Authority Agenda
Wednesday 3 July 2013
Meeting to be held at
ETC.Venues, Bonhill House, 1-3 Bonhill Street, London, EC2A 4BX

Workshop – Members Strategic Roles (10.30am)
Lunch (12.15pm)
Meeting Starts (1.00pm)

1. Welcome, Apologies and Declaration of Interests
2. Minutes of 1 May 2013 [HFEA (03/07/2013) 681]
3. Chair's Report (verbal)
4. Chief Executive’s Report (verbal)
5. Update from Committee Chairs Information
6. Directorates Report [HFEA (03/07/2013) 682] Information
7. High Level Risk Register [HFEA (03/07/2013) 683] Decision
8. PGD Reconsideration Process [HFEA (03/07/2013) 684] Decision
9. PGD Conditions Review Update [HFEA (03/07/2013) 685] Decision
11. Update on National Donation Strategy Group Presentation Information
12. Multiple Births Update [HFEA (03/07/2013) 687] Information
13. **Multiple Births and Blastocyst Transfer Outcome Data**
   Presentation
   Information

14. **Standing Financial Instructions**
   [HFEA (03/07/2013) 688]
   Decision

   *Close* 4.40pm

   *Next meeting:* Wednesday 11 September, 2013
Minutes of the Authority meeting on 1 May 2013
held at Bonhill House, Bonhill Street, London, EC2A 4BX

Members
There were 10 members at the meeting, 7 lay members and 3 professional members.

Members present
Professor Lisa Jardine CBE
(Chair)
Gemma Hobcraft
Sally Cheshire
Jane Dibblin

Debbie Barber
Rebekah Dundas
Dr Susan Price

Bishop Lee Rayfield
Dr Andy Greenfield
Dr Alan Thornhill

Observers
Ted Webb (DH)
Steve Pugh (DH)

Apologies
Professor David Archard
Sam Abdalla FRCOG

Staff in attendance
Peter Thompson
Mark Bennett
Nick Jones
Paula Robinson

Rachel Hopkins
Chris O’Toole
Catherine Drennan

Siobhain Kelly
Joanne McAlpine
Charlotte Keen
1. **Welcome, Apologies and Declaration of Interests**
   1.1. The Chair opened the meeting by welcoming Authority members to their fourth meeting of 2013.
   1.2. Apologies were received from David Archard and Sam Abdalla.
   1.3. Declarations of interest were made by:
      - Alan Thornhill (Consultant Clinical Research Scientist at Guy’s Hospital)
      - Debbie Barber (Part-time Nurse Specialist at a licensed centre).

2. **Minutes of Authority meeting held on 20 March 2013**
   2.1. Members agreed the minutes subject to some minor amendments. The Chair agreed to sign the minutes as amended.

3. **Chair’s Report**
   3.1. The Chair informed members that she had several media commitments in the coming months.
   3.2. The Chair reported that Sir Robert Edwards passed away on 10 April 2013, which had been extensively reported in the media. Sir Robert had been the pioneer of IVF treatment, together with Patrick Steptoe. The lead Inspector for Bourn Hall represented the HFEA at the funeral. The Chair expressed her thanks to Sir Robert Edwards for his dedication and passionate commitment and for everything he had done in the field of IVF.
   3.3. The Chair expressed her thanks to all members and HFEA staff for their patience and co-operation whilst the Executive had implemented the new Committee structure which came into operation on 1 April 2013.
   3.4. Members were advised that some considerable time had been spent on the McCracken report since the last Authority meeting. Both the Chair and the Chief Executive had attended a meeting on 10 April with Justin McCracken together with Alan Clamp, the Chief Executive, and Diana Warwick, the Chair, of the Human Tissue Authority (HTA). The report had been formally submitted to the Department of Health for approval and would then be circulated to the Cabinet Office and then for formal cross-Government clearance.
   3.5. The Chair confirmed that she was currently conducting appraisals with all Authority members.

4. **Chief Executive’s Report**
   4.1. The Chief Executive advised members that on 4 April he, together with the Director of Compliance, met with representatives from the Welsh Assembly Government and Healthcare Inspectorate Wales regarding IVF services in Wales.
   4.2. On 24 April, the Chief Executive had a meeting with Janet Wisely and Jonathan Montgomery, the Chief Executive and Chair respectively of the Health Research Authority (HRA), to discuss joint working on processing research applications.
   4.3. The Chief Executive advised Authority members that on 26 April, a Mitochondrial replacement dialogue wash-up meeting had taken place with Sciencewise, Office for Public Management (OPM), Dialogue by Design and Forster Communications, with Cardiff University evaluating the project.
   4.4. The Chief Executive summarised press coverage since the last Authority meeting, details of which had been circulated to members by the Press and
Public Enquiries Officer. The main story in the press had been mitochondria, which had attracted a fair amount of interest despite running parallel with the Chancellor’s Budget. It had been reported by the Telegraph, Sky News, the BBC, Nature, the Guardian, the Independent, the Mail and the Times, and was also widely covered in social media with international news interest from Germany, Austria and Russia. There had also been an article in the New Statesman, which had referred to the organisation as the “Great British HFEA”. The Chair expressed her thanks to the Communications team and Fiona Fox, the Chief Executive of the Science Media Centre, for the work they had carried out in handling the two press conferences.

4.5. The Chief Executive informed Authority members that on 17 April the Nuffield Council on Bioethics had published their report on Donor Conception, which highlighted additional efforts required in counselling patients before, during and after their treatment, to encourage them to inform their donor-conceived child that a donor was involved in their conception. There had also been coverage in the Sunday Express about the cost of IVF, together with the scrapping of Primary Care Trusts (PCTs).

4.6. The Chief Executive advised members of an article which had been published in the Daily Mail and the Daily Mirror, regarding a 50 year old UCL employed scientist who referred to himself as a private sperm donor and claimed to have fathered potentially 49 children. The individual had been arrested, but not yet charged, for sexual assault. Two women had come forward since November last year to lodge complaints of sexual assault.

4.7. The Chief Executive briefly provided members with a description of a case which had been heard in the Family Court last year where a woman who had been refused the right to adopt a fourth child, subsequently purchased sperm online and forced her eldest adopted daughter to self-inseminate so that the woman could have another child.

5. Update from Committee Chairs

5.1. Members were advised that the Licence Committee met on 28 March (and considered five PGD applications, a new centre application and an incident review) and on 26 April 2013, which had been followed by a PGD workshop. The first meeting of the new Statutory Approvals Committee (with two PGD cases for consideration) had taken place on 25 April 2013. The Remuneration Committee met on 11 April 2013.
6. **Directorates Report**

6.1. The Director of Finance and Facilities provided members with a summary of financial performance up until the end of March 2013. The Executive had planned for £6 million of expenditure in the previous financial year, reducing for the 2012/13 financial year to around £5.6 million. The end of year figure was likely to be £5.3 million, since provisions related to the exiting of Bloomsbury Street would not now be needed. Overall results on treatment fee income were about the same as the 2011/12 financial year and the HFEA bank account was just below £3 million.

6.2. The Head of Business Planning advised members that work was being carried out on the content of the full Directorates Report, including a review of the Key Performance Indicators and the summary page.

6.3. Authority members noted the summarised Directorates Report.

6.4. The Legal Adviser provided members with a legal update summary.

7. **Incidents: Openness and Transparency Relating to Serious Adverse Events**

7.1. The Head of Research Regulation and Clinical Governance presented a paper seeking an early view from members on the degree of openness and transparency in relation to incidents (serious adverse events and reactions) reported by centres to the HFEA and how centres subsequently dealt with patients affected by such incidents.

7.2. Members were reminded that in 2012 they had reviewed the Authority’s approach to openness and transparency as a whole as part of the Government’s wider transparency and open data agendas, which aim to drive up standards in the public sector through increased transparency. Part of that discussion focused on incidents and the view of members at the time was that more contextual information should be published, with the caveat that release of such information should not lead to under reporting of incidents by clinics. It was therefore important to handle publication in such a way as to avoid discouraging clinics from reporting incidents in the first place. The Head of Research Regulation and Clinical Governance emphasised that there was no evidence to suggest that this was the case.

7.3. With the publication of the Francis Report (the Mid Staffordshire NHS Foundation Trust Public Inquiry) there was now a much more urgent focus on the reporting of incidents relating to adverse outcomes and on transparency and concerns about quality of care more generally.

7.4. The Head of Research Regulation and Clinical Governance summarised the definition of an adverse incident, together with the HFEA grading system in place since April 2006, which is a ‘matrix’ for rating incidents according to the severity of the potential outcome(s), together with a further assessment of the likelihood of a recurrence.

7.5. The severity of incidents determined the response. Where an incident is graded at ‘C’, it was the responsibility of the centre to investigate and to submit an annual report to the HFEA, identifying relevant remedial actions and learning points. Incidents graded at ‘B’ or ‘C’ would not normally be referred to the Authority’s Licence Committee or Executive Licensing Panel but such matters would be passed to the Inspector with responsibility for that centre and would be used to
inform the subsequent inspection, focusing on any weaknesses identified by the review. For incidents graded at ‘A’, the HFEA contacts the centre to obtain further information. An incident inspection is undertaken to review why the incident had occurred and the actions needed to be taken to prevent a similar incident occurring in the future. Following the inspection visit and the centre’s own investigation, a ‘root-cause analysis’ report would be produced and presented to the Authority’s Licence Committee, together with the Person Responsible’s response. The Licence Committee would then determine any further regulatory action.

7.6. Members were advised that the total number of incidents reported in each category classification were set out in the HFEA Annual Report every year. For Grade A incidents, following consideration by the Licence Committee, the report and the minutes of the Committee decisions would normally be published on the HFEA website under Choose a Fertility Clinic, with the caveat that this would not be the case if, in doing so, it could potentially identify an individual patient.

7.7. Members were asked to consider whether more information should be published and the purpose, or intention, in doing so. Once the purpose had been identified, further consideration could be given to how information was published in order to achieve that purpose. The Head of Research Regulation and Clinical Governance set out several options for members to consider, emphasising that the Executive was not proposing any change to current policy as regards publishing reports relating to Grade A incidents.

7.8. **Informing patients:** This is to promote openness and transparency. Individual reports on each incident reported to the HFEA could be published, linked to the centre at which the incident occurred, although it was acknowledged that this could potentially lead to centres not reporting incidents to the HFEA. A further option was for summary data to be published on the number and severity of incidents occurring at each licensed centre during a prescribed period, although again, this may lead to centres not reporting incidents.

7.9. **Improving standards:** this goal could be achieved by disclosing aggregated information about all incidents reported, which would enable the opportunity to provide trend analysis and issue guidance to centres on how standards could be improved.

7.10. The Head of Research Regulation and Clinical Governance advised members that an analysis was currently being produced of all incidents over the last three years.

7.11. Following discussion, Authority members agreed that it was equally important for published data to both inform patients and improve standards. However, members agreed that published information should not relate to individual clinics’ performance, as this might dis-incentivise open reporting, but that ‘themes and trend’ analyses would have a more positive effect in spreading learning and best practice. Members endorsed the proposal to engage with the sector and stakeholders, and for clinics to engage more with patients when an incident had affected them. The Chair emphasised that it was vital to seek expert academic advice on when and how to inform patients in relation to incidents which could have an impact on the provision of their treatment, and serious consideration should be given from the perspective of the patient involved, and on that basis more work is needed.
8. **Vigilance and Surveillance**

8.1. The Head of Research Regulation and Clinical Governance introduced a paper on the amended tools used to grade serious adverse events, reactions and incidents.

8.2. Members were advised that the HFEA had, for the past three years, been part of a Europe wide project to develop guidelines and tools for reporting and grading serious adverse reactions, events and incidents. The project had ended in February 2013 and had delivered guidance on:

- Vigilance and surveillance in Assisted Reproductive Technologies, including reporting tools
- Communication and investigation of adverse reactions and events
- The detection and investigation of suspected illegal or fraudulent activity
- Vigilance and surveillance in living donors
- Vigilance and surveillance guidance for clinical users.

8.3. In relation to the reporting tools, the Head of Research Regulation and Clinical Governance advised members that the Executive had used the outputs of the project to amend and update the HFEA’s vigilance and surveillance tools. The development of these tools had been carried out with the involvement of stakeholders and the Authority’s (then) Compliance Committee. A number of workshops had also been held in order to involve stakeholders in the review of the impact assessment tool to determine whether it was appropriately calibrated. Several case studies had been presented to the stakeholders and participants were asked to grade them on the impact they would have on the patient (insignificant, minor, moderate, major or severe). The outcome of the case studies was varied, with little agreement as to what level of impact an incident would have on a given patient, with views generally dependent on whether the participant was considering the incident from the point of view of a patient or from the perspective of general practice within a centre.

8.4. There was, however, a consensus among stakeholders that the Authority should publish more information about clinical governance, including the tools used to grade incidents, together with an explanation of how incidents were graded and some illustrative case studies.

**Decision**

8.5. Authority members agreed that a grading system and matrix is fundamental to the Executive managing the reporting of incidents. However, there was also agreement that for the grading system to be effective in its day to day implementation, it would be beneficial for further refinement to take place, particularly as regards the grading of very rare events. The Executive agreed to give further consideration to the amended tools and present proposals to the Authority at a later date.

9. **Compliance and Enforcement Policy**

9.1. The Head of Research Regulation and Clinical Governance asked members to agree to the extension of the Authority’s current Compliance and Enforcement Policy until a full review had taken place. The revised policy would be in place by October 2013.
Decision

9.2. Authority members agreed to the extension of the Authority’s current Compliance and Enforcement Policy until a full review had taken place.

Finance and Resourcing

9.3. The Director of Finance and Facilities and the Head of Human Resources gave a presentation summarising the HFEA’s finances and staffing over the Spending Review period. The Director of Finance advised members that the objective was to inform members about the size of the organisation and to give a sense of cost and capacity of its main resources. There had been a number of efficiencies, including:

- moving to smaller, cheaper offices
- disbanding the Facilities team
- reducing the Senior Management Team
- de-layering management by going from 13 Heads to 10
- following Government restrictions on communication and external engagement
- following recruitment restrictions, hiring only to business critical roles and holding vacancies elsewhere
- participating in shared services where able
- reducing resourcing in HR and Finance
- expecting more of staff and lowering administrative need
- moving to electronic records.

9.4. The Director of Finance and Facilities provided members with an overview of funds and costs, with a total annual budget for the 2013/14 financial year of £6.1 million.

9.5. These savings should be seen in the context of the wider public sector, where there would be no more financial growth, given the deficit and cuts required. There had been significant cuts in funding across Government, with the HFEA required to make a 33% reduction in grant-in-aid income, although the organisation had managed to go further and delivered a 40% cut to date. Notice had been received for the 2015/16 spending round, indicating a further 7% saving; and a regulators’ fee cap of 5% from 2015/16 had been announced in the March 2013 budget.

9.6. The Head of Human Resources provided members with an overview of the impact the austerity measures had had on employees, including:

- job cuts
- two year pay freeze in the financial years 2010/11 and 2011/12
- pay increases limited to 1%
- increase in public sector pension contributions
- consumer Price Index between 2010 and March 2013 had risen by 10%
- London season tickets had risen 13% in the last two years.
9.7. Members were advised of the current HFEA staff profile, headcount and banding together with a summary of the core statutory, business support and corporate services functions. The Head of Human Resources emphasised the limited potential to make further efficiencies and that any further cuts would be extremely difficult for the organisation and its core business.

9.8. In the context of the delivery of recurring savings of approximately £2 million per annum and a 20% cut in posts since austerity measures had been put in place, members were asked to consider a number of issues, including:

- the balance between statutory functions, business support and corporate services
- the adequacy of maintaining staff morale and behaviour
- whether fees could be raised or reduced, noting the fee cap and other issues
- the potential for eliminating grant-in-aid from central Government entirely and the implications of that
- the impact on both existing staff and recruitment.

9.9. Authority members noted the points raised and expressed their gratitude to all the HFEA staff and their appreciation for the work they had carried out over the last three years. Members also noted the significant savings the organisation had already made and expressed the view that there was a need to be robust in dealing with any further savings which could be potentially damaging and unsustainable for the organisation as a whole. Members agreed that a regular update at future Authority meetings would be useful.

10. Authority Governance Transition Programme: Progress Report & Decision Trees

10.1. Progress Report: the Head of Business Planning provided members with an update on progress made in the Governance Transition Programme. The new Committees had been introduced as had the revised Standing Orders. The new PGD form and guidance had also been launched.

10.2. Members were provided with a summary of remaining work resulting from the programme.

10.3. The Head of Business Planning advised members on the background to the new design approach to Decision Trees, which involved grouping together those considerations that effectively formed one stage in the Committee’s thinking, to sequence those appropriately and to distinguish more clearly between straightforward facts, and issues that would require the Committee to consider the available evidence and to form a conclusion or judgement. The new design also made visually clear which steps were decisions.

