Audit and Governance Committee meeting - agenda

Human Fertilisation & Embryology Authority

4 October 2022

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

10am

Agenda item			Time
1.	Welcome, apologies and declaration of interests		10.00am
2.	Minutes of 28 June 2022 [AGC (04/10/22) DO]	for decision	10.05am
3.	Action log [AGC (04/10/22) MA]	for information	10.10am
4.	Internal audit report [AGC (04/10/22) JC]	for information	10.15am
5.	Implementation of recommendations [AGC (04/10/22) MA]	for information	10.30am
6.	External audit report [AGC (04/10/22) MP/DG]	for information	10.40am
7.	Strategic risk register and risk management policy [AGC (04/10/22) PR/SQ]	for comment	10.55am
8.	Horizon scanning & deep dive topics (verbal) [AGC (04/10/22) RS]	for decision	11.10am
9.	Digital projects/PRISM update [AGC (04/10/22) KH]	for information	11.30am
	Break		11.40am
10.	Resilience & business continuity management [AGC (04/10/22) RC]	for comment	11.55am
11.	Reserves policy [AGC (04/10/22) RS]	for comment	12.10pm
12.	AGC forward plan [AGC (04/10/22) MA]	for decision	12.20pm
13.	Fraud Risk Assessment [AGC (04/10/22) MA]	for comment	12.25pm

14.	Legal risks (verbal update) **[AGC (04/10/22) RS]**	for comment	12.35pm
15.	Update on goodwill letters (verbal update) **[AGC (04/10/22) RC]**	for information	12.40pm
16.	Items for noting (verbal update) • Whistle blowing • Gifts and hospitality • Contracts and Procurement **[AGC (04/10/22) RS]**	for information	12.45pm
17.	Any other business • Venue for future meetings		12.50pm
18.	Close		12.55pm
19.	Session for members and auditors only		
	Lunch		

Next Meeting: Thursday, 8 December 2022.

Minutes of Audit and Governance Committee meeting 28 June 2022

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	4 October 2022		
Author	Debbie Okutubo, Governance Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes of the Audit and Governance Committee meeting held on 28 June 2022 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 28 June 2022 held in person and via teleconference (Teams)

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

1. Welcome, apologies and declarations of interest

1.1. The Chair welcomed everyone present online and in person. In particular Alex Kafetz and Jason Kasraie, the two Authority members who had recently joined the committee and the Authority Chair who was observing the meeting.

1.2. There were no apologies.

1.3. There were no declarations of interest.

2. Minutes of the meeting held on 15 March 2022

2.1. The minutes of the meeting held on 15 March 2022 were agreed as a true record subject to minute 11.7, the word 'systematic' to be deleted. Amended version to read:

> " 11.7. In terms of fraud, staff should be able to escalate to a Board member or the DHSC and that their contact details should be made available to staff."

3. Action log

3.1. Members acknowledged receipt of the data security and protection toolkit (DSPT) document from the Director of Finance and Resources and agreed that the action could be closed.

Action

3.2. The Chair requested that topics for deep dives should be added to the action log as an action for the Executives.

Decision

3.3. Members noted the actions that had been completed and agreed that they be taken off.

3.4. Members noted the status of the action log and the requested additions to the action log.

4. Internal audit report

4.1. The Internal Auditor presented this item. Members were advised that based on the work undertaken during 2021/22 and the observations made regarding the organisation's governance arrangements, risk management arrangements and system of internal control, a moderate level of assurance had been awarded.

4.2. The Internal Auditor commented that there had been less traction on clearing and implementing the recommendations made during the year.

4.3. The Chair asked if this was a matter of mindset of staff realising that they had not implemented the recommendation by the deadline give up trying. Other members commented that it was probably a challenge prioritising due to the size of the organisation.

4.4. The Chief Executive responded that we were aware of the backlog of recommendations but due to conflicting priorities and the size of the organisation we had to prioritise.

4.5. The Internal Auditor gave an example of standard operating procedures (SOPs) not being updated and commented that this could lead to an inconsistent way of working in particular for new staff if there were no SOPs to follow and other staff were busy elsewhere.

4.6. The Chief Executive commented that just after the pandemic we had a turnover of staff and half of the board were also new. During this period, SOPs were not updated because staff had to cover vacancies.

4.7. The Director of Finance and Resources commented that in corporate services we had been underfunded and it was becoming untenable to meet all the asks from the various departments including Department of Health and Social Care (DHSC), the Board, and the AGC as well as carry out our regulatory functions.

4.8. Members commented that the principles of the report were accepted but asked that the internal audit recommendations to be proportionate as there were pressures across the organisation.

4.9. The Chair commented on the regularity of training and noted that as members it was an important tool especially as part of their accountability responsibility and cascading of the lessons learned.

4.10. The two final internal audit reports issued since the last committee meeting were discussed. The effectiveness of the inspection process had received a substantial assurance rating and the operational risk management review received a limited assurance rating.

4.11. Members congratulated the Director of Compliance and Information and her team on receiving a substantial assurance rating in her area as it was a core regulatory function.

4.12. Members also commented on the operational risk management review and noted that staff commissioned the audit at a time when they knew that there were deficits in the system. They commented on the maturity of the organisation and noted that the internal audit report would inform the strategic risk register coming to the October AGC meeting.

4.13. The Chief Executive commented that he was delighted with the substantial rating for the effectiveness of the inspection process and comfortable with the operational risk audit as an action plan had been developed that we would work on.

4.14. Members commented that it was important that it was looked at operational risks as it set the landscape for transparency.

Decision

4.15. Members **noted** the trends identified in the report and the areas of focus for 2022-2023.

5. Implementation of recommendations

5.1. The Head of Finance presented this item. There were 29 recommendations in total outstanding as of 21 June 2022 of which 10 were new.

5.2. For the DSPT, the Director of Finance and Resources commented that we were working through the requirements in the toolkit and that it was due for submission on 30 June. However, we were aware that we would not meet the requirements but we were expecting that it would be recognised that we had made progress since last year's submission.

5.3. The Head of IT commented that we were working on strengthening our evidence.

5.4. The Chair asked what it meant when it said evidence was rejected. The Senior Internal Auditor responded that where evidence presented was not acceptable, they would have to reject the evidence for instance discussions held at SMT without minutes as evidence of the discussion.

5.5. This also applied to the business continuity policy what was submitted as evidence. The Senior Internal Auditor commented that what had been captured as the action had been lost in translation as that action referred to records management and evidencing that there was a robust policy in place. This meant that the business continuity policy might have been strengthened but what was required was the records management policy.

5.6. Members were reminded that internal audit could only work with official documentation for instance where items had been formally discussed the minutes of the meeting was an acceptable form of official documentation.

5.7. The Director of Finance and Resources commented that SMT did discuss issues and that there were agendas at the meeting but formal minutes was not part of the process. An example was given of budget leads who received emails following the SMT meeting confirming their budgets for the year which was submitted to the internal auditors and rejected. For the records management policy, it was noted that the lead person will take this forward.

5.8. The Internal Auditor commented that there was the need to tidy up historic recommendations and that they would work with all lead officers.

5.9. Members commented that the Internal auditors and the Executive needed to agree on what was evidence for instance how do you evidence what had already been discussed and agreed. Members also noted that this could prove to be very expensive as it could mean that extra staff might be required to attend meetings with the Executives to capture items discussed in order to gather evidence.

5.10. The Chair commented that it was good practice for decisions to be minuted.

5.11. In response to a question on goodwill letters, the Director of Compliance and Information commented that with conflicting priorities and budget restraints it was difficult to say when the action on goodwill letters would be implemented.

5.12. Following further discussion on goodwill letters, the Chair suggested that the completion date be changed to June 2023. The Director of Compliance and Information stated that by the December AGC meeting a quotation of how much it would cost to have the goodwill letters scanned and saved would be submitted. However, members should be rest assured that the goodwill letters were being kept safe and secure.

Action

5.13. The completion date for the goodwill letters be changed to June 2023.

5.14. A quotation on the cost of scanning and saving the goodwill letters to be sent to the committee by the December meeting.

5.15. The Chair requested that an oral update be presented at the October AGC meeting.

Decision

5.16. Members noted the progress with implementing recommendations.

6. Annual report and accounts

6.1. The Director of Finance and Resources presented this item. The additional disclosures for the year were outlined to the committee.

6.2. Members were also advised of the total operating income which was higher compared to the previous financial year.

6.3. The changes to the accounts were explained to the committee.

6.4. Members noted the next steps and that the Accounting Officer sign off will not happen until a revised timeline was received from the National Audit Office which would ensure that the accounts were reviewed in light of any material developments.

6.5. It was also noted that if any material changes were required after the meeting they would be discussed with the Chair and the committee before the Accounting Officer signed it off.

Decision

6.6. Members noted the Annual report and accounts and next steps prior to sign off by the Accounting Officer.

7. External audit completion report

7.1. The KPMG Audit lead presented this item to the committee and started by thanking the HFEA team for the support during the audit. He commented that alongside the External Auditor they were not able to conclude on the significant risks because management still needed to make a significant estimate regarding income from clinics not yet fully onboarded to PRISM.

7.2. It was noted that they had received management's detailed assessment of the estimate and they were currently in the process of reviewing the information received and assessing what further work was required. They were also considering the implications for the audit approach and opinion.

7.3. Members were advised that there was a material estimation uncertainty relating to income, they had therefore raised a new significant risk- Income estimation. Members were informed that revenue needed to be inline with activity and that the average variance was currently at 6% with those that had been reconciled. This they stated could lead to a range of outcomes.

7.4. In response to a question, it was noted that the income uncertainty would not extend to future years. Also, that a further reconciliation would be carried out prior to the accounts being signed by the Accounting Officer.

7.5. The Chief Executive commented that as at March the activities in clinics was very different to where they are in June and that clinics were catching up with their backlogs. This remained a fluid situation in terms of clinic activity levels.

7.6. The Chair summarised the situation and confirmed with the external auditors that they were willing to work with the Executives to resolve this issue.

Decision

7.7. Members noted that PRISM delays were leading to uncertainty relating to income.

7.8. Subject to the provision that another reconciliation will occur to resolve the uncertainty around income realisation, members approved the annual report for the Accounting Officer to sign.

8. Strategic risk register and risk system review

8.1. The Risk and Business Manager presented this item. Members were advised that the risk register was in the process of being updated.

8.2. CS1 cyber security - This remained unchanged and the new Head of IT will be updating elements of the risk register following the work on the DSP toolkit. Members commented that cyber security measures taken were reassuring.

8.3. RF1 regulatory framework. Members suggested that the communications team could be tasked with horizon scanning with other regulatory bodies at regular intervals. The Director of Strategy commented that she would work with the new Head of Communication and report back to the committee.

8.4. The Chief Executive commented that at the Scientific and Clinical Advances Advisory Committee (SCAAC) meetings, horizon scanning was a standing agenda item at the meeting. Regarding the regulatory regime, the Chief Executive commented that we hold meetings with the Advisory group and they periodic horizon scanning does and will continue to happen.

8.5. The Chair agreed to share an example with the Chief Executive of what some other regulatory bodies do as part of their horizon scanning.

8.6. P1 positioning and influencing. Members cautioned the Executives and commented that we should recognise our ability to influence because as a public body we need to be careful not to present ourselves as being right about everything.

8.7. C1 capability. Members commented that it was positive that we continue to manage to recruit to our vacant positions considering the labour market.

8.8. Members asked if there were any cases where people returned after they had left. The Chief Executive responded that this was done in an ad hoc way. Members asked the Executives to consider if this could be explored as a one-off situation in certain cases.

8.9. LC1 legal challenge. The Chair requested that this be rephrased as a successful legal challenge would lead to diversion of resources if there was a legal challenge.

8.10. PBR1 public body review. The Chief Executive commented that the public body review would happen this autumn. However, the terms of reference, details and impact was currently unknown.

8.11. Also, that PBR1 could impact on the work being done on Modernising the Act depending on the terms of reference of the public body review. Members commented but there might also be the risk of amalgamating the HFEA.

8.12. The Director of Finance and Resources commented that shared services could come under review for corporate services in the ALBs.

8.13. The Chief Executive commented that this was previously in the pipeline but at this stage we needed to avoid pre-empting what would be done.

8.14. The Chair gave a synopsis of what was discussed at the March meeting for the benefit of the new members and commented that we fail to use the intelligence we have around consumers, especially with the experience gained at putting patients at the heart of everything we do.

8.15. In terms of deep dive topics, Member suggested that we could include

- overall impact of the central government requirements on the HFEA and
- public sector pay settlement and the effects on the HFEA.

Risk management review update

8.16. Members were advised that the GIAA conducted an operational risk management audit in February 2022. The opinion of this audit was 'limited' with the summary saying

> 'There are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective'.

8.17. In light of this, the new operational risk register and the internal incident report templates were revamped and shared with members.

8.18. Members commented that staff should ensure that the templates were proportionate and not over-resourced.

8.19. Members requested that the strategic risk register should have a section on:

- the executive position,
- views on mitigations taken to date and
- mitigations planned.

8.20. On the Internal incident report, members commented that it was good and asked how it would be used in terms of proportionality. They also suggested that themes should be drawn out from completed incident reports.

8.21. Members requested that proposals for future deep dives should be presented and as closely as possible be aligned to the internal audit programme.

Action

8.22. The Chair to share an example of horizon scanning with the Chief Executive of what some other regulatory bodies do.

Decision

8.23. Members noted the position of the strategic risk register and the risk management review.

9. Digital Programme update

9.1. Members were given an update by the PRISM Programme Manager on

- the current progress of PRISM use by clinics and the quality of submissions received
- the progress of work to restore reporting in PRISM and
- the progress of the PRISM handover which commenced on 11 May.

9.2. It was noted that the error rates from standalone clinics remained low at 0.8% of activity. However, error rates from API clinics were high. It was noted that Meditex had an error submission rate of 22.2%.

9.3. In response to a question, it was noted that we could absorb the errors as long as they were reconciled and backlogs were up to date by September 2022.

9.4. In terms of re-establishing reporting including 2022 Choose a Fertility Clinic (CaFC), members were advised that in the 'first CaFC' there was the need to ensure unverified EDI submitted data could be validated, amended by clinics and corrected in PRISM and that this could prove to be challenging.

9.5. This was also affecting OTR. Currently, the OTR team checked all work against EDI which increased the time to respond. The plan was for new reports to be developed through PRISM which would allow the OTR team to further improve their productivity in dealing with OTR responses.

9.6. The handover plan and activities from contractors to HFEA staff was discussed. Members commented that they were comfortable with the planned activities and the handover process.

Action

9.7. The Chair requested that an update be sent to members outside the cycle of meetings once the delivery date for OTR through PRISM was known.

Decision

9.8. Members noted the status of PRISM deployment.

10. Information assurance and security (SIRO report)

10.1. The Director of Finance and Resources presented the annual Senior Information Risk Officer's report (SIRO). Members were reminded that it was a Cabinet Office requirement for boards to receive regular assurance about information risk management.

10.2. It was noted that throughout the year scheduled activities happened to ensure that we complied with our policy.

10.3. In response to a question the Internal Auditor responded that in terms of the DSP toolkit we were waiting for the outcomes from the submission, but that there was evidence that significant improvement had occurred throughout the year.

10.4. The External Auditor commented that members needed to be comfortable with the GDPR linkages and ensure that training was happening from board level through to staff in terms of information governance and security.

10.5. Members asked if the requirements of the DSPT would ever be met. Staff responded that we were making progress and that there was an expectation that we would, but not this year.

10.6. Members thanked the SIRO and commented that the report was reassuring.

Decision

10.7. Members noted the annual SIRO report.

11. Resilience & business continuity management

11.1. The Head of IT and Head of Information presented this item.

IT

11.2. Members were advised of some IT infrastructure improvements that had not yet happened which included:

- staff being prevented from accessing HFEA's documents including emails from none HFEA laptops and mobile devices.

11.3. It was also explained that our data backup was currently within the Microsoft ecosystem and that it was not backed up to a third-party environment which could be a vulnerability if anything happened to the UK system.

