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<td>Agenda Item</td>
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<td>Paper Number</td>
<td>[AGC (18/03/2015) 442]</td>
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<td>Meeting Date</td>
<td>Wednesday, 18 March 2015</td>
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<tr>
<td>Author</td>
<td>Dee Knoyle</td>
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<td>For information or decision?</td>
<td>Decision</td>
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<td>Recommendation</td>
<td>Members are asked to confirm the minutes as a true and accurate record of the meeting.</td>
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**Members present**
- Rebekah Dundas (Chair)
- Jane Dibblin
- Gill Laver
- Jerry Page

**External attendees**
- Catherine Hepburn – NAO
- Kim Hayes – DH
- Lynn Yallop, PWC – DHIA
- James Hennessey – PWC - DHIA

**Staff in attendance**
- Sue Gallone – Director of Finance and Resources
- Morounke Akingbola – Head of Finance
- Sam Hartley – Head of Governance and Licensing
- Adam Ashiwaju – Accounts Officer
- Dee Knoyle – Committee Secretary

**Apologies**
- None

**Attendance for specific items:**
- Nick Jones – Director of Compliance and Information
- Paula Robinson – Head of Business Planning
- Rachel Hopkins – Head of Human Resources
1. Welcome, Apologies and Declarations of Interests

1.1 The Chair welcomed all attendees to the meeting.

1.2 The Chair introduced Jane Dibblin, Authority Member to the meeting and announced that Jane had agreed to become a member of the Audit and Governance Committee (AGC) for the next two meetings.

1.3 The Chair announced that Alan Thornhill was no longer a member of AGC due to other commitments.

1.4 The Chair also announced that Jerry Page had agreed to extend his term as a member of AGC, which would aid continuity.

1.5 The Chair announced that new Authority members had recently been successfully recruited. Kate Brian and Dr Anthony Rutherford had officially joined the Authority on 12 November 2014, while Margaret Gilmore and Dr Yacoub Khalaf had agreed to commence their roles on 1 April 2015, to replace other members whose terms would end at that time.

1.6 There were no apologies for absence.

2. Minutes of the Meeting held on 1 October 2014

2.1 The Minutes of the meeting held on 1 October 2014 were agreed as a true record of the meeting and approved for signature by the Chair.

3. Matters Arising

3.1 The Committee noted the status of the various matters arising and good progress made to date.

3.2 Most of the matters arising had now been completed with a few exceptions which were being monitored:

   3.2.1 Eight Authority members had completed the online governance training and other members were due to complete it.

   3.2.2 The business continuity cascade exercise was completed on 3 December 2014.

   3.2.3 The Executive is awaiting a response from the Department of Health (DH) to conclude negotiations on the minimum levels of reserves.

   3.2.4 An annual review of effectiveness action plan, which included matters such as circulating AGC minutes to all Authority members for background information and implementing an annual appraisal for external members, has been prepared for discussion later in this meeting.

4. Regulatory and Register Management – Compliance and Information Risks

4.1 The Director of Compliance and Information provided the Committee with a presentation and briefing.

4.2 The Committee noted that the core activities of the Compliance and Information Directorate were licensing, inspecting/auditing for compliance and maintaining the organisation’s statutory Register of patient/donor information. The Directorate also processed Pre-implantation Genetic Diagnosis (PGD)/Human Leukocyte Antigen (HLA) tissue typing applications for approval by an HFEA Committee. The Directorate was responsible for the organisation’s IT systems, including the
risk based assessment tool used to monitor centres’ performance. The responsibility for the organisation’s internal database and desktop support to office and home-based staff was also held with this Directorate.

4.3 The HFEA’s Corporate Management Group and Authority members were updated regularly on the Directorate’s key performance indicators. Performance had proved to be good with one or two exceptions.

4.4 There had recently been an increase in reported non-compliances. This may have been due to the criteria for non-compliance being reviewed in order to drive up standards and the HFEA’s wider remit to inspect areas of practice passed from the Care Quality Commission (CQC).

4.5 There had been an increase in PGD applications and the Directorate had been successful in processing applications quickly and meeting key performance indicator targets.

4.6 The Committee discussed the following concerns relayed by the Director of Compliance and Information:

4.6.1 **Register Infrastructure** - The IT infrastructure for the statutory Register of patient/donor information was in need of improvement. The Information for Quality (IfQ) programme would address this.

4.6.2 **Auditing and correcting errors** - Audits were usually carried out at centres during the renewal inspections and the number of errors identified remained unchanged despite guidance from the Inspectorate. There were approximately 60,000 treatment cycles carried out across the centres each year and therefore a high level of data entry. Although the majority of the errors were minor data entry errors, correcting them consumed quite a lot of HFEA staff time. Again IfQ would address this.

