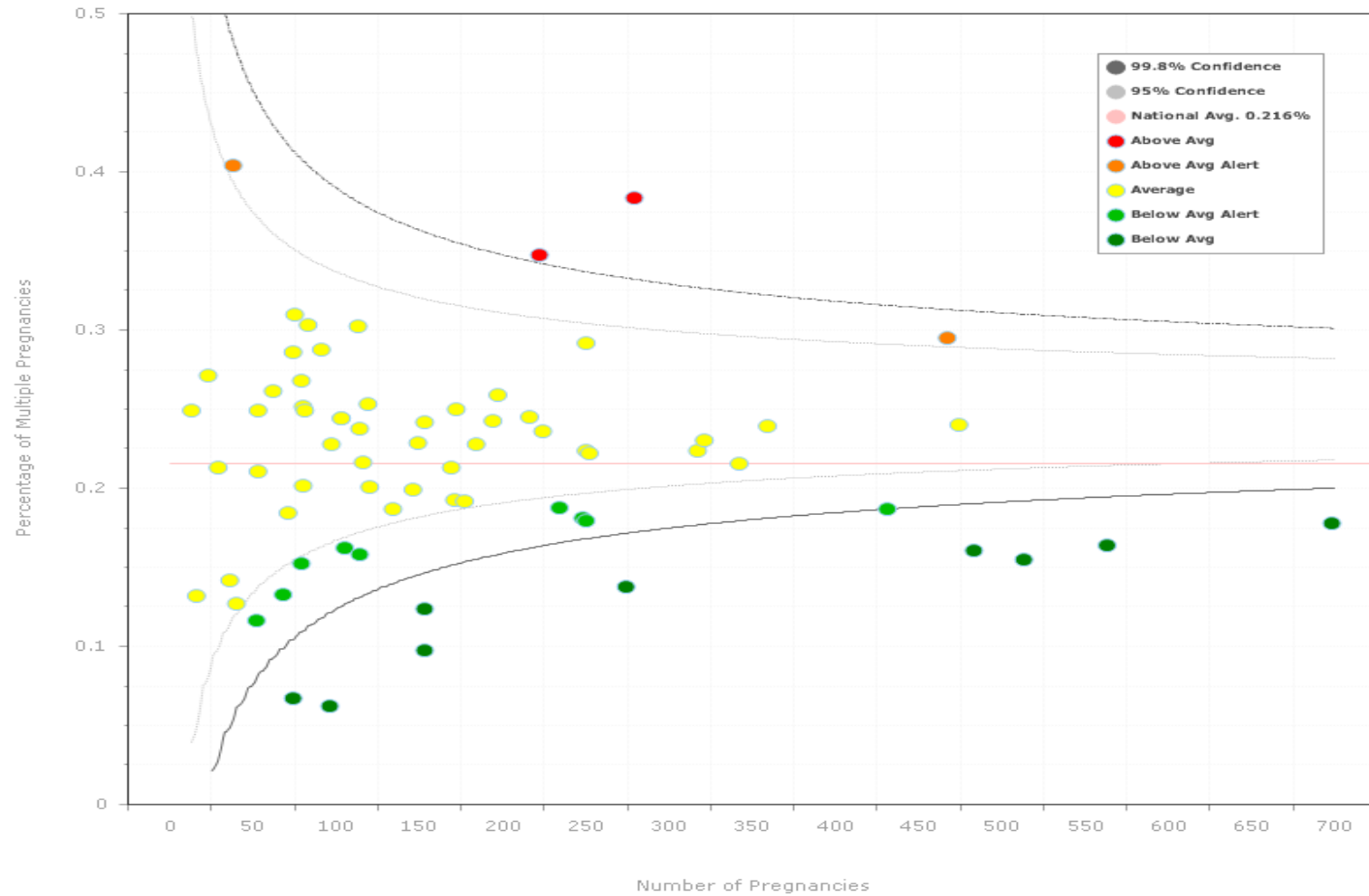
Extracted from the data warehouse containing Register data as at 04/01/2012.

