Audit and Governance Committee meeting

Date: 26 June 2024 – 10.00am to 1.00pm

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

Agenda item	Time
1. Welcome, apologies and declarations of interest	10.00am
2. Minutes of 5 March 2024 (CS) For decision	10.05am
3. Action log (MA) For information	10.10am
4. Internal Audit – results and annual opinion (JC) For discussion	10.20am
5. Progress with current audit recommendations (MA) For discussion	10.40am
6. Annual report and accounts (including the annual governance statement) (MA) For discussion	10.50am
7. External audit completion report (ND/DG) For discussion	11.05am
8. Risk Update • Strategic Risk Register – for discussion (PR) • Committee discussion on potential horizon scanning items/items to add to deep dive discussion list (CS)	11.20am
9. Digital projects • PRISM update - for information (KH) • Epicentre replacement (verbal report)- for information (MC)	11.40am
10. Resilience, business continuity management & cyber security (MC/NMc) For information	12.10pm
11. Information assurance and security (SIRO report) (TS) For discussion	12.20pm
12. Government functional standards (verbal report) (TS) For information	12.30pm

13. Bi-annual Human resource report (YA) For information	12.35pm
14. Estates (verbal report) (TS) For information	12.50pm
15. AGC forward plan (CS) For decision	12.55pm
16. Items for noting (verbal update) (TS) • Whistle blowing • Gifts and hospitality • Contracts and Procurement For information	1.00pm
17. Any other business (CS)	1.05pm
18. Session for members and auditors only	
19. Close	
Lunch	

Next Meeting: Tuesday 1 October 2024

Minutes of Audit and Governance Committee meeting 5 March 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	26 June 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 5 March 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 5 March 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 Anne-Marie Millar	
External Advisers	Jo Charlton, Head of Internal Audit (Internal Auditor) – GIAA Dean Gibbs, KPMG – External Audit lead	Nick Dovan, National Audit Office (NAO) – External Auditor James McGraw, National Audit Office – Audit Team
Observers		Farhia Yusuf, Department of Health and Social Care (DHSC)
Staff in attendance	Peter Thompson, Chief Executive Tom Skrinar, Director of Finance and Resources Rachel Cutting, Director of Compliance and Information (attended for item 14 onwards) Clare Ettinghausen, Director of Strategy and Corporate Affairs (attended for items 14 onwards) Morounke Akingbola, Head of Finance Paula Robinson, Head of Planning and Governance Shabbir Qureshi, Risk and Business Planning Manager Alison Margrave, Board Governance Manager	Martin Cranefield, Head of IT Neil McComb, Head of Information Kevin Hudson, PRISM Programme Manager

1. Welcome, apologies and declaration of interest

1.1. The Chair welcomed everyone present in person and online. A warm welcome was given to Julia Chain, the HFEA Chair, who had joined the Audit and Governance Committee until the new cohort of Authority members had been appointed.

1.2. Anne-Marie Millar declared that since her appointment to the HFEA Audit and Governance Committee she had also been appointed as an ARAC Non Executive Director for the Department for Energy Security and Net Zero (DESNZ) effective since 1 January 2024. The committee agreed that there were no conflicts arising from this appointment.

2. Minutes of the meeting held on 7 December 2023

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

2.2. The minutes of the meeting held on 7 December 2023 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 committee agreed to keep action 15.4 regarding the goodwill letters open, until the Head of Information had completed the sample inspection of records and given authorisation to destroy the hard copies.

3.3. The committee agreed that actions 5.18 and 5.12 regarding internal audit actions could be merged into one with a revised target date of October 2024.

3.4. In response to a question regarding action 7.13 the Risk and Business Planning Manager confirmed that the committee's comments regarding the risk management strategy had been incorporated into the strategy. The committee agreed that this action could be closed.

3.5. In response to a question regarding action 7.22, the Director of Finance and Resources provided the committee with an update on the bid for the replacement Epicentre project. It was agreed that this action would remain on the action log and the committee should be informed when a decision is made by the Department.

3.6. The Chief Executive informed the committee that the wellness breaks for staff had been introduced and 65% of staff had booked these, action 10.9 refers. The committee were pleased to hear of the positive introduction and looked forward to receiving the HR report in June.

3.7. The Head of Internal Audit informed the committee that GIAA would be able to provide a trainer for the assurance mapping training session scheduled for December 2024 (action point 13.6). The committee agreed to amend the target date to June 2024 for the confirmation and scoping of the proposed December training.

3.8. The committee noted that actions 11.9, 7.11, 12.8, 6.11, 7.13, 11.7 and 13.5 had been resolved and could be closed.

Decision

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

Action

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

4. Internal audit report proposed 2024/25 internal audit plan

4.1. 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.

4.2. Fieldwork is progressing well for both the Business Continuity and the Register Research Panel audits. There are no material changes to the 2023/24 audit plan.

4.3. At the request of the Chair, the Director of Finance and Resources spoke about the HFEA's experience of working with the strategic partners assigned by GIAA to complete audits. There had been a breakdown in communications, which, when escalated to GIAA had been resolved. Additionally, policy audits are generally harder to design and deliver as policy is less driven by process, therefore the use of strategic partners for them was potentially less effective due to the knowledge of the HFEA and what it delivers not existing in third part teams contracted to do one or two audits only.

4.4. The Head of Internal Audit, GIAA, responded that whilst it is preferable to resource internally, there had been increased demand on resources which necessitated the use of strategic partners. Where possible the use of strategic partners will be minimised, but it cannot be ruled out completely.

4.5. The Chair spoke about the disproportionate impact on a small organisation such as the HFEA, when using strategic partners and this should be taken into consideration when planning resources by GIAA.

4.6. The Head of Internal Audit, GIAA, introduced the proposed internal audit plan for 2024/25 and explained how this had been developed taking into consideration the strategic risks and audit coverage in previous years and discussed with the Senior Management Team (SMT).

4.7. In response to a question regarding the proposed Field Safety Notice audit, the Chief Executive explained why the SMT thought this was an appropriate audit.

4.8. The Chair referred to the longer-term view of the audit strategy and questioned why Strategic Risk Management was not included for 2025/26. The Head of Internal Audit responded that this would be added.

4.9. In response to a question the Head of Internal Audit, GIAA, provided further information about the new Global Internal Audit Standards as detailed in the supplementary pack provided to members.

4.10. The Chair referred to the review of the annual internal audit opinion ratings and descriptors and stated that a direction of travel indicator would be most welcome as it could show progress being achieved between annual opinions whose rating remained the same.

4.11. The Chair drew the members attention to the events and resources detailed in the GIAA supplementary pack.

Decision

4.12. Members noted the progress report on the 2023/24 audit plan.

4.13. Members agreed and gave formal ratification of the 2024/25 audit plan.

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 whilst the number of recommendations has remained static since the last meeting, there has been significant progress in the collection and submission of evidence to GIAA and it is anticipated that a number of recommendations could be completed in March.

5.3. The Chair commended the Head of Finance for the considerable progress being made in addressing the audit recommendations and the detail presented in the report to the committee.

5.4. The committee discussed the proposal to accept at risk audit recommendations 2.1 and 2.4 regarding Key Performance Indicators (KPIs). The Head of Internal Audit, GIAA, commented that if these recommendations were considered as business as usual, then there should be evidence available to support this which could be provided to GIAA to satisfy the audit recommendations.

5.5. The Head of Planning and Governance stated that a number of these audit recommendations arose from before the new regime of submitting audit evidence was implemented. Evidence has been submitted to GIAA previously, but was rejected, hence the proposals to accept at risk. However, further work was being undertaken to generate additional evidence, which would be submitted.

Decision

5.6. The committee noted the paper and were content with the amended target dates for several audit recommendations.

5.7. The committee agreed in principle to accept at risk audit recommendations 2.1 and 2.4 regarding KPIs but deferred this decision until the June Audit and Governance Committee meeting. It was anticipated that additional evidence would be provided to GIAA by that time, and if this was also rejected, all the evidence would be submitted to AGC for direct consideration in June.

Action

5.8. The summary of audit recommendations to be updated to reflect the decisions made by the committee.

6. External audit report

6.1. The External Audit lead, KPMG, informed the committee that there were no changes to the audit plan presented previously to the committee. Thanks were given to the HFEA team for the pre-audit work which had been completed.

