Human Fertilisation & Embryology Authority

Audit and Governance Committee meeting

Date: 1 October 2024 – 10.00am to 1.00pm

Venue: Virtual meeting via Teams

Agenda item	Time
1. Welcome, apologies and declarations of interest	10.00am
2. Minutes of 26 June 2024 (CS) For decision	10.05am
3. Action log (MA) For information	10.10am
4. Internal Audit (JC) For discussion	10.15am
5. Progress with current audit recommendations (MA) For discussion	10.30am
6. External audit report (verbal report) (ND/DG) For discussion	11.00am
7. Risk Update • Strategic Risk Register – for discussion (SQ) • Committee discussion on potential horizon scanning items/items to add to deep dive discussion list (CS)	11.10am
8. Deep Dive discussion – near misses	11.25am
9. Digital projects • PRISM update - for information (KH) • Epicentre replacement (verbal report)- for information (MC)	11.40am
10. Resilience, business continuity management & cyber security (verbal) (MC/NMcC) • DSPT and GIAA audit 2023-24 (NMcC) For information	12.05pm
11. Fraud Risk Assessment (MA) For decision	12.15pm

Human Fertilisation & Embryology Authority

Item	Time
12. Reserves Policy (TS) For decision	12.25pm
13. Government functional standards (verbal report) (TS) For information	12.35pm
14. AGC forward plan (CS) For decision	12.40pm
15. Items for noting (verbal update) (TS) • Whistle blowing • Gifts and hospitality • Contracts and Procurement For information	12.45pm
16. Any other business (CS) • Committee effectiveness review – verbal update from Chair	12.50pm
17. Session for members and auditors only	
18. Close	

Next Meeting: Friday 6 December 2024 (meeting in morning and training session after lunch)

Human Fertilisation & Embryology Authority

Minutes of Audit and Governance Committee meeting 26 June 2024

Details:			
Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Agenda item	2		
Meeting date	1 October 2024		
Author	Alison Margrave, Board 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 26 June 2024 as a true record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes			

Minutes of the Audit and Governance Committee meeting on 26 June 2024 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, Chair Julia Chain Alex Kafetz, Deputy Chair Anne-Marie Millar	
External Advisers	Dean Gibbs, KPMG – External Audit lead Holly Gaff, Senior Auditor KPMG Nick Dovan, National Audit Office (NAO) – External Auditor James McGraw, National Audit Office – Audit Team	Jo Charlton, Head of Internal Audit (Internal Auditor) – GIAA
Observers		
Staff in attendance	Peter Thompson, Chief Executive Tom Skrinar, Director of Finance and Resources Morounke Akingbola, Head of Finance Paula Robinson, Head of Planning and Governance Alison Margrave, Board Governance Manager Kazuyo Machiyama, Senior Research Manager (items 1-4 only)	Clare Ettinghausen, Director of Strategy and Corporate Affairs Martin Cranefield, Head of IT Kevin Hudson, PRISM Programme Manager

1. Welcome, apologies and declaration of interest

1.1. The Chair welcomed everyone present in person and online.

1.2. Apologies of absence were received from Rachel Cutting, Neil McComb, Shabbir Qureshi, Steve Pugh (DHSC) and Farhia Yusuf (DHSC).

1.3. Alex Kafetz stated that he had a declaration of interest for any discussions regarding member appointments, as his first term is coming to an end in March 2025.

1.4. The Chair stated that she had a declaration of interest for a sub-section of agenda item 7 and that she would vacate the Chair for that item.

1.5. The committee noted the declarations of interest and were assured that appropriate measures would be put in place to handle any conflicts arising.

2. Minutes of the meeting held on 5 March 2024

2.1. The Chair introduced the minutes from the previous meeting which had been circulated to the members.

2.2. The Chair informed members that a proposed amendment to the last sentence of minute 4.1 had been received from the Head of Internal Audit. The proposal is that the minute would now read as:

The Head of Internal Audit – GIAA presented this item and provided an update on the internal audit work undertaken since the last Audit and Governance Committee meeting. The Code of Practice report and Payroll & Expenses report have both been issued as final. The Code of Practice audit had received a substantial assurance with no recommendations. The Payroll & Expenses audit had received a moderate assurance. For clarity she highlighted that management had disagreed with several recommendations for the Payroll & Expenses report and these had ~~not been included in the final report~~ been separately highlighted to the Committee for information. These recommendations would be noted as "Closed – management accept the risk".

2.3. With this amendment the minutes of the meeting held on 5 March 2024 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.

3.2. The Head of Finance informed the committee that the requirement of item 15.4 from October 2022 regarding the goodwill letters had been completed and could be removed from the action log but would still remain active on the audit recommendations tracker. The committee agreed to this proposal.

3.3. The Head of Finance informed the committee that the two items relating to audit recommendations remain active and gave an update on progress which had been made.

3.4. The committee noted that the publication of the GIAA ARAC Handbook had been delayed, with an expected publication date of end of June. As this publication will be highlighted to members via the supplementary pack issued by GIAA it was agreed to close this item.

3.5. The committee noted that action 7.22 from December 2023 and action 10.12 from March 2024 regarding the Epicentre replacement could be closed, as this had been added as a standing agenda item so the committee will receive a report at each of its meetings.

3.6. The committee noted that action 10.9 and 13.6 had been resolved and could be closed.

Decision

3.7. Members agreed the proposed amendments to the action log.

Action

3.8. Board Governance Manager to update the action log as agreed by the committee.

4. Internal audit report results and annual opinion

4.1. The Head of Internal Audit – GIAA presented this item and members were advised that on the annual opinion, a moderate assurance had been given and some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control.

4.2. The committee were informed that from the audits completed in the year, GIAA were able to conclude that the Authority's regulatory activities continue to be well managed and there has been an improvement in the Authority's digital and data activities during the year.

4.3. In response to a question from a member the Head of Internal Audit responded that the closure of outstanding audit recommendations would not have affected the overall rating of the annual opinion.

4.4. The Chair referred to the proposed review of the annual internal audit opinion ratings and descriptors and questioned that if a direction of travel indicator was in place what would be the HFEA's rating.

4.5. The Head of Internal Audit commented that the HFEA has such a small audit plan that it is not comparing like for like, year on year, but a direction of travel indicator would indicate a slight improvement although there continues to be similar themes arising from the audits.

4.6. The Chief Executive commented that the audit burden has increased substantially in recent years against a backdrop of tighter public spending. This administrative burden relies on the goodwill and time of staff to manage the additional work without additional resources. Due to the pressures on funding, completing the inspection of clinics and servicing the register would always be prioritised, rather than improvements to corporate services. The Authority Chair concurred with the Chief Executive's statement.

4.7. The Director of Corporate Affairs and Strategy referred to the two audits on statutory responsibilities which had achieved the highest ratings with only one recommendation arising from these two audits.

4.8. The committee discussed the audit on the Register Research Panel (RRP) noting that it had achieved a substantial rating with just one recommendation. The HEFA team were congratulated for this achievement.

4.9. A member expressed surprise at the limited rating for the Business Continuity audit noting that policies were in place and the VPN change had been dealt with efficiently.

4.10. The Head of Internal Audit responded that the VPN change had been dealt with by only a small number of staff without implementing the business continuity plan. As there had been no testing of the plan there was no guarantee that staff knew their roles and responsibilities.

4.11. The Director of Finance and Resources commented that the team had been disappointed with the rating received but would ensure that the recommendations are actioned, and that the business continuity plan is rolled out to all staff. He stated that there is a plan and timetable to complete these and the HFEA team were comfortable with the proposed plan.

4.12. The Chair drew members' attention to the GIAA supplementary pack highlighting that the ARAC handbook including the addition of "key questions ARACs should ask" will be published by the

end of the summer. She remarked that it is still possible to provide feedback on the review of GIAA annual internal audit opinions and drew attention to the forthcoming members' event on 7 November.

Decision

4.13. Members noted the annual opinion and themes identified in the internal report.

5. Progress with current audit recommendations

5.1. The Head of Finance introduced this agenda item.

5.2. The Head of Finance informed the committee that the number of recommendations had increased to 28 due to the completion of two Audits in March 2024 and the closure of some recommendations.

5.3. The Head of Finance spoke about the rationale for revising the target date for recommendation 1.2 regarding records management to December 2024 so that it aligns with the latest business continuity plan audit target date.

