Audit and Governance Embryology Authority Committee meeting - agenda

14 March 2023

HFEA Office, 2nd Floor, 2 Redman Place, London E20 1JQ

10am

| Agenda item | | | | | |
|-------------|--|--------------------------|---------|--|--|
| 1. | Welcome, apologies and declaration of interests | | 10.00am | | |
| 2. | Minutes of 8 December 2022 [AGC (14/03/23) DO] | for decision | 10.05am | | |
| 3. | Action log [AGC (14/03/23) MA] | for information | 10.10am | | |
| 4. | Proposed 2023/24 Internal audit plan & 2022/23 progress update [AGC (14/03/23) JC] | for discussion | 10.20am | | |
| 5. | Progress with current audit recommendations [AGC (14/03/23) MA] | for information | 10.40am | | |
| 6. | External audit work – verbal update [AGC (14/03/23) MP/DG] | for information | 10.50am | | |
| 7. | Draft Annual Governance Statement [AGC (14/03/23) MA] | for information | 10.55am | | |
| 8. | Accounting policies 2022/23 [AGC (14/03/23) RS] | for comment | 11.05am | | |
| 9. | *Strategic risk register [AGC (14/03/23)SQ] *Deep dive – other proposed topics [AGC (14/03/23)* *Horizon scanning [AGC (14/03/23)SQ] | 23)RS] for discussion | 11.20am | | |
| 10. | Digital projects/PRISM update [AGC (14/03/23) KH] | for information | 11.45pm | | |
| 11. | Resilience, cyber security & business continuity management [AGC (14/03/23) MC/NMc] | for comment | 12.05pm | | |
| 12. | Government Functional standards [AGC (14/03/23) RS] | for comment | 12.20pm | | |

| 13. | Counter Fraud Strategy [AGC (14/03/23) MA] | for comment | 12.40pm |
|-----|---|-----------------|---------|
| 14. | AGC forward plan [AGC (14/03/23) MA] | for decision | 12.55pm |
| 15. | Items for noting (verbal update) Whistle blowing Gifts and hospitality Contracts and Procurement Estate update [AGC (14/03/23) RS] | for information | 1.05pm |
| 16. | Any other business • AGC effectiveness update • Training for December 2023 | | 1.15pm |
| 17. | Session for members and auditors only | | 1.25pm |
| 18. | Close | | |
| | Lunch | | |

Next Meeting: Tuesday, 27 June 2023.



Minutes of Audit and Governance Committee meeting 8 December 2022

| Details: | | | |
|------------------------------|--|-----------------------------|--------------------|
| Area(s) of strategy this | The best care – effective | and ethical care for everyo | one |
| paper relates to: | The right information – to ensure that people can access the right information at the right time | | |
| | Shaping the future – to en science and society | mbrace and engage with cl | hanges in the law, |
| Agenda item | 2 | | |
| Meeting date | 14 March 2023 | | |
| Author | Debbie Okutubo, Governance Manager | | |
| Output: | | | |
| For information or decision? | For decision | | |
| Recommendation | Members are asked to confirm the minutes of the Audit and Governance Committee meeting held on 8 December 2022 as a true record of the meeting | | |
| Resource implications | | | |
| Implementation date | | | |
| Communication(s) | | | |
| Organisational risk | Low | | ☐ High |
| Annexes | | | |

Minutes of the Audit and Governance Committee meeting on 8 December 2022 held in person at HFEA Office, 2nd Floor, 2 Redman Place, London E20 1JQ and via teleconference (Teams)

| | In person | Online |
|---------------------|--|--|
| Members present | Catharine Seddon Alex Kafetz Mark McLaughlin Geoffrey Podger Jason Kasraie | |
| Apologies | None | |
| External Advisers | Mohit Parmar, National Audit Office (NAO) – External Auditor Dean Gibbs, KPMG – Audit lead Joanne Charlton, Head of Internal Audit (Internal Auditor) - GIAA | |
| Observers | Amy Parsons, Department of Health and Social Care – (DHSC) | Steve Pugh, DHSC |
| Staff in attendance | Peter Thompson, Chief Executive Clare Ettinghausen, Director of Strategy and Corporate Affairs Morounke Akingbola, Head of Finance Yvonne Akinmodun, Head of HR Shabbir Qureshi, Risk and Business Manager Debbie Okutubo, Governance Manager | Rachel Cutting, Director of Compliance and Information Richard Sydee, Director of Finance and Resources Paula Robinson, Head of Planning and Governance Martin Cranefield, Head of IT Kevin Hudson, PRISM Manager |

1. Welcome, apologies and declaration of interests

- **1.1.** The Chair welcomed everyone present in person and online.
- **1.2.** There were no apologies of absence.
- **1.3.** There were no declarations of interest.

2. Minutes of the meeting held on 4 October 2022

2.1. The minutes of the meeting held on 4 October 2022 were agreed as a true record and could be signed by the Chair.

3. Action Log

- **3.1.** The Head of Finance presented this item. Actions from 9 December 2021 and 15 March 2022 meetings were agreed as complete and could be removed from the action log.
- **3.2.** Actions 3.2, 5.13, 5.14, 8.21, 9.7 and 14.8 from the 28 June 2022 meeting were agreed as complete and could be removed from the action log. Action 5.15 was on track to meet the deadline of October 2023. Members were advised that there was ongoing work with the contractor and once this was resolved it will be reported back to the committee.
- **3.3.** Action 11.9 and 11.10 from the 28 June 2022 remained outstanding and will be brought to the March 2023 meeting.
- **3.4.** The Chair commented that not all actions from previous meetings were routinely added and requested that this be addressed. Also, that all actions not yet completed to be left on the action log and brought to the next meeting.

Decision

3.5. Members agreed that future versions of the action log should be updated with all actions and all completed items to be tabled at a meeting for removal from the log.

4. Internal audit report

- **4.1.** The Head of Internal Audit GIAA presented the 2022/23 internal audit progress update. Members were advised that internal audit was on track to deliver the plan before the end of this financial year.
- **4.2.** The Chief Executive was thanked for taking part in the Customer Impact meeting.
- **4.3.** A discussion ensued on the implementation of recommendations. The Chair commented that there were too many outstanding recommendations and that we had agreed a proportionate approach to implement such. The Chair suggested that the Executives be realistic about timelines agreed with internal audit. Also, that the audit implementation log be fully looked at before the pre-planning AGC agenda meeting in February 2023.
- **4.4.** The Chief Executive commented that we made the agreement to implement the recommendations in good faith but we would look at this again before the next meeting. However, given the size of the organisation some deadlines may shift.
- **4.5.** In response to a question, it was noted that the internal audit service standards set out in the MoU are applied across Government and are set centrally within GIAA, therefore cannot be tailored to individual customers.
- **4.6.** The Chair commented that the committee found the supplementary report and Insights digest very helpful including the update on functional standards. The Chair suggested that to give the committee assurance and to know to what degree we were fully compliant with the functional standards this could be a standing item on future committee agendas.
- **4.7.** The Chief Executive responded but this will be discussed with the Executive and the committee will be apprised on the status of functional standards at every meeting.

- **4.8.** The Chair further commented that this could also be discussed with the DHSC so that the committee had further assurance that this was being escalated where necessary.
- **4.9.** Members commented that the Executive needed to prioritise as there was not enough resources to do all the things being asked for.

Action

4.10. Functional standards to be a standing agenda item at future AGC meetings.

Decision

4.11. Members noted the progress of the 2022/23 internal audit plan.

5. Progress with current audit recommendations

- **5.1.** The Head of Finance presented this item. It was noted that a number of the recommendations were awaiting internal audit sign off.
- **5.2.** The Head of Planning and Governance commented that the operational risk management area will become part of business as usual.
- **5.3.** It was agreed that the Head of Finance and the Internal Auditor will meet to discuss the action log in detail.
- **5.4.** It was noted that the Chief Executive and the deputy Chair of the AGC had a meeting scheduled for the afternoon to have a strategic discussion in relation to DSP Toolkit and a proportionate approach to cyber-security risks. The Chair suggested that the deputy Chair monitor this area and take it forward.
- **5.5.** The Chair requested that in the recommendation tracking meeting between the Internal Auditor and the Head of Finance that all agreed decisions be documented and that the audit log should state the exact wording.

Action

- **5.6.** The internal audit meeting with the Head of Finance to be documented and the wording of the IA log entries to be agreed with internal audit to avoid recommendations being misunderstood or not addressed satisfactorily in evidence submitted.
- **5.7.** Deputy Chair of AGC to monitor the DSP Toolkit.

Decision

5.8. Members noted the progress with current audit recommendations.

6. External audit planning report on the 2022-23 financial statements audit

- **6.1.** The National Audit Office (NAO) External Auditor presented this item. Members were advised of the initial assessment of the significant risk of material misstatement and audit focus areas. Two areas of significant risk were identified:
 - the presumed risk of management override of controls and
 - the accuracy of income on reconciled Prism accounts.

