Minutes of Authority meeting 14 March 2018

Strategic delivery:	☐ Safe, ethical effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence

Details:	
Meeting	Authority
Agenda item	2
Paper number	HFEA (09/05/18) 877
Meeting date	9 May 2018
Author	Helen Crutcher – Risk and Business Planning Manager
Output:	
For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting.
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	☒ Low ☐ Medium ☐ High
Annexes	

Minutes of the Authority meeting on 14 March 2018 held at Church House, 27 Great Smith Street, London SW1P 3NZ

Members present	Sally Cheshire (Chair until item 10) Kate Brian Dr Anne Lampe Anthony Rutherford Bishop Lee Rayfield	Yacoub Khalaf Margaret Gilmore (Chair for items 11-13) Bobbie Farsides Ruth Wilde
Apologies	Anita Bharucha	Andy Greenfield
Observers	Kim Hayes (Department of Health and Social Care)	
Staff in attendance	Peter Thompson Nick Jones Richard Sydee Clare Ettinghausen Catherine Drennan Paula Robinson	Caylin Joski-Jethi Helen Crutcher Yuba Bessaoud Niamh Marren Chris Hall

Members

There were 9 members at the meeting, 5 lay members and 4 professional members.

1. Welcome, apologies and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members and members of the public to the second meeting of 2018. As with previous meetings, it was audio-recorded and the recording would be made available on our website to enable interested members of the public who could not attend the meeting to listen to our deliberations.

1.2. Apologies were received from Andy Greenfield and Anita Bharucha.

1.3. Declarations of interest were made by:

- Anthony Rutherford (Clinician at a licensed centre)
- Yacoub Khalaf (Clinician and Person Responsible at a licensed centre)

2. Minutes of Authority meeting held on 24 January 2018

2.1. Members agreed the minutes of the meeting held on 24 January 2018, subject to a minor amendment to be submitted by the member after the meeting, for signature by the Chair of the meeting.

3. Chair's report

3.1. The Chair said that the Annual Conference would take place the next day. It would mark two important medical anniversaries: 2018 was 40 years since the birth of the first IVF baby, Louise Brown and 70 years since the establishment of the NHS. The Chair noted that more information about the annual conference would be provided by the Director of Strategy and Corporate Affairs under the Performance Report later in the meeting.

3.2. The Chair provided members with a summary of events that she attended since the last Authority meeting in January:

- On 29 January 2018 the Chair attended the HFEA All Staff Away Day which was a useful opportunity to meet staff outside of the office and to commend them on the great work they do.
- On 5 February the Chair attended the SCAAC meeting. Three key items were discussed:
    - Regulation of embryo culture media
    - Review of novel process applications
    - Prioritisation of issues identified during the horizon scanning process
- On 20 February, the Chair and Chief Executive met with Parliamentary Under-Secretary (Department of Health and Social Care), Jackie Doyle Price. This was a useful opportunity to discuss the shape of the fertility sector in general, and in particular:
    - Patient safety.
    - Recent service development.
    - Working with the NHS: improving commissioning.
    - Research and innovation with an emphasis on mitochondrial donation and genome editing.

4. Chief Executive's report

4.1. The Chief Executive reported on the All Staff Away Day on 29 January. This was an opportunity for staff to consider the results of a recent staff survey and agree how they wished to develop as an organisation. Feedback suggested that the day was well received and a number of important commitments were made on:

- finding more time for learning and development
- finding ways to better recognise staff contributions within very tight public-sector wage constraints
- starting work on HFEA culture, which was particularly important given a significant proportion of staff were relatively new.

4.2. The Chief Executive noted that the Authority would receive updates on progress towards these goals, including increased reporting on HR data to the Audit and Governance Committee.

4.3. The Chief Executive reported that in February, he took part in two of the four Code of Practice workshops that were run across the country. The Director of Strategy and Corporate Affairs would provide an overview of the workshops later in the meeting. The Chief Executive recorded his thanks to all the staff that participated and noted the positive feedback from conversations

with clinic staff who attended, all of whom thought the HFEA had become much more open as an organisation over the past few years.