11.4. Members asked what would happen with members access as they all use their own personal devices to access HFEA material. The Head of IT responded that this was being investigated as there was a software that could help secure trusted devices. Members would register their systems as their trusted devices to enable them to continue to use them securely.

11.5. In response to a question, it was noted that this applied to mobile devices as well as laptops and as long as it was on the list of trusted devices they would be able to access HFEA material. The Head of IT commented that he had reached out to the DHSC and NHS digital to get a resolution.

DSPT

11.6. The Head of Information commented that the DSPT self-assessment had a submission date of 30 June. Members were advised that since the last paper to the committee, the corporate management group (CMG) had met and agreed a new approach to collecting evidence for submission to the toolkit. However, due to the newness of the approach and lack of knowledge we were unlikely to meet all the requirements of the toolkit this year but that there was evidence of improvement. Staff would meet with GIAA colleagues to take this forward.

11.7. The Chief Executive commented that there is a website where outcomes are published and that we are not clear how our non-compliance would be reported but the committee will be kept up to date on progress.

11.8. During discussion it was agreed that the Chief Executive will meet up with the AGC Deputy Chair, Alex Kafetz to progress this issue.

Action

11.9. Staff will meet with GIAA colleagues the DSPT requirements and evidence.

11.10. The Chief Executive will meet with the AGC Deputy Chair to discuss the DSPT issue.

Decision

11.11. Members noted the infrastructure improvements and the current position on data security and protection toolkits.

12. Counter fraud strategy and progress of action plan and FRA

12.1. The Head of Finance presented this item. Members were reminded that the Counter-fraud Strategy was developed as part of the HFEA's commitment to tackling fraud, bribery and corruption and is a key aspect of the Government Functional Standard GovS 013 Counter Fraud.

12.2. Members welcomed the report and noted the objectives of where we needed to be and how we were planning on implementing it. The action plan was also noted.

12.3. Members commented that it was right to focus on behaviours and that the creation of a counter fraud behaviour action plan was the right way forward.

12.4. In response to a question, it was noted that the DHSC and the Cabinet Office were reviewing the Counter-fraud policy across the Civil Service.

Decision

12.5. Members noted the Counter-fraud strategy and action plan.

13. Bi-annual human resource report

13.1. The Head of Human Resources (HR) presented this item. Members were advised of the key HR activities that the organisation had been working on and shared some of the actions that would inform the next phase of our People HR Strategy.

13.2. Members asked in relation to employee exit interviews if there was a question around what the HFEA could do to make that particular staff member decide not to leave. The Head of HR responded that there was and that the question was phrased around 'what could the HFEA do differently to make the staff member stay'.

13.3. It was noted that the three main reasons staff stated were:

- lack of opportunity for progression
- personal reasons and
- pay.

13.4. On equality and inclusion members were reminded that in 2021, the Executive committed to providing AGC with key highlights and information about equality and inclusion activities within the HFEA.

13.5. Following the discussion members asked if a priority pool could be created especially with other arms-length bodies in the building.

13.6. The Head of HR responded that a group had been established and mentoring was on the radar. They were expecting that there would be several success stories.

13.7. Members commented that the area the office moved to should yield a positive outcome as the demographics in the area was more multicultural compared to our previous office area.

13.8. Members stated that some Authority members would be happy to be part of the mentoring pool.

13.9. The Chair commented that she was delighted with this initiative and hoped that it would open up career paths and retain more staff.

13.10. For the staff survey it was noted that an exercise in benchmarking with other ALBs was an ongoing piece of work.

13.11. The Chair commented that in terms of leadership development, 360 degree feedback should be encouraged.

Decision

13.12. Members noted the bi-annual HR report and commented that the next report would be in December 2022.

14. AGC forward plan

14.1. The Head of Finance presented this item.

14.2. The Chair commented that training should be periodical and the next training should be on reviewing of financial statements. The external auditor to discuss this with the Director of Finance and Resources.

Actions

14.3. The Internal Auditor commented that the approval of draft plans would be at March meetings.

14.4. The Chair requested that an additional row be inserted on horizon scanning and that topics for this should be reviewed at each meeting after the strategic risk register is presented.

14.5. In October, suggested topics for deep dives should be presented.

14.6. The digital programme update to be left on the forward plan to December 2022.

14.7. The committee effectiveness review should be included in December 2022.

14.8. The External Auditor and the Director of Finance and Resources to meet to discuss member training.

Decision

14.9. Members **noted** the current position and the requested updates to the forward plan.

15. Items for noting

15.1. Whistle blowing

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

15.2. Gifts and hospitality

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

15.3. Contracts and procurement

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

16. Any other business

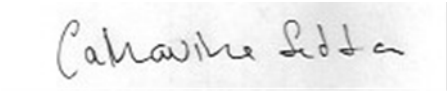
16.1. The Chair thanked the Director of Finance and Resources for the DSPT update.

16.2. Members agreed that the next meeting should be in person and that the venue would be reviewed at the next meeting.

Chair's signature

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

Signature



Chair: Catharine Seddon

Date: 4 October 2022

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	4 Oct 2022		
Author	Morounke Akingbola (Head of Finance)		
Output:			
For information or decision?	For information		
Recommendation	To note and comment on the updates shown for each item.		
Resource implications	To be updated and reviewed at each AGC		
Implementation date	2022/23 business year		
Communication(s)			
Organisational risk	☐ Low	X Medium	☐ High

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
Matters Arising from the Audit and Governance Committee – actions from 9 December 2021			
3.14 Pursue suggestions from NAO and GIAA for Board Cyber Security training	Director of Finance and Resources	Mar-22	**Update** – training to be facilitated by NAO at March meeting
5.13 Committee to receive a summary of other ALBs' experiences with DSP Toolkit	Director of Compliance and Information	Mar-22	**Update** – Report on the agenda – Chair requested it is shared with Committee
7.14/15/16 Head of HR to incorporate considerations regarding corporate culture into the proposed action plan and update AGC at October 2022 meeting on progress and effectiveness of the action plan being created from the Staff survey results. The timetable for the roll-out of the action plan to be shared with the Committee	Head of HR	Oct-22	**Update -** This will be given at the October meeting. **Update** – Action plan tabled at June meeting and includes timetable for each action.
Matters Arising from the Audit and Governance Committee – actions from 15 March 2022			
3.4 Director of Finance and Resources to circulate the summary of ALBs experiences of using the DSP Toolkit with members	Director of Finance and Resources	Mar-22	**Update –** circulated
4.7 In the 2022/23 proposed audit plan, the Board to be included in the ED&I audit	GIAA	Jul-22	**Update –** *check closer to audit date when agreed.*
Matters Arising from the Audit and Governance Committee – actions from 28 June 2022			
3.2 Topics for deep dives to be added to the forward plan	Executives	Oct 22	**Update -** It will be an agenda item at the October AGC meeting

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
5.13 Internal Audit recommendations – Goodwill letters action due date changed to June 2023	Head of Finance	By Oct-22	**Update -** date has been amended see Tracker
5.14 A quotation on the cost of scanning and saving the goodwill letters to be sent to the committee by the December meeting	Head of Information	By Dec-22	**Update -**
5.15 An oral update on goodwill letters	Director of Compliance and Information	Oct-22	**Update –** A brief paper has been submitted to SMT outlining 2 options **1.** Contract Iron Mountain to securely transport the documents, scan them and return digital images of these records for us to bulk upload them to the Register and then securely destroy the paper records. Would involve significant staff time to catalogue and remove unnecessary documents prior to scanning (proposal to recruit temp administration officer). Significant cost to HFEA. **2.** The documents we hold should be copies of originals that reside within clinics. Since we have developed the means by which clinics can send their own images of donor forms to the new Register, we could destroy all the documents we currently hold and produce a report in PRISM that identifies all donor registrations that do not have an image attached. It would then be for the clinics to submit these documents electronically. Reputational risk with sector.
8.21 The Chair to share an example of horizon scanning with the Chief Executive of what some other regulatory bodies do.	AGC Chair	Oct-22	**Update -** The Chair sent the example to the CE – completed**.**
9.7 An update is required outside of the cycle of meetings once the delivery date for OTR through PRISM is known.	Programme Manager	Sep-22	**Update –** We are still undertaking this work and we will advise AGC when the delivery dates are known. Full details on this are in the update paper.

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
11.9 HFEA to meet with GIAA to colleagues regarding DSPT requirements and evidence	Director of Finance and Resources	TBA	**Update –** Committee to receive a verbal update at the meeting
11.10 Chief Executive to meet with the AGC Deputy Chair to discuss DSPT issue.	Chief Executive	TBA	**Update -** Committee to receive a verbal update at the meeting
14.8 The External Auditor and the Director of Finance and Resources to meet to discuss member training.	Director of Finance and Resources	Oct 2022	**Update -** Committee to receive a verbal update at the meeting

Strategic risk register and risk review

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:	AGC
Agenda item:	7
Meeting date:	4 October 2022
Author:	Shabbir Qureshi, Risk and Business Planning Manager
Annexes	7a – Strategic risk register, 7b – Risk review, 7c – Operational risk register

Output from this paper

For information or decision?	For information
Recommendation:	AGC is asked to note the latest edition of the strategic risk register, the risk review paper and the operational risk register.
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	Feedback from AGC will inform the next SMT review, the risk policy and the risk registers
Organisational risk:	Medium

1. Purpose

1.1. AGC were given an updated timeline for review of the risk policy in June 2022. This included an update to the risk strategy.

1.2. The strategic risk register has had very minor changes since the last update.

1.3. A new strategic risk register Excel document is in development and this, along with the updated risk policy will be used to create a new document in time for the next Authority meeting on 16 November.

1.4. More substantial changes to the content of the strategic risk register will be made for the next AGC on 8 December.

2. Reccomendation

2.1. The Committee are requested to note and comment on the attached strategic risk register, the risk review paper and the new operational risk register.

2.2. The Committee are also asked to comment separately on the risk appetite section of the paper.

Latest review date – 14/09/2022

Human Fertilisation & Embryology Authority

Strategic risk register 2020-2024

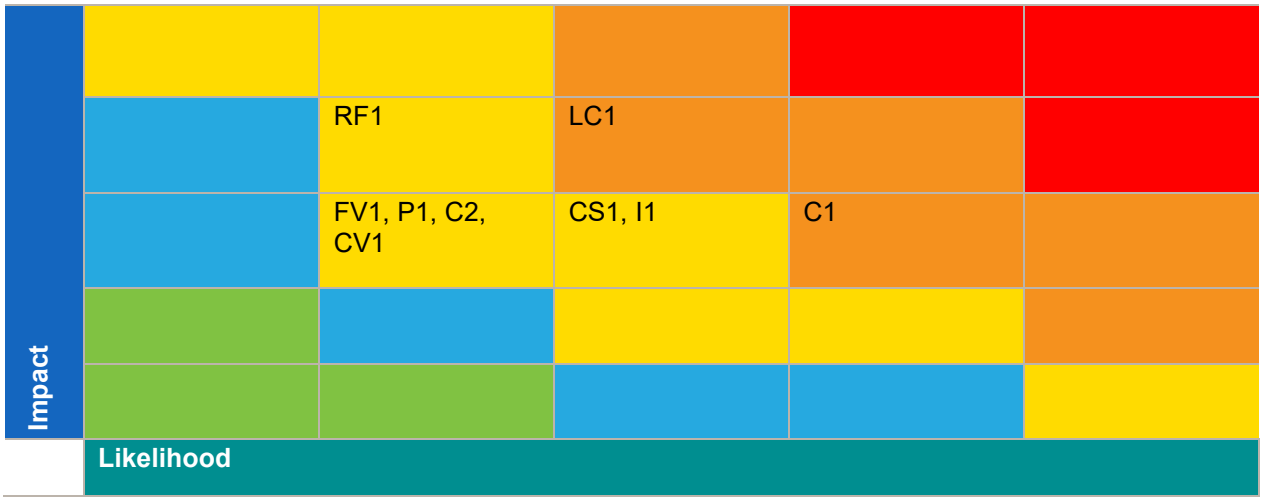
Risk summary: high to low residual risks

Risk ID	Strategy link	Tolerance	Residual risk	Status	Trend*
C2: Leadership capability	Generic risk – whole strategy	6 – Medium	**6 – Medium**	At tolerance	⇔⇔⇩⇔
LC1: Legal challenge	Generic risk – whole strategy	12 – High	**12 – High**	At tolerance	⇔⇔⇔⇔
C1: Capability	Generic risk – whole strategy	12 – High	**12 – High**	At tolerance	⇔⇔⇔⇔
CS1: Cyber security	Generic risk – whole strategy	9 – Medium	**9 – Medium**	At tolerance	⇔⇔⇔⇔
RF1: Regulatory framework	The best care (and whole strategy)	8 – Medium	**8 – Medium**	At tolerance	⇔⇔⇔⇔
FV1: Financial viability	Generic risk – whole strategy	9 – Medium	**6 – Medium**	Below tolerance	⇔⇔⇔⇔
I1: Information provision	The right information	8 – Medium	**9 – Medium**	Above tolerance	⇔⇔⇔⇔
P1: Positioning and influencing	Shaping the future (and whole strategy)	9 – Medium	**6 – Medium**	Below tolerance	⇔⇔⇔⇔
PBR1: Public body review	Whole strategy	tbc	**tbc**	n/a	

*This column tracks the four most recent reviews by AGC, SMT or the Authority (eg,⇧⇔⇩⇔).

Recent review points: SMT 10 January ⇨ SMT 21 February ⇨ AGC 15 March & Authority 23 March ⇨ SMT 23 May ⇨ AGC 28 June ⇨ SMT 14 September

Summary risk profile – residual risks plotted against each other:



RF1: There is a risk that the regulatory framework in which the HFEA operates is overtaken by developments and becomes not fit for purpose.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	5	15 - High	**2**	**4**	**8 - Medium**
Tolerance threshold:					**8 - Medium**
Status: At tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Regulatory framework RF1: Responsive and safe regulation	Rachel Cutting, Director of Compliance and Information	The best care and whole strategy	⇔⇔⇔⇔

Commentary
As a regulator, we are by nature removed from the care and developments being offered in clinics and must rely on our regulatory framework to provide sufficient powers to assure the public that treatment and research are safe and ethical. The result of not having an effective regulatory framework could be significant. The worst case of this risk would be us being without appropriate powers or ability to intervene, and patients being at risk, or not having access to treatment options that should be available to them in a safe and effective way. We reworked our inspection methodology because of Covid-19, to undertake remote and hybrid inspections to reduce risk. Hybrid inspections are continuing with unannounced inspections commencing from inspections scheduled from April 2022. We are now undertaking more on-site inspections as part of a more balanced steady state between desk-based assessments and on-site inspections, balancing workloads and risk. In September 2021 Authority received an update on the revised regime including a review of the effectiveness of the changes. The Authority endorsed this approach. There is a higher resource requirement for these new processes as they bed down, and we have kept this under close review to ensure that it remains appropriate. There is still a degree of risk – for example the licence extensions implemented in 2020/21 meant there was an inspection scheduling issue in January 2022, with a bottleneck of inspections due at that point. To manage this, we will need to continue to breach the two-yearly visit rule for some clinics and extend licences where this is possible.