- **6.2.** Members were advised that these two areas were moving in a positive direction.
- **6.3.** The External Auditors were also keeping an eye on IFRS 16 Leases and on Intangible assets valuation.
- **6.4.** Members were informed that the materiality has been determined and should it be required to be revised the committee will be made aware.
- **6.5.** The Auditors commented that they were satisfied that there was nothing to report following their assessment of the risk of fraud ISA 240. In response to a question on fees, it was noted that the rationale for the increase in fees was for the extra work taken on in the year under review, which was the introduction of ISA 315 revised, ISA 240 revised and to reflect inflationary pressures.
- **6.6.** They concluded by saying they felt that management had taken a consistent view by using a consistent methodology.

Decision

6.7. Members noted the proposed plan and that there was nothing to bring to their attention.

7. Strategic risk

7.1. The Risk and Business Planning Manager presented this item. It was noted that the Authority's attitude to, and management of, the risks it faces in carrying out its functions was described as robust but proportionate.

Risk management strategy

- **7.2.** Members commented that the framework presented was excellent but that it needed to be implemented properly. Also, as a Regulator, our decisions being open to legal challenge was an ongoing operational fact and therefore a strategic risk would be that of a successful legal challenge.
- **7.3.** On the risk scoring matrix, members asked if the percentages presented were from the Orange Book. The Risk and Planning Manager responded that the percentages are used to quantify it and that this was recommended in a previous risk training course.

Decision

7.4. Members noted the strategy.

Operational risk register

- **7.5.** Members were advised that a new operational risk register was now in use and teams had started migrating previous risk registers into the new template. It was described as a step change from how it has been previously and that it was work in progress.
- **7.6.** The Chair commented that having the top three risks in each area presented to CMG regularly was very good and it showed that it was regularly reviewed and stimulated discussion.

Strategic risk register

7.7. The new strategic risk register was presented. It was agreed that when the new risk register is next reviewed the legal risk should be closed, as suggested. Any new legal cases could be added as a distinct risk as and when needed in the future. Members commented that this was a positive way forward.

- **7.8.** It was noted that the HFEA's public body review in early 2023 had been added as a risk, but that the full scope and extent of the review were not yet known. It was therefore difficult to score the residual risk as yet.
- **7.9.** Members asked if the public body review was still going ahead. The Chief Executive responded that we did not have a start date but that it would happen, likely starting in early 2023.
- **7.10.** Members commented that in addition to being a resource risk there were also political risks and even an existential risk. Members asked the Executive to reflect on the concerns raised.
- **7.11.** Continuing, members asked if the HFEA would be involved in the Covid enquiry. The Director of Strategy and Corporate Affairs responded that the current position was that our involvement is expected to be limited but that we had done some preparatory work. We had also included a line in the business plan for 2023/24 on public enquiries but this was not seen as a priority area at present.
- **7.12.** Members were also advised that we were considering adding a risk associated with obsolescence of our older IT systems, which could impact on our ability to regulate and license effectively.
- **7.13.** The Chair commented that dynamism was present in the register and asked if there was enough sense of pace in the target dates returning to within risk appetite. The Chief Executive responded that this was the very first draft of the risk register and that it will continue to be reviewed, following the committee's approval of the new format today.
- **7.14.** Members suggested that mitigations and/ or controls could usefully be listed as bullet points rather than as a narrative. The Risk and Planning Manager responded that controls will be listed as bullet points. He also commented that closed risks will be greyed out but not deleted to enable us to demonstrate that the register was dynamic and to keep track of changes over time.

Action

7.15. Mitigations and controls to be bulleted.

Financial risk

7.16. Members asked about the reserves which had sufficient cash to function normally for period of two months and asked if this could be extended. The Chief Executive responded that we were in line with the policy which could be changed and that we would review this.

Governance risk

7.17. Members asked how this risk was monitored and at what level and if we need to reflect the onerous sub risks.

Information risk

- **7.18.** The Committee noted that it would be important to consider the wider environment and the provision of fertility data by private sector organisations. However, this risk was framed around the HFEA's own register data and wider communication capacity.
- **7.19.** Following discussion, it was agreed that our positioning on this will be discussed again with the Authority in the future in the context of developing our future Strategy for 2024 to 2027.
- **7.20.** On the Opening the Register (OTR) function, members requested that assurance be given to the committee that this risk is mitigated. The Director of Compliance and Information responded that

we would continue to look at this risk and an update would be presented to Authority in January. The Director of Strategy and Corporate Affairs commented that we had an internal project assurance group (PAG) and that it reviewed project activity on a monthly basis. The internal group reports into CMG and if there are any issues with project delivery, controls or the timeline these will be reported to AGC.

Action

7.21. The Executive agreed that reports will be brought back to the committee by exception. Specific risks will also be brought to the attention of the committee.

Legal risk

- **7.22.** The Director of Strategy and Corporate Affairs commented that if there is a specific legal challenge, we will bring it to the attention of members.
- **7.23.** Members commented that the resource issue had been highlighted in the report which made the suggestions in the paper understandable and were therefore in favour of the proposals.
- **7.24.** The Chief Executive commented that we will report by exception and if there was the risk of reputational damage would bring it to the attention of the committee.
- **7.25.** The committee were in favour of closing the legal risk in the register.

People risk

- **7.26.** Members commented that this risk consisted of both capacity and capability elements and queried the trend of ongoing recruitment and retention.
- **7.27.** The Chief Executive commented that generally we recruit in a timely manner and that in the commentary we are moving away from the negative and focusing on the work that needs to be done.
- **7.28.** Members asked if the loss of senior management team (SMT) and board members could be mitigated.
- **7.29.** The Director of Strategy and Corporate Affairs responded that appointments or re-appointments of Authority members were decisions for the Secretary of State.
- **7.30.** Members felt that it was a high risk for Authority members to only have one term of appointment, in particular considering the skillset that members had to have and the knowledge they needed to develop to sit on the various committees (particularly the quasi-legal licensing committees) and to add value to committee decision-making.
- **7.31.** Members endorsed having staggered tenures where possible, and increased appointments of second terms to mitigate this risk and requested that the DHSC representative take this request back to the Department for further discussion.

Action

7.32. Further consideration to be given by the Department to the issue of second terms and staggered terms in future appointments.

Operational risk

- **7.33.** Members commented that this part of the risk register should be populated as we are a regulator and there was the potential for things to go wrong.
- **7.34.** The Chief Executive responded that some of our operational risks were listed elsewhere for instance the OTR and IT.
- **7.35.** The Chair commented that broader structures which underpin the risk register can come to the committee as deep dive items, but that these need to be of optimal benefit to the Executive.

Security risk

7.36. It was noted that the deputy Chair of AGC was the cyber security board member lead.

Decision

7.37. Members noted the risk registers and actions requested.

Risk appetite statement

- **7.38.** AGC were advised that three options had been presented to the Authority and that they settled on option 2.
 - To combine some of the categories used in the strategic risk register (SRR) / Orange book and produce risk appetite statements that cover our position based on our risk appetite and tolerance.
 - This will allow the HFEA to make clear the areas we are more likely to be risk averse and the ones where we would consider a higher tolerance and acceptance of risk. The new risk strategy reflects this option; however not all the categories in the Orange book are directly named.
- **7.39.** Members felt that more work needed to be done on the wording as it could be misinterpreted to mean that we are closed to innovation which was not the case.
- **7.40.** Circulate a list of options and the definition of the categories to help hone in on the appetite and tolerance of risk. Members stated that the organisation recognised that it was willing to take risks but a balanced statement of this needed to be articulated.

Action

7.41. Circulate a list of options and the definition of the categories to help hone the appetite and tolerance of risk.

Decision

7.42. Members noted the risk appetite statement.

Proposal for deep dive topics

- OTR what it means for the organisation
- Retention and recruitment- resource risk
- Legal risk and how it will be mitigated
- Public body review in March 2023

7.43. Members agreed that the October deep dive topic will be agreed at the March meeting and that members can also add topics to the list.

Decision

7.44. Members noted the deep dive topics.

Financial risk on potential income position and government funding

- **7.45.** The Director of Finance and Resources presented this item. The implications of reduced activity in the fertility sector was discussed. Treatment numbers reported to HFEA had been impacted in recent years and the reconciliation of actual activity had resulted in approximately 6% higher activity against the estimates made.
- **7.46.** Members noted the difference in activities over the last three years between 2019 and 2022.
- **7.47.** Anecdotal information suggested that current economic conditions were starting to impact on treatment numbers. We were therefore starting to consider the impact of an ongoing downtown in HFEA licence fee income.
- **7.48.** Four scenarios were modelled for compound impact over the next four financial years. Of those, HFEA required a minimum of 2% growth in IVF activity year on year to meet baseline expenditure increases without further increases to fees all other income streams are likely to remain flat in the medium term.
- **7.49.** In response to a question, it was noted that the fee review will take place in 2023/24 financial year but an initial discussion will take place in 2023 with CMG and SMT.
- **7.50.** The Chair advised that once the forecasts had been reviewed that it be taken to the Authority if there are any serious concerns.
- 7.51. Members commented that there was a long wait in primary and secondary referrals which led to a drop in treatment levels. We however needed to bear in mind that people were willing to do anything to pay for fertility treatment which could lead to them having a family.
- **7.52.** The External Auditor commented that agreeing the income plan from a very early stage would be helpful.
- **7.53.** Members also felt that as a Regulator we could change the items that we charge for including consideration for charging for data.
- **7.54.** The Chief Executive commented that this could be brought up during the public body review. Also, that our current fee model was tolerable and we would look into recasting the fees to reflect the changes in clinic activities.
- 7.55. The Director of Finance and Resources stated that this would be taken to an Authority meeting and that not being able to access our reserves is not helpful as we had cash reserves that we could not access.