4.4. On 6 March the Chief Executive attended the Audit and Governance Committee meeting.

Press coverage

Trends report

4.5. The Chief Executive noted that the Fertility Trends and Figures report had been published that morning and simultaneously released to the press. A further item was included later in the meeting to discuss this in detail.

Ovarian Hyperstimulation Syndrome (OHSS)

4.6. The Chief Executive noted that that there had been some sporadic interest in the OHSS issue which was initially raised in 2017. A recent Guardian article had covered the issue again, reporting that some in the sector were arguing that clinics should compensate the NHS for OHSS admissions.

4.7. The HFEA position on this was clear: investigations had revealed no evidence of under-reporting of OHSS by clinics, and the evidence to date pointed to it being largely a reporting issue in hospitals, where OHSS was often the default coding option for fertility-related admissions.

4.8. The Chief Executive stressed that the HFEA took any risk of harm to patients very seriously, and continued to work with the BFS, RCOG and others to consider ways to provide clearer guidance to clinics in both handling and reporting OHSS.

Genome editing public dialogues

4.9. Members were informed that several studies had been published on public attitudes to genome editing. These had not yet involved the HFEA directly. A number of these had been picked up in the press.

4.10. Following a 2017 Progress Educational Trust and Genetic Alliance study, and ahead of a Nuffield report, the Royal Society had published a review into public attitudes. This had been based on a number of focus group sessions and an online survey of around 2,000 people. The results were reported in the press and included some interesting findings, such as a majority of people being in favour of using such treatments for the eradication of illness, but not for human enhancement.

4.11. The Chief Executive stressed that genome editing is currently illegal in treatment in the UK, though allowable in research, but this debate showed no signs of going away.

4.12. The Chair commented that it was important for the HFEA to undertake further work to understand the issues around OHSS and this was something that the organisation cared about and would continue to focus on.

5. Committee Chairs' updates

5.1. The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 25 January and 22 February. At the January meeting it considered six preimplantation genetic diagnosis (PGD) applications and two mitochondrial donation patient applications. The minutes for the mitochondrial donation patient applications had not yet been published. All of the PGD conditions were approved. The reason for the delay to mitochondrial donation minutes concerned

the need to balance the interests of the patient, and the need to protect their confidentiality, with the requirement to publish sufficient information to demonstrate good decision making. At the February meeting, the committee considered one mitochondrial donation application, one PGD application and one request for Special Directions. The PGD condition was approved. The minutes for the mitochondrial donation application have not been published. The application for Special Directions was also approved.

5.2. Members asked for information about the deliberations of the committee. The Chair of SAC indicated that items could sometimes take up to two hours each. Specialist and legal advisors were present in the room for each meeting and the Committee follow a decision tree for each item.

5.3. The Director of Strategy and Corporate Affairs advised members that the Executive Licensing Panel (ELP) had met four times since the Authority last met; on 22 January, 2 February, 16 February and 2 March. The panel considered fifteen items; six renewals, including one which was adjourned; two interims, both of which saw the licence continued; four variations and three executive updates, one of which was adjourned. The Licensing Officer also approved one licence variation and two voluntary revocations.

5.4. The Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC) advised members that the committee met on 5 February. The committee discussed:

- the regulation of embryo culture media. There was some evidence that culture media could impact birth weight of babies and the Committee were joined by a Senior Clinical Advisor at the Medicines and Healthcare Products Regulatory Agency (MHRA), who gave an overview about the regulatory processes for bringing medical devices to the market.
- a review of two novel processes; intrauterine culture and gamete activation using calcium ionophore. On the former the Committee were concerned that data was insufficient and more information would be needed from the centre to make a judgment on the safety of the process. On the latter, the Committee received evidence from two centres and agreed that there was no evidence to suggest it was unsafe and that it should remain on the list until new evidence suggested otherwise.
- horizon scanning to decide the Committee's workplan for the year. The following four high priority areas were identified:
    - mitochondrial donation
    - synthetic human entities with embryo-like features (SHEEFs)
    - impacts of stress on fertility treatment outcomes
    - the impact of microbiome on fertility and fertility treatment.