10.4. Following discussion, members noted the update and approved the new approach to Decision Trees. Members also agreed that the Decision Trees should now be piloted through the Committees, with changes to be made at the discretion of the relevant Chairs and with any required legal advice. The Executive confirmed that an internal quality assurance process for Committee papers was in place and that this mirrored the requirements in the Decision Trees.
10.5. The Chair expressed her thanks to Sarah Ellson at Field Fisher Waterhouse for her input into the development of the Decision Trees.

11. **Annual Report on HFEA Complaints**

11.1. For context and clarity, the Head of Business Planning advised members that the HFEA had two whistleblowing policies (one for staff to report anything improper within the organisation and one for individuals to report anything improper at a clinic); and two complaints policies in place, mirroring the same system, with a clear differentiation between complaints received by the HFEA in relation to clinics, and complaints specifically regarding the HFEA’s own service quality. This latter type of complaint was the subject of this annual report.

11.2. Members were advised that the HFEA complaints policy clearly set out what would or would not be classified as a complaint, how the organisation handled complaints, information about the Parliamentary and Health Service Ombudsman and an optional complaints form in order to assist individuals to provide the necessary information.

11.3. The latest version of the HFEA complaints policy was dated December 2007 but members were informed that a review was scheduled for later in the year.

11.4. The volume of complaints received was normally very low with typically up to three complaints per year. Four complaints had been received in 2012/13, with three of those deemed valid complaints, and in all three cases a full investigation had not been required in order to understand and resolve the issue. All three complainants had received an apology and appropriate remedial action was taken by the HFEA. The Head of Business Planning provided members with a summary of the three complaints and the learning points.

11.5. Members noted the information presented to them in the Annual Report on HFEA complaints and agreed it would also be useful for Authority members to receive a separate report on the trends in complaints made to clinics.

12. **Any Other Business**

12.1. The Department of Health representative advised Authority members and the Executive that he and a colleague had attended the HFEA workshop on surrogacy on 30 April 2013 and expressed his thanks to the staff involved in making it a success.

13. **Date of next meeting**

13.1. The Chair confirmed that the next meeting would be held on Wednesday, 3 July 2013 at ETC Venues, Bonhill House, Bonhill Street, London, EC2A 4BX.

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

Chair

Date
1. Introduction

1.1 Directorates Report Summary

The attached paper summarises the main performance indicators up to April 2013, following discussion by CMG at its June performance meeting.

1.2 Recommendation

The Authority is invited to note the summarised Directorates Report.

Paula Robinson
Head of Business Planning
June 2013
## HFEA Performance Scorecard

### Key Performance and Volume Indicators: April Performance Data

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Performance</th>
<th>RAG</th>
<th>Recent Trend</th>
<th>Aim</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average number of working days taken for the whole licensing process, from</td>
<td>69</td>
<td>⭐</td>
<td><img src="chart1" alt="Graph" /></td>
<td>Maintain</td>
<td>KPI: Less than or equal to 70 working days. Following detailed consideration over the past business year, this KPI has been increased, from 60 to 70 working days. We will continue to monitor all the steps in the process closely.</td>
</tr>
<tr>
<td>the day of inspection to the decision being communicated to the centre.</td>
<td></td>
<td></td>
<td></td>
<td>70wd or less</td>
<td></td>
</tr>
<tr>
<td>Licensing decisions made:</td>
<td>10</td>
<td>±</td>
<td><img src="chart2" alt="Graph" /></td>
<td>No KPI –</td>
<td>Volume indicator (no KPI target). ELP handling majority of decisions, as intended.</td>
</tr>
<tr>
<td>- By ELP</td>
<td>1</td>
<td></td>
<td></td>
<td>tracked for</td>
<td></td>
</tr>
<tr>
<td>- By Licence Committee</td>
<td></td>
<td></td>
<td></td>
<td>workload</td>
<td></td>
</tr>
<tr>
<td>Volume monitoring purposes</td>
<td></td>
<td></td>
<td></td>
<td>monitoring</td>
<td></td>
</tr>
<tr>
<td>Percentage of PGD applications processed within 4 months (88 working</td>
<td>66%</td>
<td><img src="chart3" alt="▲" /></td>
<td><img src="chart3" alt="Graph" /></td>
<td>Increase to</td>
<td>KPI: 90% processed (i.e. considered by LC/ELP) within 4 months (88 working days) of receipt of completed application. Following recent work on the PGD process, we believe we can achieve a sustained improvement during 2013.</td>
</tr>
<tr>
<td>days).</td>
<td></td>
<td></td>
<td></td>
<td>90% or more</td>
<td></td>
</tr>
</tbody>
</table>

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. Direction in which we are trying to drive performance. (Are we aiming to exceed, equal, or stay beneath this particular KPI target?)
<table>
<thead>
<tr>
<th>Indicator</th>
<th>Performance</th>
<th>RAG</th>
<th>Recent Trend</th>
<th>Aim²</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff sickness absence rate (%) per month.</td>
<td>0.5%</td>
<td>★</td>
<td></td>
<td></td>
<td>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%).</td>
</tr>
<tr>
<td>Percentage of Opening the Register requests responded to within 20 working days</td>
<td>100%</td>
<td>★</td>
<td></td>
<td></td>
<td>Maintain at 100% KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)</td>
</tr>
<tr>
<td>Number of visits to the HFEA website (cw previous year)</td>
<td>71,610 (51,232)</td>
<td>↓</td>
<td></td>
<td></td>
<td>No KPI – tracked for general monitoring purposes Volume indicator showing general website traffic compared to the same period in previous year. Measured on the basis of ‘unique visitors’.</td>
</tr>
<tr>
<td>Cash &amp; Bank Balance</td>
<td>£3,233k</td>
<td>↑</td>
<td></td>
<td></td>
<td>Decrease to £750k or less KPI: Balance not to exceed DH limit of £750k. There has been a rise of £555k in the cash balance, due primarily to a receipt of grant in aid in April. The £700k hypothecated for Capital Expenditure on data collection and the Register is added to the KPI (until the spend begins).</td>
</tr>
</tbody>
</table>
Agenda Item 6

Notes:
This graph presents fee income budgeted and invoiced monthly for 2012/13. Except for those months that coincided with the Olympics and Paralympics, income was fairly close to budget throughout the year, although it is not clear that those events necessarily contributed to such dramatic drops in treatment billing. The growth we had budgeted for the year did not materialise, and accordingly the fees budget for 2013/14 has been set at 2012/13 invoiced levels.

Fees income for April 2013 was slightly over budget, and activity levels will be closely monitored over the coming months. Future reports will present the 2013/14 graph.
### Summary Table:

<table>
<thead>
<tr>
<th>Scorecard area</th>
<th>KPIs / RAG Status</th>
<th>Red Indicators and Management Comments on Controls</th>
</tr>
</thead>
</table>
| **Regulatory Operational** | ![Regulatory Operational Chart](chart.png) | Red indicators:  
The publication of minutes by the Licensing team was adversely affected this month by the periodic switch-off of the uploader tool during CaFC finalisation. This occurs twice yearly and temporarily prevents uploads to the website. Minutes are still being entered by the team in a timely way, and uploading will resume once the CaFC update is completed.  
There has been some improvement in PGD processing times during the last 2 months. This is still technically performing in the red; however, this is partly due to the low numbers being counted. For instance, only one out of three applications did not meet the KPI this month, but this means performance still appears poor at 66%. The application in question needed to go to a later committee and this meant that it missed the overall KPI by just 5 days. On average, it has been taking 93 days to process PGD applications for new conditions. This figure will decrease as a result of our revised processes, particularly as we continue to improve the Peer Review arrangements. |
| **Performance**         |                   | No red indicators.                                 |

![Regulatory Operational Chart](chart.png)
### Scorecard area

<table>
<thead>
<tr>
<th>KPIs / RAG Status</th>
<th>Red Indicators and Management Comments on Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Corporate Governance</strong></td>
<td></td>
</tr>
<tr>
<td><img src="chart1" alt="Corporate Governance Pie Chart" /></td>
<td>No red indicators. All amber indicators are projects, rated amber because of manageable delays, complexity and interdependencies, or because the project is currently in a critical phase of delivery. 3 of these (Code of Practice, Sage Upgrade and Automated Billing) have recently decreased to amber from red or red/amber. The Annual Report remains on amber (busiest delivery phase in progress, with several critical external dependencies); and the PGD Conditions project is now re-starting on amber, following a period on pause.</td>
</tr>
</tbody>
</table>

| **Information Provision** |
| ![Information Provision Pie Chart](chart2) | The various new indicators set by the Register and Communications teams will in most cases need to be tracked for longer before KPIs can be set. For some of them, measurement has only been possible since the beginning of April. These are therefore currently counted as 'neutral' or volume indicators. The 2 red indicators were the pre-inspection Register submission assessments (with a target to prepare these at least 10 working days in advance of the inspection); and the provision of post-inspection audit summaries to the lead inspector, again within 10 working days. Both these KPIs were adversely affected by a high number of inspections during April. |

| **Financial Performance** |
| ![Financial Performance Pie Chart](chart3) | Red indicators: The target for producing the monthly management accounts is 5 working days. In April this took 18 working days due to the combined impact of the 2012/13 year end audit and issues with the introduction of WAP based accounts processing, which both took significant Finance resources. WAP has subsequently "gone live" (3 June) so this target should be met in coming months. The KPI target may be reduced as we gain more experience in taking advantage of the benefits available using WAP and SAGE 200. There is also a target of 5 working days for payments to suppliers, and we are currently meeting this for 7% of payments. Although this indicator has historically been difficult to meet without undue cost due to the terms of our banking service, this latest figure is a material fall. However, all invoices in April were paid within 30 days. Efforts to improve this statistic will now be... |
Scorecard area | KPIs / RAG Status | Red Indicators and Management Comments on Controls
---|---|---
made in the coming months, following WAP going live.

**Performance Highlights from 2012/13:**
- The total performance picture for 2012/13 was positive, with exceptions explained and addressed throughout the year.
- 82 inspections were delivered in the year (100% of the intended schedule, including in-year additions).
- 49 PGD applications were processed through our Committees. Despite the problems with obtaining Peer Review input, 43% were processed within the KPI – a figure we expect to improve during this year through the new PGD arrangements introduced from April 2013. The Licence Committees also considered another 33 items, while ELP considered 122 items.
- The sickness absence rate for the whole year was 2.1% (against our target of less than 3%).
- Capacity issues remained a key risk on our high level risk register throughout the year, but our performance on capacity (i.e. our headcount and our rate of turnover) remained acceptable. Turnover stayed within our 16% target for the last 4 months of the business year, although there was more variability earlier in the year. The highest figure during the year was in April 2012, when turnover was at 22%.
- 193 Opening the Register requests were responded to, 100% within the 20 working day target.
- 63 Parliamentary Questions were answered, of which only one did not meet the Department of Health’s target. (Due to staff shortage at the time the question was sent).
- Website traffic remains constant compared to the previous year, with 643,731 unique visitors.
- In general, performance remains steady and satisfactory across most indicators. Where there is poor or variable performance, the reasons for this are understood and are being managed to the extent that is possible.

**Regulatory Operational Performance:**
- CMG previously agreed that the 60 working day performance target for the ‘whole licensing process’ indicator should be reviewed after the governance transition programme had been completed. After detailed examination of all of the steps in the licensing process, it has been agreed that a performance target of 60 days is too low. Performance for 2012/13 was 72 working days, with comparatively few delays in Committee scheduling etc. We believe we can do a bit better than that, but not 12 days better. Therefore the KPI has been re-set to 70 working days.

**Financial Performance:**
- There were consistent underspends in revenue costs during the year, owing mainly to time lags in filling vacant posts. However these were balanced by income shortfall at year end.
- Design and planning has commenced for strand 2 of the Capital Expenditure project (register modernisation), while further work is
planned relating to the proposal for strand 1 (digital communications). All of this work will help partly to address the longstanding
bank balance issue.
The High Level Risk Register considered by the Audit and Governance Committee, and subsequently by the Authority will be published on the website 12 months after the meeting on which it was considered by the Authority. It will be published on the webpage for the meeting at which it was presented. For further information, see the HFEA's publication policy – http://www.hfea.gov.uk/docs/HFEA_Policy_on_Publication_of_Authority_and_Committee_Papers.pdf
The most recent version published to date is that presented to the Authority in May 2011 http://www.hfea.gov.uk/docs/May11_-_Authority_Papers_-_COMPLETE.PDF
### Paper Title
PGD Reconsideration Process

### Agenda Item
8

### Paper Number
[HFEA (03/07/2013) 684]

### Meeting Date
3 July 2013

### Author
Jessica Watkin (Policy Manager)

### For information or decision?
Decision

### Recommendation
Members are asked to consider the proposal for a PGD reconsideration process outlined in this paper and to:
- Approve the proposed stages of the procedure.
- Decide whether the Authority or the PGD working group should make the decision about whether any conditions should progress to Phase 2 of a Review (i.e. a more in-depth consultation stage)

### Resource Implications
Staff time
External legal advice (external legal adviser to draft explanatory note); Executive to draft new SOP
Communication strategy will need to be developed

### Implementation
Immediate

### Communication

### Organisational Risk
Medium

### Evaluation
Periodic review
1. **Introduction**

1.1. The HFEA maintains a published list of medical conditions for which pre-implantation genetic diagnosis (PGD) can be provided by any relevantly licensed clinic (the ‘PGD list’). Conditions are added to the list following a process of authorisation by the HFEA. PGD licensed centres cannot carry out embryo testing for a condition unless that condition is on the PGD list.

1.2. As of April 2013, this authorisation function is carried out by the newly established Statutory Approvals Committee (SAC), whose decisions are guided by the PGD decision tree. This decision tree includes criteria concerning a condition’s treatability.

1.3. In 2009, the Authority agreed that the PGD list should be reviewed periodically. The aim of such reviews would be to ensure that only conditions which meet statutory criteria remain on the list.

1.4. The statutory criteria requires that the HFEA be ‘satisfied’ that embryo testing is carried out only where there is a ‘significant risk’ that a child born with the condition in question would have or develop a ‘serious’ medical condition. It is the HFEA’s responsibility to judge when a condition meets this criteria.

1.5. Equally, it will also be the HFEA’s responsibility to decide if a condition no longer meets these criteria.

1.6. Following the Authority’s 2009 decision, the HFEA instigated a review of all conditions authorised for PGD prior to 1 October 2009, when the new statutory criteria came into force. As of this date, the HFEA also introduced a new ‘condition by condition’ system of authorisation. This first PGD review is near complete will be considered by the Authority today (see Agenda item 9).

1.7. At its February 2013 meeting, the Authority asked that a PGD reconsideration process be developed. This paper fulfils that request and sets out proposals for a formal set of procedures for considering the removal of a condition from the PGD list (a ‘PGD reconsideration procedure’). An early version of these proposals was discussed at a meeting of the Ethics and Standards Committee (ESC) on 25 April.

1.8. It therefore follows that the development of a formal PGD reconsideration procedure has taken place after the first PGD Review (see Agenda item 9) was already underway. However, following the Authority’s February meeting, various changes were made to the way this first Review was being carried out to ensure consistency with the procedures set out in this paper. Future reviews will use the procedures agreed by the Authority today.

2. **Proposed procedure for reconsidering a condition**

2.1. Paragraph 2.2 sets out the proposed set of procedures for carrying out a review of the PGD list. It would have two distinct phases.

- Phase 1 is set out at (a) to (c) and covers the initial information
gathering exercise. The aim is to identify and exclude (from any further stages of the review) any conditions which have not been subject to relevant advances since the last time they were reviewed by the HFEA.

- Phase 2 is set out at (f) and (h) below and sets out a more detailed consultation stage for the remaining (if any) shortlist of conditions. This consultation will be carried out with a broad range of stakeholders and will include assessing the potential impact of removing any of those conditions from the PGD list.

At the end of Phase 1, a decision will be made as to whether any conditions should progress to Phase 2 of a Review. Phase 2 will conclude with a final decision by SAC about whether a condition should or shouldn’t be removed from the list. It will also be responsible for how that decision should be implemented.