Decision

7.56. Members noted the risk areas discussed and the actions to follow.

8. Digital projects/PRISM update

- **8.1.** Members were given an update on PRISM by the Programme Manager. As of 21 November 2022, 291,888 units of activity had been submitted to PRISM. It was noted that Inspectors were not using live data but still on EDI pending when PRISM had bedded in.
- **8.2.** The PRISM planning assumptions to deliver OTR and choose a fertility clinic (CaFC) were discussed. The definition of PRISM completion was also highlighted as:
 - Supporting the OTR function to operate solely through PRISM
 - Delivering a first CaFC through PRISM.
- **8.3.** The plan was to focus clinic activity on addressing backdated CaFC related validations before progressing to CaFC verification. In terms of delivery dates published, they are accompanied by mitigation on CaFC.
- **8.4.** Members were also advised that given that CaFC reported at an 'aggregate level' rather than a detailed level, it was not necessarily required for all legacy data issues to be fixed before the publishing of CaFC.
- **8.5.** The delivery dates were to deliver OTR through PRISM by the end of July 2023 and to deliver a first CaFC through PRISM between September 2023 as a best-case scenario and June 2024 as a worst-case situation.
- **8.6.** The timescales for delivering CaFC were very much conditional on the pace at which clinics fixed validation errors and whether a full, partial or no verification process was required for the first CaFC.
- **8.7.** The Director of Compliance and Information commented that the OTR team were happy with the dates and the mitigations included.
- **8.8.** The Chief Executive commented that although we had started this process this was our best estimation and assured the committee that the objectives of PRISM completion were a priority.
- **8.9.** Members were advised that the ongoing resource requirements for supporting PRISM had been extended for another six months.
- **8.10.** The Chair agreed that the PRISM completion objectives should be a priority.

Decision

8.11. Members noted the PRISM status update.

9. Resilience, cyber security & business continuity

Infrastructure improvements

- **9.1.** The Head of IT presented this item. Infrastructure improvements were discussed and members were advised of security changes that had taken place Including the penetration test.
- **9.2.** Members were informed that they had deployed an Office365 backup service with a specialist third party provider called KeepIT, so that all data within Office365 (Emails, OneDrive and SharePoint) were now fully backed up in a non-Microsoft UK datacentre and changes were replicated daily.

Data Security and Protection Toolkit (DSPT)

- **9.3.** In the absence of the Head of Information, the Director of Compliance and Information presented this part of the paper on DSPT.
- **9.4.** Members were advised that the Director of Finance and Resources chaired the first information governance and security steering group on 30 November 2022.
- **9.5.** The Director of Finance and Resources commented that for the March 2023 AGC meeting, a list of DSPT audit of what has been met and what cannot be met will be brought to the meeting.
- **9.6.** The deputy Chair for AGC commented that the Mimecast evaluation should be carried out as soon as it can be done as it is a useful tool to mitigate phishing.
- **9.7.** Members asked if there was merit in bringing an indication of what similar sized ALBs were doing as this would enable us benchmark, which would be useful in our discussion with the department.

Action

- **9.8.** The Director of Finance and Resources commented that a list of DSPT audit of what has been met and what cannot be met will be brought to the March 2023 meeting.
- **9.9.** The Director of Finance and Resources agreed that we will work closely with a similar sized ALBs on their DSPT work and bring this forward.

Decision

9.10. Members noted the infrastructure improvements and the current position on DSPT.

10. Human Resource bi-annual update 2022

- **10.1.** The Head of Human Resources presented this item. The annual staff survey took place in the Autumn of 2022. Members were presented with a summary of the findings.
- **10.2.** Members commented that considering the size of the organisation the results were relatively positive and showed good leadership.
- **10.3.** Members commented that the responses on diversity and inclusion were worrying and that it was good that the Executive were analysing the responses.

Actions

- **10.4.** The committee to see the outcome of the analysis on the EDI audit at the next meeting when the HR report will be presented.
- **10.5.** The Head of HR to capture and include the free text observations from the staff survey in the report.

Decision

10.6. Members noted the results from their recent staff survey.

11. Review of AGC effectiveness

11.1. The Chair invited the Head of Planning and Governance to facilitate this item.

- **11.2.** The Chair thanked all committee members and attendees who had completed the NAO generated effectiveness document. Members discussed specific suggestions from the submissions.
- **11.3.** In terms of the proposal to co-opt people with particular expertise, members commented that this looked like a good option and would have been useful when AGC began reviewing PRISM. It was agreed that the terms of reference of the committee will be amended to allow the co-opting of external people with specific expertise as and when required.
- **11.4.** In terms of diversity and skills mapping, members also agreed that taking on associate members or considering apprentice board members could bring value to the HFEA.
- **11.5.** The DHSC representatives agreed to discuss these suggestions with the department.
- **11.6.** For clarification, the Chief Executive asked for the role of associate/apprentice board member. It was suggested that they would contribute to the discussion but not participate in decision making.
- 11.7. It was noted that climate change was not particularly relevant to what we did as an Authority.
- **11.8.** In terms of assurance and assurance mapping it was noted that this could be useful to the committee but what may be more appropriate would be the use of a deep dive to explore specific risks.

Actions

- 11.9. Assurance and assurance mapping to be kept under continuous review and form part of training.
- **11.10.** The Executive to consider risk management near misses as a potential topic for a deep dive.
- 11.11. On Financial reporting, the work on accounting judgments/financial models can be brought to the March meeting.
- **11.12.** It was agreed that all areas for improvement will be kept under review.
- **11.13.** As part of continual improvement there should be monitoring of trends in the Corporate Governance sphere.
- **11.14.** The DHSC representative to look into how the AGC Chair can sit on a forum of other ALB ARAC Chairs and discuss the possibility of having associate/apprentice board members with the department.
- **11.15.** On succession planning, the AGC Chair to speak to the Authority Chair about succession planning and associate/apprentice board members.
- **11.16.** The Chair commented that the actions need to be implemented by October 2023 in time for the 2023 committee effectiveness exercise.

Decisions

Members noted the committee effectiveness review summary. The Head of Planning and Governance would convert this into a tracking document for actions.

12. AGC forward plan

12.1. The Head of Finance presented this item. For the March 2023 agenda internal audit draft plan to be included.

12.2. Functional standards should be included as standard items for all meetings.

13. Items for noting

13.1. Whistle blowing

Members were advised that there were no whistle blowing incidents.

13.2. Gifts and Hospitality

Members noted that there were no changes to the register of gifts and hospitality.

13.3. Contracts and Procurement

 Members noted that there were no contracts or procurements signed off since the last AGC meeting

13.4. Estate update

There was no update on estate.

14. Any other business

14.1. Members were advised that the next meeting was scheduled for Tuesday, 14 March 2023.

Chair's signature

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

Signature

Chair: Catharine Seddon

Cahaine Lidda

Date: 14 March 2023



AGC Action log

| Details about this | paper | | |
|------------------------------|--|--|----------------------|
| Area(s) of strategy this | The best care – | effective and ethical care for | everyone |
| paper relates to: | The right information at the | ation – to ensure that people e right time | can access the right |
| | Shaping the futulaw, science, an | re – to embrace and engage d society | with changes in the |
| Meeting | Audit and Gove | ernance Committee | |
| Agenda item | 3 | | |
| Meeting date | 14 March 2023 | | |
| Author | Morounke Akingbola (Head of Finance) | | |
| Output: | | | |
| For information or decision? | For discussion | | |
| Recommendation | To note and co | mment on the updates sho | own for each item. |
| Resource implications | To be updated and reviewed at each AGC | | |
| Implementation date | 2022/23 business year | | |
| Communication(s) | | | |
| Organisational risk | □ Low | X Medium | ☐ High |



| ACTION | RESPONSIBILITY | DUE DATE | PROGRESS TO DATE |
|---|--|------------------|--|
| Matters Arising from the Audit and Gove | rnance Committee – a | ctions from 28 | June 2022 |
| 11.9 HFEA to meet with GIAA to colleagues regarding DSPT requirements and evidence | Director of Finance and Resources | Mar 2023 | Update – an update to be provided at the March 2023 meeting |
| 11.10 Chief Executive to meet with the AGC Deputy Chair to discuss DSPT issue. | Chief Executive | March 2023 | Update – to be provided at the March 2023 meeting |
| Matters Arising from the Audit and Gove | rnance Committee – a | ctions from 4 O | ctober 2022 |
| 4.19 Executive to hold discussion with DHSC and NHS digital for some ALBs to be assessed at a different level on the Data Security and Protection Toolkit (DSPT) and consider future DSPT actions. | Chief Executive | December 2022 | Update – The Chief Executive to give an update at the March 2023 meeting. |
| 5.12 The summary of audit recommendations to record a section of recommendations that are accepted for implementation and another section recording the recommendations that due to limited resources may not be implemented. | Head of Finance | December 2022 | Update – to be evidenced at the March 2023 meeting. |
| 15.4 Update on goodwill letters to be discussed at SMT and brought back to AGC. | Director of Compliance and Information | Oct 2023 | Update - The decision is to proceed with cataloguing the documents and to scan on to the register. Iron Mountain has been contracted. There is a delay in starting as after advertising the post there was little interest and at interview there was no suitable appointable candidate. As yet haven't been able to find anyone suitable from an agency. We are now going to try a specialist records manager jobs board. |