5.5. The Chair of the meeting noted that the minutes of SCAAC meetings were available for the public.

5.6. Members discussed culture media. The Chair noted that although this is not in the HFEA jurisdiction, it was important for this to stay on the SCAAC agenda so that the Authority could understand it as fully as possible. Members were interested in the MHRA's approach to regulation and the Director of Compliance and Information noted that further joint working was planned and that the MHRA understood the need for more and better research.

5.7. A member noted that the Nuffield Council on Bioethics had SHEEFs on their agenda for future consideration and it would be positive to work with them on this.

5.8. A member noted that stress and its effect on treatment success and infertility was a topic of research. The Chair of SCAAC agreed and said that the committee would continue to track progress, although there had not been significant changes in research in this area.

5.9. The Deputy Chair of the Audit and Governance Committee (AGC) advised members that the committee met on 6 March and, in addition to the usual standing items and updates from internal and external audit, the committee received reports on:

- Finance and Resources Update
- Impact of Brexit
- Digital Programme Update
- Resilience, Business Continuity Management and Cyber Security
- Strategic Risk Register
- GDPR (General Data Protection Regulation)
- Whistle blowing and Fraud
- Contracts and procurement
- Review of AGC activities & effectiveness, terms of reference

5.10. The Deputy Chair of AGC noted the committee's appreciation of the frank discussion with the Executive on the digital programme update, more on which would be reported later in the meeting. Further reports on GDPR progress would be provided to AGC before its next meeting.

5.11. The Deputy Chair of the Licence Committee advised members that the committee met on 11 January and the 8 March. In January the committee considered, one treatment renewal, one research renewal, one research variation and one research revocation. It approved all four items. It also noted one treatment interim.

5.12. In March, the committee considered one research licence renewal, one treatment licence renewal and one executive update. The minutes were not yet available.

5.13. Members discussed developments in the area of research by clinics. They agreed that it would be helpful to understand the trends in this area over the coming months. The Chief Executive agreed to take this forward. Members agreed that it was important for the HFEA to encourage centres to report findings and demonstrate the value of research data. A member noted that it would be helpful for the Authority to publish some of the results of the research. The Chief Executive reported that this was available on the website but he acknowledged that this could be done in a more accessible way.

5.14. A member asked about how GDPR (general data protection regulation) would impact the Register and Authority and whether patients could ask to remove their data from the Register. The Chief Executive noted that the Register was not affected by this legislation – there was no way for patients to opt out of the Register due to the HFE Act. The report on progress and the impact of the GDPR would be shared with the Authority.

5.15. The executive agreed to circulate the report on compliance with the GDPR to Authority as well as AGC and to provide further information to clinics in Clinic Focus about the GDPR

6. Performance report

6.1. The Chief Executive introduced this item, which reported on both organisational performance and progress against our strategy. The Chief Executive reflected that performance was generally positive and the organisation was in a good position at the end of the financial year. He highlighted the trend in turnover, especially establishment leavers, and reflected that this was largely as a result of a period of organisational change. Turnover had exceeded tolerance in March 2016 and not returned to the target range since then. However, the picture was now improving and viewed in a wider context of other HR indicators, the Chief Executive was of the view that this would improve going forward.

6.2. The Chief Executive reflected on the fact that better metrics to AGC on HR matters would be helpful. Some turnover was natural as people wish to progress their careers, but pay was a factor for a number of staff. Work on organisational culture and learning and development would help to embed new staff and maintain the positive culture and opportunities for staff.