5.4. The Head of Finance spoke about the rationale for revising the target dates for the recommendations relating to review of KPI indicators and operational risk management to Autumn 2024 to allow for the new evidence which had been submitted to be reviewed and processed.

5.5. An update was provided on the training provision for Authority members and the committee were informed that discussions are being held with HR to ensure that these recommendations would be progressed by Autumn.

5.6. The Chair commented that evidence being submitted is still being rejected by GIAA and asked for confirmation that the HFEA is clear on the ask of the relevant recommendations. The Chair asked what level of confidence the staff had in clearing the outstanding recommendations.

5.7. The Head of Planning and Governance provided further evidence of the new system implemented for the KPI recommendations and stated that this is a rolling annual process which is just completing its first iteration. Whilst she could not give guarantees that all teams would have new SOPs in place by October, she was confident that the HFEA is managing any potential risk well through the process that is now in place. Further evidence of existing team SOPs and the timetable for completing the remaining teams' first KPI reviews had been submitted.

5.8. The Director of Finance and Resources spoke of the actions which had been taken to improve communications between staff and GIAA, so that the HFEA can understand the "ask" of the recommendations. He believed that there is now a shared understanding of the position and where there are any areas of uncertainty the HFEA will do what is appropriate for them as an organisation.

5.9. The Head of Internal Audit, GIAA, spoke of the clarity of the recommendations made by GIAA and believed that through the various meetings with HFEA staff there is now a clear way forward to closing off audit recommendations.

Decision

5.10. The committee noted the paper and the progress being made in completing the audit recommendations.

5.11. The committee agreed the amended target dates for several audit recommendations.

Action

5.12. The Head of Finance to update the report.

6. Annual Report and Accounts

6.1. The Head of Finance introduced this item, noting that members were sent a draft copy of the governance statement by email in March and the copy before this meeting incorporates the comments and suggestions made by members. The Head of Finance informed the committee that there were some minor typos contained in the report and these would of course be corrected.

6.2. The Head of Finance spoke of the proposed timeline for these documents to be signed by the Accounting Officer, the Comptroller and Auditor General before being laid in Parliament. The current aim is that these will be laid before the summer recess.

6.3. Members were given assurance that the Accounting Officer sign-off will be delayed until a revised timeline from NAO has been received and the testing around the provision for duplicate cycles had been concluded. The Head of Finance stated that this will ensure that the accounts are reviewed in light of any material developments prior to final sign-off and before being passed to NAO. Members were advised that if any material changes were required after the meeting they would be informed accordingly.

6.4. In response to a question the External Audit Lead, KPMG, explained why PRISM had an impairment for the previous year but not for the year currently being reported. He stated that now that the benefits of the PRISM system are being realised the HFEA will be able to conduct a benefit review.

6.5. The committee discussed that whilst the internal whistleblowing policy is well described the report lacks details on the external process for whistleblowing. The Chief Executive informed members that the HFEA website contains all the information relevant for whistleblowing and whilst inspectors are visiting clinics they also provide information to staff. He did not believe that the Annual Report was the correct vehicle for conveying this information but would review the text.

6.6. In response to a question the Chief Executive provided further information about the nature of clinic complaints that the HFEA receives, and its statutory duty as set out in the Act. He would review the text to see whether any revision is required.

6.7. The Chair referred to the EDI section and the additional reporting provided under this. She questioned whether additional protected and non-protected characteristic information could be included, e.g. senior staff ethnicity/age/disability/attendance at private or public school.

6.8. In response to a question the Chief Executive stated that all information regarding the HFEA's work regarding the proposals for modernising the Act are available on the website.

6.9. In response to a question regarding staff turnover the Chief Executive stated that whilst it is higher than the KPI target, it is manageable at present. The main reasons for staff leaving the organisation are the constraints of public pay and lack of internal progression due to the small size of the organisation.

6.10. The Authority Chair commented that the Annual Report is a statutory reporting tool and is not a communication tool for clinics and patients. As an organisation the HFEA is very transparent in its work and communication and the website is the main tool for conveying this information.

6.11. In response to a question the Chief Executive and Head of Finance provided further information about the source of the HFEA's funding, the monitoring of income throughout the year and the process for clinics to verify the data submitted through CaFC.

6.12. The Chief Executive provided further information about the clinics which had submitted duplicate data and the work of the team in addressing this.

Decision

6.13. The committee agreed that subject to NAO changes the Accounting Officer could sign the Annual Report and Accounts.

6.14. The committee delegated authority to the AGC Chair or Deputy Chair to approve any amendments proposed by NAO to the Annual Report and Accounts and to authorise the Accounting Officer to sign said documents.

Action

6.15. HFEA staff to continue liaising with NAO regarding completion of the Annual Report and Accounts for signing by the Accounting Officer.

7. External audit completion report

Regularity – overpayment of Authority member

7.1. The Chair declared an interest in this matter and vacated the meeting for discussion on this item.

7.2. The Deputy Chair introduced the item regarding overpayment of an Authority member due to the ambiguous nature of the remuneration set out in the appointment letter issued by the appointments team at DHSC. The error was discovered on receipt of the Authority member's re-appointment letter and the HFEA has agreed an action recommended by the NAO that should prevent this situation arising again.

7.3. The External Audit Lead, KPMG, provided further information to support their findings and conclusion on this item.

7.4. The Chief Executive Officer provided the committee with management's position on this matter and the legal advice obtained.

7.5. The External Auditor, NAO, informed the committee that NAO had consulted with the Comptroller and Auditor General on this matter and they were comfortable with the level of transparency in the Annual Report and Accounts.

Decision

7.6. The committee were content with the disclosure in the annual report due to the ambiguous nature of the appointment letter issued by DHSC (ie that it was a genuine error) and that the payments were made and received in good faith.

External audit completion report

7.7. The Chair was invited back into the meeting and resumed position as Chair.

7.8. The External Audit Lead, KPMG, referred to the report before the committee and expressed his thanks to the management and finance team for their support in this work.

7.9. He provided further information about the extra work being undertaken regarding the duplication of billing. The committee were informed that approximately 75% of this work had been completed and whilst it cannot be guaranteed to be completed before the Authority meeting it should be completed to allow for the documents to be laid before recess.

7.10. The Senior Auditor, KPMG, informed the committee that the work regarding the presumed risk of management override of controls is still ongoing, but they had not identified any indications that bias has been applied.

7.11. The Senior Auditor referred to the adjusted misstatements and the effect these would have on the financial position. She drew attention to the internal control issues identified in the report and management's responses to these.

Decision

7.12. The committee accepted the identified misstatements and endorsed management's reasons for not adjusting the misstatements.

7.13. The committee delegated authority to the AGC Chair or Deputy Chair to approve any amendments proposed by NAO/KPMG to the audit certificate and letter of representation and to authorise the Accounting Officer to sign said documents.

Action

7.14. HFEA staff to continue liaising with NAO/KPMG regarding completion of documents.

8. Strategic risk

Strategic risk register

8.1. The Head of Planning and Governance introduced the paper and provided further information on the updates which had been made to the strategic risk register. In response to a question, she confirmed that the strategic risk register was last presented to the Authority in November 2023.

8.2. The committee discussed each section:

- Governance – the committee questioned whether the legal regime that the HFEA operates within is keeping pace with developing trends in the fertility sector, and whether clinic whistle blowers might be more likely to come forward if they knew the HFEA had a more nuanced set of powers to act.
- Information – in response to a question the Director of Strategy and Corporate Affairs informed members of the social media strategy which is additional to the communications strategy.
- Information 2 – the committee discussed the progress in clearing the waiting list for OTR applications, noting that this risk remains open. It was expected that the risk level would improve over time, but at this stage it was too early to alter the scores.
- Operational – the committee were pleased with the addition of the CaFC sub-risk and discussed the Epicentre project.