Causes / sources	Controls	Timescale / owner of control(s)
We don't have powers in some of the areas where there are or will be changes affecting the fertility sector (for instance advertising or artificial intelligence).	We are strengthening or seeking to build connections with relevant partners who do have powers in such areas (for instance, we collaborated on the CMA and ASA's work in this area to strengthen the information and advertising provision for patients). Working with other expert	In progress - Clare Ettinghausen

Causes / sources	Controls	Timescale / owner of control(s)
	regulators is effective in areas where we do not have effective powers We take external legal advice as relevant where developments are outside of our direct remit (eg, on an incidence of AI technology being used in the fertility sector) and utilise this to establish our legal/regulatory position. We are analysing where there are gaps in our regulatory powers so that we may be able to make a case for further powers if these are necessary, whenever these are next reviewed.	Ad hoc ongoing - Catherine Drennan Pre-business case project planning in progress - Joanne Anton,
Developments occur which our regulatory tools, systems and interventions have not been designed to address and they are unable to adapt to.	Regular review processes for all regulatory tools such as: • Code of Practice. • Compliance and enforcement policy • Licensing SOPs and decision trees Regular reviews enable us to revise these and prevent them from becoming ineffective or outdated. Regular liaison with DHSC and other health regulators to raise issues.	In place - Joanne Anton Revised version of the policy launched 1 June 2021– Catherine Drennan, Rachel Cutting In place and ongoing – Paula Robinson In place - Peter Thompson
The revised inspection approach (including a period of fully remote and hybrid inspections due to Covid-19, introduced November 2020) requires greater resources from the inspection team. This affects ongoing delivery. Note: risk cause arises from control under CV1.	Reviewing the new way of working and inspection approach as this continues to be embedded. Moving towards a steady state balance between desk-based elements and on-site inspections. Compliance management in discussion with the wider Inspection team to ensure that scrutiny is at the correct level and inspections are ‘right sized’ in accordance with revised methodology. Review of documentation required for DBA undertaken in July 2021 to ensure this is proportionate. Clear communication to the inspection team about appropriate level of scrutiny. Continued extensions to some licences where appropriate (ie, low risk clinics with good compliance) to manage the pressure on inspection delivery workload.	Plan in place, agreed by Authority September 2021 – Sharon Fensome Rimmer, Rachel Cutting
Some changes can be very fast meaning our understanding of the implications is limited, affecting our ability to adequately	We cannot control the rate of change, but we can make sure we are aware of likely changes and make our response as timely as possible by:	

Causes / sources	Controls	Timescale / owner of control(s)
prepare, respond and take a nuanced approach	• Annual horizon scanning at SCAAC • maintaining links with key stakeholders including other professional organisations and the licensed centres panel to get a sense of changes they are experiencing or have early sight of. We necessarily must wait for some changes to be clearer to take an effective regulatory position. However, we may choose to take a staged approach when changes are emerging, issuing quick responses such as a Chair's letter, Alert or change to General Directions to address immediate regulatory needs, before strengthening our position with further guidance or regulatory updates.	In place – Joanne Anton In place - Peter Thompson
We have limited capacity, which may reduce our ability to respond quickly to new work, since we may need to review and stop doing something else.	Monthly opportunity for reprioritising at CMG when new work arises and weekly SMT meetings for more pressing decisions. Any reprioritisation of significant Strategy work would be discussed with the Authority.	In place – Peter Thompson
Developments occur in areas where we have a lack of staffing expertise or capability.	As developments occur, Heads consider what the gaps are in our expertise and whether there is training available to our staff. If a specific skills gap was identified in relation to a new development, we could consider whether it is appropriate or possible to bring in resource from outside, for instance by employing someone temporarily or sharing skills with other organisations.	Ongoing - Relevant Head/Director with Yvonne Akinmodun
RITA (the register information team app – used to review submissions to the Register) has been built but some reporting issues still need to be resolved. If this is not completed in a timely way, we may not effectively use data and ensure our regulatory actions are based on the best and most current information. As of February 2022, development work is in progress and this risk is decreasing.	If RITA is not completed in a timely way, the Register and OTR team will still be able to use manual workarounds to get access to the information they need to support clinics and / or to provide information to support our regulatory work. although these workarounds will result in a substantial delay to responding to an OTR request or providing clinic support. RITA Phase 2 has been prioritised against other development work. A new group to prioritise and oversee development was established in October 2021.	Ongoing – Rachel Cutting (pending recruitment to Chief Technology Officer post) Prioritisation of remaining development as delivery continues – Kevin Hudson
We don't hold all the data from the sector (beyond inspection or Register data) to inform our interventions, for instance on add-ons.	As part of planning and delivering the add-ons project we have looked at the evidence available and considered whether we can access other information if we do not have this already.	In place – Joanne Anton Audit tool launched in clinics from

Causes / sources	Controls	Timescale / owner of control(s)
	We revise our approach on inspection where relevant, to ensure that the right information is available (for instance, launching an add-ons audit tool). Process to be established for reviewing the data dictionary which will allow for internal and external stakeholders to suggest that we collect more/less data, review impact assessments on the HFEA and the sector as a whole of those changes and plan for any development that will be needed (both internally and externally) to make them possible. Data review board to be initiated after PRSIM has been successfully rolled out and embedded in clinics.	Autumn 2020 - Rachel Cutting Detailed planning to follow – Neil McComb
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC - If there was a review of our regulatory powers, there would be a strong interdependency with the Department of Health and Social Care.	Early engagement with the Department to ensure that they are aware of the HFEA's position in relation to any future review of the legislation. Provided a considered response to the Department's storage consent consultation to give the HFEA position.	Ongoing - Peter Thompson

I1: There is a risk that the HFEA becomes an ineffective information provider, jeopardising our ability to improve quality of care and make the right information available to people.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	3	12 - High	**3**	**3**	**9 - Medium**
Tolerance threshold:					**8 - Medium**
Status: **Above tolerance**					

Risk area	**Risk owner**	**Links to which strategic objectives?**	**Trend**
Information provision I1: delivering data and knowledge	Clare Ettinghausen, Director of Strategy and Corporate Affairs	The right information	⇧⇔⇔⇔

Commentary

Information provision is a key part of our statutory duties and is fundamental to us being able to regulate effectively. We provide information to the public, patients, partners, donors, the donor conceived, their families and clinics alike. If we are not seen as relevant then we risk our information not being used, which in turn may affect the quality of care, outcomes, and options available to those involved in treatment.

In October 2020, the Opening the Register service reopened after being paused since clinics shut down due to Covid-19. Due to this pause, we received an influx of applications which means we are unable to meet our usual KPI for completing responses for a period. We have managed this carefully as a live issue, to ensure that applicants receive accurate data and effective support as quickly as we are able, with a focus on continuing to provide a quality, effective service. New performance reporting KPIs are being developed to give the Authority a clear picture of progress. Ongoing communication with applicants and centres has been clear to ensure they understand the position and we manage expectations. We have recruited extra resource to manage the backlog but the impact of this will take some time to resolve the issue and reduce the ongoing risk. While training has occurred over summer 2021 processing rates have dropped, but we expect this to increase again in the coming months.

As at Autumn 2021, development work is outstanding to enable us to update CaFC from the new Register. A review has been undertaken but we need to discuss the implications of this, set against other developments, before agreeing a full plan. It is now likely to be Autumn 2022 before we can update CaFC, and the management of this gap is being discussed. Given the centrality of CaFC to our services, this will require a communications plan as well.

The residual risk level was raised slightly after discussion at SMT in November, in recognition of earlier points raised at AGC about CaFC uncertainties.

There are a number of external challenges which impact on our information provision, for example the rise of social media and online groups as competing information sources, as well as clinics' own websites and other publicly available information. Working on our wider profile raising and media and social media reach may help to address these challenges.

Causes / sources	Controls	Status / timescale / owner
People don't find us/our information, meaning we are unable to get clear and unbiased information to patients, donors, and others.	Knowledge of key searches and work to improve search engine optimisation to ensure that we will be found. We have a rolling bi-annual cycle to review website content and can revise website content to ensure this is optimised for search if necessary. We undertake activities to raise awareness of our information, such as using social and traditional media. We maintain connections with other organisations to ensure that others link to us appropriately, and so we increase the chance of people finding us. We are also assessing this from the 2021 patient survey.	In place and ongoing – Clare Ettinghausen
Our information is not used by our key stakeholders	Ensure a strategic stakeholder engagement plan is agreed and revisited frequently. New Patient Organisation Stakeholder Group launched in 2021. Stakeholder engagement plans considered as part of project planning to ensure this is effective. Measurement of stakeholder sentiment and activity to be included in future comms evaluation?	In place with ongoing review – Clare Ettinghausen . Ongoing – Clare Ettinghausen
We have more competition to get information out to people. For instance, other companies have set up their own clinic comparison sites and clinics post their own data.	Ensure we maximise the information on our website and the unique features of our clinic inspection information and patient ratings. Clinics are encouraged to ask patients to use the HFEA patient rating system. We have optimised Choose a Fertility Clinic so that it is one of the top sites that patients will find when searching online and will be able to evaluate this from the outcomes of the 2021 patient survey. Review our information and distribution mechanisms on an ongoing basis to ensure relevance. (Also see below about CaFC.)	In place and ongoing - Clare Ettinghausen In place and ongoing - Clare Ettinghausen
The new Register is now live, but there is still a considerable amount of work to be undertaken to develop, test and implement new data tools. This may hamper our ability to provide the right data in a timely way across the whole organisation.	The implementation of these new data tools and systems will be prioritised, to ensure that the impact in the interim period is minimised. Teams, such as the Inspectorate, have backup plans for the gap between cutover and when the new register feeds into existing systems or processes (inspectors' notebooks, RBAT, QSUM, OTR etc.) to ensure relevant data is available. A reporting version of the Register was captured in August 2021 before EDI was switched off. This will allow the intelligence team to continue to respond to FOIs and enquiries. A reporting database has been	In place - Rachel Cutting (pending recruitment to Chief Technology Officer (CTO) post), Sharon Fensome-Rimmer Interim arrangement in

Causes / sources	Controls	Status / timescale / owner
	built in the new Register and is being tested with the team.	place - Nora Cooke O'Dowd
The data in the new Register is not yet complete or validated.	While some data can be accessed, the information is not yet of sufficient quality to be used. For Intelligence, this means that it is not possible to publish Fertility Trends in 2022 with new data and therefore a Covid report has been published instead. The intelligence team cannot provide information based on updated data until validation has been completed (expected November 2022). All responses to FOIs, PQs and enquiries will point to unvalidated 2020 treatments and unvalidated 2019 outcomes throughout 2022 and into early-mid 2023.	Interim arrangement in place - Nora Cooke O'Dowd
Pending planned post-PRISM development to re-enable the reporting of verified data from the new Register, we will be unable to update Choose a Fertility Clinic for some months. It therefore risks losing or reducing its unique selling point, which is to be an authoritative source of independent, timely, accurate information to inform patients' treatment choices.	As above - We updated the data available on CaFC ahead of the Register migration, to ensure that 2019 treatment data can be accessed, and have a reporting version of the Register captured in August 2021. This delays CaFC becoming out of date but does not close the risk. Discussions about communicating this necessary gap in updating CaFC to the sector and our stakeholders are in progress.	Completed February 2021 and August 2021 – Neil McComb In progress – Peter Thompson
Given the advent of increased DNA testing, we no longer hold all the keys on donor data (via our Opening the Register (OTR) service). Donors and donor conceived offspring may not have the information they need to deal with this.	Maintain links with donor organisations to mutually signpost information and increase the chance that this will be available to those in this situation. Maintain links with DNA testing organisations to ensure that they provide information to those using direct to consumer tests about the possible implications. Raise this in any review of the Act.	In place and ongoing – Clare Ettinghausen In place and ongoing – Laura Riley Future measure – Peter Thompson
Our OTR workload has increased and will change again in 2023 (when children born after donor anonymity was lifted begin to turn 18) and we may lack the capability to deal sensitivity with donor issues.	Service development work to review resourcing and other requirements for OTR to ensure these are fit for purpose. Service development project in progress. Temporary additional resource in place (from April and July 2021) to help mitigate increasing demands on the service in the short-term.	Future control – project in progress - Neil McComb
The OTR service may be negatively impacted by an influx of applications following	Our focus is on accuracy and effective support for applicants; therefore, we have temporarily ceased reporting against our usual KPI, during the period	Additional resource in place (from

Causes / sources	Controls	Status / timescale / owner
reopening after being paused, with demand outstripping our ability to respond. Note, this is being managed as a live issue as of September 2021.	of dealing with this pent-up demand. We are continuing to clearly communicate with applicants and the sector to manage expectations. We have recruited additional temporary resource to manage demand, however during training processing of applications has again been limited.	April and July 2021) – Neil McComb
Risk that key regulatory information will be overlooked by stakeholders owing to the number of different communication channels and information sources.	There is a statutory duty for PRs to stay abreast of updates, and we provide key information via Clinic Focus. We duplicate essential communications by also sending via email to each centre's PR and LH (for instance, all Covid-19 correspondence). We ensure that the Code and other regulatory tools are up to date, so that clinics find the right guidance on the Portal when they need it regardless of additional communicated updates. We plan to implement a formal annual catch-up between clinics and an inspector. Note: that due to revised inspection approach due to Covid-19 these plans have been delayed.	In place – Rachel Cutting In place – Joanne Anton Future control to consider following Covid-19 – Rachel Cutting
We don't provide tangible insights for patients in inspection reports to inform their decision making; because of this, we could be seen as less transparent than other modern regulators.	Review of inspection reports is planned to identify future improvements. This will be delivered alongside other transparency work. We do provide patient and inspector ratings on CaFC to provide some additional insight into clinics. Work on the inspection report is currently deprioritised due to the demands of implementing the New Storage Regulations.	Early work underway, but likely to complete 2022 – Rachel Cutting In place – Rachel Cutting Clare Ettinghausen
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None.		

P1: There is a risk that we do not position ourselves effectively and so cannot influence and regulate optimally for current and future needs.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16 - High	**2**	**3**	**6 - Medium**
Tolerance threshold:					**9 - Medium**
Status: Below tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Positioning and influencing P1: strategic reach and influence	Clare Ettinghausen – Director of Strategy and Corporate Affairs	Shaping the future and whole strategy	⇔⇔⇔⇔

Commentary

This risk is about us being able to influence effectively to achieve our strategic aims. If we do not ensure we are well placed to do this, we may not be involved in key debates and developments, and our strategic impact may be limited.

We have a communications approach, agreed with the Authority in January 2021. This supports our thinking on strategic positioning and will ensure that we are best placed to deliver on the Authority's strategic ambitions. A revised approach will be presented to CMG and subsequently Authority in late 2022

The response to the Covid-19 pandemic required close working with many other organisations and professional bodies, as well as increased engagement with the sector, which has strengthened our strategic positioning.

In 2021 we have changed our patient stakeholder organisation group to broaden it's membership and have also established a patient forum to support greater patient involvement in our work.

Wider political developments mean that the HFEA has been incorporated into the DHSC 'health family' in a closer way than previously. This has likely improved our connections with the DHSC and other ALBs and enabled us to have greater influence on specific issues.