6.2. In response to a question the External Audit lead confirmed that there were no changes to accounting policies which would affect the preparation of the 2023/24 annual accounts. There had been new regulations regarding sustainability assurances, but these were not applicable to the HFEA.

6.3. In response to a question the External Audit lead confirmed that there had not been any slippage to the time plan for the preparation of the 2023/24 annual accounts and the deadline of submitting these before recess is achievable.

Decision

6.4. Members noted the verbal report.

7. Accounting policies

7.1. The Head of Finance introduced the paper and stated that the purpose of this paper is to advise members of the accounting policies adopted for the preparation of the accounts for the financial years 2023/24. She stated that the policies adopted for 2023/24 are the same as those adopted for 2022/23.

7.2. In response to a question regarding impairments and PRISM the Chief Executive stated that a full benefits realisation for PRISM cannot be completed until CaFC has been implemented. The External Audit lead concurred with this statement.

7.3. In response to a question the Director of Finance and Resources commented that the current Epicentre has no recognisable monetary value.

7.4. The Chair commented that this was a well constructed paper which detailed clearly all the policies which will be applied during the production of the 2023/24 audited accounts.

Decision

7.5. The committee noted the paper.

8. Strategic risk

Strategic risk register

8.1. The Risk and Business Planning Manager introduced the paper and reminded members that in the risk strategy approved by the AGC in December 2023 it was agreed that the strategic risk register (SRR) would be updated bi-annually for May and December.

8.2. The next formal update of the SRR would be presented to the June AGC meeting and the version presented now contained only minor updates relating to Opening the Register (OTR). He explained the escalation route for these items from the operational risk register to the strategic risk register.

8.3. In response to a question the Chief Executive provided further information about the incident at Guy's and St Thomas' Assisted Conception Unit regarding a manufacturing issue with bottles of solution used to freeze eggs and embryos. He spoke of the field safety notices that are issued by the MHRA to the users of affected products and that the MHRA also notify us and we communicate this to licensed centres. It is the clinic's legal responsibility to report any incidents to the HFEA in accordance with the HFEA's clinical governance procedures and Code of Practice.

8.4. He reiterated that incidents such as this are rare and that of the 100,000 treatment and storage cycles which took place in 2022/23 more than 99% were conducted without any incidents occurring. Any such incidents would generally be considered an operational risk, not a strategic one.

8.5. In response to a question from a member whether the HFEA has enough staff to resource communications in response to a significant clinic incident, the Chief Executive responded that additional resources could be utilised, but cuts would need to be made elsewhere. The stretch and cuts on public body spending is being felt throughout the sector.

8.6. The Chair commended the HFEA's communications around this incident which carefully balanced the proportionality of risk.

8.7. The committee discussed the list of items for possible inclusion in the next SRR review as detailed in paragraph 2.2 of the paper. The Chief Executive provided further information about the possible inclusion of HR resources and the Director of Finance and Resources on the impact of inflation and cost of living on procurement and contract renewals. The Chair commented that the public bodies review should be removed from the SRR.

8.8. The committee discussed the risk of Authority members vacancies and the impact this could have on the organisation. The DHSC recruitment process was discussed and the introduction of additional steps of approval from the Prime Minister was described, noting that this could delay the appointments. The committee noted that the HFEA had mitigated the risk as much as it can. The HFEA Chair thanked colleagues from DHSC for their assistance in this matter.

8.9. In response to a question regarding whether thematic reviews of risk are conducted the Risk and Business Planning manager described the reviews undertaken by Heads of Service and the top three risks which are escalated to the Corporate Management Group each quarter. The Chief Executive stated that the reviews undertaken ensure that any adjacent risks are captured and actioned accordingly.

Horizon scanning

8.10. 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.

8.11. A member raised the impact of the modelling of NHS waiting lists and the impact this may have on the number of publicly funded IVF cycles.

8.12. Members discussed media interest in clinic incidents, public confidence in the sector and in the effectiveness of regulation.

Decision

8.13. Members noted the strategic risk register.

9. Deep dive discussion – use of the Debt and Commercial Government Functional Standards

9.1. The Director of Finance and Resources presented the paper and commented that the Governmental Functional Standards (GFS) are designed for large organisations, therefore not all of the questions included in the self-assessment tools are relevant to small organisations such as the HFEA.

9.2. The Director of Finance and Resources stated that the paper before the committee focuses on GovS 008 Commercial and GovS 014 Debt and the use of the self-assessment tools provided for

these GFSs. He spoke about application of the self-assessment tools and how these are helpful in providing assurance and consideration of areas of improvement.

9.3. In response to a question regarding separation of duties for procurement the Head of Finance commented that the HFEA has a robust Procurement Policy which adheres to Government guidance and best practices.

9.4. In response to a question the Risk and Business Planning Manager stated that the lessons learnt reports, incident reporting policy and risk strategy are all available to staff via the intranet. The Chair reminded the committee that the subject for the deep dive discussion in October will be near misses.

9.5. The committee discussed that the forthcoming Choose a Fertility Clinic (CaFC) exercise and the need for clinics to agree and validate their activity levels will diminish any disagreements regarding reported number of cycles and fees payable to the HFEA.

9.6. In response to a question the Director of Finance and Resources confirmed that the areas of potential further work detailed in paragraph 3.5 were listed in order of priority and would be implemented when business activities permit.

Decision

9.7. The committee noted the report and endorsed the proposed activities as business permits.

10. Digital projects/PRISM update

10.1. The PRISM Programme Manager presented the paper.

10.2. He reported that the testing of the OTR reports was concluded in December, and these have been operational with the OTR team since January 2024. The team are now using the learning and features from developing the OTR reports to create some specific reports for clinics that will help to address specific issues.

10.3. PRISM submissions are continuing at a steady rate of approximately 5,000 submissions per week.

10.4. He spoke about the process for CaFC verification reports which commenced at the beginning of March.

10.5. He provided further information about the issues with API suppliers and updated the committee on the positive progress being made by Mellowood.

10.6. He spoke about the targeted work, communications and monitoring undertaken with IDEAS, Meditex and CARE clinics.

10.7. In response to a question, the PRISM Programme Manager clarified that it is a clinic's responsibility to ensure that they do not breach the 10 Family Limit. What PRISM does is make the data more useful and relevant for clinics.

10.8. He stated that the 10 Family Limit pilot will be useful as it will help to develop and improve communications to clinics.

10.9. In response to a question the PRISM Programme Manager stated that the issues relating to CRGH data are historical and relate to duplication of reporting records.

10.10. The committee discussed the importance of the July deadline for clinics to verify their data and the impact this could have on the overall project.

Decision

10.11. The committee noted the Digital projects/PRISM status update.

Action

10.12. The committee agreed that future reports on digital projects should include a sub-section for the Epicentre replacement project, when it commences.

11. Resilience, cyber security & business continuity

Infrastructure improvements

11.1. The Head of IT presented the paper and provided further information about the development and deployment of a new VPN solution.

11.2. The committee congratulated the Head of IT and his team for working at pace to respond and react so quickly to this potential threat.

11.3. The Head of IT informed the committee that a basic business continuity test was conducted in February and a more in-depth, inclusive test was planned for later in the year. The GIAA audit report on the business continuity plan is expected at the end of March.

11.4. A member questioned whether there is a MoU in place between clinics and the HFEA for access to the HFEA systems. The Chief Executive responded that there is an accreditation process for all EPRS suppliers that clinics use to send data to the HFEA Register. It is a responsibility for clinics to have cyber security policies and procedures in place.

Data Security and Protection Toolkit (DSPT)

11.5. The Head of Information informed members of the work undertaken for DSPT and whilst this is slightly behind schedule, it is anticipated that all will be completed when required.

Decision

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

12. Draft Annual Governance Statement

12.1. The Head of Finance informed the committee that the draft annual governance statement would be circulated to members via email around 22 March and members would be allowed two weeks to review and provide feedback.

12.2. The Chair asked committee members to respond in a timely manner when this document is circulated to them.

13. Fraud Risk Assessment

13.1. The Head of Finance presented the paper and tabled a new version of the fraud risk assessment schedule which included the two risks relating to cyber security.