- People 1 – in response to a question the Chief Executive stated that agency staff could be used to fill knowledge gaps when they arise but this affects only a handful of roles.
- People 2 – the committee asked management to look at the wording of the sub-risk as the induction process for new members is robust and sufficient. Management agreed to make it clearer that the issue was the time it takes to upskill the new members before they can serve on certain committees, and the timing of appointment announcements, rather than the quality of induction arranged by the HFEA.
- Reputational – consideration could be given whether to include changes within the fertility sector which are outside the remit of the HFEA, for instance the growth in online services. Management agreed to reflect on this and consider whether the impact of the changing market should be included in the risk register.
- Security – in response to a question, members were provided with further information about how clinics interface with the HFEA's system. The committee questioned whether the text should recognise the improvements that were being made as a result of the business continuity audit.
- Strategy – the committee agreed that this risk could be closed.

Horizon scanning

8.3. The Chair informed the committee that this agenda item is for members to raise topics which could affect the HFEA in the future but are not yet reflected in the strategic risk register.

8.4. A member stated that they had attended the GIAA ARAC members event on fraud and whistleblowing and this had led them to question the external whistleblowing policy and whether this is robust enough. The office has provided them with information which had satisfied this question and this was shared to the committee.

8.5. The Chair asked management to consider whether there is any connection between whistleblowing reports and non-compliance identified by the HFEA's inspection process. Dependant on the outcome of this review this could be a future deep-dive discussion topic for the committee.

8.6. The committee discussed and agreed the future deep-dive discussions on near-misses in October 2024 and CaFC in March 2025.

Decision

8.7. Members noted the strategic risk register and that management will update the committee whether there is any connection between whistleblowing reports and non-compliance identified by the HFEA's inspection process.

9. Digital projects

PRISM update

9.1. The PRISM Programme Manager presented the paper and spoke of the challenges which had been encountered since the start of the CaFC verification process.

9.2. He spoke to the five conditions that need to be met for publishing CaFC as detailed in the table contained in the paper. He reiterated that the PRISM programme board receives weekly reports on these conditions.

9.3. He spoke about the pace of correction being completed by clinics, which is far slower than anticipated with 38% still outstanding. He spoke about the challenges faced in chasing clinics.

9.4. He referred to the duplication of cycles due to some clinics sending the HFEA cycle information for the same treatment more than once. He spoke of the detailed analysis which had been undertaken and that following discussions Mellowood (the third party provider of systems to the clinics involved) staff would attempt the de-duplications, rather than the clinics or the HFEA.

9.5. The committee discussed whether there were other options available to encourage clinics to complete the verification process.

9.6. The PRISM Programme Manager referred to the current technical challenges in completing the CaFC verification reports and spoke in detail to the three main categories these fall into.

9.7. In response to a question regarding the decision to not recruit a second data analyst until after CaFC is completed the PRISM Programme Manager provide further information to support this decision and stated that the job description will be reviewed when recruitment progresses to attract specialised individuals.

9.8. The PRISM Programme Manager referred to those clinics on special support paths and whilst CRGH was on a positive trajectory, concern was expressed at the pace of completion by ARGC.

9.9. The committee noted the clear mitigation plans in place to ensure CaFC publication.

9.10. The PRISM Programme Manager concluded his report by speaking about the publication options and timescales. In response to a question the Chief Executive stated that the decision to publish CaFC does not need ministerial approval.

Epicentre replacement

9.11. The Head of IT informed members of the work already undertaken and the proposed timeline for the project. He stated that the proposed timelines have been sent to DHSC, but as yet no response had been received.

Decision

9.12. The committee noted the progress on CaFC since the start of the verification process as of March 2024 and the mitigations that are now being put into place given that the pace of CaFC verification by clinics, and the resolution of CaFC complexities by internal technical staff are both slower than originally envisaged.

10. Resilience, cyber security & business continuity

10.1. The Head of IT presented the paper and informed the committee that he had attended a number of webinars related to the recent ransomware attack affecting several NHS trusts.

10.2. The infrastructure penetration testing had now been completed and there were no high-level vulnerabilities, other than Epicentre where mitigations were already in place.

10.3. The Chair informed members that going forward this item will be amended to “update as necessary” on the AGC forward planner, meaning that a report will only be given when there is something to report on. The committee agreed with this proposal.

Decision

10.4. The committee noted the report with thanks to the Head of IT and Head of Information.

11. SIRO Report

11.1. The Director of Finance and Resources introduced the paper and stated that he had held the role of the Senior Information Risk Officer (SIRO) for the past 10 months. This role holds responsibility for managing the strategic information risks that may impact on the HFEA's ability to meet corporate objectives and provide oversight and assurance to the Executive and the Authority.

11.2. He explained that in this role he works closely with the Head of IT, Head of Information and the Information Governance and Records Manager and has built a good working relationship with all.

11.3. He referred to the assurances provided in the paper and stated that annex A of the report is an assessment of the HFEA's compliance with the Security Policy Framework as at 31 March 2024.

Decision

11.4. The committee noted the SIRO report and the assurances contained within the report.

12. Governmental Functional Standards

12.1. The Director of Finance and Resources informed the committee of the progress which had been made using the self-assessment tools and that a more formal approach to this work will be taken to a forthcoming Corporate Management Group meeting.

12.2. The committee were informed that the GIAA audit on governmental functional standards will commence in Q2.

Decision

12.3. The committee noted the verbal report.

13. HR report

13.1. The Head of HR introduced the paper and informed members that 9 staff members had volunteered to be EDI champions and regular meetings had been established to progress this work further. This area of work is also supported by an Authority member as an EDI champion.

13.2. The Head of HR referred to the launch of the well-being breaks and spoke of the uptake of these. Extensive well-being material had been provided on the HFEA's intranet. It was reported that these breaks had been received very positively by the staff.

13.3. The committee congratulated the Head of HR on the work undertaken, especially regarding the introduction of well-being breaks.

Decision

13.4. The committee noted the verbal report.

14. Estates

14.1. The Director of Finance and Resources informed the committee that an occupancy and usage review of 2RP had recently taken place. He spoke about the level of desk usage and the

proposals that other ALBs could be brought into 2RP. He cautioned that whilst there is desk availability the meeting rooms are extensively used and very busy.

14.2. In response to a question the Chief Executive said that the Executive had not picked up on any reluctance from staff to attend the office and the uptake for the excess fares provision due to the office relocation had been limited. The Chief Executive reminded the committee that the HFEA has the provision of home-worker contracts.

14.3. The Director of Finance and Resources informed the committee that the current lease at 2RP expires at the end of 2030 and discussions will soon commence on what could happen when the lease expires.

Decision

14.4. The committee noted the verbal report.

15. AGC forward plan

15.1. The Head of Finance introduced the paper and stated that this had been amended to include a full year of meetings.

15.2. The Chair reminded members that the December 2024 meeting would also include a training session in the afternoon.

16. Items for noting

16.1. Whistle-blowing

- Members were advised that there were no whistle-blowing incidents.

16.2. Gifts and Hospitality

- Members were advised that there was nothing to report at this meeting.

16.3. Contracts and Procurement

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

17. Any other business

17.1. The Chair reminded members that the next meeting is being held on 1 October and given the previous decision regarding the cycle of AGC meetings, this meeting would be held virtually.

17.2. The Chair informed members that the schedule of meetings for 2025 would be:

- Tuesday 4 March 2025 – virtual meeting
- Tuesday 17 June 2025 – in person meeting
- Tuesday 14 October 2025 – virtual meeting
- Wednesday 3 December 2025 – in person meeting

The meeting noted that the date of the October 2025 meeting may change, and the office would confirm this as soon as possible. (**Post meeting note** October 2025 meeting date confirmed as Tuesday 14 October but meeting time changed to 1.30pm)

17.3. There being no other items the Chair thanked all for their participation and formally closed the meeting.

Chair's signature

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

Signature

Chair: Catharine Seddon

Date: 1 October 2024

Human Fertilisation & Embryology Authority

AGC Action log

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science, and society
Meeting	Audit and Governance Committee
Agenda item	3
Meeting date	1 October 2024
Author	Morounke Akingbola (Head of Finance)
Output:	
For information or decision?	For discussion
Recommendation	To note and comment on the updates shown for each item.
Resource implications	To be updated and reviewed at each AGC
Implementation date	2024/25 business year
Communication(s)	
Organisational risk	☐ Low ☒ Medium ☐ High