6.3. The Director of Finance and Resources reported on the latest budget outturns and income figures, these were in line with what had been previously reported. He explained that the income forecasting model, which the Authority agreed in January, seemed to be borne out by recent trends, which suggested that the model was accurate. Internal audit had concluded that financial governance processes were effective, which reflected the consistency of implementation of these processes around the organisation.

6.4. The Director of Strategy and Corporate Affairs reported on activity and performance within her directorate. The annual conference preparation was taking place the following day and over 300 delegates were expected. She thanked the communications team for their hard work on this and thanked the Authority members for agreeing to chair sessions throughout the day.

6.5. The Director of Strategy and Corporate Affairs noted that the Fertility Trends publication which was launched that morning had already received some press coverage and this was likely to increase. More would be reported on this later, but it represented the first in a new style of reports, written with the patient in mind. As noted by the Chief Executive, four workshops to consult on changes to the Code of Practice had been held around the country and feedback on the proposed changes had been very positive. The outlined proposals were on the right track and feedback would be consolidated before the formal consultation took place from April.

6.6. The Director of Compliance and Information summarised activity and performance within his directorate. He noted that the end to end figure for licensing was at an all-time low, which reflected the hard work across the board. Training and development was vital, to ensure that the balance was right between work and the development of staff.

6.7. The Director noted that the end to end PGD target was being missed and although this was only by a small number of days, it was still important to aim for this. These missed targets reflected the complexity of items. Members discussed the worsening trends and the reasons for this and noted that it was importance to remember the patient at the end of the process. The Chair of SAC noted that the quality of papers had improved. The Chief Executive agreed that they would prepare some statistical material to enable this discussion to continue outside of the meeting and agree appropriate actions.

6.8. The Director of Compliance and Information also reported on the remaining elements of the Information for Quality programme, being delivered as the data submission project. He gave an overview of the work and the branding of the submission system, which would be called PRISM (patient registration information system). The plan had been for a two-stage implementation; however, 3rd party suppliers and clinics using PRISM directly would now be brought onboard at the same time, in October 2018. The system would be demonstrated at the annual conference. He described the remaining timelines for implementation of the work.

6.9. The Director of Compliance and Information gave an overview of the financial situation of the project and HFEA IT generally, including updating other systems. Additional capital cover would be needed for the next year to deliver on our IT ambitions and the Department of Health and Social Care had been notified of this. Because this approval was not a given, progress would be at risk at the start of the next financial year. Further work was underway to establish firm figures for this. This situation had been reported to AGC at its last meeting and discussed in great detail.

6.10. Members welcomed this report and approved the ongoing approach to finalising and agreeing the financials of the project, particularly in relation to capital cover.

Decision

6.11. Following discussion, members noted the latest performance report.

7. Business Plan

7.1. The Head of Planning and Governance presented the draft 2018/19 business plan. Members noted that this business plan would deliver the second phase of the three-year strategy for 2017-2020. The Head of Planning and Governance noted that the activities section had not changed greatly since consideration in November.

7.2. The Head of Planning and Governance gave members an overview of how the HFEA planned to meet its strategic ambitions. Members heard that the new business year would start with a new set of tools and capabilities in place, including an intelligence strategy, to capitalise on the work done through the Information for Quality Programme and the organisational restructuring completed in 2017/18. This would enable better use of the data held – to assist clinics towards better performance, make targeted regulatory interventions when this is merited, and provide a range of improved information for patients and other stakeholders. Delivery of the 2018-20 People Strategy would also help ensure that the right Capability and Capacity was in place to deliver on the strategic aims.

7.3. The Head of Planning and Governance noted that the mid-year assessment of delivery of the new business plan (at the end of quarter two) would mark the mid-point of the current strategy, and it would be a good time to take stock of progress towards the organisation's vision. In the second half of the business year, the process for developing a new strategy from 2020 onwards would be considered.