Causes / sources	Controls	Status/timescale / owner
We are working towards currently have the range of influence we need to secure our position.	Maintaining and updating our stakeholder engagement plan.	In place, agreed with the Chair and reviewed regularly ongoing – Clare Ettinghausen

Causes / sources	Controls	Status/timescale / owner
	Chair and Authority members acting as ambassadors to expand the reach and influence of the organisation's messages and work. Stakeholder identification undertaken for all projects to ensure that these are clear from the outset of planning, and that we can plan communications, involvement and if necessary, consultations, appropriately.	In place but will need to continue to engage on this as Board membership changes. Authority members - Peter Thompson and Clare Ettinghausen In place – Project Sponsors and Project Managers
We lack some of the required influencing capacity and skills for strategic delivery.	Oversight on public affairs from senior staff and good individual external relationships with key stakeholders. As we move towards the later stages of strategic delivery, we will need to assess our capacity and capabilities in this area, alongside our strategic plans, to ensure we can engage on key issues such as legislative changes and new technologies. Senior Management to keep need for this under review.	In place – Peter Thompson and Clare Ettinghausen In place – Peter Thompson and Clare Ettinghausen, Paula Robinson
We are unable to persuade partner organisations to utilise their powers/influence/resources to achieve shared aims.	Early engagement with such organisations, to build on shared interests and reduce the likelihood of this becoming an issue. For instance, the treatment add-ons working group.	In place - Clare Ettinghausen
The sector can take a different view on the evidence HFEA provides (for instance in relation to Add-ons) and so our information may be overlooked.	The working group for the add-ons project has focused on building on earlier consensus and pull together key stakeholders to reduce the likelihood of guidance and evidence being dismissed. SCAAC sharing evidence it receives more widely and having an open dialogue with the sector on add-ons. Evidence-based and transparent policymaking, with risks considered whenever a new approach or policy is being developed.	Ongoing - Joanne Anton

Causes / sources	Controls	Status/timescale / owner
When there are policy and strategic changes, HFEA and sector interests can be in conflict, damaging our reputation.	Decisions taken within the legal framework of the Act and supported by appropriate evidence, which would ensure these are clear and defensible.	In place - Peter Thompson
We lack opportunities to engage with early adopters or initiators of new treatments/innovations or changes in the sector.	Regular engagement with SCAAC enables developments to be flagged for follow up by compliance/policy teams. Routine discussion on innovation and developments at Policy/Compliance meetings to ensure we consider developments in a timely way. Inspectors feed back on new technologies, for instance when attending ESHRE, so that the wider organisation can consider the impact of these. We plan to investigate holding an annual meeting with key innovators (in industry) in the future and in advance of this are continuing informal contact.	In place - Joanne Anton In place - Joanne Anton Delayed due to Covid – future control – Sharon Fensome-Rimmer Future control, delayed due to Covid-19 but to be reviewed in Q4 2021/2022 - Rachel Cutting
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: The Department may not consider future HFEA regulatory interests or requirements when planning for any future consideration of relevant legislation which could compromise the future regulatory regime.	Early engagement with the Department to ensure that they are aware of HFEA position in relation to any future review of the legislation. Provided a considered response to the Department's storage consent consultation to give the HFEA position.	Ongoing - Peter Thompson Completed - Joanne Anton
Government: Any consideration of the future legislative landscape may become politicised.	There are no preventative controls for this, however clear and balanced messaging between us, the department and ministers may reduce the impact. Develop improved relationships with MPs and Peers to ensure our views and expertise are considered.	Ongoing - Peter Thompson
Government: Consideration of changes to the regulatory framework may be affected by political turbulence (for instance changes of Minister).	There are no preventative controls for this, however, we will ensure that we are prepared to effectively brief any future incumbents to reduce turbulence. We would also do any horizon scanning as the political landscape changed if needed.	Ongoing - Peter Thompson

FV1: There is a risk that the HFEA has insufficient financial resources to fund its regulatory activity and strategic aims.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	4	12 - High	**2**	**3**	**6 - Medium**
Tolerance threshold:					**9 - Medium**
Status: Below tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Financial viability FV1: Income and expenditure	Richard Sydee, Director of Finance and Resources	Whole strategy	⇔⇔⇔⇔

Commentary
The in-year income position remains uncertain as actual activity data has not been available since August 2021 when clinics began the move to the HFEA's new reporting system, PRISM. Invoices have been raised and issued to clinics based on historic activity in previous years and a full reconciliation will be undertaken once clinics have entered backlog data and are submitting data in line with HFEA requirements. It is unlikely that a reconciliation for all clinics will be complete this business year, although we remain confident that most data will be reconciled ahead of the final accounts. In January 2022 the HFEA received approval from HMT and DHSC to increase the IVF licence fee by £5. A Chair's letter has been issued advising that the increase will take effect from 1 April 2022.

Causes / sources	Controls	Timescale / owner
There is uncertainty about the annual recovery of treatment fee income – this may not cover our annual spending.	Heads see quarterly finance figures and would consider what work to deprioritise or reduce should income fall below projected expenditure. We would discuss with the Authority if key strategic work needed to be delayed or changed. We have a model for forecasting treatment fee income, and this reduces the risk of significant variance, by utilising historic data and future population projections. This has been the basis for invoicing since August 2021 and provides significant confidence that the reconciliation process will not result in material variances between the current forecast and final outturn position. The agreement to a £5 increase in the IVF licence fee for 2022/23 onwards will provide additional income to meet the emerging and acknowledged operational pressures the HFEA faces.	CMG monthly and Authority when required – Peter Thompson

Causes / sources	Controls	Timescale / owner
Our monthly income can vary significantly as: • it is linked directly to level of treatment activity in licensed establishments • we rely on our data submission system to notify us of billable cycles.	Our reserves policy takes account of monthly fluctuations in treatment activity, and we have sufficient cash reserves to function normally for a period of two months if there was a steep drop-off in activity. If clinics were not able to submit data and could not be invoiced for more than three months, we would invoice them on historic treatment volumes and reconcile this against actual volumes once the submission issue was resolved and data could be submitted.	Policy in place October 2021 – Richard Sydee Control under quarterly review as sector reopens – Richard Sydee
Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.	Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with Directorates flag any shortfall or further funding requirements. All project business cases are approved through CMG, so any financial consequences of approving work are discussed. The ten-year lease at Redman Place (from 2020-2030) provides greater financial stability, allowing us to forecast costs over a longer period and adjust other expenditure, and if necessary, fees, accordingly, to ensure that our work and running costs are effectively financed.	Quarterly meetings (on-going) – Morounke Akingbola Ongoing – Richard Sydee A moto is in place for Stratford confirming details of arrangements – Richard Sydee
Inadequate decision-making leads to incorrect financial forecasting and insufficient budget.	Within the finance team there are a series of formalised checks and reviews, including root and branch analyses of financial models and calculations. The organisation plans effectively to ensure enough time and senior resource for assessing core budget assumptions and subsequent decision making.	In place and ongoing - Richard Sydee Quarterly meetings (on-going) – Morounke Akingbola
Project scope creep leads to increases in costs beyond the levels that have been approved.	Project assurance Group is chaired by the Director of Resources and a finance staff member is also present at PAG. Periodic review of actual and budgeted spend by Digital Projects Board (formerly IfQ) and monthly budget meetings with finance. Any exceptions to tolerances are discussed at PAG and escalated to CMG at monthly meetings, or sooner, via SMT, if the impact is significant or time critical.	Ongoing – Richard Sydee or Morounke Akingbola Monthly (on-going) – Samuel Akinwonmi
Failure to comply with Treasury and DHSC spending controls and finance policies and guidance may lead to serious reputational risk and a loss of	The oversight and understanding of the finance team ensures that we do not inadvertently break any rules. The team's professional development is ongoing, and this includes engaging and networking with the wider government finance community.	Continuous - Richard Sydee

Causes / sources	Controls	Timescale / owner
financial autonomy or goodwill for securing future funding.	All HFEA finance policies and guidance are compliant with wider government rules. Policies are reviewed annually, or before this if required. Internal oversight of expenditure and approvals provides further assurance (see above mitigations).	Annually and as required – Morounke Akingbola
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: Legal costs materially exceed annual budget because of unforeseen litigation.	Use of reserves, up to appropriate contingency level available at this point in the financial year. The final contingency for all our financial risks would be to seek additional cash and/or funding from the Department.	Monthly – Morounke Akingbola
DHSC: GIA funding could be reduced due to changes in Government/policy.	A good relationship with DHSC Sponsors, who are well informed about our work and our funding model. GIA funding for the SR21 period is yet to be finalised, discussions are underway with the department and expected to conclude ahead of the 2022/23 business year	Quarterly accountability meetings (on-going) – Richard Sydee December/ January annually, – Richard Sydee

C1: There is a risk that the HFEA experiences unforeseen knowledge and capability gaps, threatening delivery of the strategy or our statutory work.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	4	20 – Very high	**4**	**3**	**12 - High**
Tolerance threshold:					**12 - High**
Status: At tolerance.					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Capability C1: Knowledge and capability	Peter Thompson, Chief Executive	Whole strategy	⇔⇔⇔⇔

Commentary

This risk and the controls are focused on organisational capability, rather than capacity, though there are obviously some linkages between capability and capacity. There are also links with organisational change (such as hybrid working or the advent of PRISM), and risk elements that were formerly captured under a separate risk, OM1, which has now been discontinued, have been added to this risk accordingly.

Turnover remains above tolerance putting strain on staff generally while covering gaps, inducting new starters, and managing knowledge transfer. Moreover, recruitment has been more difficult for some individual posts, with typically fewer high-quality applicants per post advertised, which increases the risk of a post not being appointed to or taking more than one recruitment round to fill. The civil service pay freeze has not helped, although pay is an issue throughout the wider public sector, not just for the HFEA. Though overall high turnover has cumulative effects across the whole organisation, high turnover at team level can feel particularly acute. Regular conversations about resources at CMG ensure that we are aware of and can, where possible, plan mitigations.

High turnover is made more problematic in the context of expanding BAU work, reducing the opportunity to prioritise. As a consequence, discussions are ongoing with the DHSC about the need to increase the headcount of the organisation, funded from the modest fee increase that has been agreed (see FV1).

Where we have met recruitment challenges, we have considered the needs of the post and designed our response accordingly, to identify other means to cover capability gaps and redeploy skills. For example, we extended an existing contractor and asked another staff member to act up to cover pending recruitment to the Chief Technology Officer post. Anecdotal evidence is that the turnover is in line with trends in the wider public sector, though we plan to review data from exit interviews to understand this further. We are aware that some organisations have reviewed terms and conditions to attract high-quality applicants; CMG is considering ongoing arrangements for flexible and homeworking, and this should help to ensure that we continue to attract a wide range of candidates to our roles.

We are working to maintain our relative flexibility while meeting our organisational needs. Recruitment has been generally successful. Discussions with CMG are advancing and proposals on homeworking are being finalised. More engagement with staff on these issues is in progress following on from the staff survey conducted at the end of October 2021.

AGC receive 6-monthly updates on capability risks to consider our ongoing strategies for the handling of these, to allow them to track progress. Looking further ahead, we need to find ways to tackle the issue of development opportunities, to prevent this risk increasing. An idea we are keen to explore is whether we can build informal links or networks with other public sector or health bodies, to develop clearer career paths between organisations. Unfortunately, this work has not progressed further due to Covid-19, although conversations about such development opportunities continue on an individual level.

Management of Board and senior executive capability is captured in the separate C2 risk, below.

Causes / sources	Mitigations	Status/Timescale / owner
High turnover, sick leave etc., leading to temporary knowledge loss and capability gaps. Note: this is a more acute risk for our smaller teams.	Organisational knowledge captured via documentation, handovers and induction notes, and manager engagement. We have developed corporate guidance for all staff for handovers. A checklist for handovers is circulated to managers when staff hand in their notice. This checklist will reduce the risk of variable handover provision.	In place – Yvonne Akinmodun Checklist in use – Yvonne Akinmodun
	Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention. CMG and managers prioritise work appropriately when workload peaks arise. Contingency: In the event of knowledge gaps, we would consider alternative resources such as using agency staff, or support from other organisations, if appropriate. This has been required for certain posts.	In place – Yvonne Akinmodun and relevant managers In place – Peter Thompson In place – Relevant Director alongside managers
Inability to quickly appoint to key posts is extending the duration of capability gaps.	Looking for alternative ways to allocate skills and resources for hard-to-fill roles to cover gaps.	Ongoing – hiring managers, Yvonne Akinmodun
Poor morale leading to staff leaving, opening up capability gaps.	Communication between managers and staff at regular team and one-to-one meetings allows any morale issues to be identified early and provides an opportunity to determine actions to be taken. The staff intranet enables regular internal communications. Ongoing CMG discussions about wider staff engagement (including surveys) to enable management responses where there are areas of concern.	In place, ongoing – Peter Thompson In place – Clare Ettinghausen In place - staff survey October 2021 with wellbeing pulse survey September

Causes / sources	Mitigations	Status/Timescale / owner
	Policies and benefits are in place that support staff to balance work and life (stress management resources, mental health first aiders, PerkBox) promoting staff to feel positive about the wider package offered by the HFEA. This may boost good morale.	2021 and quarterly thereafter– Yvonne Akinmodun In place - Peter Thompson
Work unexpectedly arises or increases for which we do not have relevant capabilities.	Careful planning and prioritisation of both business plan work and business flow through our committees. Regular oversight by CMG – standing item on planning and resources at monthly meetings, and periodic planning workshops. Team-level service delivery planning for the next business year, with active involvement of team members. CMG will continue to review planning and delivery. Requirement for this to be in place for each business year. Oversight of projects by both the monthly Project Assurance Group and CMG. Project guidance to support early identification of interdependencies and products in projects, to allow for effective planning of resources. Planning and prioritising data submission project delivery, within our limited resources. Skills matrix completed by teams to enable better oversight of organisational skills mix and deployment of resource. Plans being drawn up in relation to findings.	In place – Paula Robinson In place – Paula Robinson In place – Paula Robinson In place– Paula Robinson In place until project ends – Rachel Cutting (pending CTO recruitment) Analysis completed February 2022 – Yvonne Akinmodun
Not putting actions in place to realise the capability benefits of colocation with other organisations, arising out of the office move, such as the ability to create career pathways and closer working.	Active engagement with other organisations early on and ongoing (HR group). We are collaborating with other relevant regulators to see what more can be done to create career paths and achieve other benefits of working more closely, including a mentorship programme. Note: delayed due to Covid-19 impacts. Future control – use of Redman Place intranet to enable cross-organisational communications.	Early progress, ongoing – Yvonne Akinmodun Planned but not yet in place – Richard Sydee
Stratford is a less desirable location for some current staff due to:	We have an agreed excess fares policy to compensate those who will be paying more following the move to Stratford (those in post before December 2019).	In place – Yvonne Akinmodun,

Causes / sources	Mitigations	Status/Timescale / owner
• increased commuting costs • increased commuting times • preference of staff to continue to work in central London for other reasons, leading to lower morale and lower levels of staff retention (resulting in knowledge loss and capacity and capability gaps) as staff choose to leave because of the office location.	Efforts taken to understand the impact on individual staff and discuss their concerns with them via staff survey, 1:1s with managers and all staff meetings to inform controls. These have informed the policies developed. Conversely, there will be improvements to the commuting times and costs of some staff, which may improve morale for them and balance the overall effect. Reduction in number of days in the office following Covid-19 is likely to have reduced the risk of loss of staff.	Richard Sydee Done - Yvonne Akinmodun,
There is a risk that staff views on the positives and negatives of homeworking due to Covid-19 are not considered, meaning we miss opportunities for factoring these into planning our future operating model and alienate staff by not considering their views, for instance on flexible working. This could lead to staff leaving.	Heads discuss impacts with teams on a regular basis and feed views into discussions at CMG. Regular communication to staff about the developing conversation and direction of travel through all staff meetings and the intranet. A further survey of staff was conducted in late October, to inform any policy reviews.	Ongoing with survey in October – Peter Thompson
The need to operate with revised arrangements during the ongoing pandemic may delay consideration of our ongoing post-covid operating model, leading to staff seeing management as extending uncertainty about arrangements, inconsistent application of temporary arrangements and inequity, causing lower morale and levels of staff retention.	All staff have been offered either a home or office-based contract. Office based requires at least one day a week in the office. We see this as a stable set of working arrangements for the foreseeable future. In addition, work on a common agreement on how best to use the office facilities is under way. Further training about leading and managing hybrid teams has commenced.	Ongoing – Peter Thompson
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
Government/DHSC The UK leaving the EU has ongoing consequences for the HFEA which we must manage.	Funding in place for additional resource to manage EU Exit workload in 2021-2022. We continue to work closely with the DHSC on any arising issues and work towards implementing the impacts of the Northern Ireland Protocol as it applies to HFEA activity across the UK.	Communications ongoing – Clare Ettinghausen/ Andy Leonard

Causes / sources	Mitigations	Status/Timescale / owner
	NB unless any further funding is secured for future years then this work will need to be absorbed within existing activity.	
In-common risk Covid-19 (Coronavirus) may at times lead to high levels of staff absence leading to capability gaps or a need to redeploy staff.	Management discussion of situation as it emerges, to ensure a responsive approach to any developments. We reviewed our business continuity plan in April 2021 to ensure it is fit for purpose.	Ongoing - Peter Thompson
NICE/CQC/HRA/HTA – IT, facilities, meeting rooms, ways of working interdependencies.	Ongoing building working groups with relevant IT and other staff such as HR. Informal relationship management with other organisations' leads.	In place – Richard Sydee, DHSC
In-common risk The general jobs market and the so-called 'great resignation' may lead to capability gaps where recruitment takes some time to complete.	Management discussion when needed to agree how to deal with recruitment gaps.	Ongoing – Peter Thompson

C2: Loss of senior leadership (whether at Board or Management level) leads to a loss of knowledge and capability which may impact formal decision-making and strategic delivery.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
2	4	8 - Medium	**2**	**3**	**6 - Medium**
Tolerance threshold:					**6 - Medium**
Status: At tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Estates C2: Leadership capability	Peter Thompson Chief Executive	Whole strategy.	⇔⇔⇔⇩

Commentary
This risk reflects both the risks related to Board and senior executive leadership. Although the causes and impacts are different, many of the mitigations are similar, and both would have an impact on the organisation's external engagement and potentially strategic delivery. The HFEA board is unusual since members undertake quasi-judicial decision-making as part of their roles, sitting on licensing and other committees. This means that changes in Board capability and capacity may impact the legal functions of the Authority. We need to maintain sufficient members with sufficient experience to take what can be highly controversial decisions in a robust manner. As such our tolerance threshold for this risk is fairly low. However, we have raised the tolerance level from 4 to 6 (February 2022) to reflect the current operational reality, which is that an unusually high proportion of new Board members are being appointed this year. Seven new Board members have been recruited. The new members have relatively long onboarding times at the HFEA owing to the need for specialist training for the licensing committees (which has been delivered), and the need to then accumulate experience and knowledge. The seven recent appointments reduce this risk considerably. The Board is now at full strength which provides a stable basis for some time to come. Were a member of the senior executive team to leave the appropriate mitigations would depend on the role, but mitigations include delegating some responsibilities to remaining members of SMT and/or the relevant Head(s) and the appointment of an interim, where professional skills allow. Recruitment to a senior role will usually take longer than the 3 months contractual notice and so there will inevitably be a gap to manage.