Date and item	Action	Responsibility	Due date	Revised due date	Progress to date
3 October and 7 December 2023 Items 5.18 and 5.12	To add to the AGC action log a review of agreeing, timetabling and providing evidence for Internal Audit recommendations within 12 months. The Executive to formalise more effectively the process to close off audit recommendations.	Director of Finance and Resources	October 2024		**Update:** This has been added to the action log and will be reviewed in October 2024. **Update Jan 2024:** Process discussed and agreed with GIAA and HFEA SMT. **Update May 2024:** Agreement of approach with CMG. GIAA Head of Internal Audit Health attended CMG for discussion. **Update Sept 2024:** documentation covering the agreed approach with GIAA to be presented to AGC in October 2024
7 December 2023 Item 5.7	Decision deferred to June meeting regarding accepting at risk audit recommendations 2.1 and 2.4. If the additional evidence is rejected by GIAA this is to be brought to the June AGC for consideration.	Risk and Business Planning Manager/Head of Finance	June 2024	October 2024	**Update June 2024**: A meeting has been held with GIAA to discuss our various pieces of evidence in relation to all the outstanding audit recommendations. We have agreed to collate and submit some additional evidence. **Update Sept 2024:** Further evidence was submitted following the June meeting, with more sent in July and September. We await the outcome, but staff are satisfied that the risks relating to these recommendations have been well managed and believe that these recommendations (and others) should now be closed.
26 June 2024 Items 6.15 and 7.14	HFEA staff to continue liaising with NAO/KPMG regarding completion of the Annual Report and Accounts for signing by the Accounting Officer.	Finance Team	July 2024		**Update Sept 2024:** Completed and the Annual Report and Accounts were laid July. This action is complete and can be removed.

Human Fertilisation & Embryology Authority

Deep dive discussion – near misses

Details about this paper

Area(s) of strategy this paper relates to:	The best care/ The right information/ Shaping the future
Meeting:	AGC
Agenda item:	8
Meeting date:	01 October 2024
Author:	Shabbir Qureshi, Risk and Business Planning Manager
Annexes	Annex A – Mitigations

Output from this paper

For information or decision?	For information
Recommendation:	AGC is invited to consider the mitigations in place to reduce the likelihood of near misses.
Resource implications:	None at this stage
Implementation date:	N/a
Communication(s):	N/a
Organisational risk:	Low

1. Introduction

1.1. At the AGC meeting on 7 December 2023 it was agreed that a deep dive paper be presented to this meeting on internal near misses reported under our internal incident procedure.

1.2. The paper does not cover incident reporting from clinics.

2. Overview

2.1. The HFEA risk management strategy outlines the internal incidents reporting procedure. The aim of our incidents system is to enable the HFEA to understand and learn from internal adverse events that cause, or have the potential to cause, harm to the HFEA and/ or patients, and which need corrective action.

2.2. Near misses are categorised as occurrences where harm was prevented or avoided, either by chance or appropriate intervention.

3. Reporting procedure

3.1. Situations where something untoward has happened are reported using an online form, which has been accessible from the HFEA intranet since January 2023. Prior to this, a Word document was completed and emailed to the RBPM. At the point of reporting the situation, the staff member filling in the form selects internal incident/ data breach/ near miss/ not sure. Following the subsequent review of the report, and/ or an investigation, the incident may be re-classified where appropriate.

3.2. Where a data breach is confirmed, a separate process is instigated. This is managed by the Information Governance and Records Manager and the SIRO.

4. Incident reporting data

Year	Incident	Data breach	Near miss	Total incidents	Not an incident
2019	8	4	1	**13**	0
2020	10	3	3	**16**	0
2021	15	3	8	**26**	0
2022	5	3	0	**8**	1
2023	1	5	2	**7**	1
2024	6	3	5	**14**	1
Grand Total	**45**	**21**	**19**	**85**	3

4.1. The table above shows the number of reports of each type in each calendar year since January 2019, when the internal incident reporting system was created. The reports which were re-classified as 'not an incident' after review are not included in the overall totals.

4.2. The total number of near misses is 19 over the last six years, an average of 3 per year. This includes two instances where near misses were initially reported as an incident and a data breach but were later deemed near misses.

4.3. Lessons learned from these near misses can be categorised into the following areas:

- Learning applies to a specific team only; generally, a process change/ update is required.
- Learning applies to most, if not all teams; this may include process changes/ updates for one or more teams and wider communication of the learning, e.g. through Corporate Management Group (CMG).
- Lessons learned are not directly to do with the incident itself. For example, if it has been a true 'one off' scenario where it is unlikely that anything similar could or would re-occur, or where an existing process should have prevented the incident (or near miss) if it had been correctly followed, but for some reason it was not. These are usually 'human errors'. In these instances, it is important to understand what factors led to the human error – if a root cause can be determined, it may be possible to put measures in place that would eliminate the possibility of the same human error happening again in the future. However, it is also the case that occasionally human error will still occur despite procedures, and knowledge of procedures, being in place – for example if the individual was distracted in the middle of a task.

5. Near miss analysis

Near miss type	Number	Details	Notes
Process update required	13	These were specific to a single or linked team and required updates to existing processes to prevent reoccurrence.	Lessons learned do not apply to the wider HFEA as these scenarios are only applicable to a limited number of roles/ teams. The team(s) responsible have made the appropriate changes to their policy/ procedure to prevent reoccurrence of the incident.
Existing process prevented incident	3	Two linked teams were involved in these situations. As per the procedures in place, information passed to the second team goes through a final QA process and this prevented harm being caused.	As above, lessons learned are specific to these teams. In these cases, processes already introduced to prevent incidents have been successful.
'Human' errors	3	These related to email use. One where BCC wasn't used, the other two where an incorrect external email address was used.	The BCC incident was initially reported as a data breach, as the email addresses revealed the names of the individuals. However, as this information was already in the public domain, it was reclassified as a near miss. The other two were due to the 'auto complete' system in Outlook when sending an email. In both instances, no confidential data was

shared, and the accidental recipients deleted the emails.

5.1. None of the near misses where process changes were required subsequently led to reports of further near misses or incidents.

5.2. Two of the near misses involved multiple issues. Following the discovery of the event, previous instances were then also identified but all were reported at once. For both such reports, process changes were made.

6. Mitigations

6.1. The only repeated near misses are where errors occur when sending emails. Historically, these have been mainly where BCC wasn't used when sending to multiple recipients, or where the message was sent to the wrong recipient, usually due to the Outlook auto complete system offering up incorrect options, and these accidentally being selected.

6.2. All teams that regularly send emails to external and/ or multiple recipients have SOPs where these scenarios are noted, and best practice is followed.

6.3. CMG also discuss incidents and near misses and IT have investigated options to limit the maximum number of recipients to emails and limit the auto complete feature in Outlook. As limiting recipients would have other undesirable impacts, this option is not currently feasible as it would lead to other risks when completing tasks.

6.4. Once the planned lessons learned web page is launched on the Hub (intranet), an email 'tips' section will be in place which will show staff how to disable auto complete, create a delay before messages are sent and show the BCC field when sending emails.

6.5. The near misses where secondary QA is already in place demonstrates our internal systems are fit for purpose.

6.6. Where processes have been updated or developed, following near misses (and for most incidents and data breaches), repeat occurrences have not been reported.

7. Points for discussion

7.1. Due to the small volume of incidents overall, especially near misses, reporting on lessons learned is a challenge to the wider HFEA as this poses the risk of identifying the person responsible for raising the incident. We are keen not to introduce a blame culture – the point of the system is to enable learning and improvement, which is a positive thing. In many cases, the actions to prevent a reoccurrence were carried out either as part of the initial actions to respond to the incident or near miss when it occurred, or during the investigation process.

7.2. As indicated above, a web page is under development for the HFEA intranet where lessons learned from incidents will be published; this will also hold links to the incident reporting and data breach reporting forms, along with the risk strategy.

7.3. AGC is asked to comment on the mitigations.

Human Fertilisation & Embryology Authority

Digital Projects / PRISM Update August 2024

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:	9
Meeting date:	1st October 2024
Author:	Kevin Hudson, PRISM programme manager
Annexes	

Output from this paper

For information or decision?	For information
Recommendation:	To note the current status on CaFC since July and particularly the challenges involved with issuing certain essential verification reports, that clinic correction rose after introducing new communications but that it is too early judge whether this is a sustained effect, and the reasons we are now suggesting that CaFC will not complete until 2025.
Resource implications:	
Implementation date:	Originally to deliver a first CaFC through PRISM by no later than October 2024, but now not likely until at some stage during the first half of 2025 with the next CaFC (data for 2024) to be published later in that same calendar year.
Communication(s):	
Organisational risk:	Medium

1. Introduction and recap from last meeting

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, 720,099 units of activity have been submitted through PRISM.