7.4. Members noted that the highlights of the 2018/19 business plan would be:

- Standards
- Leadership culture
- New Code of Practice

- Expanded information about access to treatment and donation
- Success rates
- Intelligence strategy
- using our data for quality
- more patient feedback
- Targeted regulatory interventions

7.5. The Head of Planning and Governance discussed the work underway to agree the detailed budget. Discussions were ongoing with the Department of Health and Social Care. As mentioned under the Performance Report item, in 2018/19 greater capital cover would be required. Members received the summary budget figures and heard that the overall revenue budget was £6.3m, including Grant in Aid; and a proposed £500k capital budget. This included £80k for upkeep of the IT estate, and the rest for IfQ related completion, of which the larger component (£230K) would be to finish the new data submission system.

7.6. Members were reminded that further discussion about the annual finance allocation was required with the Department, although sign-off of the business plan and the associated budget was anticipated by the end of April, after which the business plan would be published on the HFEA website.

7.7. Members gave feedback on the business plan, including some drafting notes to be followed up after the meeting. A member noted whether more could be made of the high level of engagement with the sector in 2017/18.

7.8. The Department of Health and Social Care representative noted that these had been no issues from the Department's perspective other than the ongoing question of capital cover.

Decision

7.9. The Authority agreed to approve the near-final business plan for 2018/19, and noted that year-end information would be added in April before publication.

8. Movement of gametes and embryos across borders

8.1. The. Regulatory Policy Manager and Director of Compliance and Information gave an overview of the requirements set out in the two EU directives, on coding and import, how these differed from existing HFEA requirements, and the work that had been undertaken to implement them, including the communication that would go out to clinics in April.

8.2. A member asked how the Authority would verify that centres had effectively tested the suitability of third party suppliers. Because this was about quality and safety, inspectors would be taking it very seriously and checking this on inspection.

8.3. Another member asked whether this legislation would affect arrangements for Special Directions. The Head of Legal responded that the certification of 3rd country suppliers would happen in parallel with Special Directions. If the clinic could import under General Directions then as long as they had applied for certification for the 3rd country supplier then they would be able to import as per the General Directions. Certification would be needed before movements either under Special Directions or General Directions. The Head of Legal noted that there were transitional

arrangements for gametes and embryos already in storage and clinics would need to check whether they met those criteria.

Decision

8.4. The Authority:

- Noted and approved the arrangements for implementing the two Directives.
- Noted that the arrangements for amending General Direction 0006 in relation to importing that will be brought forward in April 2018 and agreed to delegate the approval of the General Directions and accompanying letter to the Chair.
- Approved the amendments to General Direction 0006 in relation to the application of the Single European Code

9. Choose a fertility clinic – evaluation of patient rating trial

9.1. The Media and Stakeholder Relations Manager gave an overview of the patient ratings system, the decisions previously taken by the Authority in March 2017 and presented the activities and findings of the six-month trial of patient ratings on the website.

9.2. Members heard that the ratings system had made slow but steady progress in numerical terms with, to date, over 1,200 ratings. The free text system had received more responses the previous feedback system, which meant much more data was available to HFEA inspectors. Medium sized clinics seemed to be buying into the system most eagerly, large clinics less so. Periods of intense promotion by the HFEA such as November 2017, for fertility awareness week, coincided with spike in responses, suggesting promotion could make an impact.

9.3. Members heard that the trial had raised questions about the engagement of some, particularly larger, clinics. It had also identified security issues after a large number of automated ratings had been submitted by a spambot. There were also questions about how to further increase patient and clinic engagement with the system. Members heard that there were a number of improvements that could be made and were asked for their views on these.

9.4. Members discussed how best to ensure that there was an increase in patient responses and that clinics did this appropriately. One member noted that an increase in direct marketing should be done. Another option raised was the use of cards for marketing materials. It was important to note that some clinics thought that treatment has been completed at embryo transfer, however this was not the patient experience.