13.2. The counter fraud bulletin referred to in the GIAA supplementary pack will be reviewed and if required any updates will be made to the HFEA documentation.

13.3. A member suggested that the risk regarding on-boarding of new staff could also be applied to Authority Members, and this might need to be captured in this document.

Decision

13.4. Members noted the fraud risk assessment paper and that this will be submitted to the DHSC Peer Review group.

14. Governmental Functional Standards

14.1. The Director of Finance and Resources informed the committee of the progress which had been made against the standards using the self-assessment tools.

Decision

14.2. The committee noted the verbal report.

15. AGC forward plan

15.1. The Chair introduced the paper and stated that this would be amended to include a full 12 months, or 16 months cycle if possible.

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 noted that there were no additions to the gifts and hospitality register. In response to a question the Head of Finance confirmed that the HFEA's policy does include the need to report offers of hospitality which had been declined.

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 was being held in person on 26 June 2024.

17.2. 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: 26 June 2024

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	26 June 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	2023/24 business year		
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High

Date and item	Action	Responsibility	Due date	Revised due date	Progress to date
4 October 2022 Item 15.4	Update on goodwill letters to be discussed at SMT and brought back to AGC.	Director of Compliance and Information	October 2023	June 2024	**Update:** All goodwill letters have been processed on the HFEA side and have been transported to Iron Mountain where they will be securely processed. No further goodwill documents are stored on HFEA premises. IM will scan the documents they have received from us before providing us with The scanned images and securely destroying the hard copies. **Update Jan 24**: The Donor files scanning is estimated to be completed by 23 February. On initial inspection the Head of Information is satisfied with the quality of the work. Once completed a sample will be inspected and if satisfied IM will be instructed to destroy the records. **Update June 2024** All paper documents have been scanned and sampled for quality control purposes and all checks were positive. The HFEA have securely transferred all scans from IM servers to our own and we are in early discussions with technical colleagues about programmatically attaching each document to their owners on the Register and developing manual processes for the occasions when this is not possible.

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.
7 December 2023 Item 4.8	Head of Internal Audit to distribute the ARAC Handbook to members as soon as it is available.	Head of Internal Audit	March 2024		**Update May 2024**: Publication has been delayed till end of June 2024. The publication will be highlighted in the GIAA supplementary papers when it is published, so this item can be closed.
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		**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.

Date and item	Action	Responsibility	Due date	Revised due date	Progress to date
7 December 2023 Item 7.22	The Executive to keep the committee appraised of the bid for the replacement Epicentre project	Senior Management Team			**Update:** Ongoing discussion with DHSC sponsor team and finance. Holding letter to clinics informing them that 2024/25 fees not fully finalised due to ongoing budget discussions with the Department, but with decision before 31 March. Continued engagement with DHSC commercial about optimum procurement routes. The Epicentre replacement project has been added as a standing item on AGC agendas, so this action can now be closed.
7 December 2024 Item 10.9	Head of HR to update the AGC committee on implementation and impact of wellness days.	Head of HR	June 2024		**Update:** See agenda item 13 on the June AGC agenda**.** This action is now complete and can be closed**.**
7 December 2024 Item 13.6	Head of Internal Audit to forward details of any suitable trainers to the HFEA Executive.	Head of Internal Audit	March 2024	June 2024	**Update**: GIAA are able to deliver this training and will ensure that the individual reaches out to the Authority to get a view on exactly what they would like to cover in ample time. This item can now be closed.
5 March 2024 Item 10.12	Future digital projects/PRISM papers to include a sub-section for the Epicentre replacement project	Head of IT	June 2024		**Update:** This has been added as a standing item on AGC agendas. This action is now complete and can be closed.

Digital Projects / PRISM Update May 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:	26 June 2024
Author:	Kevin Hudson, PRISM programme manager
Annexes	

Output from this paper

For information or decision?	For information
Recommendation:	To note the progress on CaFC since the start of verification at the start of March 2024, and to note the mitigations that we are now putting in place given the pace of CaFC verification by clinics, and the resolution of CaFC complexities by internal technical staff are both neither as fast as originally envisaged.
Resource implications:	
Implementation date:	To deliver a first CaFC through PRISM by no later than October 2024
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, 663,173 units of activity have been submitted through PRISM.

1.2. At the March meeting we reported that:

- The OTR reports were now operational with the OTR team.
- ARGC had been trained and had just commenced submitting data to PRISM.
- PRISM developers were continuing to work with those clinics and API suppliers with technically complex issues which are most at risk of missing CaFC (Choose a Fertility Clinic) deadlines.
- We were expecting to start the CaFC verification process at the end of February 2024.
- We were intending to release a 10 Family Limit Alert pilot immediately after all CaFC verification reports are issued.
- Overall, whilst there is still a large amount of work to do during 2024, we advised the programme was on track to complete CaFC verification by the end of the summer and publish the first CaFC though PRISM by the autumn.

1.3. Since the start of CaFC verification, we have encountered challenges:

- The pace of clinics correcting their data for CaFC is far slower than expected.
- The level of complexities for completing the final elements of CaFC are higher than expected and consequently it is taking longer than expected for our sole data analyst to complete these tasks.
- Clinics who are on 'special support pathways' (specifically 0044 CRGH) or who started using PRISM much later than the rest of the sector (ARGC group who started in February) may not be caught up in order to be published alongside the rest of the sector.

1.4. It must be remembered that the first CaFC through PRISM is particularly challenging:

- This is the first time in current corporate memory that HFEA is attempting to build, sign off and verify information with clinics, all at the same time.
- Our team are justifiably worried about sending out incorrect information to clinics that will confuse them and damage HFEA reputation, but so far this hasn't happened.
- Clinics are being asked to verify a large number of years of data together at the same time.

1.5. But it must also be stressed that these report-building and catch-up exercises only need to be done once, and for future CaFCs thereafter, the process will be far more straightforward.

1.6. In this update we focus solely on CaFC and explore the issues set out above in more detail. We then outline how we are planning to mitigate these risks to ensure the quickest publication of CaFC and the publication options that may exist in the future for the HFEA.

2. Current Status of CaFC verification and future risks

2.1. The CaFC verification process started on the 28th of February 2024 with the release of 15,549 missing early outcomes and outcomes which clinics must complete in PRISM for CaFC:

- 'Early outcome' is where a clinic must indicate whether a cycle has resulted in a pregnancy or not. It requires just two fields to be completed, normally 8 weeks after embryo transfer.
- 'Outcome' is where, for those positive early outcomes, information is provided about the final outcome of the pregnancy and also detailed information about the child if it resulted in a live birth. This is normally provided within 52 weeks of the start of pregnancy.

2.2. Now that CaFC verification has started, it is possible to define the five criteria that must be in place before verification can be finished and a full CaFC published.

2.3. We report progress on these criteria each week to the PRISM programme board and highlight both current and future risks that relate to them. This report is shown in table 1 below:

Table 1: Conditions for CaFC publication and current and future risks (as shared with the weekly PRISM programme board)