2.2. The following is the proposed set of procedures for a formal PGD review:

a. Medical charities (via Genetic Alliance UK) and, where necessary, peer reviewers will be asked to review the conditions and asked whether there have been:
   - any significant treatment advances since the condition was last examined by the HFEA and whether they have a significant impact on its morbidity/ mortality.
   - the availability of those new treatments. For example, whether they are still at the research stage of development and/or whether they would be accessible to most UK patients
   - whether there have been any other developments which may be of relevance (such as the new availability of an effective treatment that was previously not easily accessible)

   To help ensure that the information we receive is fit for purpose, the Executive will develop a form, which will set out specific questions linked to the criteria set out in the bullet points above.

b. All of this evidence will be analysed by an HFEA PGD Review working group (comprising members of the Executive and the Authority) who will categorise each condition according to whether:
   - there have been no relevant advances or
   - further scrutiny might be required.

c. Conditions will be categorised as not having been subject to any relevant advances if:
• The reviewer has clearly stated as such
• Although a new treatment is available, it is not sufficiently effective/ does not have a significant impact on the morbidity or mortality associated with the condition
• The treatment is only at a research stage or would not be readily accessible to most patients.

d. On the basis of (a)-(c) above, a decision will be made (either by the Authority or by the PGD Review working group, see paragraph 3.1. and 3.2. below) as to whether any conditions should progress to a Phase 2 stage (i.e. a more in-depth consultation stage).

e. If it is decided that no conditions should go forward to this next stage, the review is drawn to a close and all the conditions remain on the PGD list. Alternatively, it may be decided that some conditions should move forward to Phase 2.

f. Phase 2 will involve gathering more in-depth information about relevant developments. This second Phase will include:

• inviting all PGD licensed centres to fill in a survey about the frequency with which PGD for the conditions is provided and whether any patients are currently or about to undergo treatment. The purpose of this survey will be to establish the potential impact of removing any of the conditions from the PGD list. Centres will be strongly encouraged to fill in this survey as fully as possible, as it may also inform the final decision on whether or not to remove a condition from the list and, if so, how and under what timeframe.

• subjecting the conditions to a more in-depth consultation with a broad range of stakeholders, including: medical professionals (including clinical geneticists); regional genetics units; patient organisations; PGD centres; professional bodies; commissioners; special interest groups and members of the public.

g. Once all the evidence has been received and analysed, it will be shared with PGD centres, to enable them to make any comments before a final decision is made by the SAC. The reason why it is proposed that SAC make any final decision is because the decision is akin to authorising a condition for PGD.

h. SAC will consider all the evidence and decide whether or not to remove any conditions from the PGD list. The
Committee will be guided in their decision by the PGD decision tree and a new explanatory note on the reconsideration procedure (to be drafted). SAC’s decision will need to take into account relevant factors, including:

- any evidence about patients currently or about to undergo treatment (particularly if embryo testing has not yet taken place)
- evidence regarding the reasons why the condition is considered ‘serious’ in that/ those particular case(s)
- the likely impact on patients of withdrawing a condition from the list
- any other relevant issues

i. The explanatory note will also set out the essential steps in the procedure, although the decision and its implementation will rest with SAC. Options open to SAC might include removing a condition from the PGD list immediately or at some future date.

j. SAC’s decision will be communicated to the sector (including PGD centres, patient organisations and genetics units).

k. If any conditions are removed from the PGD list, it will need to be updated on the HFEA website. Centres will also be notified of SAC’s decision and any special implementation issues or conditions attached to it.

2.3. We suggest that a formal PGD Review be carried out as a matter of routine every 5 years. However, it is hoped that the HFEA would be made aware of any significant treatment advances for particular conditions in between formal reviews, via the annual PGD meeting (see 2.4 below). If significant treatment advances have been made in between formal reviews, a targeted review of that/ those individual conditions could be carried out earlier. The formal 5-yearly reviews, however, will cover the full list – thereby ensuring that ‘nothing falls through the net’.

2.4. The HFEA recently hosted a successful PGD meeting with the sector and we intend that this will become an annual event. These meetings will be attended by key stakeholders including PGD centres, peer reviewers and Genetics Alliance UK. The aim of these meetings will be to anticipate, identify and address any issues as they arise.

2.5. It is suggested that the agenda for these meetings should include a standing item on the PGD list. This item, in essence, would act as an annual ‘MOT’ of the PGD list, providing delegates with the opportunity to point out any changes or anomalies (e.g. changes to a condition’s OMIM number).

2.6. Delegates from Genetic Alliance UK (and others) would also be
invited to share information about any significant treatment advances for any of the conditions on the PGD list. If those advances are particularly significant, this could trigger a targeted review of relevant condition(s) in advance of the 5-yearly formal review.

3. Issues for discussion

3.1. The proposed 2 phase process aims to provide a robust, but proportionate process for reconsidering approved PGD conditions. It allows treatment advances to be considered on a periodic basis, without raising unnecessary anxiety among families with serious inherited conditions. The Authority is invited to consider this process.

3.2. A particular issue concerns the Phase 2 decision making stage. The two options presented here were developed following ESC's consideration and they are:

- Option A: The Authority, having regard for all the evidence gathered and the recommendation of the PGD Review working group, will be asked to consider whether any conditions should progress to Phase 2 of a Review (i.e. be subject to an in-depth consultation and evidence gathering exercise).

- Option B: The PGD working group decides whether any conditions should progress to Phase 2 and this decision is communicated to the Authority in a ‘for information’ paper.

3.3. When considering both options, the Authority is asked to take into account the following:

- The benefit of option A is that it introduces an extra ‘check and balance’ to the decision making process since a wider group of Authority members would be involved. However, it might also be argued that the Authority’s usual role is to make decisions about policy frameworks and that the nature of ‘PGD Phase 2’ decisions do not fall under this category. It could therefore be argued that these sorts of decisions should fall to those with a more specialist knowledge and background of the area.

- The benefit of option B is that the decision makers will all have relevant expertise and an in-depth knowledge of the issues. However, this option could be criticised for lacking the wider ‘check and balance’ provided by Option A.

- Both options provide transparency as the decision and its rationale will be available publicly (via Authority papers).
3.4. In summary, the Authority is asked to:

- Approve the proposed procedure (outlined at 2.2), including the proposal that SAC makes any final decision about whether or not a condition should be removed from the PGD list and how that decision is implemented.
- Decide whether Option A or B (outlined at 3.2-3.3) should be adopted

4. **Next steps**

4.1. Following the Authority’s decision:

- SAC’s standing orders will be amended (if necessary)
- a PGD reconsideration explanatory note (to accompany the PGD decision tree) will be drafted
- a new SOP (for the Executive) will be developed.
# Authority Paper

<table>
<thead>
<tr>
<th>Paper Title</th>
<th>PGD Conditions Review Update</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Agenda Item</strong></td>
<td>9</td>
</tr>
<tr>
<td><strong>Paper Number</strong></td>
<td>[HFEA (03/07/2013) 685]</td>
</tr>
<tr>
<td><strong>Meeting Date</strong></td>
<td>3 July 2013</td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td>Jessica Watkin (Policy Manager)</td>
</tr>
<tr>
<td><strong>For information or decision?</strong></td>
<td>This will depend on the Authority’s earlier decision about a PGD reconsideration procedure (item XXX)</td>
</tr>
<tr>
<td><strong>Recommendation</strong></td>
<td>Members are asked to agree/ note the recommendation that no conditions progress to Phase 2 of the PGD Review.</td>
</tr>
<tr>
<td><strong>Resource Implications</strong></td>
<td>Staff time</td>
</tr>
<tr>
<td><strong>Implementation</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Communication</strong></td>
<td>Clinic Focus; the HFEA website and direct contact with embryo testing centres and patient advisory groups</td>
</tr>
<tr>
<td><strong>Organisational Risk</strong></td>
<td>Low</td>
</tr>
<tr>
<td><strong>Evaluation</strong></td>
<td></td>
</tr>
</tbody>
</table>
1. Introduction

1.1. Pre-implantation genetic diagnosis (PGD) is a process in which a genetic test is carried out on embryos, created using IVF, to ensure that only embryos unaffected by a particular genetic condition are returned to the woman's womb. The technique enables people at risk of having a child with a specific inherited condition to avoid passing it on to their children.

1.2. From the 1 October 2009, new statutory criteria came into force specifically placing the regulation of embryo testing on a statutory footing. The new legislation requires that the HFEA be ‘satisfied’ that embryo testing is carried out only where there is a ‘significant risk’ that a child born with the condition in question would have or develop a ‘serious’ medical condition. It is the HFEA’s responsibility to judge when a condition meets this criteria.

1.3. In 2009 the Authority agreed that the published list of conditions authorised for PGD should be reviewed periodically. The aim of these reviews would be to establish whether or not effective treatments had become ‘available, better established and more readily accessible’ and, if so, whether this might affect a condition’s on going suitability for PGD.

2. The review process: background

2.1. In December 2011, the HFEA’s Corporate Management Group (CMG) agreed to begin implementing the Authority’s 2009 decision and to start a review of all of the conditions approved for PGD before October 2009. It was considered unnecessary at this time to review conditions authorised after this date.

2.2. The following sets out the key stages of the review:

- External experts, with specialist knowledge of particular genetic conditions, were asked to inform the HFEA of any ‘significant’ and ‘effective’ treatment advances for various conditions over the last 10 years. Where the answer was ‘yes’, they were also asked about the availability of such treatments.

- Those responses were analysed by the Executive, with a view to identifying a list of conditions that should be removed from any further stages of the review. The remaining shortlist of conditions would then be subject to further consultation before the HFEA makes a final decision about retaining or removing any of them from the PGD list.

- The Authority, at its February 2013 meeting, decided that any further work on the Review should be put on hold while a PGD reconsideration procedure is developed, with both coming to a subsequent Authority.

- The Executive has developed a PGD reconsideration procedure (see agenda item 8)

- In response to concerns raised by the Authority in February, the Executive established a PGD Review working group.
3. PGD Review Working Group

3.1. The PGD Review working group consists of 3 members of the Authority and 4 members of the Executive and were tasked with the following:
   
   a. To categorise the list of conditions and to recommend whether any should be taken forward to Phase 2 of the Review (i.e. a more in-depth consultation stage).
   
   b. To agree a formal set of criteria for categorising all the conditions, as per (a) above. This criteria is set out at paragraph 3.3 below.
   
   c. To consider all the evidence gathered to date (including any new evidence that was received after the February Authority meeting) and to recommend which conditions, if any, should progress to Phase 2.

3.2. This working group met on 25 April and had various additional email discussions following that meeting. The group agreed that it was important that the Review avoids raising any unnecessary concerns amongst patients and patient groups.

3.3. The Working Group agreed the following set of criteria for categorising each of the conditions on the Review list:

   a. Categorical statement by external expert that there have been no significant treatment advances.
   
   b. Statements by the external expert that indicate:
      
      o they do not consider the treatment particularly effective / has minimal impact on the morbidity/ mortality associated with the condition.
      
      and/or
      
      o Peer reviewers have described existing treatments, but these are not advances that have been made since the condition was authorised (e.g. mastectomy for breast cancer).
      
      and/or
      
      o Treatment advances that are not yet established/ at the research stage.

3.4. The Group agreed that all conditions categorised under (a) and (b) should be removed from any further stages of the Review (i.e. should remain on the PGD list).

3.5. Of the remaining conditions, the Working group was asked to judge whether, despite the absence of a more clearly expressed view by the peer reviewer, the evidence suggested that the condition fell under the criteria at (b).

3.6. The working group’s classification of all of the conditions on the Review List is set out at Annex A. They agreed that none of them had been subject to any relevant treatment advances such that they would no longer meet the statutory criteria of ‘seriousness’. As such, they recommended that none should progress to Phase 2 of the Review and that the PGD Review should therefore draw to a close.

3.7. The Authority is asked to note that some changes will need to be made to the
PGD list, for reasons other than treatment advances. For example, OMIM numbers may have changed since the condition was first approved. Hence, the PGD list will need to be audited. This work will be carried out as a separate project and will start in July 2013.

4. Recommendation

4.1. The Authority is asked to approve the recommendation that no conditions be carried forward to any further stages of the Review and that any other changes to the list, should be captured as part of the PGD Audit project.

5. Next Steps

5.1. The next steps will depend on the Authority’s decision about the previous agenda item, on the PGD Reconsideration procedure.

5.2. If the Authority agreed to Option A (that the Authority should decide which conditions, if any, should progress to Phase 2 of a Review) and it agrees with the working group’s recommendation, the current PGD Review draws to a close and this decision is communicated to the sector via Clinic Focus.

5.3. If the Authority agreed to Option B (the working group decides which conditions, if any, should progress to Phase 2 of a Review and notifies the Authority of their decision), the Working Group members will be asked to formally decide that the Review draw to a close. This decision will then be communicated to the sector via Clinic Focus.
Annex A: PGD Working Group’s categorisation of conditions approved for PGD before October 2009