9.5. The Deputy Chair of AGC noted that AGC had discussed the security issue in detail. The Director of Compliance and Information reported that the ‘CAPTCHA’ security system was previously much more complex and therefore at the time of launching the system a decision had been taken not to implement this. This was now much simpler and it had been implemented following the security incident. It was unclear whether the cause was a malicious attack – there was no evidence of this.

9.6. One member noted that the trial did not investigate whether patient feedback was useful for other prospective patients when choosing a clinic. Members also discussed the average rating of 4.5 and whether this was an accurate reflection of what patients thought about a given clinic. There

were a number of variables that might be affecting this. One member noted how useful the cost information would be for patients.

9.7. Another member raised concerns that non-patients may be submitting ratings. They suggested that a token system should be provided to patients undergoing treatment to ensure that they were actual patients. However, members agreed that when there were more ratings submitted then the impact of any potential gaming would be minimised.

9.8. The Director of Strategy and Corporate Affairs reported that there were tangible actions arising from the project and these would be discussed further with the communications team. Three pieces of work, on patient ratings, patient support and a new project on a national patient survey (or similar) would enable the Authority to seek greater feedback in the future. A regular survey could include specific questions related to particular pieces of work.

Decision

9.9. The Authority agreed to:

- continue the patient rating scheme and the free text mechanism for providing views to inform inspection activity.
- further work to develop best-practice guidance for the promotion of the scheme by clinic staff, and what is acceptable practice in terms of encouraging completion of the ratings scheme in-house.
- further discussion with large UK clinics to understand why take-up of the scheme has been slower, and to encourage greater participation.

10. Beyond fertility trends: the role of intelligence

10.1. The Head of Intelligence presented an overview of the key findings of the 'Fertility treatment 2014 -2016 - trends and figures' report (the trends report), noted their potential impact on HFEA policy and set out plans to use the new IT systems and intelligence team to create more in depth and better focused reports for clinics and patients.

10.2. The Head of Intelligence explained that a communications and stakeholder engagement plan had been developed for the report. Members were given an overview of key findings on multiple births, egg freezing and donor egg treatment.

10.3. Members heard that the new perspective on HFEA-held data opened up additional possibilities for policy, such as decisions on what to do next on multiple births, clinical commissioning of IVF and how to approach communications of changes in treatment trends, such as increased egg freezing.

10.4. Members heard that a new reporting structure was proposed to enable more frequent and regular reporting. Lessons had been learnt from the report this year and these would be taken on board in future reports.

10.5. Members commented on the findings and proposed future reporting approaches. A member noted the fact that NICE guidance around the age of women undertaking treatment was based on a complex health economic model and applied solely to IVF. Donor egg treatment was a separate issue as the cost was greater for donor eggs and therefore the cost effectiveness of the

treatment was different. Members discussed the data available on male fertility and noted that more information should be included on this in the future.

10.6. A member queried the data in some of the charts in the report. The Head of Intelligence agreed to consider this (NB: a response was given at the end of the meeting under AOB).

10.7. Members asked whether it was possible to include more up to date data than 2016, while recognising there was an inevitable nine-month delay for birth data, they hoped that more recent pregnancy data could be included. Clinics themselves were able to provide more recent data. The executive noted this for investigation in future.

10.8. Members were enthusiastic about the new approach. They discussed how the Authority might be able to discuss data and input into future reporting. The Chief Executive noted that the Chair and the executive would discuss ways to enable this in the future.

10.9. In responding to the finding that in Scotland there had been an increase in NHS funded treatments, the Chair commended the Scottish Authorities for their evident adoption of the NICE guidelines.

Decision

10.10. The Authority noted the key outcomes of the Fertility Trends and Figures 2018 report and commended the Intelligence team for their hard work.

10.11. Following the conclusion of this item, the Chair noted that she needed to leave the meeting to attend a press interview and handed over to the Deputy Chair of the Authority.

11. Effective governance

11.1. The Head of Planning and Governance summarised proposed changes to Standing Orders and the results of the annual review of committee effectiveness. Members were informed of the need to formally vote on the proposed Standing Orders. This was a simple majority vote, requiring two thirds of members (8) to be present.