Condition	Current Risks	Future Risks
1: Clinics to complete all their verification activity	Activity to address missing outcomes across the sector has been slow – only 57% of missing outcomes have been addressed in 13 weeks. Clinics have been continuously chased by the team, and in mid-May, the 15 clinics with more that 50% outstanding were chased by inspectors. So far only 7 out of those 15 clinics have taken action on their missing outcomes. Mellowood are addressing 8,000 cycle duplicates. So far 45% has been de-duplicated.	Based on current evidence it is likely to take quite a time for clinics to complete the remaining missing outcomes and then address the other verification actions when they are published. The scale of work required to review and check the raw data reports could prove particularly daunting for clinics. For an average clinic, this is a spreadsheet of 12,000 rows to cover the 4 years of CaFC data.
2: HFEA to publish all verification reports	Our data analyst is completing: A: a report for clinics to address 4,800 non-migrated EDI records	Our data analyst is undertaking this work to a high level of detail and has

including raw data reports	which will require clinics to confirm submission omissions. B: to check the remaining 14 verification reports which are currently in draft form. C: to complete the remaining CaFC quality metrics to allow publication of a complete raw data report for clinics. Our data analyst is working methodically and exclusively through these tasks, but it is only himself that can undertake this work due to his knowledge and experience of fertility data. [Consequently, our other developers are either supporting clinics or are on OTR work whilst waiting for his completion on CaFC]	found the elements he has so far completed 'logically very complex' 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. We are taking mitigations to look at whether we can stagger the publication of the remaining 24 verification reports to provide as much overlap as possible between clinic activity and resolution of CaFC complexities by our data analyst.
3: Clinics on 'alternative support pathways' (ARGC / CRGH) to catch up	ARGC started entering data to PRISM in February. and have so far entered 17% of their expected CaFC volumes. Their activity increased in April but dropped back slightly in May. CRGH (the largest API clinic in the sector) had been struggling with the IDEAS system, has a large level of historic issues, and since January has received close support from HFEA developers. However, although much intelligence was gained, this didn't really help in reducing those historic issues as the clinic felt restricted by the IDEAS API interface.	For ARGC their activity will need to increase again if they are to ready for CaFC at the same time as the sector as a whole. ARGC will also need address missing EDI outcomes. At the beginning of June, CRGH are moving to manual data entry as a mechanism to better address historic errors, duplicates and missing records. Our developers will continue to provide close support to CRGH. During June and July, we will assess how a move to direct entry improves the clinic's ability to address past errors and their likely timescale for completion.
4: HFEA to complete the final CaFC build	This is the work to build the final CaFC scores and averages, to calibrate them and the	The risks outlined in condition 2 also applies here.

	mechanism to publish this information. This work will commence after our data analyst has completed the verification reports in condition 2 above. It is only our sole data analyst that can complete the core of this work.	Our data analyst also has 4 weeks leave to use before September Any estimate of the time taken for this will come with a high level of risk.
5: Clinics to sign off CaFC	As verification is progressing, the register team are reporting other issues being raised by clinic that possibly relate to CaFC. We are addressing these as part of an ongoing bug fix programme – but will not fix them all before CaFC publication. However, these are generally for very small numbers of records which won't affect the 'CaFC figures'	On the basis of these other issues, clinics may refuse to sign off CaFC. To mitigate this, once the final CaFC build is complete (condition 4 above), we will conduct sensitivity analysis to show any remaining issues (which still need to be fixed in the long term for OTR) won't materially impact what is published for the clinic for CaFC.

3. Progress on clinics verifying their data for CaFC

Correction of missing early outcomes and outcomes.

3.1. Ensuring clinics record the right outcomes, and that none are missing, is essential for an accurate CaFC fertility rate. This is why we started with these errors as they are also reasonably straightforward to correct.

3.2. Each week we track, and report to the Programme Board, the number of missing outcomes and early outcomes that has been corrected by clinics and this is shown in table 2 below:

Table 2: Summary of missing outcomes and early outcomes validation rules:

Rule	Type		03-Jun		27-May	20-May	13-May	06-May	29-Apr	22-Apr	16-Apr	09-Apr	03-Apr	29-Feb
560	IVF	Early Oucomes	**1,826**	24%	2037	2236	2,719	2930	3247	3,923	4346	4704	5734	**7,496**
561	IVF	Outcomes	**4,061**	62%	4107	4393	4,689	4721	4821	4,831	4960	5310	5622	**6,556**
625	DI	Early Oucomes	**601**	50%	627	645	671	706	737	826	843	879	971	**1,191**
626	DI	Outcomes	**187**	61%	198	199	209	222	240	243	240	240	258	**306**
			6,675		6,969	7,473	8,288	8,579	9,045	9,823	10,389	11,133	12,585	**15,549**
% of original release still outstanding			**43%**		45%	48%	53%	55%	58%	63%	67%	72%	81%	

3.3. As can be seen from the table above, the sector as a whole has only been able to address about 5% of those missing outcomes each week.

3.4. The missing outcomes that remain at the end of May are predominantly from API clinics. Of the 6,675 still outstanding, 79% relate to clinics that submit through either IDEAS, CARE or Meditex automated solutions.

3.5. We have conducted numerous chasing exercises of clinics who have not addressed their outcomes:

- Our PRISM team has chased the PRs of those clinics who have not addressed their outcomes on multiple occasions.
- In mid-May we escalated this and the HFEA Inspectors chased the 15 clinics that still had resolved less than 50% of their early outcomes. Since then, 7 of those clinics have acted although 8 so far have not. We will be asking the Inspectors to chase these clinics again.
- The CARE group was a particular outlier. The HFEA chief executive contacted the chief executive CARE and individual clinic data was shared. This resulted in an immediate correction of many missing outcomes but since then no further corrections have happened, despite continuing to share data with them. As of the end of May, the CARE group still have 1,120 missing outcomes to complete.

3.6. We outline how we plan to address these issues in our mitigation plan in section 6 below.

Correction of duplicated cycles

3.7. During March, our developers undertook detailed analysis of the PRISM register that highlighted potential areas of duplicate cycles, namely occasions where a clinic sent us cycle information for the same treatment more than once.

3.8. Approximately 8000 cycle duplicates were identified. These duplicates will significantly affect clinic CaFC scores. We have undertaken detailed analysis of these duplicates, and this is shown in table 3 below:

Table 3: Analysis of cycle duplicates identified through 2024 CaFC Verification

						Date range profile of duplication											
Clinic	Total Records affected	..of which are duplicates	% relate to migrated records *1	% submitted on the same day *2	% 'other types' of duplicates *3	to Dec 21	Jan - Jun 22	Jul - Dec 22	Jan - Jun 23	Jul - Dec 23	Since Jan 24	Records Invoiced Estimate Possible Refund on deletion		Date duplications resolved	Actual refunds made	IVF Refunds	DI refunds
Total of IDEAS clinics analysed	**6073**	**3115**	**75%**	**11%**	**15%**	**220**	**1472**	**884**	**349**	**78**	**24**	**3837**	**1909**	852	**920**	**500**	**420**
														45%		**54%**	**46%**
0044 The Centre for Reproductive and Genetic	1269	660	63%	9%	28%	9	192	298	114	4	0	352	166				
0078 Wolfson Fertility Centre - Hammersmith	1160	580	98%	1%	1%	0	559	5	10	0	0	890	444				
0035 TFP Oxford Fertility	578	308	68%	29%	4%	143	129	25	3	1	1	340	169	13-May	188	172	16
0109 King's Fertility	338	170	89%	3%	8%	53	87	19	9	2	0	253	120	02-May	163	89	74
0339 CREATE Fertility, London St Paul's	319	160	93%	8%	1%	0	53	83	8	6	1	217	106	08-May	110	40	70
0057 TFP Wessex Fertility	262	132	70%	18%	17%	5	75	19	21	8	0	162	80	20-May	54	40	14
0197 Salisbury Fertility Centre	227	120	62%	6%	33%	0	20	77	20	13	2	210	110	08-May	125	21	104
0307 Complete Fertility Centre Southampton	223	117	47%	10%	44%	0	27	26	58	3	4	195	103				
0007 Hewitt Fertility Centre	223	112	63%	9%	30%	0	16	69	11	7	0	138	68	14-May	67	33	34
0037 Glasgow Royal Infirmary	220	115	50%	1%	49%	0	32	50	29	10	1	178	93				
0316 Centre for Reproduction & Gynaecology	214	107	90%	9%	2%	0	87	12	6	1	0	190	95				
0196 Jessop Fertility	200	103	71%	21%	8%	0	42	20	39	10	2	126	64				
0250 TFP GCRM Fertility	190	97	73%	20%	7%	0	47	43	4	2	0	131	66	14-May	66	31	35
0004 Ninewells Hospital	175	88	73%	0%	27%	0	22	31	4	0	9	152	75				
0348 CREATE Fertility, Birmingham	142	71	79%	10%	13%	0	32	28	3	9	2	114	56	03-May	70	25	45
0100 Bourn Hall Clinic	123	61	92%	7%	3%	10	38	4	4	0	0	95	47	02-May	60	39	21
0051 Cambridge IVF	106	62	31%	68%	2%	0	3	56	1	1	2	34	17				
0077 Regional Fertility Centre, Belfast	104	52	85%	8%	8%	0	11	19	5	1	0	60	30	16-May	17	10	7
Total Other IDEAS clinics (in tail)	800																
Total of PRISM clinics analysed	**463**	**239**	**36%**	**53%**	**15%**	**7**	**14**	**23**	**109**	**34**	**35**	**135**	**58**				
0105 London Women's Clinic	194	95	29%	59%	14%	5	10	12	40	14	6	30	6				
0102 Guys Hospital	158	82	56%	27%	24%	1	2	8	25	6	2	81	40				
0295 Bristol Centre for Reproductive Medicine	111	62	21%	77%	3%	1	2	3	44	14	27	24	12				
Total Other PRISM clinics (in tail)	865																