<table>
<thead>
<tr>
<th>Condition</th>
<th>Peer reviewer has categorically stated that there have been no treatment advances</th>
<th>Treatments not effective and/or have minimal impact</th>
<th>Treatments already existed</th>
<th>Treatments at research stage</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrenoleukodystrophy (Adrenomyeloneuropathy)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Agammaglobulinaemia</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Alpers Syndrome</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Alports Syndrome</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Alzheimers Disease – early onset (for types 1, 3 and 4)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Aplastic anaemia – severe</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Barth Syndrome</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Condition</td>
<td>Peer reviewer has categorically stated that there have been no treatment advances</td>
<td>Treatments not effective and/or have minimal impact</td>
<td>Treatments already existed</td>
<td>Treatments at research stage</td>
<td>Recommendation</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>---------------------------------------------------</td>
<td>-----------------------------</td>
<td>----------------------------</td>
<td>--------------------------------------------</td>
</tr>
<tr>
<td>Battens Disease (infantile)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Beta Hydroxyisobutyryl CoA Hydrolase Deficiency (Methacryc Aciduria)/Hydroxyisobutyryl CoA Hydrolase Deficiency</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Beta Thalassaemia</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Bilateral Frontoparietal Polymicroguria</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Bruton Agammaglobulinemia Tyrosine Kinase (BTK)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Charcot Marie Tooth Disease</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Cherubism</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Chromosomal rearrangements (various)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Condition</td>
<td>Peer reviewer has categorically stated that there have been no treatment advances</td>
<td>Treatments not effective and/or have minimal impact</td>
<td>Treatments already existed</td>
<td>Recommendations</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------</td>
<td>-----------------------------</td>
<td>---------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Chondrodysplasia Punctata</td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
<td></td>
</tr>
<tr>
<td>Choroideraemia (CHM)</td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
<td></td>
</tr>
<tr>
<td>Congenital Fibrosis of the Extraocular Muscles</td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
<td></td>
</tr>
<tr>
<td>Congenital Stationary Night Blindness</td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
<td></td>
</tr>
<tr>
<td>Crouzon Syndrome</td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
<td></td>
</tr>
<tr>
<td>Cystinosis</td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
<td></td>
</tr>
<tr>
<td>Diamond Blackfan Anaemia</td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
<td></td>
</tr>
<tr>
<td>Dystonia 1 Torsion Autosomal Dominant (DYT1)</td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
<td></td>
</tr>
<tr>
<td>Condition</td>
<td>Peer reviewer has categorically stated that there have been no treatment advances</td>
<td>Treatments not effective and/or have minimal impact</td>
<td>Treatments already existed</td>
<td>Treatments at research stage</td>
<td>Recommendation</td>
</tr>
<tr>
<td>-----------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------</td>
<td>---------------------------</td>
<td>----------------------------</td>
<td>-----------------------------------------------------</td>
</tr>
<tr>
<td>Ectodermal dysplasia (hypoidrotic)/ Plakophilin 1 PKP1 assoc</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Facioscapulohumeral Dystrophy</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Fanconis Anaemia A</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Fanconis Anaemia C</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Gaucher’s Disease (type 2)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Greig Cephalopolysyndactly</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Haemophilia A</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Haemophilia B</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Huntingtons Disease (Huntingtons Chorea)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Condition</td>
<td>Peer reviewer has categorically stated that there have been no treatment advances</td>
<td>Treatments not effective and/or have minimal impact</td>
<td>Treatments already existed</td>
<td>Treatments at research stage</td>
<td>Recommendation</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>---------------------------------------------------</td>
<td>---------------------------</td>
<td>----------------------------</td>
<td>---------------------------------------------------</td>
</tr>
<tr>
<td>Hydrocephalus (X-linked)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Ichthyosis</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Incontinentia Pigmenti</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Krabbe Disease</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Leigs Syndrome/ Leighs Subacute Necrotizing Encephalophathy of childhood</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Lenz syndrome</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Leukocyte Adhesion Deficiency (Type 1)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Li-Fraumeni Syndrome</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Condition</td>
<td>Peer reviewer has categorically stated that there have been no treatment advances</td>
<td>Treatments not effective and/or have minimal impact</td>
<td>Treatments already existed</td>
<td>Recommendation</td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>--------------------------------------------------</td>
<td>---------------------------</td>
<td>---------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Lymphoproliferative Syndrome</td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
<td></td>
</tr>
<tr>
<td>Macular Dystrophy</td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
<td></td>
</tr>
<tr>
<td>Medium Chain acyl-Co A dehydrogenase</td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
<td></td>
</tr>
<tr>
<td>Menkes Syndrome</td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
<td></td>
</tr>
<tr>
<td>Mitochondrial Encephalomyopathy, Lactic Acidosis and stroke-like episodes (MELAS)</td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
<td></td>
</tr>
<tr>
<td>Multiple Exostoses</td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
<td></td>
</tr>
<tr>
<td>Muscular dystrophy (Occulopharangeal)</td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
<td></td>
</tr>
<tr>
<td>Myoclonic epilepsy and ragged red fibres (MERFF)</td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
<td></td>
</tr>
<tr>
<td>Condition</td>
<td>Peer reviewer has categorically stated that there have been no treatment advances</td>
<td>Treatments not effective and/or have minimal impact</td>
<td>Treatments already existed</td>
<td>Treatments at research stage</td>
<td>Recommendation</td>
</tr>
<tr>
<td>-----------</td>
<td>---------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------</td>
<td>---------------------------</td>
<td>-----------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Myotublar myopathy</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Neurogenetic muscle weakness ataxia, retinitis pigmentosa (NARP)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Oculocutaneous Albinism Type 1A</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Oculocutaneous Albinism Type 1B</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Ornithine transcarbamylase deficiency (OTD)/ Ornithine carbamoyl transferase deficiency (OCD)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Osteogenesis Imperfecta (Type II)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Condition</td>
<td>Peer reviewer has categorically stated that there have been no treatment advances</td>
<td>Treatments not effective and/or have minimal impact</td>
<td>Treatments already existed</td>
<td>Treatments at research stage</td>
<td>Recommendation</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------</td>
<td>-----------------------------</td>
<td>-----------------------------</td>
<td>-----------------------------------------------------</td>
</tr>
<tr>
<td>Ostheopathia Striata with Cranial Sclerosis (OSCS)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Otopalatodigital Syndrome (Type 2)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Pelizaeus Merzbacher Disease</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Pyrodoxine-dependent seizures</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Recurrent hydatiti mole</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Retinitis Pigmentosa</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Sandoff Disease</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of the Review</td>
</tr>
<tr>
<td>Condition</td>
<td>Peer reviewer has categorically stated that there have been no treatment advances</td>
<td>Treatments not effective and/or have minimal impact</td>
<td>Treatments already existed</td>
<td>Treatments at research stage</td>
<td>Recommendation</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------</td>
<td>---------------------------</td>
<td>-----------------------------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td>Sickle Cell Anaemia</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Spastic Paraplegia</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Tay Sachs Disease (infantile onset)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Treacher Collins Syndrome</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Wolman’s Disease Acid Lipase Deficiency</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Condition</td>
<td>Peer reviewer has categorically stated that there have been no treatment advances</td>
<td>Treatments not effective and/or have minimal impact</td>
<td>Treatments already existed</td>
<td>Treatments at research stage</td>
<td>Recommendation</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------</td>
<td>-----------------------------</td>
<td>----------------------------</td>
<td>-----------------------------------------------------</td>
</tr>
<tr>
<td>Alpha thalassaemia/ mental retardation syndrome</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of the Review</td>
</tr>
<tr>
<td>Anderson Fabry Disease</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Androgen Insensitivity Syndrome</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Working Group examined evidence in detail. Remove from any further stages of the Review</td>
</tr>
<tr>
<td>BRAC1</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Cardiac Valvular Dysplasia</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of the Review</td>
</tr>
<tr>
<td>Carney Complex</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of the Review</td>
</tr>
<tr>
<td>Chronic Granulomatous Disease</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Coffin-Lowry syndrome</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Condition</td>
<td>Peer reviewer has categorically stated that there have been no treatment advances</td>
<td>Treatments not effective and/or have minimal impact</td>
<td>Treatments already existed</td>
<td>Treatments at research stage</td>
<td>Recommendation</td>
</tr>
<tr>
<td>------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------</td>
<td>---------------------------</td>
<td>----------------------------</td>
<td>-----------------------------------------------------</td>
</tr>
<tr>
<td>Congenital Adrenal Hyperplasia (21 hydroxylase deficiency)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Working Group examined evidence in detail. Remove from any further stages of the Review</td>
</tr>
<tr>
<td>Cystic Fibrosis</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Down’s Syndrome</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of the Review</td>
</tr>
<tr>
<td>Familial Adenomatous polyposis coli (FAP)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Fragile X Syndrome</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Hereditary diffuse gastric cancer</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Homozygous familial Hypercholesterolaemia</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Condition</td>
<td>Peer reviewer has categorically stated that there have been no treatment advances</td>
<td>Treatments not effective and/or have minimal impact</td>
<td>Recommendations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hunter Syndrome</td>
<td></td>
<td>X</td>
<td>Working Group examined evidence in detail. Remove from any further stages of the Review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyper IgM Syndrome – Hypogammaglobulinaemia</td>
<td></td>
<td>X</td>
<td>Remove from any further stages of the Review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Juvenile retinoschisis</td>
<td></td>
<td>X</td>
<td>Remove from any further stages of review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leber’s Hereditary Optic Neuropathy/Leber’s Optic Atrophy</td>
<td></td>
<td>X</td>
<td>Working Group examined evidence in detail. Remove from any further stages of the Review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesch Nyan Syndrome</td>
<td></td>
<td>X</td>
<td>Remove from any further stages of the Review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marfan Syndrome</td>
<td></td>
<td>X</td>
<td>Working Group examined evidence in detail. Remove from any further stages of the Review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Condition</td>
<td>Peer reviewer has categorically stated that there have been no treatment advances</td>
<td>Treatments not effective and/or have minimal impact</td>
<td>Treatments already existed</td>
<td>Treatments at research stage</td>
<td>Recommendation</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
<td>----------------------------------------------------</td>
<td>----------------------------</td>
<td>--------------------------------</td>
<td>---------------------------------------------------</td>
</tr>
<tr>
<td>Metachromatic Leukodystrophy</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of the Review</td>
</tr>
<tr>
<td>Multiple Endocrine Neoplasia (Type 1)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Working Group examined evidence in detail. Remove from any further stages of the Review</td>
</tr>
<tr>
<td>Muscular Dystrophy (Beckers)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of the Review</td>
</tr>
<tr>
<td>Muscular Dystrophy (Duchenne)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Myotonic Dystrophy</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Neurofibromatosis (type II)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Working Group examined evidence in detail. Remove from any further stages of the Review</td>
</tr>
<tr>
<td>Niemann Pick Disease (Type C)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of the Review</td>
</tr>
<tr>
<td>Condition</td>
<td>Peer reviewer has categorically stated that there have been no treatment advances</td>
<td>Treatments not effective and/or have minimal impact</td>
<td>Treatments already existed</td>
<td>Treatments at research stage</td>
<td>Recommendation</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>----------------------------------------------------</td>
<td>-----------------------------</td>
<td>----------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Partial Lipodystrophy Familial (type 2)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Working Group examined evidence in detail. Remove from any further stages of the Review</td>
</tr>
<tr>
<td>Polycystic kidney disease</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Pompe disease (early onset)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Prader Willi Syndrome</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Working Group examined evidence in detail. Remove from any further stages of the Review</td>
</tr>
<tr>
<td>Recessive Dystrophic Epidermolysis Bullosa</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of the Review</td>
</tr>
<tr>
<td>Retinoblastoma</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Working Group examined evidence in detail. Remove from any further stages of the Review</td>
</tr>
<tr>
<td>Condition</td>
<td>Peer reviewer has categorically stated that there have been no treatment advances</td>
<td>Treatments not effective and/or have minimal impact</td>
<td>Treatments already existed</td>
<td>Treatments at research stage</td>
<td>Recommendation</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>----------------------------------------------------</td>
<td>---------------------------</td>
<td>-----------------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Severe Combined Immune Deficiency (X-linked)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of the Review</td>
</tr>
<tr>
<td>Spinal Muscular Atrophy (SMA1)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
<tr>
<td>Tuberous Sclerosis</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>Remove from any further stages of review</td>
</tr>
</tbody>
</table>
| Turner Syndrome                               |                                                                                 | X                                                  |                           |                             | Working Group examined evidence in detail.  
To be removed from the Review. |
| Von Hippel Lindau (VHL) Syndrome               |                                                                                 | X                                                  |                           |                             | Remove from any further stages of review  |
| Wiscott-Aldrich Syndrome                      |                                                                                 | X                                                  |                           |                             | Remove from any further stages of review  |
## Authority Paper

<table>
<thead>
<tr>
<th>Paper Title</th>
<th>Donation work programme for 2013/15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agenda Item</td>
<td>10</td>
</tr>
<tr>
<td>Paper Number</td>
<td>[HFEA (03/07/2013) 686]</td>
</tr>
<tr>
<td>Meeting Date</td>
<td>3 July 2013</td>
</tr>
<tr>
<td>Author</td>
<td>Juliet Tizzard, Head of Policy and Communications</td>
</tr>
<tr>
<td>For information or decision?</td>
<td>Decision</td>
</tr>
<tr>
<td>Recommendation</td>
<td>To consider the recommendations at paragraph 5.1</td>
</tr>
<tr>
<td>Resource Implications</td>
<td>To be determined. Most work strands could be achieved within existing budgets and staffing, although some public-facing work will need additional resources.</td>
</tr>
<tr>
<td>Implementation</td>
<td>Staggered implementation throughout 2013/15</td>
</tr>
<tr>
<td>Communication</td>
<td>Individual communications and stakeholder approaches to be developed for each strand of work</td>
</tr>
<tr>
<td>Organisational Risk</td>
<td>Medium</td>
</tr>
<tr>
<td>Evaluation</td>
<td>Individual evaluation plans for each strand of work</td>
</tr>
<tr>
<td>Annexes</td>
<td>Annex A: Donation work strand details</td>
</tr>
</tbody>
</table>
1. **Background**

1.1. The pathway of donor conception treatment starts from a person or couple deciding to embark upon treatment and continues through donor recruitment, to treatment, to the birth of a child and throughout that child’s life. All along the pathway, the different participants (patients/parents, donors, donor-conceived people) have different responsibilities and needs relating to information and support.

1.2. The UK has a strong legislative and policy framework around licensed donor conception, helping to provide good care in clinics and access to information about donors. However, there are some known limitations present in donor conception in the UK:

   - A shortage of donors: this results in long waiting times for recipients with some patients travelling abroad for treatment they would have preferred to have at home
   - Donors sometimes feeling undervalued: this may result in higher drop-out rates than is necessary

**The donation review and beyond**

1.3. Some of these limitations were addressed through the review of our donation policies, which took place in 2011. We reviewed the policy around compensation for donors, making it simpler and less bureaucratic for clinics (and donors) and set the maximum compensation at a level which would make donors feel valued for their donation without providing a financial incentive. We also reviewed the family limit, but found that raising it was not popular with donor conception families and, in any case, would be unlikely to increase the availability of donated gametes. Instead, we sought to address the issue of under-usage of donated gametes by introducing new Code of Practice guidance.

1.4. We acknowledged through the review that no single policy intervention along the donation pathway would solve these problems. We also heard about a number of issues which were outside the immediate regulatory remit of the HFEA, but which stakeholders felt are important. These include improving ‘customer service’ for donors at clinics and creating an information resource for those thinking about donating or accessing donor conception treatment, whether within or outside the licensed sector.

1.5. These wider issues need to be tackled in a co-ordinated and collaborative way, with the input of different organisations and professionals involved in donor conception. This was one of the key drivers for establishing the National Donation Strategy Group.

1.6. Finally, a more recent project within the HFEA has resulted in clearer policy for how we disclose information to parents, donors and donor-conceived people. This addresses issues such as hand-written donor information, those written in a foreign language and redaction of details which might identify the donor.
2. **Donation work 2013/15**

2.1. Now that we have revised policies and practices in place, we can move to address a number of complementary issues which relate more to information and support around donor conception. The aims of this work would be to:

- improve information for those considering donor conception, so that they are aware of the options, both in the UK and overseas, and make informed choices
- increase awareness of the possibility of donation and its implications, thereby increasing donor numbers and reducing drop-out rates
- improve donor information (and its availability) for recipients, so that they can make a careful decision about the donor they choose and share that information with their child(ren)
- improve the support available for all those affected by donor conception, in particular those accessing donor information from the HFEA (and/or clinics).

2.2. There are a small number of issues left over from the donation review:

- consider whether overseas donors whose gametes are imported into the UK should receive the same compensation as UK donors
- improve the mechanism for considering imports and exports of gametes and embryos in cases which don’t conform to UK requirements
- develop best practice guidelines on family donation
- evaluate the impact of new compensation policy.

2.3. Finally, the Nuffield Council on Bioethics recently made a number of recommendations relating to donor information in its report, ‘Donor conception: ethical aspects of information sharing’. Some of the recommendations, such as support for applicants to the Register, chime with recommendations from other organisations in their response to the Department of Health consultation about the HFEA’s functions.

2.4. This paper seeks the Authority’s view on an emerging work programme on donation and the relative importance to be placed on the different elements. To aid this process we have organised the work identified above into the following work strands (more details of these strands and their resource implications are set out at Annex A):

- Support services for applicants to the Register
- Improving the collection and sharing of donor information
- Improving information about donation
- Donation outcomes and evaluation of compensation policies
- Movement of gametes across borders
3. **The views of patients, donors, donor-conceived people and professionals**

3.1. There is a long tradition in the UK of public and professional debate around donor conception. One recent example is the series of debates organised by Progress Educational Trust called ‘When it takes more than two’, which raised a number of issues for policy makers. Added to that, the past year has seen a number of enquiries and consultations which have given patient and professional organisations the opportunity to suggest improvements to donor conception in the UK. The HFEA’s own on-going work with stakeholders has also brought issues to our attention.

3.2. However, it is sometimes difficult to ascertain what the public and professionals see as the most important areas of work. With this in mind, the Executive held a meeting on 13 June with a number of representatives of organisations associated with donor conception:

- British Andrology Society
- British Fertility Society
- British Infertility Counselling Association
- British Medical Association
- Donor Conception Network
- National Donation Strategy Group
- National Gamete Donation Service
- Nuffield Council on Bioethics
- Progar
- RCN Fertility Nurses Group
- Senior Infertility Nurses Group

3.3. The aim of the meeting was to discuss the donation work strands at paragraph 2.4 above to seek views about relative priorities. The meeting was very productive and there was a clear consensus about which works strands were most important. Their views are incorporated into the recommendations below.

4. **Recommendations for further work around donation**

4.1. **Support services for applicants to the Register**

We have a growing number of applications for information from the Register. As at the end of 2012, 183 people had applied for information: 103 parents, 66 donors and 14 donor-conceived people. To date, no donor-conceived have been given identifying information about their
donor, although this could happen at any time, despite the chances being low (120 anonymous donors have re-registered as identifiable).

4.2. We have a well-developed service for handling requests for information and for disclosing it to applicants. Our staff have, as a minimum, basic counselling skills training and are experienced in dealing with many of the issues that arise as people consider requesting information from the Register. They also have detailed knowledge of how the Register works and are able to verify information directly with the clinics that submitted it.

4.3. In 2009, the Authority developed a policy for handling requests to the Register (we call them OTR (Opening the Register) requests), in particular that donor-conceived applicants should be encouraged to seek counselling to support them through the process of obtaining information about their donor and that we should signpost relevant services (see the relevant page on the website: http://www.hfea.gov.uk/114.html). Since the policy was adopted, there have been suggestions that the HFEA (or another government organisation) could go further by funding or providing such support, rather than signposting it, given that currently there is no specialist professional service for donor conception.

4.4. Suggestions have also been made – by professional organisations and the Nuffield Council on Bioethics (NCOB) - that an intermediary service of some kind be established to support donor-conceived people and donors in situations where identifying information about a donor has been released and both parties wish to meet. There are a number of models for an intermediary service and each would obviously have cost implications for the HFEA (or whichever organisation provided it).

4.5. Professional bodies and the NCOB have also argued for support to be made available for people affected by donation who do not necessarily request information from the Register. These might be parents who need further support after their child is born or donor-conceived people who need support but aren’t seeking information from the Register.

4.6. At the stakeholder meeting on 13 June, there was widespread support for exploring these possible enhancements to the existing HFEA service, particularly an intermediary service, whether provided by the HFEA or by another service. Participants felt strongly that, because a request for information about a donor who has re-registered as identifiable could come to HFEA at any point, this work is a priority. Although they also felt that the existing HFEA service is good, they nonetheless felt that some applicants need further specialist counselling support and it would reasonable to explore how the HFEA or other body might provide or facilitate this.