1.2. At the June meeting we reported that:

- We had commenced the CaFC verification process at the beginning of March 2024, with the release of 15,000 missing live birth outcomes and early outcomes.
- However, progress on clinics addressing their verification errors on live birth outcomes and early outcomes had been slow.
- We had also identified 8,000 cycle duplicates which were mainly caused by API activity sending HFEA records more than once and de-duplication activity was underway.
- Our expert data analyst was working through the technical challenges of completing the final elements of the remaining PRISM verification reports.
- The ARGC group and clinic 0044 CRGH were on special support pathways either due to catching up on PRISM or a large number of issues. In June CRGH moved from IDEAS API submission to manual submission.
- Based on the experiences of CAFC verification to this point, the team were planning to undertake a 'relaunch' of CAFC verification around new verification reports to be issued at the end of June, followed up by a high level of targeted communication to clinics with large numbers of exceptions.
- There were options for publication of CAFC – either full or partial – and that we would consider this further over the summer.
- We advised we would assess the impact of the 'relaunch' at the end of August and advise AGC further at the next meeting at the start of October.

1.3. We summarise the results of the CaFC relaunch in the following sections of this report, but AGC should note that we are not in a position the confirm that CaFC is ready, and indeed because of particular technical challenges experienced in recent months relating to the complexity of PRISM, the situation is in many regards less positive that when last reported in June.

1.4. In summary, the team no longer think that there is any likelihood that the 2023 CaFC will be published during 2024. Instead, we are forecasting that it will be during the first half of 2025 with the 2024 CaFC published later that calendar year.

2. The 'CaFC relaunch' activity undertaken during July and August

2.1. In June we reported to AGC that as we were experiencing challenges with both the pace of clinic correction of verification issues, and our technical team's resolution of the final complexities, we have considered a mitigation strategy which will endeavour to create greater overlap between clinic and technical activity in order to ensure a faster than otherwise publication of CaFC.

2.2. These mitigations involved:

- Our data analyst suspending technical work on the trickier areas of quality metrics and legacy data, so that he can check the remaining draft reports and identify the ones that are safe to release immediately.
- Considering how to release the raw data reports in 'draft form' so that clinics can check the number of records that we intend including in CaFC, and particularly highlight if they find omissions.
- Doing a full 'relaunch' to the sector so that with these new releases we can reinforce the importance for clinics of quickly addressing their CaFC issues.
- Following up directly every week with clinics with more than 100 exceptions on their latest CAFC exception status and discussing any clinic impediments that are being experienced.
- We anticipated that whilst this was happening, more time would be allowed for our data analyst to focus on the CaFC complexities relating to the last quality metrics and legacy data, but which will take less time for clinics to review because the quantities involved are smaller.

2.3. AGC should note that we define 'exceptions' as any error in the submission from the clinic that needs to be corrected for either CaFC, OTR or 10 family limit and any of the other uses to which HFEA register data is subsequently applied. This may include such issues as missing outcome information, incomplete treatment data and missing fields, duplicated records, and missing links between the data, particularly when gametes are frozen, stored and then thawed for a subsequent fertility cycle.

2.4. Once we have completed verification for CaFC, we mark the data from that year as 'verified' and it is used further by the OTR, Register and Intelligence team and external researchers.

2.5. To facilitate more work on communicating with clinics and detailed testing and analytical challenge of verification reports, the PRISM programme manager increased his days from two to three days per week. This was covered in budgetary terms by the fact that the second data analyst post remains vacant.

2.6. In summary the results of the 'CaFC relaunch' were as follows.

- We successfully launched 8,500 further exceptions at the start of July for clinics to address.
- During July there was good progress in addressing exceptions although this dropped off in August. Staff leave at clinics during August could account for this.

- Critically, because of the complexities involved, the team have struggled to complete the verification report around embryo thaws, which would have included a further 12,500 exceptions. This report has failed user testing three times and will not be launched until October at the earliest.
- Consequently, the anticipation that our data analyst could move on to focus on the remaining CaFC complexities has not yet happened.

2.7. The impact of this is discussed in detail in the following sections. This also impacts any anticipated timescale on when CaFC will be published which we will discuss later in the report.

3. Progress on completing CaFC verification reports

3.1. In the previous AGC report we advised that:

- There is a high risk that because of the complexity of PRISM, completing the remaining tasks for verification reports will take more time than expected.
- There is a low risk that the final complexities of these reports may force our data analyst to a stop, and they may not be completed. This latter risk will be highly problematic for CaFC.

3.2. Table 1 below, summarises the publication status of current CaFC verification reports, the quantities of exceptions involved and the CaFC years to which they relate:

Table 1: CaFC verification reports – summary of publication status of draft report.

Phase		Report No. / Description	Status	Exceptions		2020	2021	2022	2023
		Total		45,910		8,379	15,028	11,775	10,729
1	98	Cycles missing early outcome details	Published	8,687		1,943	4,522	867	1,355
1	96	Cycles missing outcome details	Published	6,862		718	789	1,616	3,738
2	111	Cycles missing any treatment details	Published	8,737		404	1,765	3,829	2,739
2	97	Duplicate registrations	Complete	464		150	190	87	37
2	104	Thaw cycle errors affecting inventory - Detailed	Current element of work	12,517		2,474	4,740	3,722	1,581
2	105	Cycles missing donor registration records	Analyst still to check	1,262		137	277	467	381
2	114	Patient age at cycle out of bounds	Analyst still to check	1,137		232	284	300	321
3	87	Egg thaw missing link to originating storage	Analyst still to check	2,156		708	847	416	185
3	86	Missing egg donation cycles based on egg batch ID	Analyst still to check	1,297		611	631	46	9
3	101	Missing cycle reason	Analyst still to check	1,005		433	322	197	53
3	93	Missing donor details based on Gamete source Type	Analyst still to check	512		102	142	136	132
3	99	Cycles missing cycle owner	Analyst still to check	296		62	166	24	44
3	106	Cycles missing fresh egg/embryo donation records	Analyst still to check	257		160	90	3	4
3	107	Cycles showing a fetal pulsation but missing transfer details	Analyst still to check	196		16	26	32	122
3	81	Fresh donated eggs used after 7 days of donation	Analyst still to check	112		78	28	4	2
3	84	IVF cycles where there are no linked registration details (orpl	Analyst still to check	99		33	66	-	-
4		Other draft exception reports		314		117	143	29	25
Summaries									
		Published		24,286	53%	3,066	7,076	6,312	7,833
		Complete awaiting publication		464	1%	150	190	87	37
		Checking currently in progress		12,517	27%	2,474	4,740	3,722	1,581
		Remaining Phase 2 (mainly PRISM)		2,399	5%	369	561	767	702
		Remaining Phase 3 (mainly EDI)		5,930	13%	2,203	2,318	858	551

3.3. Based on reports published to date, the report we are currently working on and those in draft for still to check, there 45,910 exceptions which clinics must address for the four CaFC years between 2020 and 2024.

3.4. Although exception reports are all written in draft form, the programme is asking our longstanding data analyst to check all verification reports for data accuracy before they are released. They are then subject to 'user testing' by the programme manager and tester to ensure that all reported exceptions are valid exceptions and that it is clear to the clinic when they look at PRISM what corrective actions need to be taken. The programme manager also writes additional guidance documentation for each report ahead of any publication.

3.5. AGC should note that our data analyst of 25 years HFEA experience has exceptional (and arguably unique) knowledge of complex fertility data and was the original architect of CaFC and its associated calculations and reports when it was first published in approximately 2005.

3.6. In July we successfully completed the verification reports for cycles missing treatment details and duplicate registrations. 54% of anticipated CaFC exceptions are now published to clinics.

3.7. However, since July we have encountered significant challenges in producing a report on thaw cycle errors that can pass user testing. This report by itself represents 27% of all CaFC exceptions.