Causes / sources	Mitigations	Status/timescale / owner
The induction time of new members (including bespoke legal training) can be significant, particularly for those sitting on licensing committees, which may experience an initial	There is some degree of continuity of membership, which will help new members to acclimatise and learn.	In place, ongoing - Paula Robinson

Causes / sources	Mitigations	Status/timescale / owner
loss of collective knowledge and potentially an impact on the quality or ease of decision-making. Evidence from current members suggests that it can take up to a year for members to feel fully confident. Depending on new members to ensure committee quoracy means that their legal training must be arranged prior to their start date, and that there will be no opportunity for them to observe a meeting prior to participating as a decision-maker.	Legal training is available and is being improved to focus more on the decision-making process as well as the requirements and powers in the Act. The Governance team and the Chief Executive have reviewed recruitment information and member induction to ensure that this is as smooth as possible. A set of briefings on key issues has been introduced. All members have access to the standard licensing pack containing key documents to aid the committee in its decision-making. The guidance on licensing in the standard licensing pack is being updated, to align with the current compliance and enforcement policy and to give committee members and Chairs more support, particularly when decisions are challenging or finely balanced.	
Induction of new members to licensing and other committees, requires a significant amount of internal staff resource and could reduce the ability of Governance and other teams to support effective decision-making in other ways.	We have been mindful of this resource requirement when planning other work, to limit the impact of induction on other priorities.	In progress - Peter Thompson, Paula Robinson
Any member recruitment often takes some time and can therefore give rise to further vacancies and capability gaps. The recruitment process is run by DHSC meaning we have limited power to influence this risk source. Historically, decisions on appointments can create additional challenges for planning (the annual report from the commission for public appointments suggests appointments take on average five months).	We have focused on streamlining induction to ensure that the members who joined the HFEA this year are brought up to speed as quickly as practicable. This risk cause remains for all future recruitment.	Under way- Peter Thompson
The loss of a member of the senior leadership team (for instance through retirement, leaving the organisation for a new role etc) creates a leadership/knowledge gap.	Note: We cannot mitigate the cause of this risk, since staff may choose to leave the organisation for personal reasons. However, we can mitigate the consequences. Responsibilities could be shared across SMT and Heads to cover any gaps and maintain leadership, decision-making and oversight (this would include	In place – Peter Thompson

Causes / sources	Mitigations	Status/timescale / owner
	Chairing ELP which may be delegated under Standing Orders). Good induction process to ensure that new staff are onboarded efficiently. Effective use of delegation, to build capability of less senior staff, to enable them to step up in the case of senior staff absences (either temporarily or to apply for the role permanently in the case of staff leaving). Chief Executive would discuss recommendations for cover with the Chair if he were to move on from the organisation, to ensure that responsibilities were covered during any gap before appointment. Other controls (handover, knowledge capture, processes etc) per the wider staff turnover risk above. Clear, documented plans to enable more straightforward management of such a situation when it occurs.	In place - Yvonne Akinmodun with relevant Manager for specific role In place – Relevant Director alongside managers As required – Director and staff as relevant As required – Peter Thompson, Julia Chain As required – Peter Thompson
Recruitment to SMT or Head post often takes some time which could create a leadership gap.	Heads could temporarily act up into Director roles to manage any pre-recruitment gaps. The same would be true of manager-level staff acting up for Heads. Control employed to manage Chief Technology Officer recruitment gap.	In place, discussed as required – relevant Manager with Yvonne Akinmodun
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Status/timescale / owner**
Government/DHSC The Department is responsible for our Board recruitment but is bound by Cabinet Office guidelines.	Clear communication with the Department about the management of this risk and mitigations that sit outside of HFEA control.	Ongoing - Peter Thompson
Government/DHSC DHSC is responsible for having an effective arm's length body in place to regulate ART. If it does not ensure this by effectively managing HFEA Board recruitment, it will be breaching its own legal responsibilities.	Clear communication with the Department about the management of this risk and mitigations that sit outside of HFEA control.	Ongoing - Peter Thompson

Causes / sources	Mitigations	Status/timescale / owner
Government/DHSC HFEA operates in a sensitive area of public policy, meaning there may be interest from central government in the appointments process. This may impact any planned approach and risk mitigations and give rise to further risk.	Clear communication with the Department about the management of this risk and mitigations that sit outside of HFEA control.	Ongoing - Peter Thompson

CS1: There is a risk that the HFEA is subject to a cyber-attack, resulting in data or sensitive information being compromised, or IT services being unavailable.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	4	20 – Very high	**3**	**3**	**9 - Medium**
Tolerance threshold:					**9 - Medium**
Status: At tolerance					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Cyber security CS1: Security and infrastructure weaknesses	Rachel Cutting Director of Compliance and Information	Whole strategy	⇔⇔⇔⇔

Commentary
Cyber-attacks and threats are inherently likely. Our approach to handling these risks effectively includes ensuring we: • have an accurate awareness of our exposure to cyber risk • have the right capability and resource to handle it • undertake independent review and testing • are effectively prepared for a cyber security incident • have external connections in place to learn from others. We continue to assess and review the level of national cyber security risk and act as necessary to ensure our security controls are robust and are working effectively.

Causes / sources	Controls	Timescale / owner
Insufficient board oversight of cyber security risks, resulting in them not being managed effectively.	Routine cyber risk management delegated from Authority to Audit and Governance Committee which receives reports at each meeting on cyber-security and associated internal audit reports to assure the Authority that the internal approach is appropriate and ensure they are aware of the organisation's exposure to cyber risk. The Deputy Chair of the Authority and AGC is the cyber lead who is regularly appraised on actual and perceived cyber risks. These would be discussed with the wider board if necessary. Cyber security training needs to be included in a standard induction process for Authority members. A new induction process has been introduced in March 2022.	In place – Martin Cranefield In place - Peter Thompson Last undertaken January 2020. New course

Causes / sources	Controls	Timescale / owner
		for Authority members to be implemented Autumn 2021. – Martin Cranefield
Insufficient executive oversight of cyber security risks, resulting in them not being managed effectively	Cyber security training in place to ensure that all staff are appropriately aware of cyber risks and responsibilities. Further training including lunch and learn sessions planned for 2022. Regular review of cyber / network security policies to ensure they are appropriate and in line with other guidance. Policies reviewed, by CMG May 2022. Regular review of business continuity plan to ensure that this is fit for purpose for appropriate handling cyber security incidents to minimise their impact.	In place – Martin Cranefield Reviewed at CMG in May 2022– Martin Cranefield In place and ongoing process – Martin Cranefield
Changes to the digital estate open up potential attack surfaces or new vulnerabilities. Our relationship with clinics is more digital, and patient identifying information or clinic data could therefore be exposed to attack.	Penetration testing of newly developed systems (PRISM, the Register) assure us that development has appropriately considered cyber security. We undertake penetration testing regularly but a full network penetration test will cover access control, encryption, computer port control, pseudonymisation and physical control Clear information security guidance to HFEA staff about how identifying information should be shared, especially by the Register team, to reduce the chance of this being vulnerable. Net nanny implemented April 2022.	Testing is undertaken regularly, – Register /PRISM completed. Infrastructure July 2022– Martin Cranefield In place, reviewed in summer 2020 and fit for purpose – Neil McComb
The IT support function is small so may not provide us with the cyber security resource that we need (ie, emergency support in the case of dealing with attacks)	We have an arrangement with a third-party IT supplier who would be able to assist if we did not have enough internal resource to handle an emergency for any reason. The support arrangement will be reviewed in 2022.	Contract in place until June 2023 – Martin Cranefield
We cannot mitigate effectively for emerging or developing cyber security threats if we are not aware of these.	We maintain external linkages with other organisations (such as ALB CIO network and NHS Digital Cyber Associates Network) to learn from others in relation to cyber risk. We receive regular	Ongoing– Martin Cranefield

Causes / sources	Controls	Timescale / owner
	security alerts and action the high priority ones when they arrive.	
Technical or system weaknesses could lead to loss of, or inability to access, sensitive data, including the Register.	We undertake regular penetration testing to identify weaknesses so that we can address these. We have advanced threat protection in place to identify and effectively handle threats. We regularly review and if necessary, upgrade software to improve security controls for network and data access, such as Remote Access Service (RAS) software.	Ongoing, PRISM / Register completed, Infrastructure due July 2022– Martin Cranefield In place – Martin Cranefield Ongoing (Upgrade to Pulse RAS system completed during summer 2021) – Martin Cranefield
Physical devices used by staff are lost, stolen or otherwise fall into malicious hands, increasing chance of a cyber-attack.	Hardware is encrypted, which would prevent access to data if devices were misplaced. Staff reminded during IT induction about the need to fully shut down devices while outside of secure locations (such as travelling) to implement encryption. Conditional access being put in place for remote access by HFEA staff. This will reduce the risk of attack by devices that are not owned by HFEA.	Ongoing (regular reminders sent to staff with security best practice) – Martin Cranefield Conditional access complete April 2022.
Remote access connections and hosting via the cloud may create greater opportunity for cyber threats by hostile parties.	All cloud systems in use have appropriate security controls, terms and conditions and certifications (ISO and GCloud) in place.	In place – Martin Cranefield
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None. Cyber-security is an 'in-common' risk across the Department and its ALBs.		

LC1: There is a risk that the HFEA is legally challenged given the ethically contested and legally complex issues it regulates.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	5	20 – Very high	**3**	**4**	**12 - High**
Tolerance threshold:					**12 - High**
Status: **At tolerance**					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Legal challenge LC 1: Resource diversion	Peter Thompson, Chief Executive	Safe, ethical effective treatment: Ensure that all clinics provide consistently high quality and safe treatment	⇔⇔⇔⇔

Commentary

We accept that in a controversial area of public policy, the HFEA and its decision-making will be legally challenged. Our Act and related regulations are complex, and aspects are open to interpretation, sometimes leading to challenge. There are four fundamental sources of legal risk to the HFEA, it may be due to:

- execution of compliance and licensing functions (decision making)
- the legal framework itself as new technologies and science emerge
- policymaking approach/decisions
- individual cases and the implementation of the law (often driven by the impact of the clinic actions on patients).

Legal challenge poses two key threats:

- that resources are substantially diverted
- that the HFEA's reputation is negatively impacted by our participation in litigation.

These may each affect our ability to regulate effectively and deliver our strategy and at their most impactful they could undermine the statutory scheme the HFEA is tasked with upholding. Both the likelihood and impact of legal challenge may be reduced, but it cannot be avoided entirely. For these reasons, our tolerance for legal risk is high.

There is currently ongoing legal action in relation to two matters.

Causes / sources	Mitigations	Timescale / owner
Legal challenge about the way we have executed our core regulatory functions of inspection and licensing. For instance, clinics challenging	At every Licence Committee there is a legal advisor present and where necessary, we can draw on the expertise of an established panel of legal advisors, whose experience across other sectors can be applied to put the HFEA in the best	In place – Peter Thompson

Causes / sources	Mitigations	Timescale / owner
decisions taken about their licence.	possible position to make out a robust case and defend any challenge.	
Legal challenge if new science, technology, or wider societal changes emerge that are not covered by the existing regulatory framework.	Scientific and Clinical Advances Advisory Committee (SCAAC) horizon scanning processes. This provides the organisation with foresight and may provide more time and ability to prepare our response to developments. Case by case decisions on the strategic handling of contentious or new issues to reduce the risk of challenge or, in the event of challenge, to put the HFEA in the strongest legal position.	SCAAC horizon scanning meetings annually. In place – Catherine Drennan and Peter Thompson
Legal challenge to policies when others see these as a threat or ill-founded. Moving to a bolder strategic stance, eg, on add-ons or value for money, could result in claims that we are adversely affecting some clinics' business model or acting beyond our powers. Note: the current challenge as of September 2021 relates to this risk source.	Evidence-based and transparent policymaking, with risks considered whenever a new approach or policy is being developed. Reviewing and updating existing policy on contentious issues if required. We undertake good record keeping, to allow us to identify and access old versions of guidance, and other key documentation, which may be relevant to cases or enquiries and enable us to see how we have historically interpreted the law and implemented related policy and respond effectively to challenge. Business impact target assessments carried out whenever a regulatory change is likely to have a significant cost consequence for clinics meaning that consideration of impacts and how these will be managed is considered as part of the policymaking process. Stakeholder involvement and communications in place during policymaking process (for instance via regular stakeholder meetings) to ensure that clinics and others can feed in views before decisions are taken, and that there is awareness and buy-in in advance of any changes. Major changes are consulted on widely.	In place – Joanne Anton with appropriate input from Catherine Drennan Ongoing - Joanne Anton In place – Richard Sydee Ongoing - Joanne Anton
Legal challenges related to clinical implementation of regulation in terms of individual cases (ie, consent-related cases). Ongoing legal parenthood and storage consent failings in clinics and related cases are specific examples. The case-	We undertake good record keeping, to allow us to identify and access old versions of guidance, and other key documentation, which may be relevant to cases or enquiries and enable us to see how we have historically interpreted the law. Through constructive and proactive engagement with third parties, the in-house legal function serves to anticipate issues of this sort and prevent challenges. This strengthens our ability to find solutions that do not require legal action.	Ongoing – Catherine Drennan In place – Catherine Drennan

Causes / sources	Mitigations	Timescale / owner
by-case nature of the Courts' approach to matters means resource demands are unpredictable when these arise. Note: we are in dialogue with the Department on the proposed changes to the statutory storage period and the impact that it will have on consent for gametes and embryos currently in storage.	Legal panel in place, as above, enabling us to outsource some elements of the work. Scenario planning is undertaken with input from legal advisors at the start of any legal challenge. This allows the HFEA to anticipate a range of different potential outcomes and plan resources accordingly. We took advice from a leading barrister on the possible options for handling storage consent cases to ensure we take the best approach when cases arise. We also get ongoing ad hoc advice as matters arise. Significant amendments have been made to guidance in the Code of Practice dealing with consent to storage and this will be published in October 2021. This guidance will go further to supporting clinics to be clearer about the legal requirements. Storage consent has been covered in the revision of the PR entry Programme (PREP).	In place – Peter Thompson Done in 2018/19 and we continue to apply this advice and take further ad hoc advice as required – Catherine Drennan Revised guidance– Catherine Drennan PREP in place – Catherine Drennan/ Joanne Anton
Committee decisions or our decision-making processes being contested. ie, Licensing appeals and/or Judicial Reviews. Challenge of compliance and licensing decisions is a core part of the regulatory framework, and we expect these challenges even if decisions are entirely well founded and supported. Controls therefore include measures to ensure consistency and avoid process failings, so we are in the best position for when we are challenged, therefore reducing the impact of such challenges.	Compliance and Enforcement policy and related procedures to ensure that the Compliance team acts consistently according to agreed processes. Well-evidenced recommendations in inspection reports mean that licensing decisions are adequately supported and defensible. The Compliance team monitors the number and complexity of management reviews and stay in close communication with the Head of Legal to ensure that it is clear if legal involvement is required, to allow for appropriate involvement and effective planning of work. Panel of legal advisors in place to advise committees on questions of law and to help achieve consistency of decision-making processes. Measures in place to ensure consistency of advice between the legal advisors from different firms. Including:	In place new version launched June 2021– Rachel Cutting, Catherine Drennan In place – Sharon Fensome-Rimmer In place – Peter Thompson Since Spring 2018 and