11.2. The proposed changes to Standing Orders were minimal, although one proposed change, that the Executive Licensing Panel no longer varied or revoked licences was described in more detail. Variations and revocations would be handled by the Licence Committee.

11.3. Members noted that the proposed changes to Standing Orders had not been tracked in the Authority papers, however, the changes were clear in the paper. The Head of Planning and Governance agreed to follow up on this.

11.4. Members heard that the annual review of committee effectiveness showed that committees were working well overall with robust decision-making taking place. Terms of reference and membership were appropriate.

11.5. Members heard that several suggestions for further effectiveness had been made and the executive would take forward actions on these. These related particularly to:

- Knowledge management (member turnover).
- Balancing committee workloads and item scheduling.
- Training and induction suggestions.

- Management of adviser conflicts of interest.
- Servicing and meeting-running improvements.
- Securing the right adviser expertise.

11.6. Members noted that the Audit and Governance Committee had made the following points which were not included in the paper:

- Consider having a Board member with overall responsibility for whistleblowing.
- Suggestions on risk assurance mapping.
- Regular bilateral meetings with internal and external auditors, for the Chair.

Decision

11.7. Members unanimously voted to approve the revised Standing Orders

11.8. Members noted the summary of the annual reviews of committee effectiveness.

12. Information provision

12.1. The Interim Head of Information presented an overview of work that had been undertaken to improve information provision and implement the new information policy that had originally been presented and agreed by Authority in 2017. Much of this related to the new data submission system that would launch later in 2018.

12.2. Members heard that two changes were proposed in relation to the information submission policy; one was some small amendments to General Direction 0005, and the other was more clarity on the arrangements for clinics to confirm the quality of their data before HFEA published it, for example on Choose a Fertility Clinic. This meant a new information bargain with the sector, where in return for easier submission, HFEA would expect more timely data, of a higher quality, from clinics. The Authority in turn would commit to making more data publicly available. These expectations would be more transparent in the future.

12.3. Members heard the proposal to formally notify third party suppliers. There had already been considerable engagement with the suppliers so this should come as no surprise, but it would formalise the existing informal arrangement with them. This was necessary, as the clinics, not the Authority, have the contractual agreements with the suppliers. Clinics would be notified of the need to do this by way of a Chair's letter.

12.4. A Member raised the issue of the cost to clinics of any updates to third-party systems. The Interim Head of Information noted that the costs would depend upon the contractual arrangements clinics had with suppliers. Suppliers would continually have to update their systems already and the expectation would usually be for suppliers to ensure that their systems were fit for purpose. A member noted that it was important to give a clear message to clinics. The Chief Executive stated that this had been discussed by the Authority previously and the changes would be no surprise to clinics or to the suppliers and would represent an improvement for all. In addition, the HFEA system would be available to any clinics whose third-party suppliers were unable to comply.

Decision

12.5. Members agreed to formally advise clinics with third party patient record systems that their suppliers should be given six-months' notice of changes to be made to enable data submission to the HFEA, by way of a Chair's Letter.

12.6. Members agreed the proposed changes to General Direction 0005 and the arrangements for data confirmation.

13. Any other business

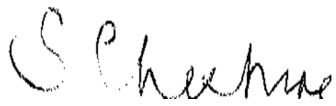
13.1. Following up on an issue raised under item 10, the Director of Strategy and Corporate Affairs noted that the electronic version of the trends report clearly showed per cycle figures in the graphs, but this was not clear in the printed format of the report. This would be investigated further and this issue resolved for future reports.

13.2. The Chair of the meeting confirmed that the next meeting will be held on Wednesday 9 May at Church House, London, SW1P 3NZ. Members were asked to confirm their attendance to the Executive Assistant to the Chair and Chief Executive as soon as possible.

14. Chair's signature

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

Signature



Chair: Sally Cheshire