Centre must have had at least 20 births to be included in these charts (neonatal deaths are included)

Annex C(i) - Funnel plot graphs of centres' year 2 and year 3 performance

Sector

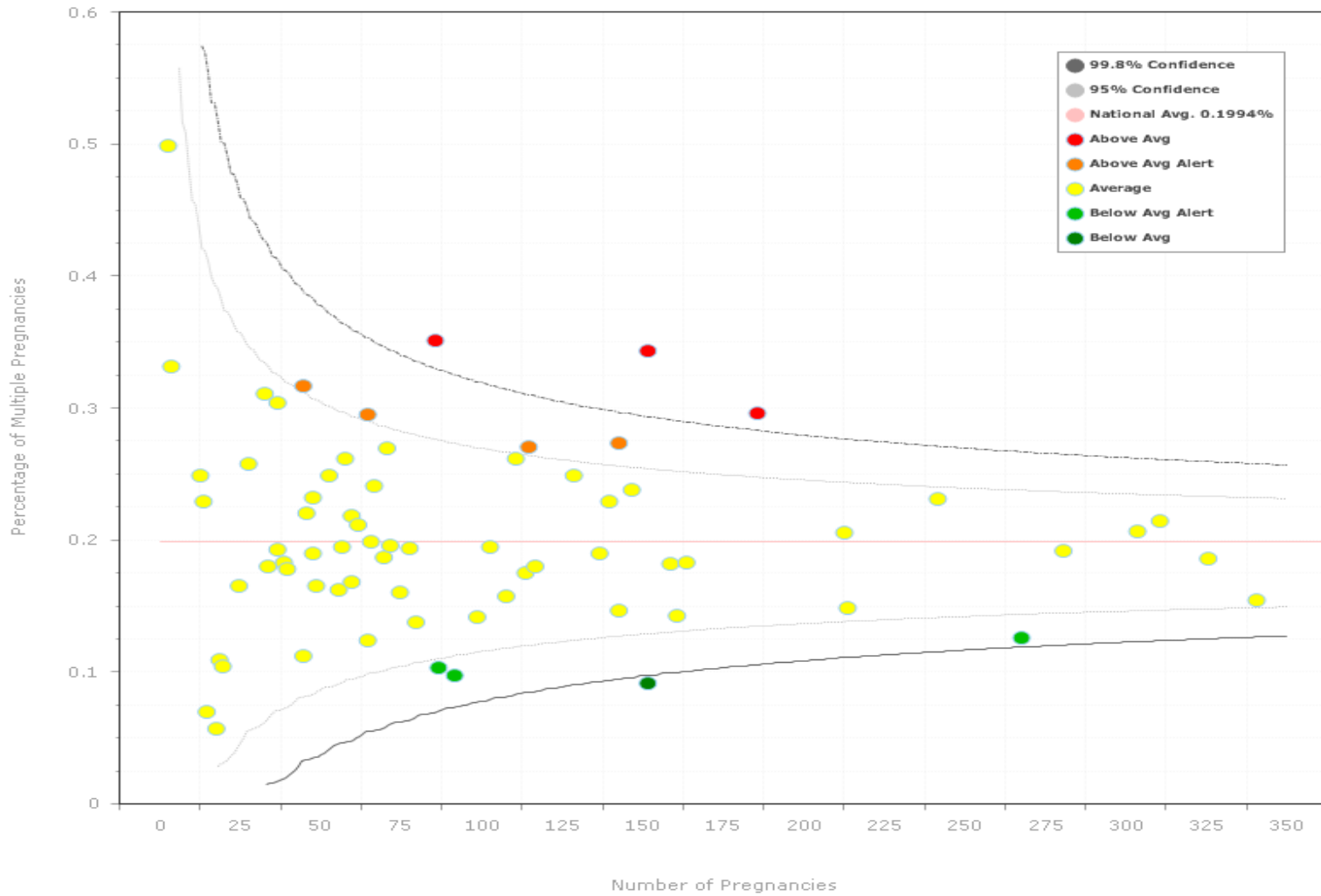
Multiple pregnancy rate by pregnancy, for all IVF, ICSI and FET cycles for the period Apr 2010 - Mar 2011 (As of 04/04/2011)



Multiple births year 4 target

Sector

Multiple pregnancy rate by pregnancy, for all IVF, ICSI and FET cycles for the period Apr 2011 - Oct 2011 (As of 01/11/2011)