4.7. A number of people at the meeting volunteered to help scope out models for counselling support and intermediary services. They also stressed the need for those accessing the Register to be consulted during the process.

4.8. Recommended work:

- To work with selected stakeholders to scope out models for counselling and intermediary services for Register applicants. To start September 2013 and report to Authority in early 2014.
• To explore, at the same time, what specialist support should be provided for other people affected by donation.

**Improving the collection and sharing of donor information**

4.9. As part of our review of access to the Register in 2009, we used our discretion to give recipients and parents access to information about their donor for which they do not have a statutory right. We also introduced Code of Practice guidance which expects clinics to share non-identifying information about the donor with recipients, from the donor selection stage onwards.

4.10. We know, from patient feedback and through inspection, that some clinics do not share information about donors with recipients and we are exploring the reasons for this. We are also strengthening the wording in the Code to make sure that clinics understand what is expected of them.

4.11. Alongside this work, we have recently reviewed our redaction process (to ensure that information released is not donor-identifying) and the National Donation Strategy Group has drafted a leaflet to help donors think about the information they provide about themselves and to remind them not to include anything that would identify them.

4.12. All of this work combined is designed to ensure that:

• donors understand why they are asked to provide information, given ideas on what they might write and are told who will see it

• the need for redaction is minimised

• recipients know what information they can receive and that clinics share it with them.

4.13. The stakeholders at the meeting felt that this area of work was also high priority, though they understood that it might take time to change practice in clinics. They recommended workshops or other face-to-face work with clinics, alongside written materials. There was strong support for:

• the donor pen portrait and goodwill message being made mandatory, although others felt that better support for donors and explanation about why this information is important might be a better place to start.

• the HFEA handling all requests for information about donors (ie, clinics should not handle such requests), in order to remove the risk of differing information being disclosed. However, clinics would still need to share information about donors with prospective recipients at the donor selection stage.

• the HFEA carrying out all redactions to avoid the risk of the clinic and the HFEA redacting the same information differently. This would require a change to the HFEA systems (planned anyway) and would have significant resource implications for us, as all donor information forms (around 2000 per year) would need to be checked for identifying details, as opposed to just those records subject to an OTR request (around 100 per year).
4.14. Recommended work:
- A programme of work to help donors provide information and support clinics in sharing information with recipients. This would be led by both the Strategy Group and the HFEA, to start in the autumn. This work could also consider the other questions raised at paragraph 4.13.

**Donation outcomes and evaluation of compensation policies**

4.15. A donation themed report is planned for publication at the end of 2013. This will report on donor conception cycles performed up to March 2012, thereby providing a benchmark to evaluate the compensation policy (starting April 2012). An evaluation report on the period from April 2012 can be carried out in late 2014.

4.16. In the meantime, donor registrations from April 2012 can be assessed later this year (given that no treatment needs to be analysed). Further work needs to be done to determine what other measures, besides donor registrations (number, provenance, age of donor etc.) should be used to evaluate the compensation policy.

4.17. The stakeholders were pleased to see that we intend to evaluate the new compensation policies and understood the difficult of accurately assessing their impact, given the limited information that the HFEA collects. They also agreed to discuss with us, nearer the time, communications around the report.

4.18. Recommended work:
- Continue with planned donation themed reports in late 2013 and late 2014 and an assessment of donor registrations in late 2013.

**Movement of gametes across borders**

4.19. One policy which was not changed following the donation review was the level of compensation permitted to overseas donors whose gametes are imported into the UK. At present, these donors are permitted £250 plus expenses for each cycle of donation (the same as the pre-2012 policy for UK donors). Although there have been no calls for a review of this policy, we need to consider whether the discrepancy between UK and overseas donors should remain.

4.20. A number of other issues have since emerged which sit well with this strand of work. They are:
- Consent requirements for donors of imported gametes: overseas sperm banks have asked whether their donors need to complete HFEA consent forms and provide the same donor information.
- Import of gametes to private addresses in the UK: this issue emerged from the recent W case and has been discussed amongst European Competent Authorities.
- Special Directions for imported gametes and embryos: following the governance review, it was suggested that we review the
process for considering imports and exports of gametes and embryos which do not meet UK requirements.

4.21. The stakeholders could see the value of this work but didn’t consider it to be particularly high priority.

4.22. Recommended work:

- Start project in autumn 2013.

**Donor re-registration**

4.23. The HFEA recently implemented a system which enables people who have previously applied for information from the Register to find out whether their donor has since re-registered by checking a dedicated page on the website. This avoids the need for repeated applications (with the identification process it entails) in the hope of finding new information. Further work is needed to consider how to raise awareness of this new system with parents.

4.24. With only 120 donors registering as identifiable, there is a need to make past donors more aware of possibility of re-registration. Parents also need to know of the possibility that their donor could re-register and think about how to handle this with their child(ren). A small group of stakeholders have been meeting (with an observer from the HFEA) to see what can be done to advertise re-registration and to help clinics.

4.25. Recommended work:

- Make sure information about donor re-registration is included on the donation website (see below) and mentioned in other projects as appropriate. Given all the other commitments, media work in this area may have be scheduled for a later date, say mid-2014 (stakeholders didn’t rank this as a high-priority issue).

**Improving information about donation**

4.26. Prospective (and actual) donors and recipients are sometimes unsure about where to find information about all types of donation. There is obviously a wealth of information about licensed donation and donor conception treatment on the HFEA website (which stakeholders at the meeting thought was good). But people visiting the website have usually decided to go down the UK licensed clinic route by the time they come to our website.

4.27. At the end of the donation review, the Authority suggested developing a stand-alone website for donors, recipients and donor-conceived people. Using the model of the One at a Time website, it would reach a broad audience, including those considering going abroad for treatment and having unlicensed treatment with donor sperm. The website could also raise awareness of donor re-registration (recommended by the Nuffield Council on Bioethics) and help to make donor conception an ‘unremarkable’ route to parenthood (also a Nuffield recommendation).

4.28. The idea of this website has been picked up enthusiastically by the National Donation Strategy Group and it had much support from
stakeholders at the meeting. Ideas for types of information on the website will have been sought at the Strategy Group workshop on 25 June.

4.29. Recommended work:

- To continue to plan a dedicated donation website through the National Donation Strategy Group.

Other issues

4.30. The stakeholder meeting on 13 June also discussed a number of other issues, although there was limited time to explore them.

4.31. The Nuffield Council on Bioethics made a number of other recommendations (our suggested response in italics):

- Donor screening: to review the professional body guidelines, particularly in relation to family history information. We understand that the BFS is initiating a review and we will liaise with them.

- Sharing medical information: to establish a clear mechanism to share serious medical information about the donor with donor-conceived people/donor. To be considered for the October 2014 Code of Practice update.

- Reassuring patients about screening: Parents should be provided with clear and comprehensible information about the significant heritable diseases that have been screened out. To be considered for the October 2014 Code of Practice update.

- Guidance on disclosure of pre-1991 records: to issue guidance to clinics setting out what they can and cannot do with respect to making pre-1991 records available to donor-conceived people. To be considered for the October 2014 Code of Practice update.

- Making donor conception ‘unremarkable’: The state has a 'stewardship' role in promoting an inclusive and accepting environment for individuals becoming parents in different ways. A goal which cuts across many of the work strands, particularly the donation information website.

- Counselling: Produce guidance that counselling should not be judgemental about disclosure, but recipients are made to feel confident in their own choices. Also, clinics should present counselling sessions as a routine part of the series of consultations undertaken before treatment or donation begins, and should routinely offer parents an additional support session that could be taken up either later in pregnancy or in the first few years of the child’s life, the cost of which should be included within the overall treatment fee. To be considered for the October 2014 Code of Practice update, picking up other comments made about counselling provision at the stakeholder meeting.

- Information exchange: Consider merits of information exchange between donors and recipients (when the children are young). This was not discussed at the stakeholder meeting, but the Executive’s
assess is that this is low priority for the HFEA, given that it would require a change to the law.

- Best practice guidelines on family donation: this was recommended after the donation review. To discuss further with BICA.

5. Recommendations

5.1. The Authority is asked to consider and approve the following strands of work (higher priority strands come first):

- To work with selected stakeholders to scope out models for counselling and intermediary services for Register applicants. To start September 2013 and report to Authority in early 2014 (paragraph 4.8).

- To explore, at the same time, what specialist support should be provided for other people affected by donation (paragraph 4.8).

- A programme of work to help donors provide information and support clinics in sharing information with recipients. This would be led by both the Strategy Group and the HFEA, to start in the autumn. This work could also consider the other questions raised regarding collecting and sharing donor information (paragraph 4.14).

- To continue to plan a dedicated donation website through the National Donation Strategy Group (paragraph 4.29).

- Make sure information about donor re-registration is included on the donation website and mentioned in other projects as appropriate. Given all the other commitments, media work in this area may have be scheduled for a later date, say mid-2014 (paragraph 4.25).

- Continue with planned donation themed reports in late 2013 and later 2014 and an assessment of donor registrations in late 2013 to start to measure the impact of the compensation policy (paragraph 4.18).

- Start project on imports and exports in autumn 2013 (paragraph 4.22).

- To liaise with the BFS and others around donor screening guidelines (see paragraph 4.31).

- To address a number of smaller issues through the next update to the Code of Practice in October 2014, including a review of counselling guidance regarding donor conception (paragraph 4.31).

- To deprioritise work on information exchange before age 18, though review this position in late 2014 (see paragraph 4.31).

- To discuss with BICA the drawing up of best practice guidelines on family donation (see paragraph 4.31).
## Annex A: Donation work strand details

<table>
<thead>
<tr>
<th>Strand and main elements</th>
<th>Origin and comments</th>
<th>Actions proposed</th>
<th>Proposed key dates</th>
</tr>
</thead>
</table>
| **1. Support services for applicants to the Register and others affected by donation**  | **Aim:** to enhance the support available for people accessing information from the Register  
   a) Enhance the skills of Register staff disclosing identifying information to donor conceived people.  
   b) Explore providing counselling support for all OTR applicants (seeking non-identifying information)  
   c) Explore providing counselling support for OTR applicants receiving donor identifying information  
   d) Explore providing/referring to intermediary services for when donors and donor-conceived people meet  
   e) Explore support needs for those not necessarily seeking information from the Register  | Request from the Register team to enhance their skills in advance of an application for identifying information.  
   Calls support and intermediary services coming from BMA, BICA, and BFS. Also a recommendation from Nuffield Council on Bioethics (NCOB).  
   Significant resource questions here, and not necessarily the responsibility of the HFEA to provide all of this (could tap into existing structures).  | Member of the Policy team (with input from OTR staff) to work with selected stakeholders to scope out models for counselling and intermediary services. To start September 2013 and report to Authority in early 2014.  | Support service project to start autumn 2013, leading into 2014. |
| **2. Improving the collection and sharing of donor information**  | **a) and b) underway: held small workshop and run Clinic Focus survey. Workshop planned to promote sharing and redacting donor information.  
   c) Work underway with NDSG on a leaflet to help donors provide better information.  
   d) Review of donor information form**  | Identified through HFEA information disclosure project and issues raised about some clinics by recipients.  | a) and b) underway: held small workshop and run Clinic Focus survey. Workshop planned to promote sharing and redacting donor information.  
   c) Work underway with NDSG on a leaflet to help donors provide better information.  
   d) Review of donor information form as part of data review.  | Workshop for early 2014 Donor leaflet due autumn 2013. |
| **2. Improving the collection and sharing of donor information**  | **a) Encourage clinics to disclose non-ID information to prospective parents  
   b) Redaction of non-ID donor information  
   c) Encourage donors to provide better non-ID information which does not need redacting.  
   d) Review of donor information form**  | **Identified through HFEA information disclosure project and issues raised about some clinics by recipients.**  | a) and b) underway: held small workshop and run Clinic Focus survey. Workshop planned to promote sharing and redacting donor information.  
   c) Work underway with NDSG on a leaflet to help donors provide better information.  
   d) Review of donor information form as part of data review.  | Workshop for early 2014 Donor leaflet due autumn 2013. |
<table>
<thead>
<tr>
<th>Strand and main elements</th>
<th>Origin and comments</th>
<th>Actions proposed</th>
<th>Proposed key dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim: To see whether donor registrations are increasing, what kinds of donors are being recruited and outcomes for donor conception treatment.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Movement of gametes across borders</td>
<td>a) Compensation for donors of imported gametes&lt;br&gt;b) Consent requirements for donors of imported gametes&lt;br&gt;c) Issue raised by W case re import to private addresses&lt;br&gt;d) Review of process for agreeing imports and exports falling outside General Directions</td>
<td>Policy to lead on the main body of work to begin from September 2013.</td>
<td>To start September 2013 and be implemented via October 2014 Code of Practice update.</td>
</tr>
<tr>
<td>Aim: To ensure consistency (where appropriate) between UK and overseas recruitment practice without incentivising imports.</td>
<td>a) is a hang-over from the donation review and b) has been raised with overseas sperm banks. c) comes from a recent court case and d) emerged from committee restructuring at the HFEA. Some evaluation of impact of revised donation policies on import of sperm needs to be carried out in autumn 2013 and decision about to what extent imported gametes should be facilitated.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Donor re-registration</td>
<td>Increasing awareness about donor re-registration recommended range of stakeholders, including NCOB.</td>
<td>OTR response reference system completed. Include information on re-registration on the new Donation Website and in other projects where appropriate.</td>
<td>Initiate media campaign in mid-2014?</td>
</tr>
<tr>
<td>Aim: to enable Register applicants to more easily discover whether their donor has re-registered as identifiable and to raise awareness of the possibility of re-registration with past donors and recipients.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Improving information about donation</td>
<td>Recommended by Authority after the donation review and by Nuffield Council on Bioethics. Picked up by the Strategy Group.</td>
<td>Will need approval from DH.</td>
<td>Early 2014 - Launch website (subject to more careful resource planning)</td>
</tr>
<tr>
<td>Aim: to develop a special website for patients, parents and donors looking for licensed, non-licensed or overseas treatment or considering donation and for donor-conceived people.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strand and main elements</td>
<td>Origin and comments</td>
<td>Actions proposed</td>
<td>Proposed key dates</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>-----------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td><strong>7. Donor screening</strong></td>
<td>Aim: to review the donor screening guidelines</td>
<td>BFS etc planning a review once SaBTO review of MSM guidance is complete.</td>
<td>TBD</td>
</tr>
<tr>
<td><strong>8. Sharing medical information</strong></td>
<td>Recommended by NCOB.</td>
<td>Consider as part of next Code of Practice update.</td>
<td>October 2014</td>
</tr>
<tr>
<td><strong>9. Reassuring patients about screening</strong></td>
<td>Recommended by NCOB.</td>
<td>Consider as part of next Code of Practice update.</td>
<td>October 2014</td>
</tr>
<tr>
<td><strong>10. Guidance on disclosure of pre-1991 records</strong></td>
<td>Recommended by NCOB.</td>
<td>Recommended by NCOB. Seek legal advice and consider as part of next Code of Practice update.</td>
<td>October 2014</td>
</tr>
<tr>
<td><strong>11. Making donor conception ‘unremarkable’</strong></td>
<td>Recommended by NCOB.</td>
<td>Could be addressed through existing initiatives (one NDSG objective is to increase awareness of donation).</td>
<td>On-going work</td>
</tr>
<tr>
<td><strong>12. Family Donation guidance</strong></td>
<td>From donation review. Produce guidance to spread good practice around?</td>
<td>Discuss with BICA possibility of their taking this work forward.</td>
<td>TBD</td>
</tr>
<tr>
<td>Strand and main elements</td>
<td>Origin and comments</td>
<td>Actions proposed</td>
<td>Proposed key dates</td>
</tr>
<tr>
<td>--------------------------</td>
<td>--------------------</td>
<td>------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>13. Counselling</td>
<td>Recommended by NCOB.</td>
<td>Work with BICA and consider as part of next Code of Practice update.</td>
<td>October 2014</td>
</tr>
<tr>
<td></td>
<td>Produce guidance that counselling should not be judgemental about disclosure, but recipients are made to feel confident in their own choices. Also, clinics should present counselling sessions as a routine part of treatment, and should routinely offer an additional, free, support session for parents.</td>
<td>Recommended by NCOB. Important issue, but would require a change to the law.</td>
<td></td>
</tr>
<tr>
<td>14. Information exchange</td>
<td>Consider merits of information exchange between donors and recipients (when the children are young).</td>
<td>To not prioritise this work.</td>
<td></td>
</tr>
</tbody>
</table>
**Authority Paper**

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper Title</td>
<td>Multiple Births Update</td>
</tr>
<tr>
<td>Agenda Item</td>
<td>12</td>
</tr>
<tr>
<td>Paper Number</td>
<td>[HFEA (03/07/2013) 687]</td>
</tr>
<tr>
<td>Meeting Date</td>
<td>3 July 2013</td>
</tr>
<tr>
<td>Author</td>
<td>Hannah Darby, Senior Policy Manager (Data provided by Suzanne Hodgson)</td>
</tr>
<tr>
<td>For information or decision?</td>
<td>Information</td>
</tr>
<tr>
<td>Recommendation</td>
<td>Members are asked to note overall sector (and centres’) performance against the 15% Year 3 multiple live birth rate target (April 2011 – October 2012) and the 10% Year 4 multiple live birth rate target so far</td>
</tr>
<tr>
<td>Resource Implications</td>
<td>Accounted for in business plan</td>
</tr>
<tr>
<td>Implementation</td>
<td>N/A</td>
</tr>
<tr>
<td>Communication</td>
<td>Centres and other stakeholders are regularly updated on the decisions and progress regarding the multiple births policy through our publications, stakeholder group meetings and the HFEA and One at a Time websites.</td>
</tr>
<tr>
<td>Organisational Risk</td>
<td>High</td>
</tr>
<tr>
<td>Evaluation</td>
<td>The policy has been evaluated on an annual basis which has allowed the Authority to set the next multiple births target.</td>
</tr>
<tr>
<td>Annexes</td>
<td>Annex A - Funnel plot graph of centres’ Year 3 performance</td>
</tr>
<tr>
<td></td>
<td>Annex B – Explanation of funnel plot graph</td>
</tr>
</tbody>
</table>
1. **Introduction**

1.1. The overall aim of the Authority’s multiple births policy is to reduce the UK IVF multiple birth rate to 10% in stages over a period of years. In order to achieve this the Authority decided on an outcomes based approach. The Authority would set a maximum multiple birth rate that clinics should not exceed, which would be lowered each year. In addition, the policy requires centres to devise their own ‘Multiple Births Minimisation Strategy’ setting out how they will not exceed the maximum multiple birth rate.