Notes:

*1 - for IDEAS clinics, if the duplication relates to a migrated record then this is suggesting issues with sychronising the records - either systematic or operational

*2 - for all clinics, if duplicates are entered on the same day, then this suggests 'intentional' acitivity. Further work is being undertaken to check whether this is 'correct activity' and whether these should be merged

*3 - for all clinics 'other duplicates' is where this is not related to either migrated records or done on the same day. It can possibly point towards operational issues in the clinic where they submitted the records since PRISM launch at different times

3.9. As can be seen from the table above, the majority of these clinics relate to IDEAS clinics (approximate 6,900). The also relate to historic periods closer to the start of PRISM. Only approximately 100 relate to the current 2023/24 financial year, which means that currently, and going forward, PRISM is robust, and this issue is not arising to any material extent.

3.10. More detailed analysis has shown that a large proportion of these (75%) arose from early issues with the IDEAS synchronisation function, which keeps clinic system data synchronised with PRISM data and ensures the clinic updates an existing record where it is required rather than submit a new one.

3.11. Technically it is tricky to delete these duplications as in a relational database, many submissions now have 'downstream dependencies'. Moreover, from an HFEA perspective, we cannot see the clinic's own system to know what should have been submitted. In addition, the clinics themselves cannot see these duplicates because the IDEAS API interface restricts what clinics can see in PRISM to 'just once cycle'.

3.12. After discussions during April with Mellowood (the company that runs IDEAS), it was agreed that Mellowood staff were best place to attempt the de-duplications, rather than clinics or the HFEA.

3.13. Mellowood started de-duplication activity in May and so far, have addressed 45% of duplicates.

Financial impact of duplicated cycles

3.14. Cycle duplications also have a financial effect as some of these records might have been billed twice and the process of de-duplication may generate refunds.

3.15. The current estimated financial element of cycle duplications is approximately £195,000 and relates to the financial years ending March 2021, 2022, and 2023. The PRISM team are in close communication with Finance and KPMG concerning how this is accounted for and audited.

4. Progress on completing CaFC verification reports

Current technical challenges

4.1. At the start of verification, we published the 15,549 missing outcomes and early outcomes to the sector, so that they could get on with simple verification activity whilst our technical staff dealt with the more complex and difficult areas of CaFC.

4.2. Those complexities and tasks fall into three main categories:

- Completing the final quality metrics for the last CaFC flags for the Raw Data reports and then CaFC overall. These are algorithms that select from the register database the records that should be counted against a particular CaFC measure. In total there are 38 different individual CaFC measures within the CaFC calculations. 6 are still outstanding and others need to be carefully checked otherwise there is a risk that we would provide erroneous fertility rates to clinics.
- Addressing challenges in legacy EDI data between January 2020 and August 2021 that will surface in CaFC verifications. Particularly this relates to 4800 records where there were migration issues arising from lack of information from clinics, which they will need to advise on omitted information, but firstly we need to construct a report that details those omissions so that clinics can advise against them.
- Checking the remaining unpublished verification reports before they are released to clinics. Currently there are 14 reports that are written in draft form, but these require a detailed and expert check before they are released to clinics otherwise there is a high risk we could erroneous information to clinics.

4.3. Whilst the raw data and verification reports have been constructed in draft form by our data developer, it is only our longstanding data analyst, who has the detailed experience of HFEA fertility data in both PRISM and legacy forms, that can do the final detailed checks and can build the final quality metrics that are still outstanding.

4.4. Our data analyst has been working on these exclusively since the start of CaFC verification. However, he is reporting that he is finding some of these final areas very logically complex, and whilst eventually some of these complexities are resolved, and more work needs to be done to finish, it has taken quite a bit of extra time to resolve them.

4.5. At present, both the quality metrics and legacy EDI report remain partially completed. We outline in the future section our mitigation plan to get reports out to the sector so that we can maximise the overlap between the slow speed of clinic correction and the technical complexities being experienced by our data analyst.

4.6. We outline how we plan to address these issues in our mitigation plan in section 6 below.

Data Analyst Resource

4.7. AGC should note that, as previously reported, a second data analyst was recruited in September 2022 but went on long term sick from May 2023. After an unsuccessful phased return to work in January 2024, HFEA terminated this employment in April 2024.

4.8. It is not our intention to commence the re-recruitment of this post until after CaFC is completed as it previously took our data analyst a lot of their own time to support the new member of staff in getting them up to speed with the complexities involved with HFEA fertility data.

4.9. This decision allows our data analyst to dedicate all his immediate time towards CaFC. In addition, we are also looking at the job description of this second analyst with a view to attempting to recruit a more expert and proficient candidate.

4.10. Nevertheless, it will remain essential to fill the role of second data analyst for HFEA.

5. Clinics on 'special support paths' or catching up on PRISM

ARGC

5.1. The ARCG group (3 clinics) started submitting PRISM manually in February 2024.

5.2. So far, they have submitted 17% of the total activity that we are expecting for the 2024 CaFC. We provided the PR with monthly submission statistics. Activity increased in April but fell back slightly in May.

5.3. The PRISM submissions that we have received so far are of good quality and their current PRISM error rate is 0.5%. However, for CaFC, ARGC will also need to address EDI errors. There are currently 533 errors that they will also need to address of which 86% are missing outcomes and early outcomes.

5.4. Outside of sharing these reports there is almost no engagement from these clinics.

5.5. We have encouraged the PR to increase their PRISM submissions, but on current progress they are not going to catch up for CaFC in this calendar year.

CRGH

5.6. CRGH were the largest API submitted in the sector but also had by far the largest level of errors, duplicated cycles, and were advising of many records that they could not put through the IDEAS system, although we were not hearing similar complaints from other IDEAS clinics.

5.7. From January 2023, one of our developers has been closely working with CRGH staff to understand their issues. Clinic engagement has been good. However, de-duplication was providing to be particularly difficult due to issues of data entanglement.

5.8. In May the clinic decided they would stop using IDEAS API to automatically submit their data to PRISM and instead submit data manually. They felt this would better help them address their CaFC issues and in any event, they were planning a clinical system change away from IDEAS later in the year.

5.9. On 4th June 2024, the PRISM team trained CRGH in direct entry to PRISM and our developer will continue to support them as they make this change and attempt to rectify their CaFC issues directly in PRISM rather than through IDEAS.

5.10. During June and July, the PRISM team will get a good feel as to whether this change will help CRGH rectify their issues by the same time as the sector as a whole.

6. Mitigation plan to ensure the quickest CaFC publication

6.1. As we are 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.

6.2. These mitigations involve:

- 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.

- In parallel whilst this is happening, this allows more time 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.

Remaining Verification Reports

6.3. Table 4 below outlines the remaining verification reports that are in draft form, and due to be published together with their year-on-year effect on clinics, split by supplier type.

Table 4: Outstanding exceptions for as yet unpublished CaFC verification reports

		Total	2023	2022	2021	2020
	Total	22216	5272	7186	6367	3391
104	Cycles missing thaw usage	3781	1503	1373	643	262
111	Cycles missing any treatment details	8904	2589	4172	1733	410
99	Cycles missing cycle owner	1107	39	21	898	149
105	Cycles missing donor registration records	1191	358	450	265	118
106	Cycles missing fresh egg/embryo donation records	259	6	2	90	161
107	Cycles showing a fetal pulsation but missing transfer details	193	121	32	24	16
97	Duplicate registrations	141	14	23	39	65
87	Egg thaw missing link to originating storage	2111	177	400	828	706
81	Fresh donated eggs used after 7 days of donation	99	2	0	21	76
84	IVF cycles where there are no linked registration details (orphaned)	508	0	0	443	65
101	Missing cycle reason	1112	62	254	358	438
93	Missing donor details based on Gamete source Type	387	76	113	115	83
86	Missing egg donation cycles based on egg batch ID	1289	8	45	623	613
114	Patient age at cycle out of bounds	1134	317	301	287	229
Exceptions split by Clinic Provder						
	Prism (33 clinics)	**3,152**	461	526	1,234	931
	Ideas (37 clinics)	**9,791**	2,349	3,582	2,556	1,305
	Care (13 clinics)	**5,265**	1,468	1,853	1,477	468
	Meditex (11 clinics)	**2,032**	573	581	591	287
	Special Support (4 clinics)	**1,975**	422	645	509	399

6.4. Our data analyst has switched work to concentrate on fully checking and signing off those verification reports, particularly if they relate to data after launch of PRISM, so that these can be fed to the clinics with highest likely exceptions.