4.6.3 **Non-Compliances – long standing issues** – Informed consent was a recurring problem in some clinics. The recent workshops organised by the HFEA had helped, especially having a barrister present to give further guidance and clarity about the potential impacts for clinics of getting this important matter wrong. The HFEA was reviewing some aspects of consent forms but there needed to be a cultural shift among clinics, to attain a better understanding that their practices had a lifelong relevance for patients/donors.

4.6.4 **Representations and Appeals** - Handling representations and appeals against licensing decisions took significant staff and member time. Lessons learned were always considered, to identify any needed improvements to procedures.

4.6.5 **Resources** – The Directorate had lost a number of staff within a short period of time. There has been a small restructure to strengthen resilience and recruitment is underway. There are some issues with staff morale in the IT Team, as a result of potential changes arising from IfQ. Better communication between staff and management had helped to alleviate some anxiety and it was agreed that this open communication would continue.
5. **Information for Quality (IfQ) Programme – Managing Risks**

5.1 The Director of Compliance and Information provided the Committee with a presentation and briefing.

5.2 The Committee were reminded of the McCracken report and the recommendations made relating to information. The IfQ programme would help the HFEA fulfil these recommendations in relation to the information collected, how that data was received and verified and information such as success rates was published.

5.3 Meetings, consultations and workshops had been held and the Authority would consider the recommendations from the Advisory Group in January 2015.

5.4 Two additional and necessary pieces of work (business requirements and approval of the business case by the Department of Health) had caused some delay to the planned timeline. Key stages were:

5.4.1 December/January 2015 - Business case approval
5.4.2 January 2015 – Authority approval of the Programme initiation document
5.4.3 January to March 2015 - Design of technical architecture
5.4.4 April 2015 to March 2016 - Implementation of core components
5.4.5 Throughout – work on Register migration and data warehousing.

5.5 The Internal Auditors had suggested that some improvements to the IfQ programme were required, to ensure the programme was defined clearly and that funding was in place. These challenges from IA were helpful to the ongoing development of the programme and further third party assurance was planned.

5.6 The Committee discussed spend so far on the programme, work completed and the realism of future plans. They were supportive of the work completed to date and agreed that it was necessary to have a degree of flexibility in the programme at this stage. They suggested that the HFEA might consider whether the Gateway review should start before the planned date in March, although that date had been determined by the lead-in period required by the Gateway review team.

5.7 The Annual Conference in March 2015 would be used as another platform to communicate information to the sector on the IfQ programme and how it was progressing.

5.8 AGC would continue to receive reports on the IfQ Programme and Peter Thompson, HFEA Chief Executive, would attend the March 2015 meeting.

**ACTION:**

5.9 Director of Compliance and Information to consider the optimum timing for the Gateway review.

6. **Internal Audit**

6a **Progress Report Audit**

DH Internal Audit presented their report:

6.1 **Information for Quality (IfQ)** – The IfQ audit report was issued with recommendations and guidance on risks for assurance over the programme. The report gave a moderate rating.
6.2 **Standing Financial Instructions** – a draft was under quality review and the final report would be submitted to AGC to review in March 2015.

6.3 **Internal Policies** – the terms of reference had been agreed and fieldwork would start in January 2015.

6.4 **Register of Treatments** – work was currently being scoped.

6.5 The Panel noted the report ratings in use, following a change of definitions.

### 6b IfQ Audit Report

6.6 DH Internal Audit presented this report. The opinion was a moderate rating. Good governance was in place for the programme, however there were some areas that required improvement.

6.7 The Committee noted that, overall, the key issues were the data migration and the finances underpinning the Programme.

6.8 The National Audit Office (NAO) would carry out their audit in February 2015 and the scope of this would include the effectiveness of sign off and approvals procedures.

### 6c Implementation of Recommendations – Progress Report

6.9 The Committee noted the progress made with the recommendations, and that there were just two recommendations outstanding from 2011/12. The Committee expected these to be completed by March 2015. Good progress was being made with more recent recommendations in the areas of risk management and corporate governance.

### 7. External Audit

7.1 The NAO provided the Committee with an update of their plans for the interim audit in February and March.

7.2 The NAO would be visiting clinics to undertake their tests to confirm income.

7.3 The NAO would also be looking at the treatment of IfQ costs during the interim audit.

### 8. Risks

#### a. Strategic Risk Register

8.1 The Head of Business Planning presented proposals for the new high level risk register for the Committee’s comments.

8.2 The Strategic Risk Register was now in a new format to align with the HFEA Strategy for 2014-2017, and included various high level risks including Information for Quality (IfQ) programme risks. The redesign had also taken in some of the key points from the internal audit report on the HFEA’s risk management framework, including a less composite approach to articulating the risks, and improved read-across between risk sources, controls, and implementation dates.