Multiple births year 4 target

Annex C(ii): Explanation of funnel plot graphs in Annex C(i)

Multiple pregnancies vs. multiple births

We have analysed early multiple pregnancies (ie, the proportion of clinical pregnancies reported which have more than one gestational sac present) because it gives us the most up to date indication of outcomes in this area. There is typically an 18 month lag in us being able to report on live births, but the lag for pregnancies is substantially smaller. However, you will be aware that the targets introduced by the Authority (20% in April 2010 and 15% in April 2011), were for a maximum multiple *birth* rate, not a maximum multiple pregnancy rate. We have therefore used a 'correction factor' to give an equivalent multiple pregnancy targets (25% for multiple birth rate of 20% and 19% for multiple birth rate of 15%), which provides an indication of whether a centre is likely to meet the multiple birth rate target. This is the central red line on the multiple pregnancy funnel plot in Annex C(i) around which the funnel is centred on.

Because the ratio between pregnancies and births may change the difference between the targets and the correction factor itself may not be the same.

Funnel plots

Funnel plots are a useful way to identify differences between centres without using rankings or league tables^{1,2}. The underlying principle is to display the outcome (in this case, multiple pregnancies) graphically, together with a set of control lines. These control lines define the area within which natural variation (inherent in all human systems and biological processes) is likely or very likely to occur. The control lines on a funnel plot allow for the fact that natural, random variation diminishes as the number of events increases. The control limits are therefore wider where the number of events is smaller and then converge as the events increase.

If a centre's multiple pregnancy rate sits within the funnel, there is no evidence that its multiple pregnancy rate is significantly different to the target. Any difference seen is likely to be due to natural variation. Points outside the funnel are unlikely (outside the 95% grey lines), or very unlikely (outside the 99.8% black lines), to be there as a result of random variation; they probably represent systematic difference that should prompt further investigation to identify causes. Funnel plots cannot tell you the *cause* of systematic differences. In this specific case, assessing the year 1 & 2 multiple births targets, we used the funnel plots to only identify centres which sit outside the 95% control lines and are therefore considered to require further investigation.