6.5. Specifically, our mitigation plan involves prioritising analyst sign off on reports 104, 111, 105 and 114. Together these represent an estimated 15,000 errors, 68% of the remaining exceptions. One of these reports is already signed off (report 104) and we will use the three of these reports to spearhead the full relaunch to the sector which we describe later in this section.

6.6. Our analyst will retain for further checking those other reports, particularly that relate to EDI and migrated data, where a more detailed check is involved, or they may cut across the legacy EDI report that is also being built.

6.7. In terms of clinic impact, from table 4 above we have observed the following:

- Since PRISM launch (September 2021) there is a preponderance of errors for IDEAS and CARE clinics.
- Before PRISM launch, with EDI errors there is a higher proportion of errors in PRISM clinics (i.e. those entering directly and not through API), although these clinics have significantly lower error rates since launch.

6.8. AGC should also note that although there is a large number of outstanding verification errors (see table 2 and 4 above), there are also quite a cohort of clinics with low numbers of verification errors overall:

- 3 clinics have 1000 errors or more to fix…
- ...and 20 clinics have 500 errors or more to fix.
- But 58 clinics have less than 250 errors to fix…
- and some of this last group (such as Glasgow Royal, St Mary's Manchester) are quite large and there is a large number of 'middle ranking clinics' in this cohort.

6.9. This concentration of errors only in certain clinics has led us to start to think about possible approaches for partial publication of PRISM which is described in section 7 below.

Raw data reports

6.10. The raw data reports are very large spreadsheets which are provided to clinics so that they can check the underlying data that will be used in the CaFC fertility rate calculations. There are separate spreadsheets for IVF, DI and FET treatments, and each row contains the detail relating to cycle to be included with data across 78 columns that includes information we have recorded about that cycle and the 38 CAFC flags that will be applied to that cycle.

6.11. For an average clinic in the IVF raw data report there is about 3000 rows representing different cycles, which for the 4-year CaFC period mean about 12,000 rows to correct.

6.12. Clinics deem these reports an important component of CaFC and advise they do want to make these checks so that they can be assured we are including all possible cycles in the calculation. In all likelihood, they may not fully check the documents but may just check that their records with positive outcomes have been included.

6.13. It therefore proposed as a mitigation strategy that whilst we are still working to complete all the 'columns' of the raw data report in relation to the CaFC flags, we will release the raw data report in draft form to clinics, so that they have maximum time to check the 'rows'.

Re-launch to the Sector

6.14. As per 6.5 above, we will aim to release further verification reports in the next few weeks and then we will issue a full set of fresh communications to the sector so that we can increase the pace of clinic corrections of errors across the summer.

6.15. The previous work that we have undertaken with trying to escalate verification issues with IDEAS, CARE and through inspectors means that we already established channels to raise the importance of these new reports with key individuals in clinics as soon as they are released.

6.16. Going forward we will conduct a large amount of repeated targeted communication to clinics. We have observed that once alerted, most errors get corrected by that individual clinic at quite a fast pace.

6.17. Whist the previous pace of clinic correction of errors has been slow, will be able to get a much clearer understanding of the future pace of corrections once these mitigations have been enacted.

7. Publication Options and timescales

Timescales

7.1. We have previously advised clinics that will aim to complete verification in the summer with a view to publishing CaFC in the autumn. We have not yet specified a target date.

7.2. So far, we have not proceeded at the expected pace for CaFC, so these targets are at risk.

7.3. As stated above, we will have a clearer understanding of when clinic verification for the sector as a whole will complete after we have undertaken the mitigation actions described in section 6 above and have been able to gauge whether the pace of clinic corrections has subsequently increased.

7.4. The distribution of errors between clinics (see section 6.8 above) also means that over the summer we will move to a position where we can identify clinics that we think are now ready for CaFC although this won't yet apply to the sector as a whole.

Publication Options

7.5. We do not need to take a decision on publication yet, but it might be helpful at this stage for AGC to be aware of the options. There are essentially two publication options for CaFC.

- **Full Publication:** When all five conditions in table 1 in section 2 are met. This has the virtue of completeness but runs the risk that publication is delayed beyond the autumn and patients are denied access to updated outcome data for even longer.
- **Partial Publication:** For the sector as a whole, less those on special pathways (ARGC and CRGH) if they are not ready by the time of the rest of the sector, and any further clinics that might not complete the remaining steps of the mitigation plan at the same pace of the rest of the sector. In this scenario, we will need an engagement plan for those clinics (and the HFEA staff that have been supporting them) to manage the disappointment of not being included in CaFC.

7.6. We will be able to look further at the scope of any partial publication from September.

7.7. AGC should note that there is a 'technical backstop' for the 2024 CaFC, namely the end of February 2025. This is because:

- from March 2025, we would want to start the CaFC verification for the 2025 CaFC on schedule.
- we would not want to further delay clinics that have kept their data in a well-maintained state if the 2025 verification reports are now available to them (which will of course be the case at that time).

7.8. Should CaFC be delayed beyond the autumn, we will want to consider whether an element of the data should be suspended because it is too old. AGC should note that:

- Although it needs to be verified for the purposes of the OTR and intelligence team, as CaFC reports over 3 years, data from 2020 is already excluded in the 2024 CaFC that clinics and the HFEA are currently working on.
- Likewise, the 2025 CaFC would exclude data for 2021 and 2020.

8. AGC recommendations

8.1. AGC are asked to:

1. Note that we have started verification, but the pace is not as expected.
2. Note that clinic corrections are slower, and it has taken some time for the sector just to address their outcomes.
3. Note that we have encountered higher than expected technical complexities in finishing the final elements of CaFC verification, and that this work can only be done by one experienced member of staff.
4. However, also note that we have implemented a mitigation plan to maximise the pace of CaFC from this point forward and create as much overlap between clinic corrections and technical complexities.
5. Note that we will have an understanding of how this mitigation plan affects our timescales from September.
6. Also to note there are two options for CaFC publication, namely full or partial, and that there will also be greater clarity concerning the feasibilities of these from September.

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:	10		
Meeting date:	26 June 2024		
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:
	• IT updates
	  • IT security
	  • Business Continuity
	  • Infrastructure penetration testing
	• Current position on Data Security and Protection Toolkit		

Implementation date	Ongoing		
Communication(s)	Regular, range of mechanisms		
Annexes			
Organisational risk	☐ Low	☒ Medium	☐ 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. IT Updates

IT security

After the recent ransomware attack on 3 June affecting several NHS trusts, NHS England briefed all NHS trusts and ALBs of the current incident. The incident is ongoing and limited information was shared. We continue to closely monitor the situation.

The new VPN solution continues to perform well after replacing the Ivanti solution in February when security vulnerabilities were identified.

Business Continuity

2.1. GIAA delivered their final report in May after auditing our business continuity plan and exercise. The overall audit opinion of the report is 'Limited'. HFEA were keen to emphasise we had recently revised our plans and were still embedding them. The general theme of the recommendations was to improve the awareness and communication of the plan, to ensure all stakeholders are well-prepared to execute roles in various scenarios, which we plan to do in 2024.

Infrastructure penetration testing

2.2. There was a delay onboarding our new penetration testing supplier and we originally planned for this test to start in March but instead it started in May. We will address any vulnerabilities highlighted in order of severity once we receive the final report.