| ACTION | RESPONSIBILITY | DUE DATE | PROGRESS TO DATE |
|---|--|-----------------|---|
| Matters Arising from the Audit and Gove | rnance Committee – a | ctions from 8 D | ecember 2022 |
| 4.10 Functional standards to be a standing agenda item at future AGC meetings. | Head of Finance | Ongoing | Update – This has been added to the forward plan- propose to close |
| 5.6. The internal audit meeting with the Head of Finance to be documented and the wording of the IA log entries to be agreed with internal audit to avoid recommendations being misunderstood or not addressed satisfactorily in evidence submitted. | Head of Finance | Mar 2023 | Update – meeting to take place in February ahead of the March AGC |
| 5.7. Deputy Chair of AGC to monitor the DSP Toolkit. | Alex Kafetz, Deputy AGC Chair | Ongoing | Propose to close |
| 7.15. All mitigations and controls in the strategic risk register to be bulleted. | Risk and Business Planning Manager | Mar 2023 | Update – This will be added as appropriate as the SRR develops at each iteration. |
| 7.21. The Executive agreed that OTR reports will be brought back to the committee by exception. Specific risks will also be brought to the attention of the committee. | Director of Compliance and Information | June 2023 | Update - No further updates. Authority are reviewing OTR key issues and risks at every meeting in 2023. |
| 7.32. Further consideration to be given by the Department to the issue of second terms and staggered terms in future appointments. | DHSC representative | Oct 2023 | Update - The HFEA Chair and Chief Executive met with DHSC sponsors to discuss the case for re-appointment of members whose first terms finish in 2024. Chair agreed to supply evidence and rationale to sponsors in support of the case for re-appointment of all four members. DHSC Appointments team will signal this intention to Cabinet Office. While second terms are not automatic, a strong case can be made for them to ensure effective delivery of statutory business. |
| 7.41. Circulate a list of options and the definition of the categories to help hone the appetite and tolerance of risk. | Risk and Business Planning Manager | June 2023 | Update – This will be added to the Risk Strategy review which will be presented at the June AGC. |

| ACTION | RESPONSIBILITY | DUE DATE | PROGRESS TO DATE |
|--|---------------------------------------|------------|--|
| 9.8. The Director of Finance and Resources commented that a list of DSPT audit of what has been met and what cannot be met will be brought to the March 2023 meeting. | Director of Finance and Resources | March 2023 | To be discussed at the March 2023 meeting |
| 9.9. The Director of Finance and Resources agreed that we will work closely with a similar sized ALBs on their DSPT work and bring this forward. | Director of Finance and Resources | March 2023 | To be discussed at the March 2023 meeting |
| 10.4. The committee to see the outcome of the analysis on the EDI audit at the next meeting when the HR report will be presented. | Head of Human Resources | June 2023 | Not due |
| 10.5. The Head of HR to capture and include the free text observations from the staff survey in the report. | Head of Human Resources | June 2023 | Not due |
| 11.9. Assurance and assurance mapping to be kept under continuous review and form part of training. | Head of Planning and Governance | Oct 2023 | Not yet due; will be discussed when we arrange training. |
| 11.10. The Executive to consider risk management near misses as a potential topic for a deep dive. | The Director of Finance and Resources | Oct 2023 | Note due |
| 11.11. On Financial reporting, the work on accounting judgments/financial models can be brought to the March meeting. | The Director of Finance and Resources | Mar 2023 | Update – Paper to be presented at March meeting. propose to close |
| 11.13. As part of continual improvement there should be monitoring of trends in the corporate governance sphere | Head of Planning & Governance | Oct 2023 | Update – The annual review of committee effectiveness for 2022/23 is complete, and there will be a summary report to the March Authority meeting. This will be accompanied by a small update to Standing Orders, to allow AGC to co-opt external expertise if needed in the future. We monitor for new trends continually, often in conjunction with our internal audits or external reviews, but also with the annual review |

| ACTION | RESPONSIBILITY | DUE DATE | PROGRESS TO DATE |
|--|---------------------|-----------------|---|
| | | | of committee effectiveness, which commences every October. Since this is well-established ongoing work, AGC may wish to close this action item. |
| 11.14. The DHSC representative to look into how the AGC Chair can sit on the forum of other ALB ARAC Chairs and discuss the possibility of having associate board members with the department. | DHSC representative | Mar 2023 | Update - The DHSC Audit and Risk Committee Chair and Committee do routinely invite ALBs and respective ARC Chairs to attend meetings. If there are specific items the HFEA ARAC would like to discuss or present to the Committee, this can be notified to the DHSC ARC Chair and an invitation to attend can be arranged. The HFEA Chief Executive discussed the use of Associate Board Members with DHSC sponsors at the last quarterly accountability meeting, where it was agreed this would be an appropriate route for the HFEA to address skills and diversity gaps on the Board and committees. As Associate Members are not overseen by Ministers they are not within the public appointments remit, so it's entirely up to the HFEA how they go about recruiting and appointing such members. There is nothing in the legislation to direct on this either – Propose to close – also DHSC rep to add Chair to distribution list |
| 11.15. On succession planning, the AGC Chair to speak to the Authority Chair about succession planning and associate/apprentice board members. | AGC Chair | Mar 2023 | Update – This was discussed with the Chair, and it was felt that this was not a current priority. It will however be kept under consideration. We have a large board with frequent turnover as we cannot assume members will get more than a term in office. |



2022-23 Audit Recommendations

| Details: | | | |
|------------------------------|--|----------------------------------|--------------------|
| Area(s) of strategy this | The best care – effe | ctive and ethical care for every | one |
| paper relates to: | The right information – to ensure that people can access the right information at the right time | | |
| | Shaping the future – science and society | to embrace and engage with c | hanges in the law, |
| Agenda item | 5 | | |
| Meeting date | 14 March 2023 | | |
| Author | Morounke Akingbola, Head of Finance | | |
| Output: | | | |
| For information or decision? | For information | | |
| Recommendation | AGC are requested to note the reduced number of outstanding recommendations | | |
| Resource implications | On-going | | |
| Implementation date | 2022/23 and per audit tracker | | |
| Communication(s) | | | |
| Organisational risk | Low | | ☐ High |
| Annexes | | | |

Update

There has been two new audits since the December 2022 meeting. A total of 13 recommendations have been closed. These are:

- Anti-fraud controls recommendations (4) 1.4,2.4,2.5 & 2.6 have been removed from the tracker
- Budgeting Process recommendations (4) 1.2,2.1, 2.2 & 3.1 have been removed from the tracker
- Operational Risk recommendations (5) 1.1,1.2,1.3,1.4 & 1.6 have also been removed from the tracker.

Minutes of AGC meeting 28 June 2022

Human Fertilisation and Embryology Authority

The attached is a summary of the remaining outstanding recommendations. The committee are requested to note one recommendation that has not been agreed to (ED&I rec 1.1) which remains on the tracker for the Committee to agree whether it remains or is removed.

The Committee are invited to comment on those outstanding recommendations.



Accounting policies 2022/23

| Details: | | | |
|------------------------------|--|-------------------------------------|-----------------------------|
| Area(s) of strategy this | The best care – effe | ective and ethical care for every | one |
| paper relates to: | The right informatio at the right time | n – to ensure that people can ac | ccess the right information |
| | Shaping the future science, and societ | – to embrace and engage with c y | hanges in the law, |
| Agenda item | 8 | | |
| Meeting date | 14 March 2023 | | |
| Author | uthor Richard Sydee, Director of Finance and Resources | | |
| Output: | | | |
| For information or decision? | For information | | |
| Recommendation | AGC are requested | to review and comment on the | key policies |
| Resource implications | None | | |
| Implementation date | 2022/23 | | |
| Communication(s) | | | |
| Organisational risk | Low | | ☐ High |
| Annexes | None | | |

Purpose of paper

1. This report advises the Audit and Governance Committee of amendments and updates to the accounting policies adopted for preparation of the accounts for the financial year 2022/23.

Summary

- 2. This report summarises the main elements of the accounting policies adopted by the HFEA and proposed changes to ensure the accounts for 2022/23 are prepared in accordance with accounting regulations. Any further changes to accounting regulations may require the policies to be changed further, however none are anticipated at this stage. Any significant impacts from changes to the 2022/23 policies will be highlighted to the committee in the Annual Report and Accounts report in June 2023.
- 3. The polices remain broadly unchanged from the previous financial year. Of significance the Leasing Standard IFRS 16 was adopted on 1st April 2022 by the HFEA in line with other public sector organisations. This standard brings leased assets onto the balance sheet where the lease period was greater than 12 months year.
- 4. It is good practice for Audit Committees to review accounting policies on an annual basis. Adoption of the 2022/23 policies also means draft policies are in place for the start of the financial year to which they relate.