Causes / sources	Mitigations	Timescale / owner
	• Provision of previous committee papers and minutes to the advisor for the following meeting • Annual workshop • Regular email updates to panel to keep them abreast of any changes. Consistent and well taken decisions at licence committees supported by effective tools for committees and licensing team (licensing pack, Standard operating procedures, decision trees etc) which are regularly reviewed.	ongoing – Catherine Drennan In place – Paula Robinson
Any of the key legal risks escalating into high-profile legal challenges resulting in significant resource diversion and reputational consequences for the HFEA which risk undermining the robustness of the regulatory regime.	Close working between legal and communications teams to ensure that the constraints of the law and any HFEA decisions are effectively explained to the press and the public. The default HFEA position is to conduct litigation in a way which is not confrontational, personal, or aggressive. We have sought to build constructive relationships with legal representatives who practice in the sector and the tone of engagement with them means that challenge is more likely to be focused on matters of law than on the HFEA. Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise workload should this become necessary.	In place – Catherine Drennan, Clare Ettinghausen In place – Peter Thompson, Catherine Drennan In place – Peter Thompson
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: If HFEA face unexpected high legal costs or damages which it could not fund. This is an interdependent risk as the Department must ensure the ability to maintain the regulatory regime.	If this risk was to become an issue, then discussion with the Department of Health and Social Care would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also an interdependent risk because DHSC would be involved in resolving it.	In place – Peter Thompson
DHSC: We rely upon the Department for any legislative changes in response to legal risks or impacts.	Our regular communications channels with the Department would ensure we were aware of any planned change at the earliest stage. We highlight when science and medicine are changing so that they can consider whether to make changes to the regulatory framework. Joint working arrangements would then be put in place as needed, depending on the scale of the change. If necessary, this would include agreeing any associated implementation budget.	In place – Peter Thompson

Causes / sources	Mitigations	Timescale / owner
	Departmental/ministerial sign-off for key documents such as the Code of Practice in place.	
DHSC: The Department may be a co-defendant for handling legal risk when cases arise.	We work closely with colleagues at the Department to ensure that the approach of all parties is clear and is coordinated wherever possible. We also pre-emptively engage on emerging legal issues before these become formal legal matters.	In place – Peter Thompson

PBR1: A public body review has been confirmed for the HFEA in Autumn 2022, however the detail and impact is, as yet, unknown.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	4	20 – Very high	**Tbc**	**Tbc**	**Tbc**
Tolerance threshold:					**Tbc**
Status: **Tbc**					

Commentary

Reviews and revisions

SMT review – May 2022:

- The SRR has been reviewed and no further changes have been made.
- A full SRR review will take place in October once the new format has been agreed and implemented.

AGC review – 28 June 2022:

AGC noted the report and presentation including an update on all risks, controls and scores and made the following points in discussion (about both the SRR and risk review):

- RF1 – Consider including an element of horizon scanning. Consider whether we can 'borrow' any learning from other ALBs.
- I1 – AGC were notified updates will be made as we have now appointed a new head of Comms.
- P1 – Wording to be reconsidered as the risk is 'the ability to influence'. Cannot reduce political turbulence.
- C1 – considering the high turnover over the last two years, have still managed the capability well.
- C2 – no comments
- CS1 - AGC were notified significant updates will be made as we have now appointed a new head of IT.
- LC1 – wording to be reconsidered; the risk is a successful legal challenge.
- PBR1 – No further information received from DHSC.
- Consideration should also be given to impact and changes to central government requirements including public sector pay which has been reported to have had a 7% cut in real terms.
- Current SSR is unwieldly and doesn't give a clear sense of risk in place, more a historical summary. Would like the following:
    - What is the executive position on the risk?
    - Their view of mitigations to date and outline of upcoming planned mitigations.
    - Target of bringing a risk back into appetite.

AGC liked the new incident reporting proposal of a simplified web-based system. They asked for the policy to draw out how the system will be used to show the lessons learnt.

They also asked, when the proposal for deep dives is presented, this should outline the purpose, format and list of topics which are important. As sense of why a particular topic has been selected. Is it prior to (or post) an audit? Also, this should not create an undue demand on the executive.

AGC asked for executive or AGC priorities to be added to deep dives and this should also be added to the AGC forward plan.

A key comment was made to ensure all the work is proportionate and takes into account resource considerations.

SMT review – May 2022:

- The following have been updated:CV1 – This risk has now been removed and residual elements (such as those relating to capacity) integrated into other risks as appropriate.
- C1 – Reference to CTO removed. Added new contract offer to all staff for home or office-based working.
- C2 – The inherent risk likelihood has been reduced to 2 from 4 as new board members have been appointed and we are now at capacity.
- PBR1 – This risk has been added, however, as no further information is available at the time of the update, the detail has not been completed.

Authority review – 23 March 2022:

The Authority noted a report and presentation including an update on all risks, controls and scores and feedback from the previous week's AGC meeting.
Additional comments included:

- I1 – It was suggested that this risk also be reviewed based on the findings from the patient survey.
- CS1 – It was observed that the increase in OTR traffic could be a factor in this risk.
- C2 – It was suggested that the inherent risk scores should also now be reviewed.

AGC review – 15 March 2022:

AGC noted a report and presentation including an update on all risks, controls and scores and made the following points in discussion:

- I1 – the plan to update this again following further work on the communications strategy was noted. Also agreed to further review the scoring in light of progress towards updating CAFC and the reputational consequences of delays. This is already somewhat mitigated by the communications plan that has been put in place.
- P1 – noted that this risk would also be updated after the communications strategy had been further developed. AGC recommended reflecting on future factors such as increased cross-government working, shared risks such as cyber security, and the strong government agenda on innovation, sustainability, and digital developments.
- C1 – noted that the suggestion of using the proximity of other ALBs to help with staff development and career paths was not yet in place, since the different ALBs occupying 2 Redman Place are returning to the office at different rates. Th executive were encouraged to consider other ways of ensuring staff benefit from things like secondment opportunities, since it was unlikely that a full return to office working would take place.
- CS1 – cyber security was recognised as a major issue for all organisations, especially give the war in Ukraine and a probability of increased attacks in the future. The committee welcomed the additional training on cyber security that they would be attending that afternoon. The executive was encouraged to consider the possibility of the HFEA experiencing outages as a result of collateral damage from wider attacks (for instance if London's power network were targeted). It was also possible that an attack on a smaller body like the HFEA could be used to undermine bigger parts of government.
- CV1 – agreed with the proposal to discontinue this risk from June onwards and fold any outstanding risk elements into other relevant risks such as C1, capacity. A lessons learned exercise should be conducted to identify useful learning points.

AGC also approved the plan for reviewing the risk policy, the risk register, and risk appetite and tolerances. It would be important to ensure the risk system did not become complex and unwieldy, and to focus on ensuring the system is not only effective, but also efficient. The idea of surfacing the most active issues in the risk register, and making other improvements to the presentation, was welcomed. The executive were particularly asked to prioritise making it a more dynamic management tool, to guide planning and strategic thinking, and to regularly consider risk tolerances and the effectiveness of current controls. This should include a plan and timeline for bringing risks back into tolerance where they were above tolerance. The committee also gave some thoughts on current risks coming over the horizon, and welcomed the plan to develop more of a methodology for doing this exercise regularly in the future.

SMT review – 21 February 2022:

SMT reviewed all risks, controls and scores and made the following points in discussion:

- RF1 updated to reflect the latest position related to the ongoing effects of earlier Covid impacts.
- I1 will need further work when our new communications strategy is more advanced. This risk will then be reframed, to focus more on the risks to us achieving the desired impact and reach with our information.
- P1 updated, but as with the above risk, may need to be updated further as we progress the work on our communications strategy.
- FV1 comprehensively updated following the approval of HMRC for our fees increase this year.
- C1 updated slightly throughout, including the addition of an 'in common' risk affecting all ALBs relating to recruitment in the current job market.
- C2 revised to update the position on Board appointments. The risk score has been lowered. The tolerance threshold has also been raised.
- CS1 updated significantly following a planned review.
- LC1 no significant changes have been made on this occasion.
- CV1 updated to reflect the current position. It is proposed that this risk be retired (with AGC's permission sought in March) in or around June, at which point any remaining elements could be fed into the ongoing capability risk.

SMT review – 14 January 2022:

SMT reviewed all risks, controls and scores and made the following points in discussion:
SMT reviewed the risks and agreed to review several of the risks in more detail after the meeting, as follows:

- RF1 to be reviewed in light of comments at AGC.
- I1 to be reviewed in light of our latest thinking on the communications strategy and the forthcoming paper to the Authority about this.
- P1 to be reviewed to include the possibility of the Act not being reviewed in the next few years.
- FV1 to be reviewed in light of latest Q3 position and to update the commentary to reference the covid inquiry, storage regulations, PRISM handover and the latest position on fees and funding.
- CS1 to be referred to the Head of IT for review following recent work on device security.

SMT considered the point raised at AGC about risk tolerances, but felt that the tolerances set remain appropriate for the time being. While it is not ideal that several risks remain above or at tolerance, there are no further controls to add at the present time, and it remains very unlikely that all of the risks would become live issues simultaneously. While risks are running above tolerance, this tends to create more strain in the system, rather than making the risk unmanageable. It will likely mean increased effort and possibly some resource diversion at times, and so we would seek to implement any further controls we can identify in order to bring the risk back within tolerance. There will be occasions, however, when there are no more actions we can take. It is worth noting that the intended future control of obtaining additional resources would make a positive difference, if achieved, to the tolerability of a number of the risks.

AGC review – December 2021:

AGC noted a report and presentation including an update on all risks, controls and scores and made the following points in discussion:

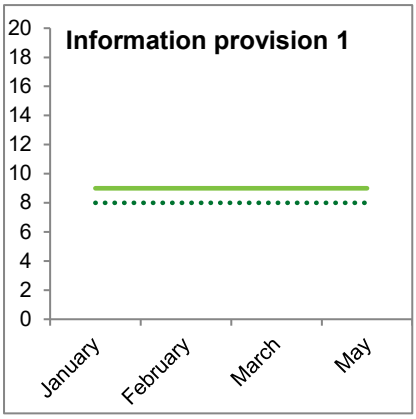
- The plan for reviewing the risk system in line with earlier input was noted. An outline plan and timetable should come to the next AGC meeting.

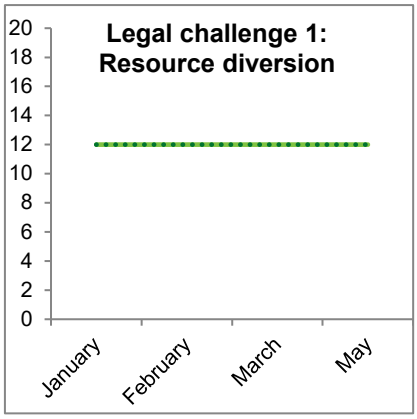
- RF1 – may need to be reframed to reflect that our work on the Act may see us seeking new powers. A question was also raised about whether the impact of the Covid restrictions on inspection meant that we had been in breach of the law – it was confirmed that it was a statutory duty to inspect clinics every two years, and that while this had not been possible, other methods had been adopted to ensure that clinics were safe and patients were not at risk.
- C1 – changes were noted.
- I1 – it was noted that this risk was now slightly over tolerance. It was suggested that the communications strategy should be incorporated into the risk description.
- C2 – the update on leadership capabilities and succession planning was noted.
- CS1 – noted the current work being done to improve our resilience against ransomware and hacking attacks, and that this risk would be reviewed shortly.
- P1 – members asked if we needed to increased the rating for this risk. If we failed to keep up the momentum, we would need to consider the consequences.
- The Committee was keen to see more horizon scanning incorporated into the risk register, to anticipate upcoming areas of risk.
- Members questioned whether having so many risks above tolerance was factually correct, as this implied that everything was collapsing, and this evidently wasn't the case. It was worth considering whether the tolerances, or the overall risk appetite, may have changed.

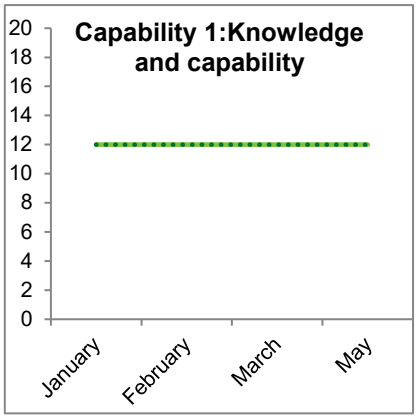
Risk trend graphs (May 2022)

Key:

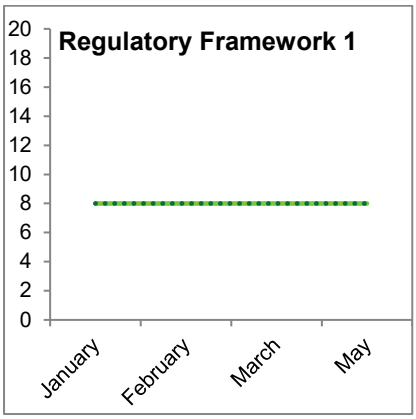
High and above tolerance risks

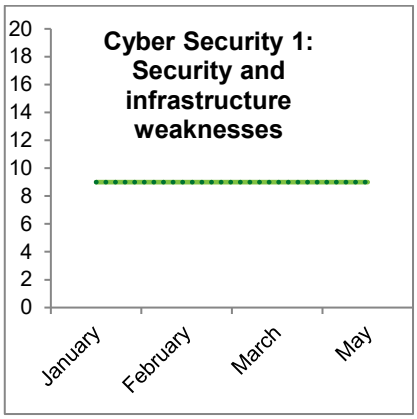


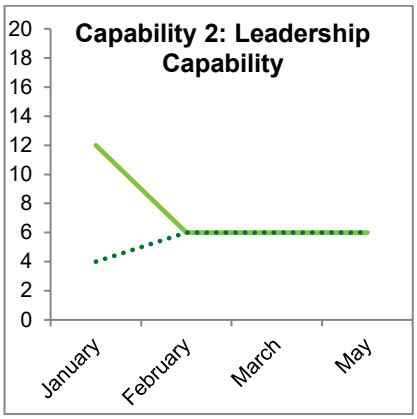


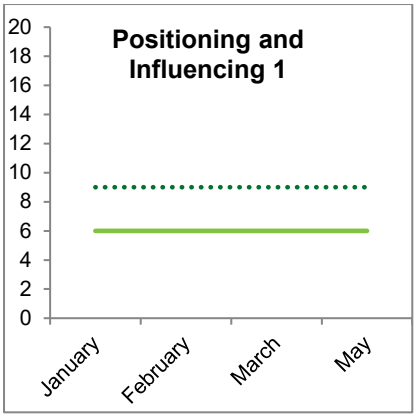


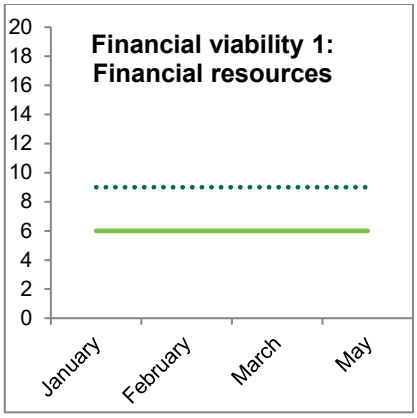
Lower and below tolerance risks








Positioning and Influencing 1
20
18
16
14
12
10
8
6
4
2
0
January
February
March
May


Financial viability 1: Financial resources
20
18
16
14
12
10
8
6
4
2
0
January
February
March
May

Criteria for inclusion of risks

Whether the risk results in a potentially serious impact on delivery of the HFEA's strategy or purpose.