3. Data Security and Protection Toolkit (DSPT)

Background

3.1. The deadline for submission for 2024 DSPT is June 30th. As in previous years we will be concentrating on only the mandatory requirements, of which there are 108.

3.2. The GIAA has sent us the draft findings of their audit of our response to a number of DSPT requirements in the past few days, with an opinion of 'unsatisfactory'. We are currently working with GIAA to review our evidence and have also undertaken an internal risk assessment of the issues highlighted by GIAA. More detailed findings will be presented at the next meeting of AGC.

SIRO Report

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:	11
Meeting date:	26 June 2024
Author:	Tom Skrinar, Director of Finance & Resources
Annex:	Annex A – Assessment of the HFEAs compliance with the Security Policy Framework 2014 (As at 31 March 2024)

Output from this paper

For information or decision?	For information
Recommendation:	N/A
Resource implications:	N/A
Implementation date:	N/A
Communication(s):	N/A
Organisational risk:	Medium

1. Background

The Senior Information Risk Officer's (SIRO) holds responsibility for managing the strategic information risks that may impact on our ability to meet corporate objectives, providing oversight and assurance to the Executive and Authority of the HFEA. It is a Cabinet Office (CO) requirement that Boards receive regular assurance about information risk management. This provides for good governance, ensures that the Board is involved in information assurance and forms part of the consideration of the Annual Governance Statement (AGS). This report is my annual report to the Accounting Officer and AGC.

The Security Policy Framework (SPF) provides a suitable format for the HFEA's report. ALBs are also asked to assess themselves and report against the 10 Steps to Cyber Security, the guidance issued as part of the Government's Cyber Security strategy. The HFEA has made such an assessment and recorded relevant actions and risks as part of the operational risk register, which is reviewed monthly by the HFEA Management Group.

2. Report

The HFEA routinely assess the risks to information management across the organisation, through its assessment of the risk of data loss, cyber security and the inclusion of guidance on creating and managing records throughout its Standard Operating Procedures (SOPS) and policies.

The HFEA has historically held and processed personal data and records and maintained robust controls and security protocols around all data relating to fertility treatments, which it is required to hold under the HFE Act. In recent years we have also responded to changes in legislation relating to the broader personal data we hold in relation to our staff, clinic staff and members of the public who may have contacted us. We continually review the effectiveness of our policies and procedures to ensure we comply with the UK General Data Protection Regulation and the Data Protection Act 2018.

This work is overseen by the HFEA's Information Governance Manager who makes periodic reports to the Information Governance Steering Group. We continue to review our process for assessing our approach to capturing the level of information risk and our tolerance of it. Given the size of the HFEA there is limited resource to provide continuous oversight of this issue, as such our approach is proportionate and looks to embed the consideration of information risks within the broader assessment of organisational risks.

Our self-assessment against the DSPT for the 2023/24 submission was one of general compliance with the DSPT mandatory assertions. In terms of the required audit of our evidence, required by the toolkit to be independent of the HFEA and undertaken by our Internal Auditors, this led to an opinion of 'Unsatisfactory' though it should be noted that this is before we responded with our improvement plan.

Although the overall rating is disappointing, the more detailed view presents a somewhat different picture. We were found to be fully compliant with more assertions this year than last for example. The risk ratings assigned to those requirements which we did not meet were high, thereby resulting in 'unsatisfactory' ratings. We have performed our own risk assessment for each of these requirements (including input form SIRO, Heads of I.T and Information and the IGRM manager) and found the risks to be acceptable.

Our internal assessment is that the HFEA will still not meet the requirements of the 2024 mandatory assertions. We are currently working with GIAA colleagues to assess the substance of our evidence for this. We expect to submit our assessment in line with the 30 June 2024 deadline and the AGC will receive the findings from the internal audit review at the next meeting.

Overall, we have a low tolerance of risk for information on our Register database, that which falls within the auspices of GDPR and is commercially sensitive or business critical. The focus of our resource will continue to be the secure and compliant storage of these records.
In terms of the security of our data the HFEA has appropriate cyber security polices in place. AGC regularly receive updates on cyber security and I am assured that the HFEA's approach to cyber security provides significant protection of our information assets and that there is active monitoring of cyber security with appropriate action taken to improve the level of protection against new and emerging cyber threats.

I have considered the HFEAs compliance with the mandatory requirements set out in the SPF, (Security policy framework: protecting government assets - GOV.UK (www.gov.uk)). The requirements were last updated in December 2022 and focus on eight areas (governance, culture and awareness, risk management, information, technology and services, personnel, physical security, responding to incidents) with three types of consideration for each of those (information, physical and people). The requirements have been applied proportionately and matched to the HFEA's organisational risks. Not all of the areas apply to the HFEA. This is contained at Appendix A to this document.

In line with the SIRO training I have undertaken this year I have also considered a number of the factors that underpin the management of the HFEA's information risks.

- I believe the HFEA have an effective Information Governance framework in place and that the HFEA complies with all relevant regulatory, statutory and organisation information security policies and standards.
- I am satisfied that the HFEA has introduced and maintains processes to ensure staff are aware of the need for information assurance and the risks affecting corporate information.
- The HFEA has appropriate and proportionate security controls in place relating to records and data and that these are regularly assessed.

In conclusion I believe the HFEA has progressed in its approach to data, information and records management over the past year and is in a stronger position in terms of its governance in this area as a consequence. As SIRO I believe the HFEA takes issues relating to information risk seriously and has appropriate processes in place to assess and minimise these risks. We will continue to maintain and improve processes over the coming year and ensure we consider how we can maximise the use of our information as a business asset.

Annex A – Assessment of the HFEAs compliance with the Security Policy Framework 2014 (As at 31 March 2024)

	Mandatory Requirement	Compliance	Further actions required
1	Departments and Agencies must establish an appropriate security organisation (suitably staffed and trained) with clear lines of responsibility and accountability at all levels of the organisation. This must include a Board-level lead with authority to influence investment decisions and agree the organisation's overall approach to security.	Director of Resources is SIRO, Chief Information Officer has day to day responsibility of information security.	Ongoing review and refresher training as required.
2	Departments and Agencies must: * Adopt a holistic risk management approach covering all areas of protective security across their organisation. * Develop their own security policies, tailoring the standards and guidelines set out in this framework to the particular business needs, threat profile and risk appetite of their organisation and its delivery partners.	Risks identified as part of routine operational and strategic risk management as well as detailed on the information asset register. Policies are in place and reviewed annually.	Ongoing review and development of the information asset register
3	Departments and Agencies must ensure that all staff are aware of Departmental security policies and understand their personal responsibilities for safeguarding assets and the potential consequences of breaching security rules.	All staff and Authority members are informed of policies and given guidance. Annual training is undertaken by all through Astute, our training content provider (a monitored system).	Ongoing reminders and awareness raising with staff.
4	Departments and Agencies must have robust and well tested policies, procedures and management arrangements in place to respond to, investigate and recover from security incidents or other disruptions to core business.	Systems in place that offer security protection. Recently revised business continuity plan and critical incident plan.	Formal organisational sign-off for business continuity plan, also comms and testing plan

	Mandatory Requirement	Compliance	Further actions required
5	Departments and Agencies must have an effective system of assurance in place to satisfy their Accounting Officer / Head of Department and Management Board that the organisation's security arrangements are fit for purpose, that information risks are appropriately managed, and that any significant control weaknesses are explicitly acknowledged and regularly reviewed.	System in place and SIRO reports annually - any weaknesses identified in Governance Statement (none). Response to GDPR and Records management audits during 2018/19 have also been reflected in HFEA processes	None
6	Departments and Agencies must have an information security policy setting out how they and any delivery partners and suppliers will protect any information assets they hold, store or process (including electronic and paper formats and online services) to prevent unauthorised access, disclosure or loss. The policies and procedures must be regularly reviewed to ensure currency.	Policies and procedures are in place and reviewed annually.	None
7	Departments and Agencies must ensure that information assets are valued, handled, shared and protected in line with the standards and procedures set out in the Government Security Classifications Policy (including any special handling arrangements) and the associated technical guidance supporting this framework.	The HFEA's assets are all classified OFFICIAL and are appropriately controlled.	None
8	All ICT systems that handle, store and process HMG classified information or business critical data, or that are interconnected to cross-government networks or services (e.g. the Public Services Network, PSN), must undergo a formal risk assessment to identify and understand relevant technical risks; and must undergo a proportionate accreditation process to ensure that the risks to the	ICT systems are risk assessed as part of the overall operational risk register. IT security was reviewed by Internal Audit in 2017/18 and is audited annually under DSPT, audited by Internal Audit.	None