Recommendations

5. The Committee is asked to note and comment on the accounting policies applicable to financial years 2022/23.

Accounting Policies

Introduction

- 6. This report sets out the revised accounting policies that will be applied during the financial years 2022/23 and 2023/24 in preparation of the HFEA's financial statements. The full policies are shown in appendix A to this report and will be included in the Annual Report and Accounts. The policies are prepared under the International Financial Reporting Standards (IFRS). Members of the Audit, Risk and Assurance Committee are invited to note these policies and make comment.
- 7. Unless there are major changes to accounting rules and regulation, accounting policies do not change significantly between years because the accounts would not be comparable from one year to the next.
- 8. The audited Annual Report and Accounts for 2022/23 are expected to be presented to the June 2023 Audit, Risk and Assurance Committee for approval. The accounting policies

statement will be included within the accounts and any changes made during the course of the closedown programme and/or audit will be highlighted and explained by officers. There might be a need to make changes to these policies following the completion of the audit.

Purpose of Accounting Policies

- 9. The definition of accounting policies is "the principles, bases, conventions, rules and practices applied by an organisation that specify how the effects of transactions and other events are to be reflected in its financial statements through recognising, selecting measurement bases for, and presenting assets, liabilities, gains, losses and changes in reserves".
- 10. The application of accounting policies supports the implementation of the main accounting concepts of best practice. These ensure financial reports:
 - Are relevant providing appropriate information on the stewardship of Authority monies.
 - Are reliable financial information can be relied upon and is without bias and free from error, within the bounds of materiality and has been prudently prepared.
 - Allow comparability the interpretation of financial reports is enhanced by being able to compare information across other accounting periods and other organisations.
 - Are understandable though financial reports have to contain certain information, they have to be understandable.
 - Reflect material information significant transactions must be incorporated in the financial reports.
 - Prepared on a going concern basis the assumption that the authority will continue in operational existence for the foreseeable future.
 - Prepared on an accruals basis accounts are prepared to reflect the benefit of goods and services received and provided rather than when cash transactions occur when invoices are paid in a later accounting period.
- 11. The significant accounting policies currently adopted by the HFEA are in line with the concepts set out paragraph 11.

Underlying Assumptions

12. The International Accounting Standard (IAS 1) requires that management make an assessment of an entity's ability to continue as a going concern and to disclose any material uncertainties related to events or conditions that may cast a significant doubt

upon an entity's ability to continue as a going concern. The Authority discloses that the accounts have been prepared on a going concern basis and that the HFEA will continue in existence for the foreseeable future. The HFEA has based its considerations of Going Concern around the continuous provision of service.

Accounting Policies

- 13. Below are the significant accounting policies, the remaining policies are as detailed in the 2021/22 Annual Report and Accounts and will not change for the 2022/23 financial year...
- 14. **Property, Plant and Equipment (PPE)** these assets have a physical substance and are held for use in the provision of services or administrative purposes and are expected to be used for more than a year (e.g., Information Technology IT equipment). Expenditure on the above on acquisition is capitalised on an actual basis provided it yields benefit to the Authority and the benefit it provides exists for more than one financial year.
 - Measurement Property, plant and equipment are initially shown on the Balance Sheet at cost, comprising the purchase price and all expenditure that is directly attributable to bringing the asset into working condition for its intended use. Assets under construction are held at historical cost and are not depreciated until brought into use (this was applied in 2021/22 when laptops were purchased towards the end of the financial year and not deployed till early 2022/23).
 - Depreciation on PPE Depreciation has been calculated using a straight-line method (i.e. apportioned equally over each year of the life of the asset) for all assets. The estimated useful life of each asset is determined by its type i.e. laptops generally have a useful life of 3-4 years or leases or refurbishment costs in line with the lease term of buildings occupied.
- 15. Intangible Assets expenditure on non-monetary assets that do not have physical substance but are controlled by the Authority as a result of past events (e.g. software licences) is capitalised when it is expected that the future economic benefits or service potential will flow from the intangible asset to the Authority. Internally generated assets are capitalised where it is demonstrable that the project is technically feasible and is intended to be completed and the Authority will be able to generate future economic benefits or deliver service potential by being able to use the asset. Expenditure is capitalised where it can be measured reliably as attributable to the asset and is restricted to that incurred during the development phase.
 - Measurement intangible assets are measured initially at cost. Amounts are only revalued where the fair value of the asset held by the Authority can be determined by reference to an active market. In practice, no intangible asset held by the Authority meets this criterion, and they are therefore carried at amortised cost.

- Depreciation/amortisation The depreciable amount of an intangible asset is amortised over its useful life and is charged to the Statement of Comprehensive Income and Expenditure.
- 16. Right of Use Assets and Liabilities IFRS 16 Leases was adopted on 1 April 2022. In the 2022/23 accounts, IFRS 16 provides a single lessee accounting model, requiring lessees to recognise assets and liabilities for all leases, unless the lease term is 12 months or less, or the underlying asset is of low value. On the date of transition to IFRS 16, the HFEA recognises a right of use asset and a lease liability. The asset described as 'right of use' asset, will be presented under note 11 within the annual accounts. Our lease previously treated as an operating lease has been measured at the present value of the remaining lease payments, adjusted for any prepayments or accruals in respect of lease payments. The HFEA has taken into account the commencement date of the lease in determining the remaining term of its lease.
- 17. Impairments Appropriate assets are reviewed for impairment at the end of each reporting period. The HFEA has financial assets (Receivables debtors) that are reviewed and using a simplified approach to impairment in accordance with IFRS 9. An impairment loss allowance is made for debts that are not considered collectable referred to as impairment of financial assets. The provision is calculated based on the expected amount that will not be collected and applied to the amount of outstanding debt. The balance of debtors on the Statement of Financial Position (Balance Sheet) is reduced by the amount of provision made.
- 18. **Critical accounting judgements** in applying the accounting policies, the HFEA has to make certain judgements about complex transactions or those involving uncertainty about future events. The critical judgements that will be made in the Annual Report and Accounts are:
 - O IAS 36 Impairments management will make a judgement on whether there are any indication of impairment to the carrying amount of PRISM. A benefits realisation review will be undertaken by the team with oversight of PRISM as to whether benefits as detailed in the original business case have been realised. The outcome of which will impact on whether management decides to write down further the value of PRISM which currently sits on the Statement of Finance Positions (SoFP).
- 19.Income recognition income is recognised when the performance obligations in a contract have been satisfied. In application to HFEA licence fees, which are based on IVF and Donor IUI cycles each year, income is recognised on all treatment cycles that meet the qualifying criteria in the financial year.
- 20.**IFRS 16 Leases**¹ effective 1 April 2022; requires the recognition of all leases on the Statement of Financial Position (SoFP), including leases for rented office space. A lease is

1 Accounting policy from the DHSC Group Accounting Manual which will be further tailored in the notes to the annual accounts

a contract or part of a contract that conveys the right to use an asset for a period of time in exchange for consideration. In transition to IFRS 16 the HFEA as other government departments and ALBs applies a practical expedient that is offered in the Standard (para C3)² to apply IFRS 16 to contracts or arrangements previously identified as containing a lease under the previous leasing standard IAS 17 Leases and IFRIC 4 Determining whether an Arrangement contains a Lease and not to those that were identified as not containing a lease under previous leasing standards.

- 21. The HFEA is a lessee under IFRS 16. On initial application, the HFEA has measured the right of use assets for leases previously classified as operating leases per IFRS 16 C8 (b)(ii) at an amount equal to the lease liability adjusted for accrued or prepaid lease payments. Lease payments are apportioned between finance charges and repayment of the principal. Finance charges are recognised in the Statement of Comprehensive Income / Net Expenditure. Irrecoverable VAT is expensed in the period to which it relates and therefore is not included in the measurement of a lease liability and consequently the value of the right of use asset.
- 22. The incremental borrowing rate of 0.95% has been applied to the lease liabilities recognised at the date of initial application of IFRS 16. Where changes in future lease payments result from a change in rate or rent review, the lease liabilities are remeasured sing an unchanged discount rate.
- 23. No adjustments have been made for operating leases in which the underlying asset is of low value per paragraph C9 (a) of the Standard. The transitional provisions have not been applied to operating leases whose terms end within 12 months of the date of initial application has been employed per paragraph C10 (c) of IFRS 16.
- 24. The Committee are requested to note the above policies that will be applied to the 2022/23 annual accounts.

² IFRA 16 Leases – application guidance



Digital Projects / PRISM Update February 2023

Details about this paper

Area(s) of strategy this paper relates to:

The right information – to ensure that people can access the right information at the right time.