1.2. In January 2012 the Authority reviewed the progress of centres so far and decided, taking into account advice from the Multiple Births Stakeholder Group, to set the final (Year 4) maximum multiple birth rate target at 10%. The Authority appreciated that the current 15% Year 3 target had been challenging, so decided to implement the Year 4 target of 10% with effect from October 2012 (extending the 15% by 6 months), in order to give centres time to refine their strategies and implement changes.

1.3. A series of ‘One at a Time’ workshops were carried out in early 2012 to help support centres to share best practice and move towards the 10% target. The Authority was last updated on the sector’s performance and the outcomes of these workshops in June 2012.

1.4. This paper summarises centres’ overall performance against the 15% Year 3 target (April 2011 – October 2012) and the 10% target so far (from October 2012) using data available at the time this paper was prepared (end June 2013).

2. **Year 3 and 4 sector performance**

2.1. This section of the paper provides an overview of the performance of the sector as a whole as we currently understand it taking into account performance in Year 3 (April 2011 - October 2012) and Year 4 of the policy (October 2012 onwards).

2.2. 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 remained broadly steady. Table 1 and Figure 1 provide the key information. The national average data shows the performance of the sector as a whole was within the Year 1 maximum multiple birth rate target of 24% and within the Year 2 maximum multiple birth rate target of 20%.

2.3. The Year 3 multiple birth rate target of 15% was, however, harder for some centres to meet. Data for the full 18 months of the 15% target ‘year’ (much of which is unverified) shows that the multiple live birth rate for this period is 17.3%.

2.4. A ‘correction factor’ is used to provide an indication of how the multiple pregnancy rate gives an equivalent multiple birth rate target. For year 4 of the policy, then, we consider a clinical multiple pregnancy rate of 13% is likely to result in a multiple live birth rate of 10% (a full explanation of how this is calculated is at Annex B). We cannot yet analyse the multiple birth rate for Year 4 because of the normal delay in reporting (ie, a treatment
cycle which took place in October 2012 would not result in a live birth until June 2013 and the centre has until September 2013 to report it).

2.5. In preparing the data for this paper, we re-run the analysis for all years, from 2008 to the present. Because clinics may submit data relating to past cycles at any time and because of improvements to the structure and function of the database, the figures published here differ slightly from those published in the papers presented to the Authority previously.

2.6. The data presented here as regards performance for Year 3, that is April 2011-September 2012, is verified (i.e., signed off by the clinics as correct) for ‘pregnancies’ to end of June 2012, and ‘births’ to end of June 2011. This means that for Year 3, some of the pregnancy data presented is unverified and most of the live birth data presented is unverified or incomplete. We have presented two columns for Year 3: one showing the period for which verified data is available and one showing the whole period. The Year 4 data for both pregnancies and births is unverified. Unverified data is presented as part of this multiple births paper, as well as in previous papers, in order to provide the Authority with the most up to date understanding of current performance.

Table 1: Overview of embryo transfers, multiple pregnancies and overall pregnancies and live birth data

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion of transfers that are eSET (%)</td>
<td>4.6</td>
<td>11.2</td>
<td>15.7</td>
<td>18.5</td>
<td>19.3</td>
<td>25.6</td>
</tr>
<tr>
<td>Proportion of transfers that are blastocyst transfers (%)</td>
<td>12.8</td>
<td>20.6</td>
<td>30.1</td>
<td>38.0</td>
<td>38.9</td>
<td>46.8</td>
</tr>
<tr>
<td>Multiple pregnancy rate (%)</td>
<td>26.6</td>
<td>24.4</td>
<td>21.6</td>
<td>19.6</td>
<td>19.4</td>
<td>16.7</td>
</tr>
<tr>
<td>Multiple live birth rate (%)</td>
<td>23.6</td>
<td>21.7</td>
<td>19.3</td>
<td>19.5* (only 3 months live birth data April 11-June 11 has been)</td>
<td>17.3 (18 months data, but missing outcomes)</td>
<td>n/a</td>
</tr>
</tbody>
</table>
Agenda item 12: Annex B  

Figure 1: Overview of embryo transfers, multiple pregnancies & overall pregnancies

<table>
<thead>
<tr>
<th>Overall pregnancy rate (%)</th>
<th>30.3</th>
<th>32.2</th>
<th>31.6</th>
<th>32.7</th>
<th>32.6</th>
<th>26.5</th>
</tr>
</thead>
</table>

Note the pregnancy rate is broken after Year 3. The line dips but is based on incomplete submission of outcomes.

Has elective single embryo transfer (eSET) impacted upon pregnancy rates?

2.7. A common concern is that carrying out more eSET will impact on overall pregnancy rates. The Authority considered this in January 2012, based on the Year 2 data, and concluded the following (which is consistent with the updated Year 3 data):

- Overall pregnancy rates for eSET and double embryo transfer (DET) are very similar for all age groups.
- The majority (about two thirds) of eSETs are blastocyst transfers. The proportion of blastocyst transfers has increased dramatically over the period the policy has been in force.
- DET has a slightly higher pregnancy rate as patients increase in age. However the number of patients having eSET in the slightly older age groups is small, so we cannot draw firm conclusions from this.

Multiple births update 4
There are still three times more DETs than eSETs, the majority (around 75%) of which are cleavage stage transfers. 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 the multiple pregnancy rates following double blastocyst transfer (DBT) are very high.

- The pregnancy rates from blastocyst transfers are higher, though this is probably because patients having blastocyst transfer have a higher chance of pregnancy anyway. The average pregnancy rates for younger patients are comparable for blastocyst eSET and blastocyst DET. The multiple pregnancy rates from double blastocyst transfers are unacceptably high.

2.8. The figures for Year 3 (see tables 2 and 4) are very similar to those for Year 2 and early Year 3 (April 2011-March 2012). There appears to be a drop in both the overall pregnancy rate and multiple births rate, in all categories, for Year 4. However, these figures may be affected by incomplete submission of outcomes.

<table>
<thead>
<tr>
<th>Patient age</th>
<th>eSET preg. rate</th>
<th>eSET multiple preg. rate</th>
<th>DET preg. rate</th>
<th>DET multiple preg. rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 35</td>
<td>42.0</td>
<td>1.7</td>
<td>39</td>
<td>35.2</td>
</tr>
<tr>
<td>35 – 37</td>
<td>37.6</td>
<td>1.6</td>
<td>35.4</td>
<td>28.9</td>
</tr>
<tr>
<td>38 – 39</td>
<td>34.4</td>
<td>&lt;1</td>
<td>30.6</td>
<td>24.7</td>
</tr>
<tr>
<td>All ages</td>
<td>39.6</td>
<td>1.5</td>
<td>34.0</td>
<td>30.2</td>
</tr>
</tbody>
</table>

Table 3: Overall pregnancy rates (per embryo transfer) and multiple pregnancy rates in Year 4 of the policy, October 2012 onwards

<table>
<thead>
<tr>
<th>Patient age</th>
<th>eSET preg. rate</th>
<th>eSET multiple preg. rate</th>
<th>DET preg. rate</th>
<th>DET multiple preg. rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 35</td>
<td>34.3</td>
<td>1.4</td>
<td>32.0</td>
<td>32.3</td>
</tr>
<tr>
<td>35 – 37</td>
<td>31.9</td>
<td>1.9</td>
<td>27.9</td>
<td>29.2</td>
</tr>
</tbody>
</table>

1 eSET cycles are those where the eSET box has been ticked on the Register and only one embryo has been transferred. The work on eSET billing has indicated that there are a number of unreported eSET cycles.
Table 4: Overall pregnancy rates (per blastocyst transfer) and multiple pregnancy rates from blastocyst transfers in Year 3 of the policy from April 2011 – October 2012

<table>
<thead>
<tr>
<th>Patient age</th>
<th>eSET blastocyst preg. rate</th>
<th>eSET multiple preg. rate</th>
<th>DET blastocyst preg. rate</th>
<th>DET multiple preg. rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 35</td>
<td>46.7</td>
<td>1.9</td>
<td>45.5</td>
<td>42.8</td>
</tr>
<tr>
<td>35 – 37</td>
<td>43.0</td>
<td>1.8</td>
<td>44.6</td>
<td>36.6</td>
</tr>
<tr>
<td>38 – 39</td>
<td>40.0</td>
<td>&lt;1</td>
<td>41.5</td>
<td>31.2</td>
</tr>
<tr>
<td>All ages</td>
<td>44.8</td>
<td>1.7</td>
<td>42.6</td>
<td>37.0</td>
</tr>
</tbody>
</table>

Table 5: Overall pregnancy rates (per blastocyst transfer) and multiple pregnancy rates from blastocyst transfers in Year 4 of the policy from October 2012 onwards

<table>
<thead>
<tr>
<th>Patient age</th>
<th>eSET blastocyst preg. rate</th>
<th>eSET multiple preg. rate</th>
<th>DET blastocyst preg. rate</th>
<th>DET multiple preg. rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 35</td>
<td>36.4</td>
<td>1.6</td>
<td>36.2</td>
<td>38.9</td>
</tr>
<tr>
<td>35 – 37</td>
<td>34.6</td>
<td>1.7</td>
<td>32.9</td>
<td>35.1</td>
</tr>
<tr>
<td>38 – 39</td>
<td>31.4</td>
<td>0.5</td>
<td>31.2</td>
<td>29.1</td>
</tr>
<tr>
<td>All ages</td>
<td>35.0</td>
<td>1.5</td>
<td>32.9</td>
<td>34.9</td>
</tr>
</tbody>
</table>

2.9. In summary:

- From the information we hold, the trends seen since the introduction of the policy in January 2009 (the increase in the proportion of eSET and blastocyst transfers, the decrease in the multiple pregnancy rate and the pregnancy rate remaining steady) have continued in Year 3 and the first half of year 4. From the early Year 4 data it appears that the eSET and blastocyst transfer rates have continued to increase. It is too early to report accurately on

---

2 Table 4 is a subset of table 2 data; the results in table 2 are likely to be being pulled up by the blastocyst results themselves.

3 Table 5 is a subset of table 3 data; the results in table 3 are likely to be being pulled up by the blastocyst results themselves.
the pregnancy and birth rates for Year 4.

- The national average data shows the sector as a whole was close to meeting the Year 3 maximum multiple birth rate of 15%, but centres found it more challenging than the Year 2 target.

- The pregnancy rates from eSET continue to be similar to the pregnancy rates from DET and the multiple pregnancy rate after double blastocyst transfer continues to be unacceptably high. However eSET reduces the risk of multiple pregnancies to a level similar to that of spontaneous conceptions.

3. Individual centres’ Year 3 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 a smaller lag in our reporting of pregnancies, whereas there is typically an 18-month lag for live births (see section 2.4). Measuring performance against a multiple pregnancy rate (an indicative 19% multiple pregnancy rate for Year 3) provides an indication of whether a centre is likely to meet the multiple birth rate target of 15%.

3.2. The funnel plot at Annex A shows anonymised individual centres’ performance against the Year 3 target, using data to the end of September 2012. This shows that the majority of centres are statistically below or not significantly different from the Year 3 target (using the multiple pregnancy rate as an indicator). Seven centres are statistically above the equivalent multiple pregnancy rate indicative figure (ie, they are not at variance due to ‘random variation’).

3.3. As reported to the Authority in January 2012, two centres were considered unlikely to meet the Year 2 target. Only one of these centres is considered unlikely to meet the target in Year 3.

Table 6: Overview of centres’ performance in relation to the target

<table>
<thead>
<tr>
<th>Number of centres³</th>
<th>2009 Year 1 target</th>
<th>2010 Year 2 target</th>
<th>2011 Year 3 target</th>
</tr>
</thead>
<tbody>
<tr>
<td>On or below target</td>
<td>60</td>
<td>54</td>
<td>37</td>
</tr>
<tr>
<td>Above target (not statistically)</td>
<td>10</td>
<td>17</td>
<td>31</td>
</tr>
<tr>
<td>Statistically</td>
<td>3</td>
<td>2</td>
<td>7</td>
</tr>
</tbody>
</table>

---

Multiple births update

7
3.4. The funnel plot also gives an indication (from an analysis of the multiple pregnancy rate) of the number of centres which have already met the Year 4 target or which will be above the Year 4 target, if their performance continues at Year 3 levels and do not change their practice at all.

3.5. In summary, the sector is largely compliant with the Year 3 target, although more centres are likely to be statistically above the target for Year 3 than were statistically above the Year 2 target. In the majority of cases, centres which are significantly above the target one year improve their performance in the next target year.

4. Compliance and on-going monitoring

4.1. Centres’ multiple births minimisation strategies are critically important, as are their arrangements for reviewing and auditing the strategy. At inspection we look at evidence that strategies and outcomes are reviewed in light of centres’ performance with regard to the target.

4.2. Compliance with the target is monitored on an on-going basis. The Executive monitors multiple pregnancy rates using the latest performance information available through the Risk Based Assessment Tool. Where analysis of clinical multiple pregnancy rates indicates that the resulting multiple live birth rate is likely to be in excess of the target at a statistically significant level, centres will be alerted to this so that they can review their multiple births minimisation strategy.

4.3. Since February 2012 it has been possible for centres to access an analysis of their own outcomes, including multiple clinical pregnancy rates, from the Risk Based Assessment Tool available to clinics through the Clinic Portal. From April 2012, the Person Responsible of a licensed centre has received an alert from the HFEA if our monitoring indicates performance that may require review and/or improvement. For the last six months of the Year 3 target (April – October 2012) nine alerts were issued. In the first six months of the Year 4 target period sixteen alerts were issued, indicating that centres are finding meeting the 10% target more challenging compared to the 15% target.

4.4. Where the Executive has concerns that a licensed centre is likely to be non-compliant with requirements in place, our contact with the centre will be in line with the HFEA Compliance and Enforcement Policy.

5. Conclusion

5.1. As predicted the Year 3 maximum multiple birth rate target of 15% is proving to be more stretching for clinics than previous targets. However, the performance of the sector as a whole was close to meeting the target. The performance of the majority of centres is statistically below or not significantly different from the Year 3 target, as calculated by reference to the multiple pregnancy rate (seven centres are statistically above target, compared to three when the early Year 3 data was presented to the
5.2. The pregnancy rates from eSET continue to be similar to the pregnancy rates from DET and the overall pregnancy rate per embryo transfer continues to remain steady.

5.3. Over the period the policy has been in force there has been a dramatic increase in the proportion of eSET and blastocyst transfer.

5.4. The risk based assessment tool is now embedded and allows for monthly on-going monitoring and feedback to centres about their multiple pregnancy rate performance, which in many cases has proven to be effective in preventing centres from breaching the target.

6. **Next steps**

6.1. We will continue to work closely with the professional bodies and the wider sector to review and share best practice around minimising multiple births. The Multiple Births Stakeholder Group will continue to meet.