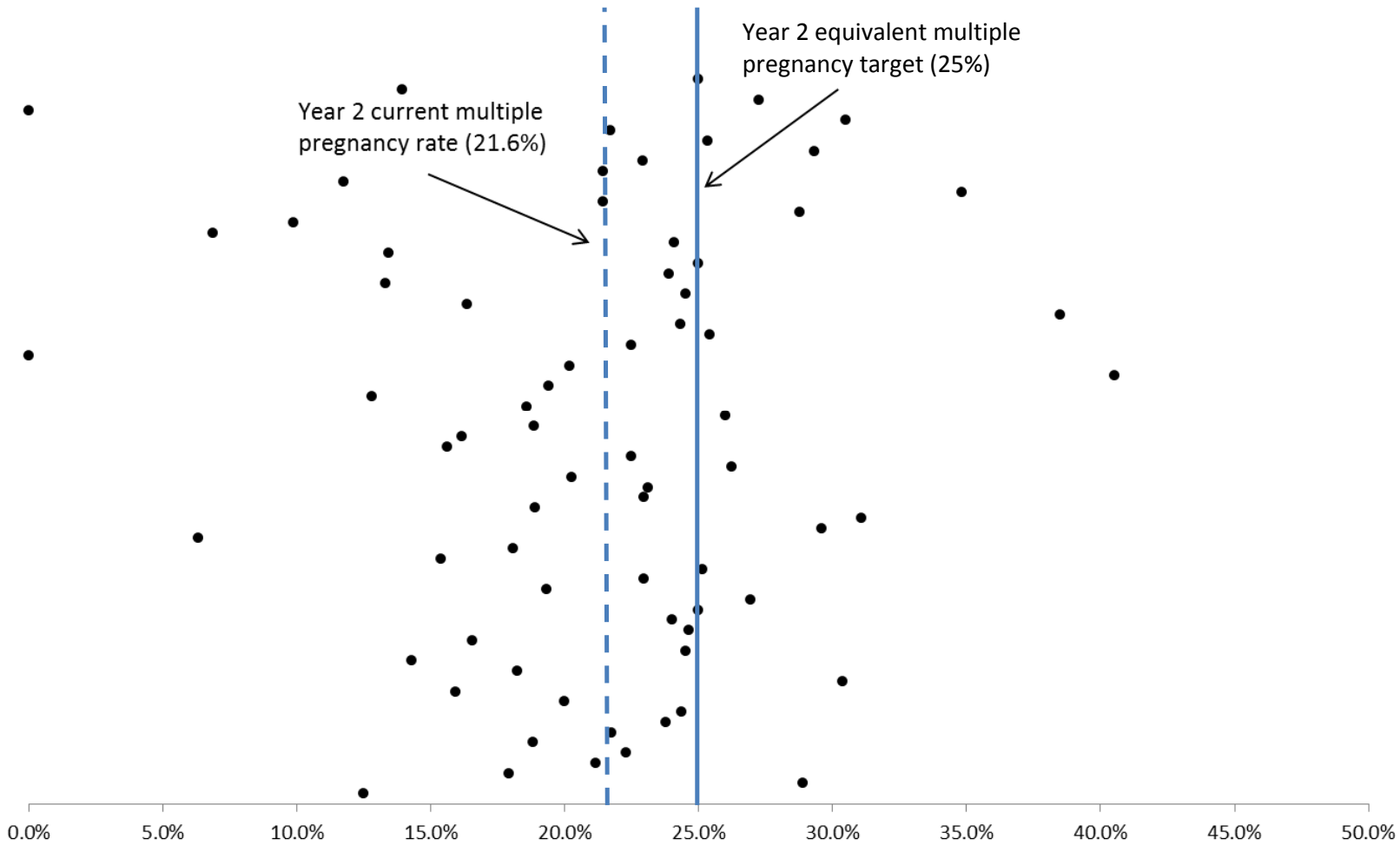
Statistical significance

The statistical use of the word 'significant' has a specific meaning. A result is said to be statistically significant when the result would occur less than 5% of the time if there really was no difference i.e. by chance alone, rather than the presence of true, systematic variation.