Whether it is possible for the HFEA to do anything to control the risk (so external risks such as weather events are not included).

Rank

The risk summary is arranged in rank order according to the severity of the current residual risk score.

Risk trend

The risk trend shows whether the threat has increased or decreased recently. The direction of the arrow indicates whether the risk is: Stable ⇔ , Rising ⇧ or Reducing ⇩.

Risk scoring system

We use the five-point rating system when assigning a rating to the likelihood and impact of individual risks:

Likelihood:	1=Very unlikely	2=Unlikely	3=Possible	4=Likely	5=Almost certain
Impact:	1=Insignificant	2=Minor	3=Moderate	4=Major	5=Catastrophic

Risk scoring matrix

Impact	1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
5.Very high	5 Medium	10 Medium	15 High	20 Very High	25 Very High
4. High	4 Low	8 Medium	12 High	16 High	20 Very High
3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
1. Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium
Risk Score = Impact x Likelihood	Likelihood				

Risk appetite and tolerance

Risk appetite and tolerance are two different but related terms. We define risk appetite as the willingness of the HFEA to take risk. As a regulator, our risk appetite will be naturally conservative and for most of our history this has been low. Risk appetite is a general statement of the organisation's overall attitude to risk and is unlike to change unless the organisation's role or environment changes dramatically.

Risk tolerance on the other hand is the willingness of the HFEA to accept and deal with risk in relation to specific goals or outcomes. Risk tolerance will vary according to the perceived importance of particular risks and the timing (it may be more open to risk at different points in time). The HFEA may be prepared to tolerate comparatively large risks in some areas and little in others. Tolerance thresholds are set for each risk, and they are considered with all other aspects of the risk each time the risk register is reviewed

Assessing inherent risk

Inherent risk is usually defined as 'the exposure arising from a specific risk before any action has been taken to manage it'. This can be taken to mean 'if no controls at all are in place'. However, in reality the very existence of an organisational infrastructure and associated general functions, systems and processes introduces some element of control, even if no other mitigating action were ever taken, and even with no particular risks in mind. Therefore, for our estimation of inherent risk to be meaningful, we define inherent risk as:

'the exposure arising from a specific risk before any additional action has been taken to manage it, over and above pre-existing ongoing organisational systems and processes.'

System-wide risk interdependencies

We explicitly consider whether any HFEA strategic risks or controls have a potential impact for, or interdependency with, the Department or any other ALBs. There is a distinct section beneath each risk to record any such interdependencies, so we identify and manage risk interdependencies in collaboration with relevant other bodies, and so that we can report easily and transparently on such interdependencies to DHSC, or auditors as required.

Contingency actions

When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation must achieve balance between the costs and resources involved in limiting the risk, compared to the cost of the risk translating into an issue. In some circumstances it may be possible to have contingency plans in case mitigations fail, or, if a risk goes over tolerance, it may be necessary to consider additional controls.

When a risk exceeds its tolerance threshold, or when the risk translates into a live issue, we will discuss and agree further mitigations to be taken in the form of an action plan. This should be done at the relevant managerial level and may be escalated if appropriate.

HFEA 2022 Risk Management review

1. Overview

1.1. The risk management policy and associated processes were due to be reviewed in 2021, however, the departure of the previous Risk & Business Planning Manager (and before that, the Covid pandemic) delayed this.

1.2. A review plan was submitted to AGC in June 2021, this was subsequently updated for AGC on 15 March 2022 and a further update issued to AGC on 28 June 2022.

1.3. GIAA conducted an operational risk management audit in February 2022. The opinion of this audit was 'Limited' with a summary of 'There are significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective'. That audit has been helpful in informing our review of the operational aspects of our risk management.

2. Plan for the risk review

2.1. Below is the plan provided to AGC in June with progress notes:

Month	Proposed plan	October update
March	Support the internal audit of our risk systems and begin to consider recommendations once the report is ready.	Completed. Final internal audit report presented to AGC on 28 June 2022.
April	Review of best practice guidance and other organisational approaches with reference to the revised Orange Book and risk improvement groups (DHSC and Cross-government). Consideration of how to feed latest best practice into a revised version of our risk strategy.	Completed. A draft of the updated strategy is attached. Details below.
May	Commence review of operational risk management practices and identification and mitigation of weaknesses, in line with recommendations arising from the current audit, and our own observations about current team practices. Redrafting of policy to begin.	Completed. See details below.

	Consideration of content/structure changes in the strategic risk register, to surface the most active issues and improve presentation. Feedback for AGC on progress to date to be drafted in readiness for the June meeting.	The strategic risk register will be developed further following the implementation of the new operational risk register.
June-September	Design and implementation of rolling improvement plans for operational risk management. Ongoing work on the revised risk strategy and risk register. Consideration of how to frame the discussion on our overall risk appetite and the setting of tolerances for individual risks. Design of a horizon scanning methodology.	Completed. See details below.
October	Revised draft of risk strategy and risk register completed and presented to AGC for consideration. Discussion on risk appetite and tolerance levels.	Draft strategy and template for operational risk register attached.
November	Agreement of risk appetite with Authority alongside their periodic review of the risk register.	No change.
December	Finalisation and launch of the revised risk strategy and feedback to AGC on the Authority's discussion on risk appetite.	No change.

3. Policy changes

3.1. The previous risk management policy was released in November 2018 and was due to be reviewed in 2020 but was put back to 2021 due to COVID.

3.2. The GIAA audit stated: 'The current risk management policy is out of date and doesn't incorporate some of the recent changes that have been made to the Orange Book or the introduction of Risk Champions within the Authority.'

3.3. The Orange book was revised in 2020 and updated in August 2021 to include a Risk Management Skills and Capabilities framework, a Good Practice guide to risk reporting and a revised Risk Appetite guidance note.

3.4. The new 'Risk strategy' (changed from 'Risk policy') has addressed the following, using both Orange book principles and audit feedback:

- The structure and some of the text from the Orange book has been used.
- The role and responsibilities of the 'Risk Champions' have been amalgamated into the strategy.

- A continuous improvement and horizon scanning methodology have been included.
- Guidance to aid with the assessment of the impact of risk; taking into account the legal, financial, regulatory and reputational risks have been included. The risk categories from the Orange book have been included in the new operational risk register.
- The risk strategy and departmental risk registers have been framed using the causes/ events/ consequences system. The strategic risk register template will use the same system.
- Guidance for Heads on selecting the top three risks to bring to CMG and the process of escalating risks to the Strategic Risk Register have been included in the new strategy.
- The risk appetite concept has been referenced, highlighting the differences between current/ tolerable/ optimal risk positions.
- A section on horizon scanning and future risk identification has been added. This is to identify opportunities and focussing on making risks both dynamic and time-framed where appropriate.
- The 'deep dives' concept and references to risk assurance mapping have been added taking into account resource limitations to frame actions and mitigations.
- The links between risk management, service delivery plans and performance management have been included.
- The 'Risk Management Skills and Capability Framework' has been included which includes risk inductions and the requirements of both informal and formal risk training.

4. HFEA risk registers

4.1. The 'Project Risk Registers' were identified in the audit as having some good practice elements and these have been adopted into the new operational risk register template which will be used by all teams. A separate project to update the Project Management system used by HFEA is currently under way and this is due to be completed by the end of 2022 for implementation in 2023. A new monthly project performance report, completed on an online form, will be used to identify current risks to make the focus on in-project risks more dynamic and targeted.

4.2. A standardised Excel template for the operational risk register has been created. This has incorporated the following:

- All teams have a tab on a single sheet so they can compare each other's risks and scores.
- Teams can 'tag' other teams where the risk is shared or impacted by actions from other teams.
- Risks have an 'Open/ Closed/ Future' system to make risks dynamic.
- The sheet has automation built in, so calculations and colours for risk scores are selected automatically.
- There is also a 'dashboard' which shows how many risks have been identified across teams and the residual risk scores total.

4.3. Guidance on completing the operational risk register along with 'best practice' examples have been developed.

4.4. The strategic risk register is under development. A draft Excel based register has been created and this will be further developed once the new operational risk register has been launched. The new strategy demonstrates

5. The role of Risk Champions

5.1. The previous risk champions policy has been amalgamated with the new risk strategy.

5.2. A key addition is the clarification that the risk champions are not expected to spend more than a half day each month on risk-based activities. Their role is to support Heads, but the responsibility for each team's operational risk management remains with the Head.

5.3. Risk champions are expected to undergo additional training and development work, so they are better able to support heads. Collaboration activities between the risk champions will be restarted with quarterly meetings to share best practice and learning from internal incidents.

6. Performance reporting

6.1. A new performance reporting sheet has been put in place for reporting data from the new financial year. This has had the following changes:

- Tabs for each team to aid navigation.
- The sheet is 'locked' to prevent formulas and formatting to be restricted.
- All RAG ratings are automated.
- The majority of data, comments and charts required for generating the performance reports for SMT, Authority and AGC have been automated.

6.2. All teams have reviewed their KPIs; some are still under review, with Comms KPIs the most challenging as some indicators are not available with the systems HFEA currently use. The new Compliance KPIs have been running since April and are now revealing a better picture of inspection reporting and licensing activity.

6.3. A 'dip check' system is being developed and will be in place from 2023. During the process of updating KPIs, the data used has been interrogated and assessed to gain an accurate picture of how robust data gathering processes are. Several changes have been implemented in teams data collection already and this work is ongoing.

7. Service delivery plans

7.1. Teams currently use their own templates for SDPs; the completion quality and frequency of updates varies significantly between teams.

7.2. A standardised Excel template for SDPs will be created and referenced after the new risk strategy is in place. Where possible, in line with the performance reports and risk registers, this will be a single document with each team having their own tabs. However, as there are significant differences between how teams articulate delivery, there will need to be scope to adapt the template to suit each team. This work is due to be completed in the first quarter of 2023.

8. A 'joined up' approach

8.1. The new risk strategy makes it clear that risk management sits alongside performance reporting and service delivery plans to shape operational delivery. Impact from one area should be reflected in the other areas. Specific examples are referenced in the strategy using a cyclical

approach demonstrating how service delivery plans should be updated based on previous performance with risk management linking the two.

8.2. This approach will make both the risk registers and service delivery plans more dynamic and allow us to anticipate future performance risks.

8.3. Interdependencies between these three areas will be easier to identify and this move to a more evidence-based approach will enhance our ability to demonstrate at audits how we identify risks in a timely manner and apply controls to minimise impact. Where risks sit between teams, again the new register will allow teams to formally record plans, note any follow up actions and once resolved, close the risk.

9. Internal incidents

9.1. The previous Word document based internal incident system is in the process of being replaced by an online form which is in the final phase of testing. This is due to be launched in October.

9.2. The new web-based form is more user-friendly and allows for more automation as the data captured from the form is made available in both a pdf document and an automated Excel document.

9.3. A report will be presented at CMG meetings quarterly to summarise the issues and learning.

9.4. The internal incident reporting system will be placed as a link on the intranet homepage (the Hub) to allow for greater visibility of the process and to encourage timely reporting and follow-up. This will also be used to highlight learning, promote best practice and hold links to appropriate policies and procedures.

9.5. Examples to better define the differences between internal incidents, near misses and data breaches are included.

9.6. As part of the role of the Risk Champions, reporting and learning from internal incidents will be a key focus area.

9.7. The KPIs used for internal incidents are also under review and will be in place by the time the new system is launched.

10. Training and development

10.1. The GIAA audit findings were that “individuals in the Business Planning & Governance team who have overall responsibility for risk management arrangements in the organisation receive formal training, in line with the requirements of the Risk Management: Skills and Capability Framework (2021)”.

10.2. The audit also recommended that the HFEA assess the training needs with regards to Risk Management across the organisation and ensure staff deemed to be in scope are provided with regular training.

10.3. Formal training needs will be assessed, and plans put in place after the new risk strategy is in place, for the Risk and Business Planning Manager and the Head of Planning and Governance.

10.4. A full training needs analysis will be completed in the first quarter of 2023, with more risk training added to the formal induction for all staff. Options for including modules on Civil Service Learning will also be considered as part of the review.

11. Risk appetite

11.1. The Orange book has further expanded on risk appetite and referenced the further challenge for the public sector organisations to achieve value for money. A key consideration for the HFEA is ensuring risk management is proportionate, taking into account the size of the organisation and the resource constraints this creates.

11.2. The HFEA approach has changed over the years from a view that we should be naturally conservative as a regulator, to more of a view that there are opportunity costs if you are always conservative, and that we need to consider our appetite for risk in relation to things like big Authority decisions and new areas of policy or law. We want to support innovation, but we also then need to consider how we would mitigate and manage the resulting risks.

11.3. Using more dynamic risk registers, increasing awareness of how we approach risk within the organisation and having a more balanced approach, the HFEA will highlight its risk position, better defining the current, optimal and tolerable risk positions.

11.4. The new strategy will define risk appetite levels, stating examples from the Orange book and providing guidance to define risk approaches from risk averse to cautious, to eager.

11.5. The development of the new strategy will include references to increasing risk appetite and will include a risk appetite summary, defining the HFEA's position for risk tolerance. Some areas, such as our register functions, we will be risk averse; whereas in others, our position may be more open.

12. Recommendation

12.1. AGC is asked to note the above and comment on the attached risk strategy and team risk register.

Digital Projects / PRISM Update September 2022

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:	04 October 2022
Author:	Kevin Hudson, PRISM programme manager
Annexes	

Output from this paper

For information or decision?	For information
Recommendation:	
Resource implications:	
Implementation date:	PRISM already live
Communication(s):	
Organisational risk:	Medium

1. Introduction and summary

1.1. PRISM went live on 14th September 2021. Within its first year of operation, 242,155 units of activity have been submitted through PRISM from 101 clinics.

1.2. At the AGC meeting on 28th June 2022, we advised on:

- The progress of PRISM deployment in the first quarter of 2022/23, and the deployment of the 25 Mellowood and Meditex clinics that occurred particularly in May and early June.
- We advised for information on the new General Direction for PRISM submissions (which came into effect from 1st April 2022) and our new policy for new API deployments and migrations.
- Our approach to addressing legacy (before August 2021) data issues, re-establishing reporting including a first Chose a Fertility Clinic through PRISM and ensuring OTR can operate 'solely through PRISM' (without reference to the old legacy EDI system for pre-PRISM data).
- The approach for PRISM handover to employed staff including details of the PRISM development handover operating in May and June 2022.

1.3. The purpose of this paper is to update AGC on:

1. The latest status for clinics catching up on their submission backlogs, the audit of backlog submissions undertaken in August to provide assurance for the 2021/22 annual accounts, and the current state of deployment for the ARGC group of clinics.
2. The ongoing work being undertaken to resolve current known issues on PRISM, including movements and validations.
3. The progress on resolving legacy data issues and re-establishing full reporting from PRISM.
4. Ongoing progress with the handover of PRISM following departure of the contracted lead PRISM developer at the end of June 2022.

2. Current PRISM status – clinic catch up and outstanding deployments

Current PRISM activity and error rates

2.1. As of June 2022, we reported that 161,045 units of activity has been recorded through PRISM. The change in PRISM activity and error rates over the summer is shown in table1 below.