Meeting:

AGC

Agenda item:

10

Meeting date:

14 March 2023

Author:

Kevin Hudson, PRISM programme manager

Annexes

Output from this paper

| For information or decision? | For information |
|------------------------------|---|
| Recommendation: | To note the plan for delivery of OTR and CaFC through PRISM, the anticipated delivery dates and the mitigations to be enacted to ensure those delivery dates are met. |
| Resource implications: | |
| Implementation date: | To deliver OTR through PRISM by the end of July 2023 and to deliver a first CaFC through PRISM between September 2023 (best case) and June 2024 (worst case). |
| Communication(s): | |
| Organisational risk: | Medium |

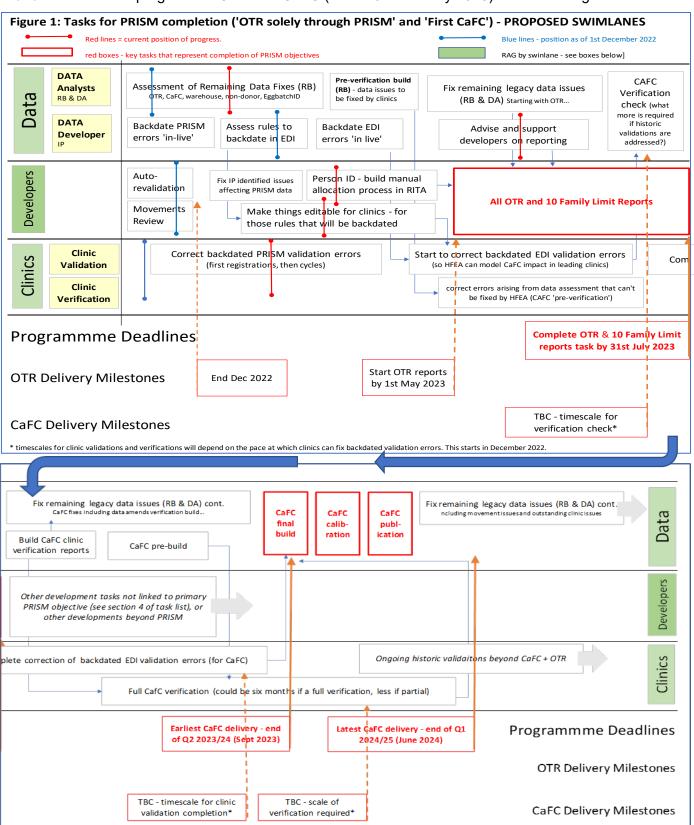


1. Introduction and summary

- **1.1.** PRISM went live on 14th September 2021 for 40 direct entry clinics and API deployment was completed by the end of June 2022 for the other 62 clinics. Since then, 352,253 units of activity have been submitted through PRISM.
- **1.2.** At the AGC meeting on 8th December 2022, we advised on:
 - The current state of PRISM activity and error rates, and that since the summer PRISM validation rates had now stabilised and we were progressing to ask clinics to start to correct backdated validation errors necessary for CaFC.
 - Nine large clinics with submission backlogs at the end of August were advising they
 would be caught up by the end of December 2022. ARGC (3 clinics) deployment was
 dependent on a new technical fix with Meditex that would be first deployed at St Mary's
 Manchester.
 - The proposed four planning assumptions to deliver OTR and CaFC, namely:
 - 1. Given the removal of anonymity from late 2023 onwards, we will prioritise OTR with data and reporting support to ensure they have maximum efficiency.
 - 2. We will focus on clinics fixing validation errors before verification and only on backdated errors relating to OTR or the new CaFC period from 1st January 2020.
 - 3. For CaFC we will assess to what extent 'validated data' is sufficient to run a CaFC which will be possible once leading clinics has fixed their backdated errors.
 - 4. Our long-term strategic aim is for CaFC to be produced without a formal verification, which will be possible once CaFC is reporting solely from PRISM if error rates are sufficiently low.
 - The detailed plan for completing OTR and CaFC on PRISM, and the details of the three separate planning swim-lanes for developers, data and clinics.
 - The anticipated completion timescales, namely:
 - To meet the requirements of the OTR team, to deliver all OTR and 10 family limit reports from PRISM by the end of July 2023.
 - As requested by AGC, the 'best and worst' for CaFC delivery were a best date of September 2023 or a worst date of June 2024 depending on the level of further 'verification after validation' that was required by clinics (see assumption 3 above).
 - We would be able to provide a more accurate assessment of CaFC timescales by the end of June 2023.
- 1.3. In this paper we will update AGC on the latest progress against the detailed plan that was shared in December 2022, and the latest progress towards delivery of OTR requirements and the first CaFC through PRISM.
- **1.4.** Regrettably, due to a longstanding leave commitment the PRISM programme manager will not be able to attend the AGC meeting.

2. Latest progress against plan for OTR and CaFC through PRISM

2.1. The current progress for OTR and CaFC (as of 20th February 2023) is shown in figure 1 below:



- **2.2.** To recap, the main features of our plan are three distinct planning swim-lanes to deliver OTR and CAFC through PRISM with reference to:
 - **Data:** Establish the underlying framework, undertake key reconciliations and correct any arising legacy data issues that will impact either on OTR and CaFC.
 - **Developers:** Continue to develop PRISM as required by data and clinics, and to build the OTR and 10 family limit reports according to the stakeholder requirements.
 - **Clinics:** To address validation errors in relation to data submitted to HFEA and then, subject to review, to conduct further verification exercises prior to CaFC publication.
- **2.3.** Presently, we are on track on all planning swim-lanes for PRISM. In particular, we are making very good progress towards delivering the requirements for OTR; namely to complete all OTR and 10 family limit reports from PRISM by the end of July 2023. (See section 3 below)
- 2.4. However, progress of the data team has been impacted by the requirement to additionally undertake registration renumbering exercises for clinics moving to Meditex API. This is required because it is part of the technical solution necessary to ensure eventual deployment of PRISM to ARGC. Currently, our work on data is still on track, but we are monitoring the impact of 'registration renumbering' closely. (See section 4 below).
- **2.5.** In addition, whilst also on track, progress by clinics on addressing their backdated errors is sometimes sporadic and requires careful monitoring and close liaison from the Register team. (See section 5 below).

3. Progress on development: delivering OTR requirements

3.1. The development team are making good progress towards delivering the OTR and 10 family limit reports by the end of July 2023.

Extracting detailed OTR data from PRISM

- **3.2.** Our data developer has developed a proof of concept for extracting OTR data sources that has been reviewed and well received by the OTR team.
- **3.3.** This approach is based on new egg and embryo batch tables generated from the raw cycle data from clinics. These tables will hold linkages of a cycle's ancestor and descendant cycles for both egg and sperm sources and will be updated in near real time to give an more accurate reflection of egg and embryo usage than previous overnight updates.
- **3.4.** Taking a centre and registration number, this approach will use the batch tables to extract all associated cycles. Summary tables will hold for the OTR team a tally of what has been used, what is in storage for future use, and details of actual or prospective outcomes. Detailed tables will show more usage details on a cycle-by-cycle basis.
- **3.5.** The OTR team believe this report suite will make the process more time efficient. Based on their feedback we are working further to review areas where patients are also acting as donors, linking half siblings as single families for the purpose of 10 family limit compliance, and identifying where

- historic data linkages may be broken which will remove areas of data checking currently undertaken by the team.
- **3.6.** Our data developer is continuing to develop the data extract routines in advance of planned commencement of PRISM developers starting to build the required reports in May 2023.

Person ID (unique person identifiers)

- **3.7.** Before PRISM, a function known as HFEAID was in operation to attempt to identify the same person undertaking treatment in different clinics across the sector. This is vital to ensure that OTR and 10 family limit reporting do not omit any information arising from duplicate patient registrations which are a common occurrence in the sector.
- 3.8. NHS number cannot currently operate as a unique identifier for fertility purposes, particularly due to its proportionately lower use in private sector and also foreign patients and donors. Historically, there have been a number of issues with HFEAID, particularly in relation to the large number of un-matched records that require manual assessment by the register team.
- **3.9.** Since PRISM's launch, a new 'Person ID' algorithm has been working through patient records in PRISM to assign unique identifiers to all individuals on the register. This completed at the end of December 2022 and has delivered a significantly better result compared to HFEAID.
- **3.10.** Of the 1.6 million records reviewed, there were approximately 6,000 records that the Person ID algorithm couldn't match. Further work is taking place to amend the algorithm to better match the remaining records and then of those that still cannot be matched, to provide 'options' for register team staff to review manually, but which will not incur any additional work for clinic staff.
- **3.11.** The final step will be for developers to build a user interface in RITA for the Register team so that Person ID can be completed for all registrants, and we are on plan to complete this interface before the beginning of May.
- **3.12.** With person ID fully complete, a key underlying component for both OTR and 10 family limits will be addressed.

Reporting Development

- **3.13.** As per the plan shared with AGC in December (see figure 1 above), our developers areon track to complete all the required preliminary tasks before commencing exclusively on 'OTR reporting and 10 family limit reports' activity from 1st May 2023.
- **3.14.** We remain confident that given the mechanisms of data extract have already been established and approved, the 13 weeks planned for this development focus will be more than sufficient to build for the OTR team the complete reporting suite that is required and tailor it to their needs.
- **3.15.** Moreover, the programme intends to use this development window to also develop the current PRISM reporting engine which will allow more functional reports for users. We will be introducing new reporting tools that are already well known by members of the development team. We do not expect this to impact delivery schedules.
- **3.16.** A focus on different ways of presenting information from PRISM will give better outcomes and further improved efficiency for the OTR team who will be able to shape the design of the reports during this time.