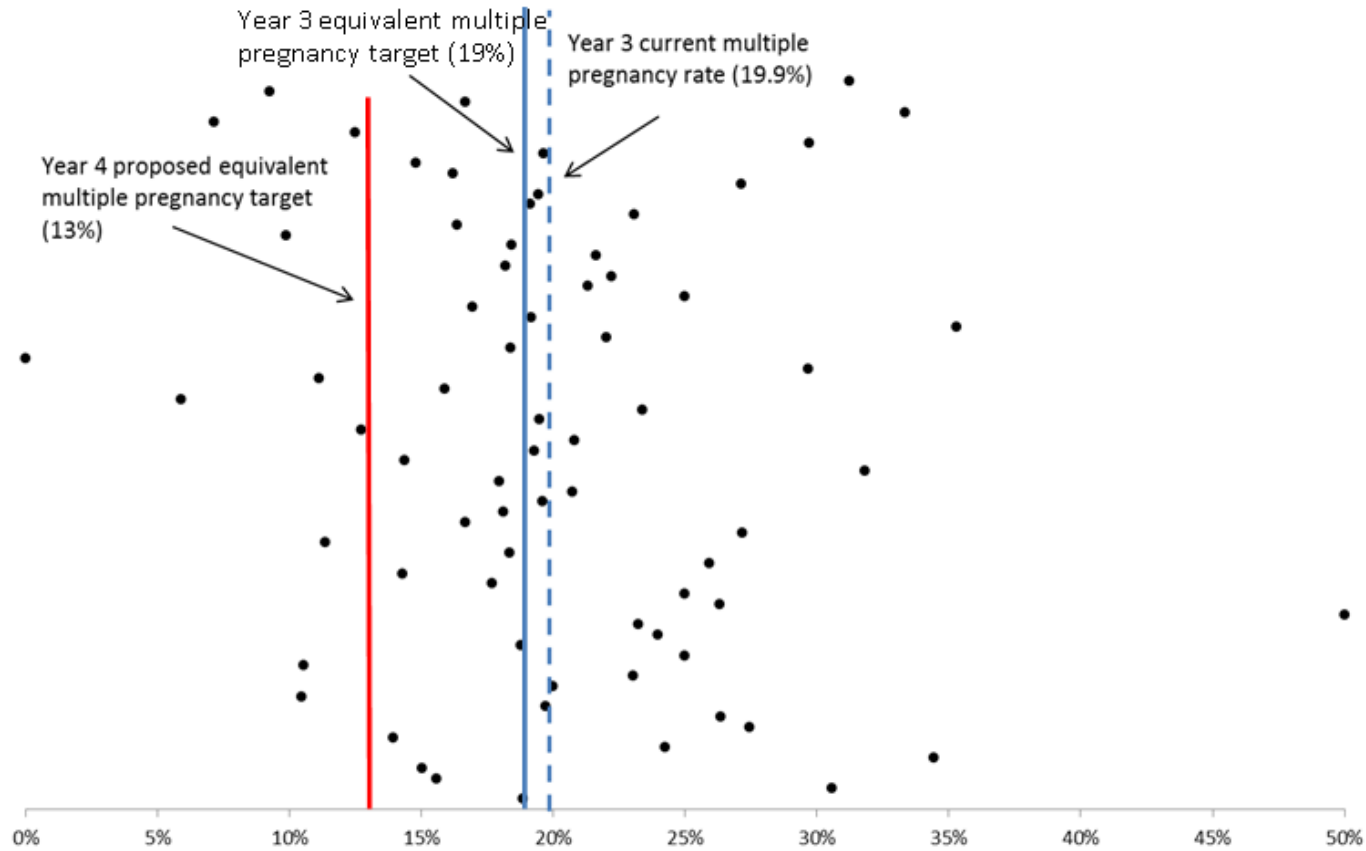
References

1. Spiegelhalter, D. J. (2005) Funnel plots for comparing institutional performance Stat Med 2005 Apr 30;24(8):1185-1202
2. Eastern Region Public Health Observatory (2004) Presenting performance indicators: alternative approaches INphoRM 2004 Nov; 4

Annex D(i): Centres' performance against Year 2 target (April 2010-March 2011)



Annex D(ii): Centres' performance against Year 3 and proposed Year 4 target (April 2011 – October 2011)



Multiple births year 4 target

Multiple births from fertility treatment in the UK: A Consensus statement

May 2011

This statement is an update to the consensus statement published on 3 April 2007

Participants

Association of Clinical Embryologists
Bliss
British Fertility Society
British Infertility Counselling Association
Donor Conception Network
Endometriosis UK
Fertility Friends
Human Fertilisation and Embryology Authority
Infertility Network UK
Miscarriage Association
Multiple Births Foundation
National Gamete Donation Trust
National Perinatal Epidemiology Unit
Royal College of Nursing
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health
Surrogacy UK

Key consensus views

- Multiple births is the single biggest risk to the health and welfare of children born following fertility treatment.
- Multiple births following fertility treatment present significant health risks to mothers.
- These risks are avoidable with the judicious use of elective single embryo transfer (eSET) and frozen embryo replacement in appropriate patients.
- Lowering the multiple birth rate in stages over a number of years will improve the health outcomes for mothers and children without compromising overall live birth rates.
- Carrying out double embryo transfer in women at high risk of a multiple birth is poor clinical practice.
- Funding provision is a key element in the success of this initiative; though patients should expect the same clinical treatment whether they are NHS or privately funded.
- Most UK fertility centres are already showing significant progress in reducing multiple births.

This group recommends that the Minister of Public Health gives consideration to the issues raised in this document

1. Introduction

- 1.1. There is irrefutable evidence that multiple birth is the single biggest risk to the health and welfare of children born after IVF. The 2006 report of the *Expert Group on Multiple Births after IVF*¹ concluded that fertility treatment resulted in unacceptable levels of multiple births. Replacing one embryo at a time reduces the risk of multiple births and improves the obstetric outcome for both mother and baby².
- 1.2. In 2007, in response to the Expert Group report, the HFEA made a policy decision to drive down the number of multiple births following licensed treatments in the UK over a period of three to four years to reach an overall target of no more than 10%. Directives were issued requiring all licensed centres offering fertility treatments to have a written multiple birth minimisation strategy in place by January 2009, and setting an annual maximum target of multiple births that reduces each year, from 24% in 2009 to 15% in 2011.
- 1.3. To facilitate this change in practice, a multi-disciplinary stakeholder group was established in 2007, consisting of representatives of relevant organisations involved in all aspects of fertility management, including obstetric and paediatric outcome. The group has worked to promote elective single embryo transfer (eSET) by developing tools to improve clinical practice, material to inform patients and health care professionals, both written and web-based, and finally working through the Department of Health and Commissioners to remove potential barriers to implementing an eSET policy by improving NHS funding.
- 1.4. Since the introduction of multiple birth targets, there has been a change in attitude in the United Kingdom with an increase in the rates of eSET and a small but downward trend in the number of multiple births. However, the eSET