6.2. We will continue to make information available to centres through the One at a Time website and through future reviews of professional body guidance.

6.3. The Code of Practice guidance will be updated in October 2013 to reflect recent findings of three embryo transfer (following discussion by the Authority in June 2012).

7. **Recommendations**

7.1. The Authority is asked to note the sector’s and centres’ performance against the 15% Year 3 target (April 2011 – October 2012) and 10% Year 4 target so far.
Annex A - Funnel plot graph of centres’ Year 3 performance
Annex B - Explanation of funnel plot graph in Annex A

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 the targets introduced by the Authority (20% in April 2010 and 15% in April 2011), were for a maximum multiple birth rate. We have therefore used a ‘correction factor’ to give an equivalent multiple pregnancy rate (25% for multiple birth rate of 20%, 19% for multiple birth rate of 15% and 13% for multiple birth rate of 10%), 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 A 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. 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 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, ie, by chance alone, rather than the presence of true, systematic variation.

References
# Authority Paper

<table>
<thead>
<tr>
<th><strong>Paper Title</strong></th>
<th>Standing Financial Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Agenda Item</strong></td>
<td>14</td>
</tr>
<tr>
<td><strong>Paper Number</strong></td>
<td>[HFEA (03/07/2013) 688]</td>
</tr>
<tr>
<td><strong>Meeting Date</strong></td>
<td>3 July 2013</td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td>Mark Bennett, Director Finance &amp; Facilities</td>
</tr>
<tr>
<td><strong>For information or decision?</strong></td>
<td>Decision</td>
</tr>
</tbody>
</table>

**Recommendation**

Standing Orders identify Standing Financial Instructions (SFIs) as an element of the governance framework ‘with which the Authority must comply’. Standing Orders also reserve approval and amendments of SFIs to the Authority. Changes proposed by Audit & Governance Committee on 19 June are included. The Authority is recommended to approve the enclosed.

In September, approval will be sought, similarly, to revised Financial Procedures.

**Resource Implications**

None

**Implementation**

Continual

**Communication**

Communicated to all staff and placed on intranet

**Organisational Risk**

Low. Up to date and useable SFIs ensure financial transactions can be effectively recorded and managed.

**Evaluation**

Periodic evaluation and review

**Annexes**

None
Standing Financial Instructions
June 2013

These instructions have been reviewed by the Audit and Governance Committee on 19 June 2013 and approved by the Authority on 3 July 2013. These instructions are mandatory for all members and employees.
Contents

1. Introduction .......................................................................................................... 3
2  Audit and Governance ......................................................................................... 7
3  Cash Limit Control................................................................................................ 8
4  Financial & Budget Management.......................................................................... 8
5  Annual Accounts and Reports ............................................................................ 10
6  Bank Accounts ................................................................................................... 10
7  Income & Fees and Security of Cash & Cheques ............................................. 11
8  Members and Employees Terms of Service and Pay ....................................... 12
9  Non-Pay Expenditure (Buying & Procurement) ................................................. 13
10 External Borrowing and Investments ................................................................. 15
11 Capital Investment & Security of Assets and Data ............................................. 15
12 Disposals of Assets, Losses and Special Payments .......................................... 17
13 Information Technology ..................................................................................... 18
14. Delegations from the Department of Health ..................................................... 19

Note to editors – if you create either a new chapter, or a new sub-heading or a new paragraph, please copy the format of an existing equivalent.
1. **Introduction**

1.1 **General**

1.1.1 All organisations need a framework of financial control and to help you appreciate your role in this, we have highlighted text we believe is particularly relevant. Please read all of this section 1.1 and look at Diagram 1, to find the part of the framework most relevant to what you wish to do.

1.1.2 These Standing Financial Instructions (SFIs) are issued in accordance with best practice in corporate governance and are referenced in the Standing Orders of the Authority. These instructions are based upon guidance issued by the Government and the Department of Health, modified to comply with the HFE Act and the circumstances in which the HFEA operates.

*The framework of documents within which the Standing Financial Instructions sit is shown in Diagram 1:*  

![Standing Financial Instructions - Framework](image-url)

These all sit within a context defined by:

- Managing Public Money: [http://www.hm-treasury.gov.uk/psc_mmp_index.htm](http://www.hm-treasury.gov.uk/psc_mmp_index.htm)
- The Human Fertilisation and Embryology Act 1990 (as amended)

1.1.3 These SFIs describe the financial responsibilities and principles the Authority has adopted and signpost to the policies and procedures to be followed. They are designed to ensure that financial transactions are carried out in accordance with the law and
Government policy in order to achieve probity, accuracy, economy, efficiency and effectiveness. For detailed help on a particular type of transaction, we suggest you look at Diagram 1 or go to the relevant chapter of this document and then navigate to either the HFEA delegation scheme or the financial procedures.

1.1.4 These SFIs identify financial responsibilities which apply to everyone working for the Authority, including contractors and expert advisors when acting on behalf of the HFEA. Changes to SFIs require the agreement of the Director of Finance, who will then obtain the approval of the Accounting Officer, the Audit and Governance Committee and full Authority as appropriate.

1.1.5 Any difficulties that arise regarding interpretation or application of SFIs should be notified to the Director or Head of Finance – before further action is taken.

1.1.6 Most of the time, you will be reading here for help on procurement (buying / contracting) goods and services. This process is set out in more detail in chapter 9 and the financial procedures, but there are two main methods you may use, the first of which is strongly preferred:

(a) Using a framework arrangement via the Government Procurement Service (GPS); Department of Health or one of its ALBs

(b) An HFEA tender and contract management exercise – only to be used in particular circumstances, please see 1.1.5.

1.1.7 Failure to comply with the standing financial instructions is potentially a disciplinary matter, which could lead to dismissal. Please see 1.1.5.

1.2 Terminology

1.2.1 Any expression to which a meaning is given in Health Service Acts, or in the Financial Directions made under the Acts, shall have the same meaning in these instructions; and

(a) "Authority" means the Human Fertilisation and Embryology Authority (HFEA)

(b) "Chief Executive" is the chief officer of the Authority and the Accounting Officer designated by the Accounting Officer of the Department

(c) "Director of Finance" means the chief financial officer of the Authority.

(d) "Budget" means a resource, expressed in financial terms, proposed by the Authority for the purpose of carrying out, for a specific period, any or all of the functions of the Authority

(e) "Budget Holder" means the director or employee with delegated authority to manage finances (Income and Expenditure) for a specific area of the organisation
(f) “Head of Internal Audit” means the person designated for this role under the contract for the provision of internal audit services to the Authority

(g) "Legal Adviser" means the properly qualified person appointed by the Authority to provide legal advice

(h) “the Act” means the Human Fertilisation and Embryology Act 1990 as amended by the Human Fertilisation and Embryology Act 2008

(i) “the Department” means the Sponsor Department of the HFEA.

1.2.2 Wherever the title Chief Executive, Director of Finance, or other nominated officer is issued in these instructions, it shall be deemed to include such other director or employees who have been duly authorised to represent them.

1.3 Responsibilities and Delegation

1.3.1 The Authority exercises financial supervision and control by:

(a) Formulating the financial strategy

(b) Requiring the submission and approval of budgets within approved allocations/overall income

(c) Defining and approving essential features of important procedures and financial systems (including the need to obtain value for money)

(d) Defining specific responsibilities placed on members and employees as indicated in the HFEA Scheme of Delegation.

1.3.2 The Authority will delegate responsibility for the performance of its functions in accordance with its Standing Orders and the framework set out in this document. This will be kept under review by the Authority.

1.3.3 Within the SFIs, it is acknowledged that the Chief Executive is ultimately accountable to the Authority and to the Department for ensuring that the Authority meets its obligation to perform its functions within the available financial resources. The Chief Executive is the Accounting Officer and has overall executive responsibility for the Authority’s activities and is responsible for ensuring that its financial obligations and targets are met.

1.3.4 The Chief Executive and Director of Finance will, as appropriate, delegate detailed responsibilities but they remain accountable for financial control.

1.3.5 The Chief Executive and Director of Finance ensure that existing members and employees and all new appointees are notified of and understand their responsibilities within these instructions.

1.3.6 The Director of Finance is responsible for:

(a) Implementing the Authority’s financial policies and for co-ordinating any corrective action necessary to further these policies

(b) Ensuring that detailed financial procedures and systems incorporating the principles of separation of duties and internal checks are prepared, documented and maintained to supplement these instructions
(c) Ensuring that sufficient records are maintained to show and explain the Authority’s transactions, in order to disclose, with reasonable accuracy, the financial position of the Authority at any time

(d) Provision of financial advice relevant to the management of the organisation to the Authority, its members and employees

(e) The systems of financial control

(f) Preparation and maintenance of such accounts, certificates, estimates, records and reports as the Authority may require for the purpose of carrying out its statutory duties.

1.3.7 All members and employees are responsible for complying with the requirements of Standing Orders, Standing Financial Instructions, Financial Procedures and the HFEA Delegation Scheme and ensuring that there are procedures in place to:

(a) Secure the property of the HFEA

(b) Avoid loss or fraud

(c) Obtain value for money and efficiency in the use of resources.

1.3.8 Any contractor or employee of a contractor who is empowered by the Authority to commit the Authority to expenditure or who is authorised to obtain income shall be covered by these instructions. It is the responsibility of the Chief Executive and Director of Finance to ensure that such persons are made aware of this.

1.3.9 When any matter arises which involves, or is thought to involve, irregularities concerning cash, stores, or other property or any suspected irregularity in the exercise of any function of a pecuniary nature, the Director of Finance must be notified immediately.

1.3.10 For any and all members and employees who carry out a financial function, the form in which financial records are kept and the manner in which employees discharge their duties must be to the satisfaction of the Director of Finance. The manner in which members discharge their duties must be to the satisfaction of the Chair.

1.3.11 When urgent issues requiring Authority approval arise between meetings, the Chair of the Authority is able to take appropriate action following consultation with at least two members, if possible. Any such action taken under this procedure should be reported to the next meeting of the Authority.

1.3.12 At least one Authority member will be required to be a member of any HFEA-originated tender panel established in accordance with financial procedures. Three Authority members will be required for membership of any similar tender panel established for letting contracts worth in excess of £150k. This does not apply to framework arrangements (see 1.1.5 (a)).
2 Audit and Governance

2.1 Audit and Governance Committee

2.1.1 The Authority shall establish an Audit and Governance Committee which will provide an independent and objective view of internal control as described in Standing Orders.

2.1.2 Where the Audit and Governance Committee feel there is evidence of ultra vires transactions, evidence of improper acts, or if there are other important matters the committee wish to raise, the Chair of the Audit and Governance Committee should raise the matter in an appropriate manner with the Accounting Officer, the Chair or the Authority, as appropriate.

2.1.3 There shall be an adequate internal audit service and it is the responsibility of the Director of Finance to ensure it is properly supported and able to be effective.

2.2 Director of Finance

2.2.1 The Director of Finance is responsible for consulting with the Chief Executive, Chair of Audit and Governance or Chair of the Authority in determining at what stage to formally report to the Department and/or involve the police in cases of loss, fraud, misappropriation and other irregularities.

2.2.2 The Director of Finance will determine the appropriate action to take on discovery of a significant internal financial control weaknesses. He/she will also ensure that a strategic audit plan is developed that responds to the High Level Risk Register and, in turn, covers areas of potential systematic financial weakness in HFEA activities. This will include reporting to the Audit and Governance Committee and responding to reports and advice from the Health Group Internal Audit Service.

2.2.3 The Director of Finance will ensure designated auditors receive proper access to HFEA information, premises, people and property and also receive explanations concerning any matter under investigation.

2.3 Internal Audit

2.3.1 Internal Audit will prepare an audit plan in liaison with the Director of Finance, obtain approval of the plan from the Audit and Governance Committee and then deliver and report on the audit work it entails. This will be performed within the Service Level Agreement signed by the Department and the HFEA and be in accordance with Internal Audit standards.

2.3.2 The Head of Internal Audit will attend Audit and Governance Committee meetings and has a right of access to all Audit and Governance Committee Members, the Chief Executive and Chair of the Authority.

2.3.3 The Head of Internal Audit is required to report annually to the Audit and Governance Committee on the work completed in the year along with recommendations. An Annual Assurance report must also be made.
2.4  **External Audit**

2.4.1  As per section 6(4) of the Act, “the Comptroller and Auditor General shall examine, certify and report on every statement of accounts under subsection 3 above and shall lay a copy of the statement and of his report before each House of Parliament”.

2.4.2  The Audit Committee must ensure a cost-effective service and consider risk and value for money of the external audit function, in discussion with the National Audit Office.

3  **Cash Limit Control**

3.1  The Authority is expected normally to stay within the cash limits set out in the Management Statement (Financial Memorandum) subject to any discretion offered by the Department of Health.

3.2  The Director of Finance will:

(a) Provide monthly reports in the form required by the Department

(b) Ensure money drawn from the Department against the Cash Limit is required for approved expenditure only, and is drawn down only at the time of need

(c) Ensure that an adequate system of monitoring financial performance is in place to enable the Authority not to exceed its Annual Revenue and Capital Limits.

4  **Financial & Budget Management**

4.1  **Business Plans and Budgets**

4.1.1  The Chief Executive will compile and submit to the Authority an annual Business Plan which takes into account financial targets and forecast limits of available resources. This will contain:

(a) A statement of the significant assumptions on which the plan is based

(b) Details of major changes in workload, delivery of services or resources required to achieve the plan.

4.1.2  Prior to the start of the financial year, the Director of Finance will prepare and submit budgets for approval by the Authority:

(a) In accordance with the aims and objectives in the Business Plan

(b) Aligned to with workload and resource plans

(c) Following discussion with appropriate budget holders

(d) Within the limits of expected available funds

(e) Identify potential risks.

4.1.3  The Director of Finance shall monitor financial performance and report to the Chief Executive and Authority, as required.

4.1.4  All budget holders must provide information as required by the Director of Finance to enable budgets to be monitored.
4.1.5 The Director of Finance has a responsibility to ensure that adequate training for these purposes is delivered to budget holders.

4.2 **Budgetary Delegation**

4.2.1 The Chief Executive may delegate the management of a budget to permit the performance of a defined range of activities. This delegation is for the purposes established in the business plan and budget and is defined by:

(a) The amount

(b) The purpose(s) of each budget heading

(c) The individual and group responsibilities of the team delivering the activities involved

(d) Limits of virement (moving money between budget headings).

4.2.2 The Chief Executive and delegated budget holders must not exceed the budgetary total or virement limits set by the Authority.

4.2.3 Budgeted funds not required for designated purpose(s) revert to the control of the Chief Executive, subject to any authorised use of virement.

4.2.4 Non-recurring budgets should not be used to finance recurring expenditure without the authority in writing of the Chief Executive.

4.3 **Budgetary Control and Reporting**

4.3.1 The Director of Finance will devise and maintain systems of budgetary control. These will include:

(a) Regular financial reports to the Authority containing

   (i) Income and expenditure to date showing trends and forecast year-end position

   (ii) Project spend and projected outturn against plan

   (iii) Explanations of material variances

   (iv) Details of any corrective action, where necessary, and whether such actions are sufficient

(b) Timely, accurate and comprehensible advice and financial reports to each budget holder

(c) Monitoring management action to correct variances

(d) Arrangements for the authorisation of budget transfers and virements.

4.3.2 Each Budget Holder is responsible for ensuring that:

(a) Any likely overspending or reduction of income which cannot be met by virement is not incurred without the prior consent of the Chief Executive

(b) The amount provided in the approved budget is not used in whole or in part for any purpose other than that specifically authorised subject to the rules of virement

(c) No employees are appointed without agreement with HR and the approval of the Chief Executive.
4.3.3 The Chief Executive is responsible for identifying and implementing cost improvements and income generation initiatives in accordance with the requirements of the Annual Business Plan and a balanced budget.

4.4 Capital Expenditure
4.4.1 The general rules applying to delegation and reporting shall also apply to capital expenditure. (The particular applications relating to capital are contained in Chapter 11.)

4.5 Monitoring Returns
4.5.1 The Chief Executive is responsible for ensuring that the appropriate monitoring forms are submitted to the requisite organisation. These include the submission of budget monitoring returns to the Department of Health.

5 Annual Accounts and Reports
5.1 The Director of Finance will arrange preparation of:
   (a) Financial and other reports in accordance with requirements from Treasury, Cabinet Office and the Department
   (b) Certified annual financial returns as required for the Secretary of State and in accordance the timetable prescribed by Parliament.

5.2 The Authority will publish an Annual Report, in accordance with guidelines on local accountability and Treasury guidance.