4. Progress on data: ensuring legacy accuracy for OTR and CaFC Current work on legacy data issues

- **4.1.** Whilst our developers are preparing to shape how PRISM information is reported in the future, our data analysts have been working to ensure that data in PRISM is appropriately structured, reconciled and accurate, particularly in relation to the data migrated from EDI.
- **4.2.** In January 2023, our analysts built the functionality for populating 'Eggbatch ID' which will underpin the egg and embryo batch tables required for OTR (see 3.3 above).
- **4.3.** Our analysts are now working on reconciling donors which will underpin OTR information. They will then move to the CaFC reconciliations.
- **4.4.** Each reconciliation will identify a 'non-reconciled' cohort of potential individual issues or missing legacy data linkages that are scheduled to be checked and fixed later in the plan. So far, the reconciliations are yielding encouraging results and a lower than potentially expected level of required data fixing.
- 4.5. Therefore overall, our data teams currently remain on plan. However, an additional complication has arisen resulting from the requirement for patient re-numbering at migrating Meditex clinics.
 Migrating Meditex clinics (including ARGC)
- **4.6.** As previously reported, we are working with a number of clinics to support their move from direct data entry into PRISM to automatic API submission through Meditex. These were clinics that had previously used the Acubase clinical system which has been discontinued in 2022 and include large fertility clinics such as 0067 St Mary's Manchester and 0006 The Lister Fertility Clinic.
- 4.7. These clinics historically submitted data automatically to HFEA through Acubase. They are now undertaking a clinical system move from Acubase to Meditex and then to migrate onto Meditex API for automatic submission of data to PRISM. In the meantime, they are entering data manually. We have already built the required bulk-backport data synchronisation functionality to support new Meditex API migrations and are trialling this functionality with 0067 St Mary's Manchester.
- **4.8.** Also as previously reported, this trial is particularly important as it is the same technical API migration solution that will deliver PRISM deployment for the ARGC clinics who have not yet commenced on PRISM. Once this process is fully ironed out, it will be taken to ARGC.
- **4.9.** A complicating factor has arisen concerning historic Acubase generated registration numbers at 0067 St Mary's which contain non-standard characters. These need to be replaced in PRISM before any API migration can be deployed, and there is the potential for significant risk in the accuracy of our register, particularly in relation to identifying correct individuals, if this is not done carefully.
- **4.10.** Therefore, our head data analyst has already established a detailed process for 'registration renumbering' and this is now being deployed to 0067 St Mary's Manchester. However, this is analyst time that is not currently in our plan.

- **4.11.** Moreover, there is also a risk that this reconciliation identifies discrepancies between the historic patient lists at HFEA and St Mary's Manchester that will need to be investigated and resolved. We are currently prioritising this work so that we do not impede the API migration process for other clinics (including ARGC), but at the same time we are closely monitoring this through the PRISM programme board to ensure that it does not impact internal timescales for CaFC.
- **4.12.** There always remains an option to pull our head analyst back to CaFC work if renumbering challenges are proving too time consuming, although this will delay the API migration for St Mary's Manchester and therefore ARGC deployment.

5. Progress by clinics: readiness for CaFC

Current PRISM activity, error rates and submission backlogs

5.1. As of 20th February 2023, 352,253 units of activity has been submitted to PRISM. This is shown, split by clinics using PRISM direct entry and API supply, in table 1 below.

Table 1 – Cumulative PRISM activity as of 20th February 2023

Current Activity Previously reported activity Method of data As of 20th February As of 21st November As of 19th September As of 6th June 2022 submission 2023 2022 2022 Cumulative Cumulative No of Cumulative Cumulative Cumulative Cumulative Cumulative Cumulative Clinics **PRISM** PRISM PRISM e PRISM PRISM PRISM **PRISM** PRISM Activity error rate Activity error rate Activity error rate Activity error rate Direct Entry 43 104,017 1.7% 87,205 1.3% 72,126 1.0% 52,705 0.7% API - IDEAS 38 152,881 4.0% 127,902 2.9% 105,533 3.4% 60,792 6.6% 9 API - Meditex 30,384 4.8% 28,575 5.2% 26,137 5.3% 15,177 22.3% API - CARE 13 64,971 9.1% 48,206 7.2% 42,537 6.6% 32,371 12.3% Total 103 352,253 4.3% 291,888 3.3% 246,333 3.4% 161,045 7.3%

- **5.2.** PRISM submissions are continuing at a steady state of approximately 5,000 submissions per week. Error rates have fluctuated as we have commenced the process of backdating CaFC and OTR errors for clinics to rectify (see 5.5 below).
- **5.3.** In November 2022, we reported that nine large clinics were still to catch up on their backlog of clinic submissions. Six had advised the HFEA that they would hope to catch up on their submissions by the end of December 2022, with two clinics advising January 2023 and one February 2023.
- **5.4.** Since November, we have been following up progress with these clinics. All have now confirmed that they have caught up on the submissions backlog, and we have advised the HFEA finance team accordingly for billing purposes. The only clinics that will continue to receive estimated invoices are the ARGC group.

Progress by clinics on correcting backdated validation errors for CaFC and OTR

- **5.5.** On 7th December 2022, after communicating to clinics through Clinic Focus and contacting clinics individually that were due to incur a high number of new errors, we released the first of three backdated tranches of errors that clinics will require to fix for both OTR and CaFC.
- **5.6.** This first tranche related to 5,755 registration errors and in the following weeks we have been monitoring the pace at which clinics have been correcting these errors. This is shown in table 2 below:

| • | | J | | | | | | | | | |
|-------------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| Week ending | 12-Dec | 19-Dec | 26-Dec | 02-Jan | 09-Jan | 16-Jan | 23-Jan | 30-Jan | 06-Feb | 13-Feb | 20-Feb |
| Backdate added | 5755 | | | | | | | | | | |
| errors fixed by clinics | -424 | -1189 | -115 | -245 | -113 | -226 | -834 | -93 | 0 | -184 | -657 |
| %age fixed | 7% | 28% | 30% | 34% | 36% | 40% | 55% | 56% | 56% | 59% | 71% |

Table 2 – Analysis of PRISM registration errors since 7th December 2022

- **5.7.** So far 71% of those errors added in December have been corrected. It is important to also note that the rate of correction by clinics varies substantially week on week.
- **5.8.** Behind the scenes there has been significant liaison and encouragement from the register team to clinics to address errors. We are undertaking a reconciliation of the remaining clinics and errors that need to be fixed from this tranche.
- **5.9.** We are now at the stage where we will release to clinics the second backdated tranche of validation errors that are required to be fixed for OTR and CaFC. These relates to cycle errors incurred in PRISM and each validation rule has been carefully checked to ensure the backdated errors are valid and editable in PRISM.
- **5.10.** We are communicating to clinics on this second tranche in the February Clinic Focus and will then release approximately 6700 backdated cycle errors for clinics to correct. We will monitor and support clinics as we have done for the registration backdate.
- 5.11. The final validation backdate will involve cycle errors incurred in EDI which will need to be fixed in PRISM. Work to assess and check this backdate will commence in March. We hope to release this final backdate in May.

Assessment of 'validated data' for CaFC

- **5.12.** As per our planning assumption, we are still on track to make an assessment of "to what extent 'validated data' is sufficient to run a CaFC which will be possible once leading clinics has fixed their backdated errors" within the timescales we had originally planned (see 1.2 and 2.1 above)
- **5.13.** This assessment will be made during May and June 2023 which will allow us to understand the level of subsequent CaFC verification activity required after clinics have corrected their validation errors.
- **5.14.** Consequently, we are still on track to advise by the end of June an accurate publication date for the first CaFC through PRISM within the best and worst scenarios we have previously advised.

6. Update on resources on PRISM

Employed resource

- **6.1.** We currently have two employed developers and two employed data analysts working on PRISM and register data. New starters have picked up the complexity of each well, and as previously stated, we believe the resilience of these teams has been significantly strengthened.
- **6.2.** In November 2022, we reported to AGC that our contracted PRISM support officer had declined to apply for the vacant testing analyst role and that we would keep this recruitment on hold. Subsequently it was agreed with executives to recruit for this role, and in February 2023 we appointed an employed testing analyst with 20 years testing experience.

Contracted resource

- **6.3.** The contract for the PRISM support officer and operational expert in PRISM has been extended to the end of June 2023. During this time handover activity is being conducted to our new employed testing analyst. The HFEA Head of IT will be closely monitoring this transition.
- 6.4. The contract for the PRISM support manager's contract has also been extended to June 2023 on a two day a week basis, to continue ongoing oversight of the overall PRISM plan and PRISM troubleshooting, managing the re-establishment of data functions through PRISM, prioritisation of PRISM developments, and acting as the managerial interface for new and current API system suppliers and future API migrations.
- 6.5. The arrangement for our longstanding contracted data developer remains to retain them at 3 days per week until March 2024. Close to retirement age, this individual deals with all matters relating to the underlying PRISM database, PRISM validation and reporting, HFEAID and Person ID, and CAFC verification reports. They also deal with HFEA's billing system and Epicentre and is currently building the important proof of concept for extracting OTR data (see 3.2 above).
- 6.6. It remains our plan that the 3-month block of development work on OTR reports scheduled to start in May 2023 also serves as a handover of all PRISM reporting functions and would mark the start of an 11-month staged handover of all technical functions covered by this contractor.