Embryo thaws, missing storage links, and Data Dictionary discrepancies

3.8. Ensuring accurate information in the register about embryo thaws is essential to report comparative CaFC rates for donor treatments and, arguably more importantly, ensuring that on all future OTR enquiries, if a frozen embryo was thawed for a subsequent FET treatment, then the HFEA knows what gametes contributed to that embryo when the gametes were originally mixed, the embryo created and then frozen and stored.

3.9. In PRISM, since 2020, we have identified over 12,500 cases of thaws with missing storage links. This means that in these cases we do not know the gamete composition of the embryo thawed. This is mainly relating to clinics using the CARE and Meditex API solutions where they have sent us data without the appropriate links to previous storage records.

3.10. Indeed, PRISM allows the team to interrogate data to greater detail than was possible with EDI, and we can see there is a further 22,500 missing storage links for records earlier than 2020. Attempting to correct these earlier records will need to be a piece of work that is initiated after CaFC is completed.

3.11. Endeavouring to produce a report on this topic has been further complicated by a discrepancy between the PRISM data dictionary and General Direction 0005 in terms of the definition of a 'viable thaw'. Whist this is a very complex issue to describe, and the source of this discrepancy can be tracked back to the approval of the data dictionary in 2016, it means in practice today that clinics who are entering data directly to PRISM (and are following GD005) are entering data slightly differently to those clinics that use an API solution to submit records (which is following the data dictionary).

3.12. The practical impact of this is that any attempt to issue sector wide verification report around embryo thaws and ensuring clinics enter correct quantities, either reports large quantities of false and misleading verification instructions on either side. This would have resulted in large scale confusion and complaints at clinics. This is why this report has failed testing multiple times.

3.13. As of the start of September, our data analyst is taking his remaining annual leave and will then start on a further iteration of this report that will focus exclusively on missing thaws so we can properly alert clinics (particularly CARE and Meditex) to this issue and they can start actions on it.

3.14. However, our data analyst does remain concerned about the embryo accounting discrepancies. We will need to carefully risk assess this to make sure that if we chose to address this in a future CaFC cycle, and essentially leave embryo accounting 'unverified' at present, then that approach will not materially affect reported CaFC statistics at either high or detailed levels.

3.15. Addressing this discrepancy for embryo accounting in the future will be important as we report on embryo inventory for OTR and 10 Family Limit, and PRISM is structured in such a way that if, according to its records (not the clinic's), there is no gamete inventory, then it will prevent the clinics from sending any further records relating to that treatment.

3.16. We expect to publish this report on thaws with missing linkages during October 2024.

3.17. Note that publication of the thaws report will represent publication of 82% of all CaFC exceptions. Thereafter there is 5% of PRISM exceptions and 13% of EDI exceptions outstanding.

Other 'Phase 2' and 'Phase 3' reports

3.18. Phase 2 of the verification are all those reports which are primarily triggering exceptions for PRISM submissions since September 2021. These are the reports that will have 'CaFC longevity'. After the thaws report there are two further reports representing only 5% of total exceptions. These has been partially checked already and are not thought to contain the levels of complexity that we have experienced with the thaws report.

3.19. Phase 3 of the verification relates mainly to EDI errors in the CaFC period prior to September 2021. They account for 13% of all exception errors. These reports will be important to ensure that this period of EDI data is verified but may not be so important for future CaFC cycles. Our analyst has part developed the solution for this verification phase and will address it once phase 2 reports are complete and published.

Will PRISM complexities ever have an end?

3.20. In summary, we would stress that complexities of PRISM have been already alerted to AGC in the lessons learned report issued after publication, but the team are encountering further complexities particularly as they undertake the necessary deep dives into clinic data to prepare for CaFC.

3.21. But the team would also want to stress that once these verification reports are built, they 'stay built' for a large number of foreseeable years, just as original CAFC verification reports in EDI were used repeatedly for the subsequent 15 years that CaFC was published from EDI data. In

short this is a one-off transitional issue that once resolved will not impact on future CAFC updates.

4. Progress on clinics verifying their data for CaFC

4.1. So far during the CaFC verification, we have identified and issued 24,286 exceptions to be addressed by UK fertility clinics. As of the end of August 2024, six months since the launch of verification, 9,409 exceptions (39%) remain unaddressed.

4.2. Table 2 above shows the current status of how clinics have addressed those exceptions that have so far been issued to them. There are significant discrepancies between the different methods of submission, particularly direct entry (PRISM) versus API submissions (IDEAS, CARE and Meditex). When reviewing Table 2, AGC should note that there are still a further 21,000 exceptions to issue:

Table 2: CaFC verification exceptions – amounts outstanding as of the end of August 2024

	Exceptions at start of verification				**Current Exceptions**				*Percent remaining*			
Method of PRISM submission *(number of clinics)*	Missing early outcomes (1st Mar)	Missing outcomes (1st Mar)	Cycles missing any treatment details (1st Jul)	All verification reports	**Missing early outcomes**	**Missing outcomes**	**Cycles missing any treatment details**	**All verification reports**	*Missing early outcomes*	*Missing outcomes*	*Cycles missing any treatment details*	*All verification reports*
Prism *(37)*	**2,349**	**1,189**	**572**	**4,110**	**14**	**113**	**134**	**261**	***1%***	***10%***	***23%***	***6%***
Ideas *(38)*	**2,742**	**2,908**	**5,430**	**11,080**	**416**	**1,487**	**3,451**	**5,354**	***15%***	***51%***	***64%***	***48%***
Care *(15)*	**1,824**	**1,505**	**1,314**	**4,643**	**262**	**633**	**738**	**1,633**	***14%***	***42%***	***56%***	***35%***
Meditex *(8)*	**1,045**	**884**	**611**	**2,540**	**96**	**469**	**440**	**1,005**	***9%***	***53%***	***72%***	***40%***
Special *(4)*	**727**	**376**	**810**	**1,913**	**337**	**110**	**707**	**1,154**	***46%***	***29%***	***87%***	***60%***
	8,687	**6,862**	**8,737**	**24,286**	**1,125**	**2,812**	**5,470**	**9,407**	***13%***	***41%***	***63%***	***39%***

Pace of exception corrections

4.3. At the start of July, there were 40 clinics with more than 100 exceptions which started to receive weekly status reports to the PR and any other members of staff that the PR advised should receive this information.

4.4. From an average of 2,240 exceptions fixed per month prior to July, in July 3,666 exceptions were addressed but only 1,505 in August. This could be due to clinic staff holidays during August. The pace of corrections during September will provide clarity on whether this additional clinic support is proving effective.

4.5. Feedback from clinics has been that receiving this information has been helpful. However there have been clinics that have addressed their outstanding exceptions during August and others that have not changed during August.

4.6. Of the 40 clinics with more than 100 exceptions at the start of July, as of the end of August this figure has reduced to 30 clinics. These 30 clinics account for 73% of the 9,407 published exceptions that were outstanding at the end of August. We will review those remaining for further actions.

4.7. The team are also mindful that the level of clinic support will increase once we publish a completed thaws report and there will need to be quite a lot of technical support for clinics in addressing this particular issue.

Duplicated cycles

4.8. There has been good progress in de-duplicating the 8000 cycle duplications identified in May. Most of these relate to IDEAS clinics and over the summer Mellowood (the system supplier for IDEAS) has been undertaking a manual process to de-duplicate the cycles for these clinics.

4.9. All IDEAS clinics have now had their duplicate cycles addressed except 0307 Complete Fertility Southampton (250 duplicates) who are presently not allowing Mellowood access to the clinic's IDEAS system for general IT security issues.

4.10. All that remains in terms of duplicated cycles are those for 0044 CRGH (approx. 1000 duplicates still outstanding) who have moved to manual entry and are addressing the duplicates themselves and 0316 CRGW Wales (250 duplicates) which has been taken over by CARE.

5. Clinics on special support

ARGC

5.1. ARGC started submitting data to PRISM in February 2024. So far, they have made 2,013 submissions which is 27% of the expected CaFC catch-up totals for the group.

5.2. We have provided frequent updates to ARGC on the activity submitted and the need to increase volumes, but we haven't detected any marked increase since launch.

5.3. On current pace, ARGC will not catch up on their current CaFC submissions until March 2026, at which time 2024 and 2025 submissions will be outstanding.

5.4. We have observed that ARGC are concentrating on the smallest of their three clinics first. 0206 Reproductive Genetics Institute is now 85% complete. ARGC is soon to be in a position where one of its clinics has submitted sufficient data for the current CaFC but not the group as a whole.