	Mandatory Requirement	Compliance	Further actions required
	confidentiality, integrity and availability of the data, system and/or service are properly managed.		
9	Departments and Agencies must put in place an appropriate range of technical controls for all ICT systems, proportionate to the value, importance and sensitivity of the information held and the requirements of any interconnected systems.	Patching and firewalls in place. Assurance reports received and reviewed regularly with suppliers. Portable devices and removable media is secured.	None
10	Departments and Agencies must implement appropriate procedural controls for all ICT (or paper-based) systems or services to prevent unauthorised access and modification, or misuse by authorised users.	Policies and staff induction in place, to clarify proper use and implications of breaches.	None
11	Departments and Agencies must ensure that the security arrangements among their wider family of delivery partners and third-party suppliers are appropriate to the information concerned and the level of risk to the parent organisation. This must include appropriate governance and management arrangements to manage risk, monitor compliance and respond effectively to any incidents. Any site where third party suppliers manage assets at SECRET or above must be accredited to List X standards.	Contracts include required conditions and where appropriate third parties are given copies of the HFEA's system policies. Changes to arrangements and incident monitoring and results are reviewed at quarterly meetings with suppliers.	None
12	Departments and Agencies must have clear policies and processes for reporting, managing and resolving Information Security Breaches and ICT security incidents.	Policies have been revised and are in place.	None
13	Departments must ensure that personnel security risks are effectively managed by applying		None

	Mandatory Requirement	Compliance	Further actions required
	rigorous recruitment controls, and a proportionate and robust personnel security regime that determines what other checks (e.g. national security vetting) and ongoing personnel security controls should be applied.	Recruitment and references provide assurance. No vetting in place as very little sensitive data.	
14	Departments and Agencies must have in place an appropriate level of ongoing personnel security management, including formal reviews of national security vetting clearances, and arrangements for vetted staff to report changes in circumstances that might be relevant to their suitability to hold a security clearance.	N/a.	
15	Departments must make provision for an internal appeal process for existing employees wishing to challenge National Security Vetting decisions and inform Cabinet Office Government Security Secretariat should an individual initiate a legal challenge against a National Security Vetting decision.	N/a.	
16	Departments and Agencies must undertake regular security risk assessments for all sites in their estate and put in place appropriate physical security controls to prevent, detect and respond to security incidents.	Assessment and sufficient controls provided by building management.	None
17	Departments and Agencies must implement appropriate internal security controls to ensure that critical, sensitive or classified assets are protected against both surreptitious and forced attack and are only available to those with a genuine “need to know". Physical security measures must be proportionate to the level of threat, integrated with other protective security controls, and applied on the basis of the “defence in depth" principle.	Visitor and entry controls provided by building management. Lockable furniture provided for storage. Clear desk and clear screen requirements reinforced through training, checks and reminders.	None

	Mandatory Requirement	Compliance	Further actions required
18	Departments and Agencies must put in place appropriate physical security controls to prevent unauthorised access to their estate, reduce the vulnerability of establishments to terrorism or other physical attacks, and facilitate a quick and effective response to security incidents. Selected controls must be proportionate to the level of threat, appropriate to the needs of the business and based on the “defence in depth" principle.	Sufficient controls around access and mail provided by building management.	None
19	Departments and Agencies must ensure that all establishments in their estate put in place effective and well tested arrangements to respond to physical security incidents, including appropriate contingency plans and the ability to immediately implement additional security controls following a rise in the Government Response Level.	HFEA recently revised its business continuity and critical incident plan, which underwent an audit by GIAA. The GIAA audit identified a number of actions for improvement which will be taken forward in 2024/25.	Taking forward actions for GIAA recommendations on revised business continuity plans.
20	Departments and Agencies must be resilient in the face of physical security incidents, including terrorist attacks, applying identified security measures, and implementing incident management contingency arrangements and plans with immediate effect following a change to the Government Response Level.	HFEA recently revised its business continuity and critical incident plan, which underwent an audit by GIAA. The GIAA audit identified a number of actions for improvement which will be taken forward in 2024/25.	Taking forward actions for GIAA recommendations on revised business continuity plans.

Bi-annual Human Resources report 2024

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:	13
Meeting date:	26 June 2024
Author:	Yvonne Akinmodun, Head of Human Resources
Annexes	

Output from this paper

For information or decision?	For information
Recommendation:	The Committee is asked to note and comment on the actions taken to date.
Resource implications:	Within budget
Implementation date:	n/a
Communication(s):	n/a
Organisational risk:	Medium

1. Introduction

1.1. HR papers come to the Audit and Governance Committee twice a year. This paper, which represents our first HR report of the year, sets out half-year information on key HR activity within the HFEA.

2. Staff survey

2.1. The annual all staff survey took place in the autumn of 2023. We had an 83% response rate which is higher than last year's response of 74%. Our overall engagement score was 84%, up by 1% on last year. Pleasingly, the HFEA engagement score is significantly above the average for comparable public sector bodies (76%).

2.2. We shared the headline results with our Corporate Management Group (CMG) and then all staff at our December all staff event. Following discussions, we identified one of the biggest areas of concern is around staff's perception of fairness and equality. To this end, we have increased awareness of our EDI champions as set out in section 4 below.

3. Wellbeing

3.1. Our first wellbeing breaks took place on 6/7 March 2024. 96% of our staff booked a break.

3.2. We arranged chair yoga, a wellbeing walk for those in the office and distributed fact sheets on looking after yourself. Only one person attended the chair yoga and nobody wanted to go on the walk. We found that everybody preferred to do their own thing, from resting, walking the dog, going to the gym or even getting their nails done! Fruit was available for those in the office too.

3.3. However, during the March Mental Health Awareness week, we arranged the Chair Yoga again, 22 people attended. We also arranged a Wellbeing Maintenance Webinar in which 32 people attended.

3.4. We now have a dedicated landing page on Wellness Cloud - **https://hub.the-wellness-cloud.com/client-landing-page/hfea/** 58 people have logged on to this hub and on average two employees attend every webinar that Wellness Cloud promote (the top performing client has 6 attend in Organisations similar to us).

3.5. At Christmas the mental health first aiders (MHFAs) promoted tips around "Christmas blues – tackling feelings of isolation during the festive period". We also organised a gift by way of a raffle, all those in the office put their names in a gift box and one name was picked out and they won a Christmas treat.

4. EDI

4.1. Our autumn staff survey identified that responses on diversity and inclusion, although showing 69% positive, are 14% lower than the sector average and 1% lower than our score from last year.

4.2. One of the ways in which we are seeking to address this is through the introduction of EDI champions. In addition to the appointment of champions, we are also supported at board level by an authority member, Geeta Nargund

4.3. We have successfully recruited 7 members of staff from a cross section of the workforce. The champions will be responsible for leading and promoting a range of EDI initiatives to help raise awareness of EDI in all its forms.

5. Recommendation

5.1. The Committee is asked to note and comment on the actions taken to date.

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	15
Meeting date	26 June 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:	26 June 2024	1 Oct 2024	6 Dec 2024	4 Mar 2025	17 June 2025
Following Authority Date:	3 July 2024	20 Nov 2024	Jan 2025	21 Mar 2025	2 July 2025
Internal Audit	Results, annual opinion	Update	Update	Approve draft plan	Results, annual opinion
Internal Audit Recommendations Follow-up	Yes	Yes	Yes	Yes	Yes
External audit (NAO) strategy & work	Audit Completion Report		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				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	Yes	Update as necessary	Update as necessary	Update as necessary	Update as necessary
Information Assurance & Security	Yes, plus SIRO Report				Yes, plus SIRO Report

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

AGC items Date:	26 June 2024	1 Oct 2024	6 Dec 2024	4 Mar 2025	17 June 2025
HR, People Planning & Processes	Bi-annual HR report		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				Yes
Review of AGC effectiveness and terms of reference		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			
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