7. AGC recommendations

7.1. AGC are asked to note:

- 1. The latest position on our plan and that we remain on track for data, developers and clinics.
- 2. That we are making particularly good progress towards delivering the requirements for OTR reporting by the end of July 2023.
- That our data team are necessarily balancing work on OTR/CaFC and supporting API migrations at clinics, and that this is being closely monitored by the PRISM programme board.
- 4. That clinics are continuing to fix their validation rules essential for CAFC, although the level of error fixing fluctuates and is being closely monitored by the register team.

5. We are on track to release to clinics all the backdated validation errors required for CaFC, and consequently are on track to advise an accurate publication date between our best and work estimates by the end of June 2023.



Resilience, Business Continuity Management and Cyber Security

| Area(s) of strategy this paper relates to: | The right information – to ensure that people can access the right information at the right time | | | | | |
|--|--|--|--|--|--|--|
| Meeting: | AGC | | | | | |
| Agenda item: | 11 | | | | | |
| Meeting date: | 14 March 2023 | | | | | |
| Author: | Martin Cranefield, Head of IT and Neil McComb, Head of Information | | | | | |
| For information or decision? | For information | | | | | |
| Recommendation | The Committee is asked to note: | | | | | |
| | Infrastructure improvements | | | | | |
| IT security changes | | | | | | |
| | Data backup review | | | | | |
| | Application penetration testing | | | | | |
| | Current position on Data Security and Protection Toolkit | | | | | |
| Implementation date | Ongoing | | | | | |
| Communication(s) | Regular, range of mechanisms | | | | | |
| Annexes | 7a –HFEA Risk Strategy, 7b – Operational risk register and Top 3 risks screenshots, 7c – Risk appetite statement, 7d strategic risk register | | | | | |
| Organisational risk | □ Low □ High | | | | | |

1. Introduction and background

- 1.1. In recent months, AGC has received regular and detailed updates on Resilience, Business Continuity Management and Cyber Security, in line with the strategic risk register.
- **1.2.** This paper provides an update on IT infrastructure and cyber security in a number of areas.
- 1.3. It also includes an update on our current approach to submitting evidence for next year's Data Security and Protection Toolkit

2. Infrastructure improvements

IT security changes

2.1. As part of the audit and NCSC's recommendations, we were advised to enable DMARC (Domain-based Message Authentication Reporting & Conformance) setting on our domain name hfea.gov.uk to prevent unauthorised email servers on the internet from sending out malicious emails purporting to be from HFEA. On 2nd March we moved our DMARC policy to 'quarantine' as per the recommendations and we continue to closely monitor email flow to ensure email deliverability is as expected.

After a successful evaluation we have placed an order for Mimecast who offer advanced malicious email filtering and security services. We are waiting for Mimecast to provide availability dates for their installation team to start integrating their service into HFEA's environment. Mimecast offers the ability to send large files to external parties with tight security controls when required on an ad-hoc basis. Their service also offers email phishing training to end users by simulating phishing attacks and can identify users which are more prone to fall prey to malicious emails and subsequently target them for further training.

Data backup review

2.2. On 27th February the infrastructure team conducted the data discovery scan of HFEA's systems with MTI, a supplier recommended by DHSC to provide independent assessments on data backups. We are now waiting for their findings and recommendations, if any, for us to implement. We will also review the backup data retention periods and make any adjustments where necessary.

Application penetration testing

2.3. We plan to instruct a pen test supplier to conduct penetration tests on our application infrastructure in the coming months, which will cover our web-based services such as HFEA portal and PRISM. With regards to PRISM, only the front-end of PRISM (which standalone clinics use) has undergone penetration testing and we are looking to include the API in the testing scope. Clinics submitting via EPRS suppliers use API to submit data to us.

3. Data Security and Protection Toolkit (DSPT)

Background

- 3.1. AGC will recall that the Data Security and Protection Toolkit (DSPT) is an online self-assessment tool that allows organisations to measure their performance against the National Data Guardian's ten data security standards. We have completed our submission for 2020/21 and are now preparing for 2022/23.
- **3.2.** This will be our second submission and we expect our experience of last year to proof helpful in this year's performance.
- 3.3. In 2020/21 the HFEA the HFEA was in category 2 of the list of organisations who completed the DSPT. This year NHS digital have raised the bar and moved the HFEA into category alongside NHS trusts and CCGs.
- 3.4. This means that there are now 113 mandatory evidence items out of 133 in total to complete. This is over 20 more than last year and will require a significant amount of work for the IG manager and Head of IT.
- 3.5. In a recent webinar, NHS Digital said that they will increase the work year-on-year as they re-categorise non-mandatory items as mandatory. This may have resourcing implication in the future.

Next steps

3.6. The next IG and Security Steering Group will meet on 6th March 2023 and will focus primarily on our DSPT submission. A verbal update will be given on the outcomes of this meeting.



Audit and Governance Committee Forward Plan

| Strategic delivery: | ☐The best care – effective and ethical care for everyone | XThe right information – to ensure that people can access the right information | ☐ Shaping the future – to embrace and engage with changes in the law, science and society |
|------------------------------|--|---|---|
| Details: | | | |
| Meeting | Audit & Governance C | ommittee Forward Plan | |
| Agenda item | 14 | | |
| Meeting date | 14 March 2023 | | |
| Author | Morounke Akingbola, I | Head of Finance | |
| Output: | | | |
| For information or decision? | Decision | | |
| Recommendation | The Committee is asked comments and agree the | | y further suggestions and |
| Resource implications | None | | |
| Implementation date | N/A | | |
| Organisational risk | ⊠ Low | ☐ Medium | ☐ High |
| | Not to have a plan risl or unavailability key o | • | e, inadequate coverage |
| Annexes | N/A | | |

Audit & Governance Committee Forward Plan

| AGC items Date: | 14 Mar 2023 | 27 Jun 2023 | 4 Oct 2023 | 7 Dec 2023 |
|---|---------------------|--|---|--------------------------------|
| Following Authority Date: | 22 Mar 2023 | 12 July 2023 | 15 Nov 2023 | 31 Jan 2024? |
| Strategic Risk Register | Yes | Yes | Yes | Yes |
| Horizon scanning | | | | |
| Deep dives | PBR -TBC? | | Increasingly onerous standards of corporate governance reporting materially impacting our ability to put the patient at the heart of all that we do | |
| Risk Management Policy ¹ | | Updated Risk Strategy/ Appetite statement | | Risk management strategy |
| Digital Programme Update | Yes | Yes | Yes | Yes |
| Annual Report & Accounts (including Annual Governance Statement) | | Yes – For approval | | |
| External audit (NAO) strategy & work | Interim Feedback | Audit Completion Report | | Audit Planning Report |
| Information Assurance & Security | | Yes, plus SIRO Report | | |
| Internal Audit Recommendations Follow-up | Yes | Yes | Yes | Yes |
| Internal Audit | Update | Results, annual opinion | Update | Update |

¹ Policy will have been reviewed by the Executive, including updated appetite statement for Authority approval.

| AGC items Date: | 14 Mar 2023 | 27 Jun 2023 | 4 Oct 2023 | 7 Dec 2023 |
|---|--|------------------------|---|-----------------------------------|
| | | approve draft plan | | |
| Whistle Blowing, fraud (report of any incidents) | Update as necessary | Update as necessary | Update as necessary | Update as necessary |
| Public Interest Disclosure (Whistleblowing) policy | Not due till Mar 2024 | | | |
| Anti-Fraud, Bribery and Corruption policy | Not due till Mar 2024 | | | |
| Counter-fraud Strategy (CFS), Fraud Risk Assessments (FRA) and progress of Action Plan | Counter- fraud Strategy (CFS) | | | |
| Contracts & Procurement including SLA management | Update as necessary | Update as necessary | Update as necessary | Update as necessary |
| HR, People Planning & Processes | | Bi-annual HR report | | Bi-annual HR report |
| Training | | | | Yes- see action from Dec 22 |
| Resilience & Business Continuity Management | Yes | Yes | Yes | Yes |
| Reserves policy | | | Yes | TBC |
| Estates | | Yes | | |
| Review of AGC effectiveness and terms of reference | | | Yes – update from 22/23 effectiveness review | Yes |
| Functional standards | Yes | Yes | Yes | Yes |
| AGC Forward Plan | Yes | Yes | Yes | Yes |
| Session for Members and auditors | Yes | Yes | Yes | Yes |

Suggested training for Committee Members

- Understanding good governance Dec 23 PR to take forward ideally external (RS/MA to check with HTA provider)
- Risk Management
- Counter fraud
- External Audit Knowledge of the role/functions of the external auditor/key reports and assurances.

Suggested deep dive topics as agreed at the 4 October 2022 meeting and not yet listed

- The effectiveness of performance management and risk (as this would be a year after the new system has been embedded).
- Staff retention
- Impact of communication
- HFEA's regulatory effectiveness if some or all of our ambition for legislative change fails.

Suggested deep dive topics as agreed at the 8 December 2022 meeting but yet to be decided when to have them

- OTR what it means for the organisation
- Retention recruitment- resource risk
- Legal risk and how it will be mitigated
- Public body review in March 2023?