CRGH

5.5. In early June 2024, 0044 CRGH, one of the largest UK fertility clinics, made a switch from IDEAS API submissions to direct entry into PRISM. They receive training on PRISM from the HFEA team.

5.6. So far, manual submissions from 0044 CRGH seem on track, and they are addressing outstanding CaFC verification including approximate 1,400 cycle duplicates. These are reducing but not as fast as has taken place for other IDEAS clinics.

5.7. Our HFEA developer continues to provide close support for this clinic.

6. Impact on publication dates for the 2023 CaFC

Projected timescales for CaFC publication

6.1. Because of the issues described in the earlier sections of this update, the team no longer think that the 2023 CaFC will be published during 2024.

6.2. It must be remembered that for PRISM and the 2023 CaFC in particular:

- We are asking clinics to verify four years in one.
- We are trying to write CaFC verification reports (that were essentially last created in 2005) at the same time as asking clinics to verify them.
- With PRISM, we are attempting to host previous non-relational data (EDI) in a relational database, and then report equally across the information base.
- We are uncovering further complexities and discrepancies in PRISM which is further complicating an already complicated process.
- The team at all costs want to avoid sending out incorrect verification information which will just rebound and severely impact the reputation of HFEA and PRISM.

6.3. Whilst the programme appreciates the desire to publish CaFC as soon as possible, it also wants the stress that it is vital to get the verification reports right, particularly as HFEA will be relying on these to assure themselves of the quality of register data for many, many years to come.

6.4. It also true to say the complexity of PRISM has meant that producing these reports to an acceptable standard has not been as straightforward as anyone initially envisaged at the start of the year. But once built, these reports will stay in place and available for all future CaFC iterations with little or no further amendment required.

6.5. Hence in answer to the question: “When will CaFC be published?”, the most honest response is “when we have built the final verification report and have issued a final deadline”.

6.6. Given the difficulties encountered we have considered whether it would be possible to split the verification so that we try to publish CaFC earlier and then return to verify other ‘non-CaFC elements’ later. Unfortunately, we think this approach would create more problems than it solves because:

- Everything in the reporting framework is linked – for instance the thaws report is important both for OTR and being able to accurately report some categories of CaFC.

- There will be a high level of nervousness about publishing information where we are not assured on its technical accuracy and later steps which otherwise might happen quicker will probably take much longer.
- There may particularly be some areas in the detail of CaFC (it historically reports across 42 different categories) where there are particular data concerns arising from incomplete verification. This could introduce potential 'continuity' issues between the EDI CaFC and a PRISM CaFC.
- We would have to consider the engagement strategy for clinics about a 'double verification' approach which they have not experienced in the past. Moreover, asking them to sign off their CaFC figures without signing off the verification could be problematic.
- Therefore, it is the strong recommendation from the programme and the technical team that time be allowed within this process in order to get these reports right.

6.7. Nevertheless, the schedule of reports in Table 1 and the mitigations below (see para 6.10 onwards)) do give a clear road map on how to achieve a CaFC publication, and that it is a finite process.

6.8. If we consider that the thaws report is completed in October (and by doing this, that 82% of all exceptions are now published), then if all other smaller reports are completed by Christmas, then given that clinics have already started verification, in that scenario we would likely issue a final verification deadline of the end of March 2025 with a view to signing off and published the first CaFC through PRISM by the end of May 2025.

6.9. Consequently, the programme can currently envisage a scenario where we are finalising the 2023 CaFC during the first half of 2025 but starting the 2024 CaFC verification on time from March 2025 and running this in parallel with a view to publishing the 2024 CaFC later in 2025.

Internal discussion on full v's partial CaFC publication

6.10. The delay in publication means that the clinics that are on special support (as set out in section 5) will have more time to verify their data and may therefore be ready to publish alongside all the other clinics.

6.11. However, we have considered the risks associated with full and/or partial publication of CaFC and in our view partial publication would be preferable given the need to provide a more recent data to most patients. The mitigations in respect of partial publication would include:

- A plan to allow for the remaining clinics to have their data included as soon as possible after final submission and verification.
- Support to encourage clinics to make the deadline. This is already in play and the two clinics that are really struggling are on a special pathway with a significant amount of HFEA support.

- Leaving a reasonable amount of time between publication of final verification reports and final submission date.
- Clear communication. The plan for weekly, individualised updates is already in place.
- Upon publication, there should be clear and visible note on the CaFC pages for clinics whose data is not included clarifying that the data has not yet been updated. Clinics should be warned of this in the pre-publication updates too.

6.12. The mitigation to ensure a reasonable time between the publication of the last verification report and the final submission, does mean that this is advice that can apply only once HFEA has completed its final verification reports.

6.13. AGC should note that this has already been included in HFEA communications to the sector. In March we outlined our aspiration to complete CaFC verification during the summer but also advised that we would confirm the deadlines once the final report has been published. However, we did not at that time think there would have been such a significant delay to the issuing of the reports.

6.14. Given the strategic importance of updating CaFC to the HFEA, the Authority was given an overview of this issue at a workshop session this week. The Authority agreed that the CaFC pages of the website should carry new text to inform readers of the limitations of the data currently available and the steps being taken to rectify the situation. In addition, consideration should be given to radical interim options should the resolution of the verification issues take even longer than currently estimated.

7. AGC recommendations

7.1. AGC are asked to:

1. Note that the results of the 'CaFC relaunch' have not been as hoped.
2. Note the particular challenges around the production of the thaws report, but that this is will eventually have a successful outcome, most likely in October.
3. Note that publication of the thaws report will represent publication of 82% of all CaFC exceptions. Thereafter there is 5% of PRISM exceptions and 13% of EDI exceptions outstanding.
4. Note that we are providing increased support to clinics for addressing exceptions and this showed results in July but not August. However, it also means we already following the recommended legal guidance if we are progressing to a partial publication of CaFC.
5. Consequently, we currently expect the 2023 CaFC to complete during the first half of 2025, which will also likely see the 2024 CaFC published later that same year.

Human Fertilisation & Embryology Authority

Reserves Policy

Details about this paper

Area(s) of strategy this paper relates to:	The best care /The right information /Shaping the future
Meeting	AGC
Agenda item	12
Paper number	HFEA (16/03/2021) MA
Meeting date	1 October 2024
Author	Morounke Akingbola (Head of Finance)

Output from this paper

For information or decision?	For information
Recommendation	The Committee are requested to approve the increased level of reserves from £1.38m to £1.42m
Resource implications	N/a
Implementation date	2025/26 business year
Communication(s)	Na
Organisational risk	

Human Fertilisation & Embryology Authority

Purpose

To provide the Committee with a update on the HFEA's Reserves Policy

Update

The policy was last reviewed by the Committee in October 2023. The Committee agreed that the HFEA should maintain an ongoing cash minimum of £976k to facilitate usual cash flow requirements plus £400k buffer for exceptional events. To note, the actual level of reserves held by the HFEA at the end of 2023/24 was circa £3.5m.

A review of our annual costs has resulted in increases to the level of contingency (maintained to meet immediate liabilities should an extraordinary financial incident occur; the reserve for other commitments which are those costs related to IT that must be maintained at a minimum.

Action

The Committee are requested to approve a revised reserve level of £1.42m which is made up of:

- Working capital of £500k
- Contingency level of £892k
- Other commitments of £30k

Human Fertilisation & Embryology Authority

Reserves Policy

Purpose

The purpose of this policy is to ensure that both the Executive and Authority of the HFEA are aware of the minimum level at which reserves are maintained and the reasons for doing so. The minimum level of reserves set out in this policy has been agreed with the Department of Health.

Principles

An organisation should maintain enough cash reserves to continue business operations on a day-to-day basis and in the event of unforeseen difficulty and commitments that arise. It is best practice to implement a reserves policy in order to guide key decision-makers.

Reserves Policy

1. The Authority has decided to maintain a reserves policy as this demonstrates:

   - Transparency and accountability to its licence fee payers and the Department of Health and Social Care;
   - Good financial management;
   - Justification of the amount it has decided to keep as reserves.

2. The following factors have been taken into account in setting this reserves policy:

   - Risks associated with its two main income streams - licence fees and Grant-in-aid - differing from the levels budgeted;
   - Likely variations in regulatory and other activity both in the short term and in the future;
   - HFEA's known, likely and potential commitments.