6 Bank Accounts
6.1 General
6.1.1 The Director of Finance is responsible for managing the Authority's banking arrangements and for advising the Authority on the provision of banking services and operation of accounts. It is expected the HFEA will use the Government Banking Service for its Department transactions and any significant surplus amounts and, eventually, for all its banking services.

6.1.2 The Authority shall approve the banking arrangements and the Director of Finance shall review and report on them at least every five years.

6.2 Bank Accounts
6.2.1 The Director of Finance is responsible for the operation of bank accounts; ensuring payments made from bank accounts are properly managed, whilst not exceeding the agreed mandates, and reporting to the Authority all arrangements made with the Authority's bankers when accounts are overdrawn and the reasons why the overdraft arose.
7 Income & Fees and Security of Cash & Cheques

7.1 Income Systems
7.1.1 The Director of Finance is responsible for designing, maintaining and ensuring compliance with systems for the proper recording, invoicing, collection and coding of all monies due.

7.1.2 The Director of Finance is also responsible for the prompt banking of all monies received.

7.2 Fees and Charges
7.2.1 The Authority shall follow HM Treasury’s Managing Public Money and the Act in setting prices for services as specified in the Act.

7.2.2 The Director of Finance is responsible for approving and regularly reviewing the level of all fees and charges. Independent professional advice on matters of valuation shall be taken as necessary.

7.2.3 All employees must inform the Director of Finance promptly of money due arising from transactions which they initiate / deal with, including all contracts, leases, tenancy agreements and other transactions.

7.3 Debt Recovery
7.3.1 The Director of Finance is responsible for the appropriate recovery action on all outstanding debts.

7.3.2 Income not received should be dealt with in accordance with losses procedures.

7.3.3 Overpayments should be detected (or preferably prevented) and recovery initiated.

7.4 Security of Cash, Cheques and Other Negotiable Instruments

7.4.1 The Director of Finance is responsible for:

(a) Approving the form of all receipt books, forms or other means of officially acknowledging or recording monies received or receivable

(b) Ordering and securely controlling any such stationery

(c) Provision of adequate facilities and systems for employees whose duties include collecting and holding cash, including the provision of safes or lockable cash boxes, the procedures for keys, and for coin operated machines

(d) Prescribing procedures for handling cash and negotiable securities.

7.4.2 Official money shall not under any circumstances be used for cashing private or personal cheques.

7.4.3 All cheques, postal orders, cash etc., shall be banked intact. Disbursements shall not be made from cash received, except under arrangements approved by the Director of Finance.

7.4.4 Charity collections of cash organised by staff cannot be banked via the HFEA account and must be the responsibility of the event organiser. Such cash donations are not to be made in the name of the HFEA.
7.4.5 The holders of safe keys shall not accept unofficial funds for depositing unless such deposits are in special sealed envelopes or locked containers. It shall be made clear to the depositors that the Authority is not to be held liable for any loss, and written indemnities must be obtained from the organisation or individuals absolving the Authority from responsibility for any loss.

8 Members and Employees Terms of Service and Pay

8.1 Staff Appointments
8.1.1 Appointments of staff must remain within the limit of approved budgets and be authorised according to current HR procedures as agreed by the Remuneration Committee.

8.1.2 The Remuneration Committee and Authority will approve procedures presented by the Chief Executive for setting commencing pay rates, conditions of service and similar, for employees.

8.2 Processing of Payroll
8.2.1 The Director of Finance is responsible for:
(a) Specifying timetables for submission of properly authorised time records and other notifications
(b) The final determination of pay
(c) Making payment on agreed dates by an agreed method.

8.2.2 The Director of Finance will issue instructions for:
(a) Verification and documentation of data
(b) The timetable for preparation of payroll and assuring its integrity and payment
(c) Maintenance of subsidiary records for superannuation, income tax, social security and other authorised deductions from pay
(d) Security and confidentiality of payroll information
(e) Authority to release payroll data under the provisions of the Data Protection Act
(f) Procedures for payment by cheque, bank credit or cash
(g) Procedures for the recall of cheques and bank credits
(h) Pay or similar advances and their recovery
(i) Regular and independent reconciliation of pay control accounts
(j) Separation of duties of preparing records and handling payments
(k) Recovery from leavers of money and property due to the Authority.

8.2.3 Appropriately nominated managers have delegated responsibility for:
(a) Submitting time records and other notifications in accordance with established timetables and procedures
(b) Submitting termination forms in the prescribed form immediately upon knowing the effective date of an employee's resignation, termination or retirement. Where an employee fails to report for duty in circumstances that suggest they have left without notice, the Director of Finance must be informed immediately.

8.2.4 Regardless of the arrangements for providing the payroll service, the Director of Finance shall ensure that the chosen method is supported by appropriate (contracted) terms and conditions, adequate internal controls and audit review procedures and suitable arrangements are made for the collection of payroll deductions and payment of these to appropriate bodies.

8.3 Contracts of Employment
8.3.1 The Authority shall delegate responsibility to a manager for:
(a) Ensuring that all employees are issued with a Contract of Employment in a form approved by the Authority Committee and which complies with employment legislation
(b) Dealing with variations to, or termination of, contracts of employment.

9 Non-Pay Expenditure (Buying & Procurement)

9.1 Delegation of Authority
9.1.1 This is set out in the HFEA Scheme of Delegation approved by the Chief Executive. There is no delegation for anything that is not described there, please refer to 1.1.5.

9.2 Buying or Procuring Goods and Services
9.2.1 In order to requisition goods and services, you need to select how to proceed using one of the two methods summarised below. You should always try to obtain the best value for money for the Authority and follow the principles set out in 9.3:
(a) The preferred or default option is to use a framework arrangement via the Government Procurement Service (GPS); Department of Health or one of its ALBs. An up to date list of these is available on the intranet (insert reference here)
(b) An HFEA tender and contract management exercise – only to be used in particular circumstances, please see 1.1.5.

9.2.2 Small (<£1,000), infrequent, urgent or one-off purchases may be done using the Government Procurement Card (GPC) held by a few senior employees – this process is described in more detail on the intranet (insert reference here). Where possible, this should use GPS suppliers.

9.2.3 The buyer / procurer, or their manager, must:
(a) Follow the instructions, prepared by the Director of Finance, set out in financial procedures depending on the method followed
(b) Prepare a scope of work or order that is capable of being fulfilled by a supplier or the tenderers, including timelines of preparation and delivery

(c) Record the offer/s or tender/s received and evaluate them transparently; award appropriately and then commit to and obtain the goods and services in a controlled manner

(d) Ensure that the buyer/ procurer and the budget holder certify receipt of goods and services and record this in the relevant manner

(e) Ensure subsequent invoices are certified and approved in accordance with goods or services receipt – that invoices are arithmetically correct and contractually due.

9.2.4 Prepayments are only permitted where exceptional circumstances apply:

(a) The appropriate Director must provide all relevant circumstances of the purchase, including the effects if the supplier is at some time during the course of the prepayment period unable to meet their commitments

(b) The Director of Finance is satisfied with the proposed arrangements in advance

9.3 Principles for Buying or Procuring

9.3.1 Managers must follow some principles, irrespective of the procurement route used:

(a) All contracts, leases, tenancy agreements and other commitments which may/will result in a future liability are agreed with the Director of Finance in writing and in advance of entering into any commitment

(b) HFEA-originated contracts above specified thresholds are advertised and awarded in accordance with EU procurement regulations (refer 1.1.5)

(c) No order shall be issued for any item or items to any firm which has made an offer of gifts, reward or benefit to members or employees, other than recorded isolated gifts of a trivial or inexpensive character, such as calendars or conventional hospitality, such as lunches during working visits. These should be recorded in the Register of Interests maintained in the Chief Executive’s office

(d) No requisition/order is placed for which there is no budget provision, unless authorised in writing by the Director of Finance

(e) All goods, services or works are bought on an official order

(f) Verbal orders are immediately followed by an official ‘confirmation’ order and are only issued very exceptionally - in cases of emergency or urgent necessity. The issuing employee should have permission from their manager or the Director or Head of Finance
(g) Orders may not be split or placed in a manner to avoid delegation or financial limits

(h) Goods are not taken on trial or loan in circumstances that could commit the HFEA to a future uncompetitive purchase

(i) No gifts for employees or members are bought using HFEA funds

(j) Standards for sustainable procurement are met or exceeded – refer to [http://sd.defra.gov.uk/advice/public/buying/products/] and consider the natural resources involved and how they may be minimised for the intended procurement.

10  External Borrowing and Investments

10.1  External Borrowing
10.1.1 In accordance with Para. 2 of Schedule 1 to the Act the HFEA has no power to borrow money.

10.2  Investments
10.2.1 Temporary cash surpluses must be held in a bank deposit account where funds are immediately available.

11  Capital Investment & Security of Assets and Data

11.1  Capital Investment
11.1.1 The Chief Executive shall:
   (a) Ensure there is an adequate appraisal and approval process in place for determining capital expenditure priorities and the effect of each proposal upon business plans
   (b) Be responsible for the management of all stages of capital schemes and for ensuring that schemes are delivered on time and to cost
   (c) Ensure capital investment is not undertaken without confirmation of purchaser(s), business support and the availability of resources to finance all revenue consequences, including capital charges.

11.1.2 For every capital expenditure proposal the Chief Executive shall ensure:
   (a) A business case in line with current HM Treasury and Departmental guidance is produced setting out:
      (i) Appraisal of relevant options
      (ii) Appropriate project management and control arrangements
   (b) The Director of Finance has certified professionally to the costs and revenue consequences detailed in the business case.

11.1.3 For capital schemes where the contracts stipulate stage payments, the Chief Executive will issue procedures for their management. The HFEA would not usually embark on a Private Finance Initiative (PFI) proposal. Consideration of any such proposal must therefore involve the Chief Executive, Director of Finance, Department and Authority.
11.1.4 The approval of a capital programme shall not constitute approval for expenditure on any scheme. The Chief Executive shall issue to the manager responsible for any scheme:
(a) Specific authority to commit expenditure
(b) Authority to proceed to acquire resources.

11.1.5 The Director of Finance shall issue procedures governing financial management of capital investment projects and valuation for accounting purposes.

11.2 Asset Registers
11.2.1 The Chief Executive is responsible for the maintenance of registers of assets, taking account of the advice of the Director of Finance concerning the form of any register and the method of updating. The Director of Finance shall ensure effective annual physical checks of assets against the asset register are conducted. Spot checks of samples of assets should be undertaken on a regular basis and recorded.

11.2.2 Additions to the fixed asset register must be clearly identified to an appropriate budget holder and be validated by reference to:
(a) Properly authorised and approved agreements, certificates, invoices and other documentary evidence
(b) Stores, requisitions and wages records for own materials and labour including appropriate overheads
(c) Lease agreements in respect of assets held under a finance lease and capitalised.

11.2.4 Where capital assets are sold, scrapped, lost or otherwise disposed of, their value must be removed from the accounting records and each disposal must be validated by reference to authorised documents or invoices, where appropriate.

11.2.5 The Director of Finance shall approve procedures for reconciling balances on fixed assets accounts in ledgers against fixed asset registers.

11.2.6 The value of each asset shall be indexed to current values in accordance with methods specified by HM Treasury, unless the adjustments are considered to be not material.

11.2.7 The value of each asset shall be depreciated using methods and rates stipulated in the accounting policies.

11.3 Security of Assets
11.3.1 The overall control of assets is the responsibility of the Chief Executive.

11.3.2 Asset control procedures (including fixed assets, cash, cheques and negotiable instruments, and also including donated assets) must be approved by the Director of Finance. This procedure shall make provision for:
(a) Recording managerial responsibility for each asset
(b) Identifying additions and disposals
(c) Identifying repairs and maintenance expenses
(d) Physical security
(e) Periodic verification of the existence, condition and title to assets
(f) Reporting costs associated with retention of an asset
(g) Recording and safekeeping cash, cheques and negotiable instruments.

11.3.3 All discrepancies revealed by verification of physical assets to the fixed asset register shall be notified to the Director of Finance.

11.3.4 Whilst each employee has a responsibility for the security of property of the Authority, it is the responsibility of members and senior employees in all disciplines to apply such appropriate routine security practices in relation to Authority property as may be determined by the Authority. Any breach of agreed security practices must be reported in accordance with instructions.

11.3.5 Any damage to the Authority's premises, vehicles and equipment, or any loss of equipment, stores or supplies must be reported by members and employees in accordance with the procedure for reporting losses.

11.3.6 Where practical, assets should be marked as Authority property.

11.4 Security of Data
11.4.1 The overall responsibility for data security rests with the Chief Executive.
11.4.2 Procedures for data security are set out in the Authority’s Information Governance Policies.

12 Disposals of Assets, Losses and Special Payments

12.1 Disposals of Assets
12.1.1 When it is decided to dispose of an Authority asset, the head of department or authorised deputy will determine and advise the Director of Finance of the estimated market value of the item, taking account of professional advice where appropriate.

12.2 Losses and Special Payments
12.2.1 The Director of Finance must prepare procedural instructions on the recording of and accounting for losses and special payments. For the purposes of this section the term “losses” includes constructive losses.
12.2.2 Subject to the terms of the Authority’s Whistle Blowing and Anti-Fraud policies, any employee discovering or suspecting a loss of any kind should immediately inform their head of department, who must immediately inform the Chief Executive and the Director of Finance. Where a criminal offence is suspected, the Director of Finance in consultation with the Chief Executive, Chair and Legal Adviser must immediately inform the police if theft or arson is involved, but if the case involves suspicion of fraud, then the particular circumstances of the case will determine the stage at which the police are notified.
12.2.3 For losses apparently caused by theft, fraud, arson, neglect of duty or gross carelessness, except if trivial and where fraud is not suspected, the
Director of Finance, in consultation with the Chief Executive, must immediately notify:

(a) The Chair and the Authority
(b) The External Auditor and the Department.

12.2.4 Within limits delegated to it by the Department, the Authority shall approve the writing-off of losses.

12.2.5 The Director of Finance shall be authorised to take any necessary steps to safeguard the Authority's interests in bankruptcies and company liquidations.

12.2.6 For any loss, the Director of Finance should consider whether any insurance claim can be made against insurers.

12.2.7 The Director of Finance shall maintain a Losses and Special Payments Register in which write-off action is recorded.

12.2.8 No special payments exceeding delegated limits shall be made without the prior approval of the Department and HM Treasury. The process for which is set out in the Management Statement and the limits for which are in the Delegations assigned to the HFEA, see Diagram 1.

13 **Information Technology**

13.1 The Director of Finance, who is responsible for the accuracy and security of the financial and statutory data of the Authority, shall:

(a) Devise and implement any necessary procedures to ensure appropriate protection of HFEA data, programs and hardware from accidental or unintentional disclosure to unauthorised persons, deletion or modification, theft or damage

(b) Ensure that appropriate controls exist over data entry, processing, storage, transmission and output to ensure security, privacy, accuracy, completeness, and timeliness of the data, as well as the efficient and effective operation of the system/s used

(c) Ensure that adequate controls exist such that the computer operation is separated from development, maintenance and amendment

(d) Ensure that an adequate management (audit) trail exists through the system and that such computer audit reviews as he/she may consider necessary are being carried out.

13.2 The Director of Finance shall satisfy him/herself that new financial systems and amendments to current financial systems are developed in a controlled manner and thoroughly tested prior to implementation. Where this is undertaken by another organisation, assurances of adequacy will be obtained from them prior to implementation.

13.3 The Director of Finance shall ensure that contracts for computer services for financial applications or any other agency shall clearly define the responsibility of all parties for the appropriate security, privacy, accuracy, completeness, and timeliness of data during processing, transmission and storage. The contract should also ensure rights of access for audit purposes.
13.4 Where another agency provides a computer service for financial applications, the Director of Finance shall periodically seek assurances that adequate controls are in operation.

13.5 Where computer systems have an impact on corporate financial systems the Director of Finance shall be satisfied that:

(a) Systems acquisition, development and maintenance are in line with the Authority’s Information Risk policy, and Cabinet Office regulations together with relevant legislation where appropriate

(b) Data produced for use with financial systems is adequate, accurate, complete and timely, and that a management (audit) trail exists

(c) Finance staff have access to such data

(d) Necessary computer audit reviews are being performed.

14. Delegations from the Department of Health

14.1 All officers of the HFEA, particularly those with financial responsibility, should note that these instructions form part of a system of delegation. This arises in Government and flows to the HFEA via the Accounting Officer of the Department of Health to the Chief Executive, the HFEA Accounting Officer.

14.2 The Management Statement contains further information on these delegations and, in particular, on their limits and processes. The Department has updated these delegations in March 2013, the reference link is in Diagram 1.

14.3 In particular, these delegations cover: losses and special payments; insurance; restricted categories of expenditure; limits and spending controls and a definition of front-line posts.