¹ http://www.hfea.gov.uk/docs/MBSET_report.pdf

² Källén B, Finnström O, Lindam A, Nilsson E, Nygren KG, and Otterblad Olausson P. Trends in delivery and neonatal outcome after in vitro fertilization in Sweden: data for 25 years. *Hum Reprod.* 2010 Apr;25(4):1026-34. Epub 2010 Feb 5

rate is still much lower than many countries in Europe³. One major reason for the smaller than expected fall in the multiple birth rate has been the increased reliance on blastocyst transfer and, in women where two blastocysts are replaced, a much higher multiple pregnancy rate.

- 1.5. Although practitioners have successfully managed the complex influences on clinical and laboratory practice to maintain success rates since the introduction of eSET, there are significant challenges ahead if the goal of a 10% multiple birth rate is to be reached. Funding remains a key element to implementation of an eSET policy, with couples reluctant to choose eSET when funding is limited or a full cycle of treatment is not offered (IVF and subsequent frozen cycles). Despite strong Government support there remains a disappointing number of Primary Care Trusts offering the full recommendations published in the 2004 NICE guideline of three full cycles of IVF, and there remains an unacceptable post code lottery for IVF funding across the United Kingdom.

2. General principles

- 2.1. The goal of all fertility treatment should be to provide comprehensive support to maximise the opportunity for a live birth of a healthy singleton child, born at full term. This is the safest outcome for both the mother and child.
- 2.2. Reducing death and disability in children conceived following infertility treatment is of concern to commissioners, providers and recipients of care.
- 2.3. Overall, eSET has success rates comparable to double embryo transfers if cumulative pregnancy rates are calculated (from fresh and subsequent frozen transfers).

³ De Mouzon J, Goossens V, Bhattacharya S, Castilla JA, Ferraretti AP, Korsak V, Kupka M, Nygren KG, Nyboe Andersen A; European IVF-monitoring (EIM) Consortium, for the European Society of Human Reproduction and Embryology (ESHRE). Assisted reproductive technology in Europe, 2006: results generated from European registers by ESHRE. *Hum Reprod.* 2010 Aug;25(8):1851-62. Epub 2010 Jun 22.

- 2.4. eSET results in a much higher chance of a singleton term delivery.
- 2.5. Providers of IVF should endeavour to identify those good prognosis women at significant risk of multiple pregnancies, and offer eSET as a matter of routine. High rates of multiple pregnancies derived from IVF treatment in individual centres are no longer acceptable clinical practice.

3. Regulation

- 3.1. The HFEA has played a key role in reducing the multiple birth rate by introducing realistic and achievable targets. The policy targets were set at 24% in 2009/10, 20% in 2010/11 and 15% in 2011/12.
- 3.2. All providers of IVF have a written multiple birth minimisation strategy which clearly identifies patients suitable for eSET.
- 3.3. It is essential that all IVF providers audit the effectiveness of their strategy to ensure continued compliance with multiple birth targets.
- 3.4. The HFEA should consistently enforce the policy across all centres and monitor compliance.
- 3.5. The HFEA should report clinic data as cumulative live birth rates per initiated cycle to encourage good clinical practice.

4. Provision of information

- 4.1. Providers of IVF should ensure consistent, accurate information is given to patients by all staff throughout a patient's treatment course.
- 4.2. The key messages to inform patients include:

- eSET in good prognosis patients will maximise the chance of delivering a healthy baby born at term,
 - eSET is not appropriate for all patients, and
 - success rates can be maintained by taking into account subsequent frozen cycles and calculating the cumulative pregnancy rate.
- 4.3. Responsible education initiatives are required to appraise patients, commissioners, GPs, and the wider public about potential adverse outcomes of twin pregnancies.
- 4.4. The media should ensure that reporting of issues surrounding multiple births is accurate, informed and avoids sensationalism.