3. The policy requires reserves to be maintained at least at a level that ensures the HFEA's core operational activities continue on a day-to-day basis and, in a period of unforeseen difficulty, for a suitable period. The level should also provide for potential commitments that arise.

Cashflow

4. To enable sufficient cover for day-to-day operations, a cash flow forecast is prepared at the start of the financial year which takes account of when receipts are expected, and payments are to be made. Most receipts come from treatment fees - invoices are raised monthly and on average take 60 days to be paid. Cash reserves are needed to ensure sufficient working capital is available to make payments when they become due throughout the year.

5. Historically the HFEA experiences some negative cashflows (more payments than receipts), however during 2022/23 we experienced an outflow of cash across the whole year. This was due to prompt payments to suppliers offset by clinics taking longer to clear their accounts (the latter as a result of implementing PRISM and the temporary changes to our billing process). In order to ensure that there is always a positive cash balance we would wish to maintain a working capital cash balance of £500k (2023/24 £400k), based on our most unfavourable outflow in the last 3 years.

Contingency

6. The certainty and robustness of HFEA's key income streams, the predictability of fixed costs and the relationship with the Department of Health and Social Care, would suggest that HFEA would be unlikely to enter a prolonged period of financial uncertainty that would result in it being unable to meet its financial liabilities.

7. However, it is clearly prudent for an organisation to retain a sufficient level of reserves to ensure it could meet its immediate liabilities should an extraordinary financial incident occur.

8. In arriving at a reserve requirement for unforeseen difficulty we have considered the likely period that the organisation might need to cover and whilst discussions are undertaken to secure the situation, the immediate non-discretionary spend that would have to be met over that period.

9. We believe that a prudent assumption would be to ensure a minimum of two months of fixed expenditure is maintained as a cash reserve; in terms of the costs that would need to be met we consider the following to be non-discretionary spend that would be required to ensure the HFEA could maintain its operations:

    a. salaries (including employer on-costs);

    b. the cost of accommodation.; and,

    c. Sundry costs related to IT contracts, outsourced services, and other essential services.

10. These fixed costs would have to be paid in times of unforeseen difficulty, salaries and accommodation costs alone represent 77% of the HFEA's total annual spend.

11. Based on the HFEA's current revenue budget, the combined monthly cost of salaries and accommodation is £446k. A reserve of two months for these two elements would therefore be £892k (2023/24 £888k).

12. A further reserve for other commitments for two months is estimated to be £30k (2023/24 £80k).

Minimum reserves

13. The HFEA's minimum level of reserves will be maintained at a level that enables positive cashflow (£500k), provides £922k for contingency. The minimum level of cash reserves required is therefore £1.42m (increased from £1.38m 23/24). These reserves will be in a readily realisable form at all times.

14. Each quarter the level of reserves will be reviewed by the Director of Finance and Resources as part of the HFEA's ongoing monitoring of its cash flow.

15. Each autumn as part of the HFEA's business planning and budget setting process, the required level of reserves for the following financial year will be reassessed.

16. In any assessment or reassessment of its reserves policy the following will be borne in mind.

    - The level, reliability, and source of future income streams.
    - Forecasts of future planned expenditure.
    - Any change in future circumstances - needs, opportunities, contingencies, and risks – which are unlikely to be met out of operational income.
    - An identification of the likelihood of such changes in these circumstances and the risk that the HFEA would not be able to meet them.

17. HFEA's reserves policy will be reviewed annually by the Audit and Governance Committee.

Document name	Reserves Policy
Original release date	October 2014
Author	Head of Finance
Approved by	AGC
Next review date	September 2025
Total pages	3

Version/revision control

Version	Changes	Updated by	Approved by	Release date
1.0	Created	DoF	AGC	Feb 2015
2.0	Branded/amended	HoF	AGC	Dec 2016
2.1	Cashflow figures amended	HoF	AGC	Oct 2017
2.2	Reviewed	HoF	AGC	Oct 2018
2.3	Reviewed by DoF and amended	HoF	AGC	Dec 2019
2.4	Reviewed unchanged	HoF	AGC	Oct 2020
2.5	Reviewed; min reserves balance amended	HoF	AGC	Oct 2021
2.6	Reviewed: no changes	HoF	AGC	Oct 2022
2.7	Reviewed: amends to budget figures	HoF	AGC	Oct 2023
2.8	Reviewed: amends to budget figures	Hof	AGC	Oct 2024

Human Fertilisation & Embryology Authority

Audit and Governance Committee Forward Plan

Strategic delivery:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science, and society
Details:	
Meeting	Audit & Governance Committee Forward Plan
Agenda item	14
Meeting date	1 October 2024
Author	Morounke Akingbola, Head of Finance
Output:	
For information or decision?	Decision
Recommendation	The Committee is asked to review and make any further suggestions and comments and agree the Forward Plan.
Resource implications	None
Implementation date	N/A
Organisational risk	☒ Low ☐ Medium ☐ High Not to have a plan risks incomplete assurance, inadequate coverage or unavailability key officers or information
Annexes	N/A

Audit & Governance Committee Forward Plan

AGC items Date:	1 Oct 2024 *Virtual*	6 Dec 2024 *In-person*	4 Mar 2025 *Virtual*	17 June 2025 *In-person*	14 October 2025 *Virtual*
Following Authority Date:	**20 Nov 2024**	**Jan 2025**	**21 Mar 2025**	**2 July 2025**	**19 Nov 2025**
Internal Audit	Update	Update	Approve draft plan	Results, annual opinion	Update
Internal Audit Recommendations Follow-up	Yes	Yes	Yes	Yes	Yes
External audit (NAO) strategy & work		Audit Planning Report	Interim Feedback	Audit Completion Report	
Session for Members and auditors	Yes	Yes	Yes	Yes	Yes
Annual Report & Accounts (including Annual Governance Statement)				Yes, for approval	
Strategic Risk Register	Yes	Yes	Yes	Yes	Yes
Risk Management Policy[1]		Risk management strategy and risk appetite statement			
Horizon scanning committee discussion	Yes	Yes	Yes	Yes	Yes
Deep dives	Near misses		CaFC		
Digital Programme Update	Yes	Yes	Yes	Yes	Yes
Resilience & Business Continuity Management	Update as necessary	Update as necessary	Update as necessary	Update as necessary	Update as necessary

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

AGC items Date:	1 Oct 2024 *Virtual*	6 Dec 2024 *In-person*	4 Mar 2025 *Virtual*	17 June 2025 *In-person*	14 October 2025 *Virtual*
Information Assurance & Security				Yes, plus SIRO Report	
HR, People Planning & Processes		Bi-annual HR report		Bi-annual HR report	
Contracts & Procurement including SLA management	Update as necessary	Update as necessary	Update as necessary	Update as necessary	Update as necessary
Whistle Blowing, fraud (report of any incidents)	Update as necessary	Update as necessary	Update as necessary	Update as necessary	Update as necessary
Estates				Yes	
Review of AGC effectiveness and terms of reference	Yes	Yes			Yes
Functional standards	Yes	Yes	Yes	Yes	Yes
AGC Forward Plan	Yes	Yes	Yes	Yes	Yes
Accounting policies			Yes (annually)		
Public Interest Disclosure (Whistleblowing) policy			Yes		
Anti-Fraud, Bribery and Corruption policy			Yes		
Counter-fraud Strategy (CFS), Fraud Risk Assessments (FRA) and progress of Action Plan					Yes
Reserves policy	Yes				Yes

AGC items Date:	1 Oct 2024 *Virtual*	6 Dec 2024 *In-person*	4 Mar 2025 *Virtual*	17 June 2025 *In-person*	14 October 2025 *Virtual*
Meeting specific items	Wholesale review of agreeing, timetabling and providing evidence for internal audit	Training session on Assurance Mapping			

Training topics

This list below are suggested topics which could be considered for AGC members -note a training session on Assurance Mapping is proposed for December 2024.

- Risk Management
- Counter fraud
- External Audit – Knowledge of the role/functions of the external auditor/key reports and assurances.

Suggested deep dive topics

Suggested topic	Date added	Potential meeting to be discussed
Near misses	3 Oct 2023	October 2024
CaFC	27 June 2023	March 2025