8.3 High level risks, operational risks and project risks were all monitored through the Corporate Management Group (CMG) and Programme Board. There would also
be a CMG workshop in January 2015 to look in detail at the tolerance levels, residual and inherent risk scores and controls in the new version of the risk register, since Directors and Heads had so far had only limited opportunities to comment through items considered at CMG meetings.

8.4 The Committee agreed that the new format for the Strategic Risk Register was an improvement and that this gave a sense of the top risks.

8.5 The potential risk of inconsistent legal advice in relation to decision-making, when there is a rotation of legal advisers to Committees, was raised. It was suggested that minutes of previous hearings might be shared with subsequent legal advisors and that the Executive should look at other ways of increasing consistency of legal advice to Committee’s.

8.6 The Committee agreed that the Risk Register reviewed in December 2013 would be published shortly.

**ACTION:**

8.7 Committee Secretary to Publish Risk Register reviewed in December 2013.

8.8 Head of Governance and Licensing to approach the organisation’s legal advisers to discuss any actions to aid consistency in legal advice for the Authority’s committees.

9. **Public Interest Disclosure (“Whistleblowing”) Policy**

9.1 The Head of Human Resources presented the updated policy to the Committee.

9.2 The Whistleblowing Policy had been updated, guided by the Public Concern at Work code of practice. The staff forum and CMG had approved the policy.

9.3 Staff had been made aware of the Whistleblowing Policy and how to use it via all staff meetings, the intranet and email, and the updated policy would be similarly promoted.

9.4 The Committee discussed the approach outlined in paragraph 6.8 of the policy if a member of the Senior Management Team (SMT) was implicated in a case. Paragraph 6.10 of the policy sets out the relevant people to be consulted in each case.

9.5 The Committee noted that the policy is a formal document and by nature may appear off-putting to staff. Further guidance could be provided when it was discussed with staff and it was suggested that there should be a statement up front on the intranet to encourage staff to raise any concerns and feel assured during the process.

**ACTION:**

9.6 Amend paragraph 6.8 of the policy to show that in the event that an SMT member was implicated in a case, the Chair should be approached with concerns.

9.7 Head of Human Resources to add a statement to the intranet to encourage staff to raise concerns.

10. **Resilience and Business Continuity**

10.1 The Director of Finance and Resources presented developments to the Committee.
10.2 A more streamlined approach had been taken to identify critical activities, resources needed to manage in an emergency and to update the business continuity plan. This approach was more proportional to the type of organisation the HFEA was. The HFEA’s assessment and approach had been shared with the Department of Health. A proportionate approach was required as the HFEA was a small organisation.

10.3 The Committee were informed of the key components taken into account to achieve business continuity in the event of a disaster happening. These components included maintaining essential communications, availability of the emergency site and staff working from home.

10.4 The Committee were informed of the results of the recent communications test. It had worked well generally, although there were some issues that the organisation had learned from and would improve.

10.5 The Committee were pleased with the progress made, the testing and improved communication channels, and that the needs of staff working out of the office were covered.

10.6 The Committee encouraged the Executive to be ever mindful of the possibility of sabotage to IT systems including through viruses and to guard against these.

**ACTION:**

10.7 Director of Finance and Resources to raise the issue of the possible sabotage of IT systems and how these possibilities are identified and mitigated, for the Executive to consider.

11. **Action Plan following review of AGC activities and effectiveness**

11.1 The Head of Governance and Licensing provided the Committee with a completed NAO checklist and an action plan following the annual review of AGC’s effectiveness in October 2014.

11.2 The Committee noted that actions were in hand and would be reported on in Matters Arising at future meetings.

11.3 The Committee referenced point 8 of the Action Plan and clarified that the discussions planned should be with both internal and external auditors.

11.4 The Committee discussed the executive role Authority members had when sitting on panels and that this should be noted on the NAO checklist.

**ACTION:**

11.5 The Head of Governance and Licensing to add external audit to the AGC Action Plan point 8.

11.6 The Head of Governance and Licensing to add a comment to the response to the first question in the NAO checklist, to reflect Authority members’ executive role.

11.7 Director of Finance and Resources to add actions to Matters Arising.
12. **AGC Forward Plan**

12.1 The Director of Finance and Resources provided the Committee with an updated forward plan of topics to be discussed at future meetings.

12.2 The Committee suggested that the number of meetings to be held each year should be reviewed in June 2015.

12.3 The Committee agreed the future topics.

13. **Any Other Business**

13.1 The Chair noted that the Committee Secretary had circulated the 2015 Committee Dates and asked AGC members to confirm their availability for those meetings, to ensure quoracy. Lynn Yallop gave her apologies for the March 2015 meeting – James Hennessey would attend instead for DH Internal Audit.

13.2 There were no further items of business.

**Date of the next meeting:**

Date: Wednesday, 18 March 2015  
Time: 10:00 am  
Location: The Royal Statistical Society, 12 Errol Street, London EC1Y 8LX

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

Chair  

Date