5. Clinical practice

- 5.1. All centres should modify their eSET policy to reflect the audit of their clinical practice as well as changing regulatory requirements.
- 5.2. Each patient should be treated as an individual. Patients most likely to become pregnant, and therefore also most at risk of a multiple pregnancy, should have eSET. eSET is not appropriate for all patients. Important prognostic indicators include female age and available embryo quality.
- 5.3. Single blastocyst transfer is an effective strategy for eSET but replacing two blastocysts is associated with a higher risk of multiple births.
- 5.4. A key to a successful eSET programme is the cumulative rate from fresh and frozen cycles. An effective validated cryopreservation and thawing/warming strategy is essential to maintain success rates and decrease multiple birth rates.

5.5. The multiple birth minimisation strategy should be extended to cover all aspects of fertility treatment (eg, ovulation induction and intra uterine insemination).

6. Commissioning and funding of treatment

6.1. The NHS should commission services from providers who are committed to and consistently compliant with the HFEA multiple birth rate targets.

6.2. Commissioners should not set blanket compulsory eSET policies, which do not allow individualisation of treatment to ensure best outcome.

6.3. National commissioning would allow consistency and fairness in line with NICE guidelines, and avoid the current postcode lottery.

6.4. The definition of a single full treatment cycle is the replacement of a fresh embryo and subsequent replacement of all the frozen embryos derived from that cycle.

6.5. Implementing the full three cycles recommended by the NICE Guideline on Fertility (2004)⁴ will play a fundamental part in IVF centres meeting future multiple birth rate targets. Provision of three full cycles with appropriate use of eSET will reduce multiple births from fertility treatment.

6.6. Health economic analysis has shown that eSET is more cost effective than double embryo transfer by reducing the multiple birth rate from IVF, saving significant costs to the health service by reducing maternal and neonatal hospital admissions (The Netherlands⁵).

⁴ <http://www.nice.org.uk/nicemedia/live/10936/29269/29269.pdf>

⁵ Lukassen H, Schönbeck Y, Adang E, Braat D, Zielhuis G, and Kremer J. Cost analysis of singleton versus twin pregnancies after in vitro fertilization. *Fertil Steril*. 2004 May;81(5):1240-6.

6.7. Pricing policies should be developed to include the cost of frozen/thaw cycles into a treatment package, making eSET more attractive to both commissioners and patients.

7. Support for neonatal and child health services

7.1. Neonatal care facilities in the UK should be organised and equipped to provide the best care possible for all children, including those derived from multiple birth.

7.2. Neonatal health care services are under considerable strain in the UK, with units across the country failing to meet minimum standards on staffing levels⁶. Reducing the multiple birth rate to 10% or less following IVF will have a significant positive impact on neonatal care services, reducing the gap between current provision and the agreed standard of care that babies should receive. It will also enable more resources to be available for the provision of increasingly complex and expensive care, essential for some babies, whether conceived naturally or after fertility treatment.

8. Follow-up studies

8.1. The HFEA should analyse and publish national data to monitor the balance between overall multiple birth rates and the overall live birth rates.

8.2. Paediatric follow-up studies should be encouraged with greater cooperation between fertility specialists and paediatricians.

9. Conclusion

9.1. The aim of all fertility treatment should be the birth of a healthy singleton child, as there is extensive evidence that this minimises the health risks to both mother and child.

⁶ British Association of Perinatal Medicine, Service standards for hospitals providing neonatal care (3rd edition), August 2010

- 9.2. There is irrefutable evidence to show a link between the practice of transferring multiple embryos and a significantly greater risk of health complications to both mother and child. Multiple births can also cause distress for the parents and family and has an unsustainable immediate and long-term financial cost for society.

- 9.3. The national IVF treatment data shows that modifying embryo transfer practice through careful patient and embryo selection can significantly reduce these risks.

- 9.4. Ongoing and standardised funding is essential to enable providers and patients to comply with multiple birth rate targets and to improve neonatal and maternal outcomes.