Table 1 – Cumulative PRISM activity across Summer 2022

Method of data submission		As of 6th June 2022		As of 19th September 2022		Change over Summer 2022	
	No of Clinics	Cumulative PRISM Activity	Cumulative PRISM error rate	Cumulative PRISM Activity	Cumulative PRISM error rate	increase in submitted activity	Change in error rate (percentage points)
Direct Entry	40	52,705	0.7%	72,126	1.0%	37%	0.2%
API - Mellowood	38	60,792	6.6%	105,533	3.4%	74%	-3.3%
API - Meditex	11	15,177	22.3%	26,137	5.3%	72%	-17.0%
API - CARE	12	32,371	12.3%	42,537	6.6%	31%	-5.7%
Total	**101**	**161,045**	**7.3%**	**246,333**	**3.4%**	**53%**	**-3.9%**

2.2. Table 1 shows there were more significant increases in activity from Mellowood and Meditex clinics during the summer. This represents clinics catching up on their submission backlogs that would have been incurred between the end of August 2021 (when EDI was switched off) and the date of their deployment. The CARE Group had caught up on their data backlog by the end of May 2022 and direct entry clinics had been entering data PRISM continuously since September 2021.

2.3. Error rates for all methods of data submission have improved during the summer and the overall direction of travel for data quality for most clinics is positive and error rates are falling. The overall error rate is now 3.4% although API clinics still have further improvements to achieve if they are to reach the 1% quality benchmark being set by clinics who are entering data directly to PRISM.

2.4. However, we are observing significant weekly variation in error rates, particularly for Meditex. This a cause for concern and is discussed in more detail in the section 3 of this update.

Activity audit of clinics not yet caught up on PRISM

2.5. During July and August, we undertook significant work to provide additional reassurance for the auditors concerning the level of PRISM activity and HFEA income attributable to the 2021/22 financial year (FY2021/22) for clinics that were the last to deploy in PRISM and particularly those where their deployment took place after the end of March 2021. This work is described below:

2.6. In early July the Finance team undertook a comparison of clinic-by-clinic billing for FY2021/22 as currently calculated based on the data submitted through PRISM against expected amounts for that clinic based on past EDI billing and month-on-month estimates.

2.7. That analysis identified that there were 12 clinics (1 standalone, 8 Mellowood, 3 Meditex) with large (greater than £10,000) FY2021/22 billing shortfalls that could be represented by that clinic not being properly caught up on submitting FY2021/22 data through PRISM.

2.8. For these clinics, it was agreed with Finance that we would undertake further detailed engagements to understand the nature of any activity not yet submitted to PRISM. Therefore, through the inspectors we asked:

- *"Notwithstanding some submissions that you cannot make for technical reasons (e.g., movement issues), are you in general caught up on the backlog of submissions that was*

incurred between the EDI switch off at the end of August 2021We and your deployment to PRISM?"

- *"If you are not yet caught up on your backlog, will you be able to catch up on records with cycle dates before 31st March 2022, by the end of August 2022? If not, when will you be able to catch up on this cohort of data?"*
- *"If by the end of August 2022, you are not yet caught up on your backlog of records with cycle dates before 31st March 2022, then as of the close of business on 31st August 2022 can you please provide to the HFEA the number of still outstanding submissions for IVF and DI treatments (as separate totals) that took place before 31st March 2022. This will allow us to accurately reconcile your activity for the previous financial year."*

2.9. We received a count of all outstanding activity from those 12 clinics with large shortfalls that were not caught up on their FY2021/22 data by the end of August 2022. We added these quantities to the FY2021/22 billable amounts calculated from PRISM submissions to that same date. The results are shown in table 2 below.

Table 2: Results of outstanding submission audit for clinics not caught up on PRISM

Submission and FY2021/22 Billing Audit of clinics with large submission backlogs | Report Date:

Identification of clinics with large backlogs for submitting data to PRISM - as of the end of June 2022				Billing activity submmitted in PRISM	Status of PRISM catch up for these clinics	Clinic declarations of FY2021/22 activity still to be submitted to PRISM			
Clinic No	Clinic Name	Method of PRISM data entry	Estimated billing variance @30/6/22 (PRISM billing v's predicted totals)	Total Billing for FY2021/22 recorded through PRISM	When are they likely to catch up on all PRISM submissions	Outstanding cycles yet to be submitted to PRISM	Billing Value of outstanding submissions	**Total FY2021/22 billing for the clinic**	%age activity still awaiting submission
0006	Lister Fertility Clinic	Direct	- 81,475	160,470	caught up	0	-	**160,470**	0%
0007	Hewitt Fertility Clinic	IDEAS	- 80,770	109,748	Dec-22	375	30,000	**139,748**	21%
0033	Manchester Fertility	Meditex	- 16,625	147,885	caught up	0	-	**147,885**	0%
0051	Cambridge IVF	IDEAS	- 29,357	43,060	Aug-22	11	880	**43,940**	2%
0153	Homerton Fertility Centre	IDEAS	- 29,277	31,270	Feb-23	554	44,065	**75,335**	58%
0299	CREATE Fertility, London Wimbledon	IDEAS	- 37,975	42,170	Dec-22	241	18,770	**60,940**	31%
0314	Care Fertility Leeds	Meditex	- 108,297	112,535	Dec-22	269	21,010	**133,545**	16%
0339	CREATE Fertility, London St Pauls	IDEAS	- 77,692	94,535	Dec-22	984	76,680	**171,215**	45%
0344	Hewitt Fertility Clinic, Knutsford	IDEAS	- 33,385	51,560	Dec-22	245	19,600	**71,160**	28%
0348	CREATE Fertility, Birmingham	IDEAS	- 34,497	70,640	Dec-22	87	4,835	**75,475**	6%
0359	CREATE Fertility, Manchester	IDEAS	- 48,682	47,540	Dec-22	405	31,423	**78,963**	40%
0367	The Evewell	Meditex	- 15,140	38,233	Dec-22	104	8,320	**46,553**	18%
	TOTAL		**- 593,172**	**949,645**		**3275**	**255,583**	**1,205,228**	21%

2.10. Of the 12 clinics identified with large submissions shortfalls at the end of June, 3 were reporting they were caught up by the end of August for treatments incurred in FY2021/22. The Lister Clinic (one of the largest fertility clinics in the UK) advised that any observed billing shortfall is due to the clinic undertaking less treatments after COVID.

2.11. However there remain 9 large clinics who had not caught up on their FY2021/22 submissions by the end of August. Therefore, a key purpose of this analysis is to quantify any potential additional accrual to HFEA income for FY2021/22 arising from activity not yet submitted on PRISM. In this case that accrual amount, based on clinic declarations of their backlogs, has been calculated to be £255,582.

2.12. A more detailed version of table 2 has been shared with Finance for sharing with the auditors. We are awaiting the audit response and we will update AGC further at the meeting.

2.13. Another very important piece of learning from this exercise is that most clinics are advising they will be caught up on PRISM submissions by December 2022. This is to catch up on both last financial year and the current year. The Homerton are advising that they have staffing issues and will not catch up until February 2023. The catch-up period for these clinics is about the same as for other clinics in the sector, although of course those others were deployment much earlier.

2.14. It will be important to closely monitor these clinic's submissions during the autumn to ensure clinics achieve or exceed their stated catch-up ambition.

ARGC deployment update

2.15. As was reported to AGC in June, the 3 clinics of the ARGC group are the last clinics remaining to be deployed in PRISM. As previously reported, these clinics require a special 'backport' deployment to ensure that their data in PRISM synchronises with previously submitted data.

2.16. In May, HFEA built the backport functionality in anticipation of deployment for ARGC. Backports are also required whenever a clinic wishes to move from direct entry to API submission or to move between API suppliers, so this function has wider utility in the ongoing development of PRISM.

2.17. As previously advised to AGC, Meditex had told HFEA that they had no development capability to undertake the ARGC deployment until the middle of September 2022. This was because their staff were on extended leave. We have had no development communication from Meditex since July. Meditex are a very small IT based in Germany.

2.18. The Meditex developer returns from their extended leave on 13th September, and we have already communicated with them concerning commencing the deployment process for ARGC. We are awaiting further communications from them, and we will update AGC further at the meeting.

2.19. As per our policy on new API migrations, published 1st April 2022, we will not permit other UK clinics to migrate to the Meditex API solution until the ARGC deployment is complete. St Mary's Hospital Manchester (0067) has requested such a migration and we are in the process of communicating to St Mary's that Meditex must first complete the ARGC deployment before we will approve their own migration to Meditex.

2.20. We do not expect St Mary's to be happy with this decision, but it is important, particularly with small suppliers of limited capacity, that HFEA overall requirements are prioritised. This is the stated HFEA policy concerning API system suppliers that has been published on the Clinic Portal since April this year.

3. Update on resolving current known issues in PRISM

PRISM 'bedding-in' phase

3.1. From 1st April 2022 we published a new version of General Direction (0005) outlining the standards to which clinics must adhere when entering PRISM. At the same time, through a Chair's letter we also advised clinics that PRISM would continue to be in a 'bedding in phase'. In the letter, we stated:

With any new system, once deployment is complete and clinics are caught up on any submission backlog, there will be an ongoing period of bedding in and refinement for PRISM. During this time there may be instances where clinics are unable to submit specific elements of information because of system related issues. We keep clinics informed of such issues on the message board of the PRISM Homepage, to which all clinics have access.

If a clinic has records that are 'on hold, awaiting submission' then clinics must keep a detailed list of these, so that they can advise HFEA of the number and reasons for records being on hold, and clinics must then submit these to HFEA at the earliest opportunity once any system issues have been resolved.

[CH22/02 1st April 2022]

3.2. The number of records that can't be submitted to PRISM for technical reasons is thought to be around 1%. That means 10-20 records for a small clinic and 50-100 records for a larger clinic.

3.3. The types of 'known issues' fall into three main categories:

- **Movements:** Where issues arise when one clinic tries to record the movements of gametes from another. This is the issue most often reported by clinics. (See 3.4 below)
- **(False) Validations:** Where the PRISM validation rules advise the clinic that there is an issue with the record, but on manual inspection, the data submitted is found to be correct. (See 3.7 below)
- **Legacy Data Issues:** Where a clinic tries to update a record that was previously submitted in EDI but finds that they cannot correctly access the data. This is closely linked to the work to re-establish reporting in PRISM (see section 4)

Action on Movements

3.4. The reasons that errors arise in movements is complex. Within PRISM clinics have two routes to submit movements – either directly in the registration records, or through a function called 'sidebar movements'.

3.5. If the sending clinic is an API clinic, then the movement out details may be different than if the sending clinic was entering directly to PRISM. We are also still observing that the level of movements from Mellowood clinics appear less than those measured from direct entry or CARE or Meditex API. Over the summer Mellowood have issued a number of 'new builds' to their API solution in relation to movements.

3.6. Consequently, we have assigned our new PRISM developer (who started in April but has picked up PRISM exceptionally well) to undertake a full code review of movements – both standalone, API and sidebar movements. He is making good progress in rationalising this code. We hope to deploy a 'new build' of the PRISM code during October 2022

Action on (false) validations

3.7. Whilst we are seeing reductions in error rates across all methods of submission (see table 1 above), during the summer validation rates through PRISM have demonstrated a large amount of 'week on week variability'. This is demonstrated in table 3 below.

Table 3: Week by week variation in validation errors recorded during Summer 2022.

	Weekly movement in total number of errors measured in PRISM during Summer 2022																				
Method of submission	19-Sep	12-Sep	05-Sep	29-Aug	22-Aug	15-Aug	08-Aug	01-Aug	25-Jul	18-Jul	11-Jul	04-Jul	27-Jun	20-Jun	13-Jun	06-Jun	30-May	23-May	16-May	09-May	02-May
Direct Entry	- 14	- 26	27	- 96	56	- 674	756	89	- 71	9	125	- 11	72	50	22	10	27	3	25	- 26	- 30
IDEAS	- 903	- 127	287	174	158	488	435	132	- 816	160	197	- 1,346	189	214	267	133	246	542	56	8	- 42
Meditex	- 114	96	- 888	96	158	92	15	117	- 59	160	220	- 2,576	657	199	- 171	88	1,465	959	22	213	- 669
CARE	- 345	55	46	70	65	65	17	28	- 450	- 39	141	- 1,136	1	157	160	1,915	317	289	74	115	- 12
	Weekly error rates measured in PRISM during Summer 2022																				
Direct Entry	-1.2%	-2.4%	2.4%	-7.9%	3.9%	-62.6%	52.5%	5.2%	-5.3%	0.6%	8.2%	-0.9%	6.4%	3.9%	1.8%	1.2%	2.2%	0.2%	1.8%	-1.9%	-2.2%
IDEAS	-41.1%	-4.8%	9.2%	5.3%	4.4%	13.4%	11.5%	5.3%	-26.0%	6.1%	8.1%	-45.8%	7.7%	6.6%	8.4%	6.7%	7.9%	15.8%	1.8%	0.3%	-2.6%
Meditex	-30.8%	20.9%	-164.1%	24.5%	18.6%	9.4%	2.0%	19.9%	-13.5%	17.8%	29.1%	-299.5%	50.0%	27.7%	-24.1%	13.2%	46.9%	38.9%	2.4%	21.4%	-55.9%
CARE	-71.7%	9.2%	6.0%	14.3%	7.2%	18.3%	2.9%	3.1%	-98.0%	-6.2%	21.0%	-164.6%	0.2%	16.4%	15.8%	40.6%	7.5%	10.4%	9.9%	13.0%	-1.8%

3.8. Meditex is demonstrating the most variability. In the table above, some weeks there are 50% error rates and then a few weeks later a big drop in errors. The large decreases in errors and error rates are caused by our data developer undertaking a 'manual revalidation' of the records currently held in PRISM and the build-up ahead of that reduction represents periods of time where the original error was being incorrectly reported to clinics.

3.9. The fact that PRISM data is coming from clinics 'in piecemeal' fashion as part of normal clinic working processes, is a contributory factor to the observed problems in the validation rules. We also think that PRISM is not always properly removing a validation rule when it is fixed.

3.10. Ensuring stable variations is essential both for ongoing use of the system and for progressing the verification work on CaFC.

3.11. Consequently, over the summer our data developer has been undertaking a rule-by-rule review of all validation rules. Also, to ensure we can put a 'failsafe' on the system we are automatically incorporating his 'revalidation routines' at the point where the clinic originally saves the record. Putting this in place will eliminate variability in error rates in all cases, and we hope to have this in place during October 2022.

3.12. Once this is established, our data developer will need to proceed to reviewing how historic data submitted through EDI is treated by the PRISM validation system, and then develop the 40 or so historic verification reports that are required for CaFC.

4. Re-establishing reporting including 2022 Choose a Fertility Clinic

4.1. Previously we reported that the first CaFC in PRISM is particularly challenging. Not only is it a 'first-time' process for clinics in a new system, arguably still unfamiliar to them, and that all the 'building blocks of CaFC' previously built in EDI need to be re-established in PRISM, but the first CaFC also requires 'a verification of old data in a new system' with all the data migration challenges that this might entail. In the 'first CaFC' we need to ensure unverified EDI submitted data can be validated, amended by clinics and corrected in PRISM.

4.2. In the future the process should be far more straightforward, both because it is re-established, and because it is increasingly using PRISM submitted data. Ultimately, onerous clinic verifications exercises will not be needed if clinic errors can be largely eliminated at source. This is a key objective of the work described in 3.10 above, and the underlying error rates from all current methods of submission into PRISM is increasingly encouraging in this regard.

4.3. We also previously reported that our sole data analyst was undertaking an assessment of all the remaining data fixes, both to establish the first CaFC through PRISM and to ensure OTR can operate solely in PRISM without reference to the EDI legacy system.

Progress on assessing legacy data issues

4.4. The work to assess all remaining legacy data fixes is still in progress. It has been slowed during the summer both because of annual leave and necessary business as usual interruptions to support inspectors with data for inspections in progress. The final assessment process that we are working through involves:

- Look at what fields are remaining to be fixed for OTR legacy data
- Add to this, any discrepancies in key CaFC fields that we use.
- Reconcile all of this against the data warehouse
- Extend legacy discrepancies to non-donor cycles in PRISM
- Look at where we are with eggbatchID – both in term of (a) where mapping was lost in data migration and (b) where we never had the mapping in legacy.

4.5. Because of its complexity there is only one member of HFEA staff that can currently undertake this detailed work, and we are not yet sufficiently progressed in this assessment to give a firm date of when the assessment will be complete. However, we have finally been successful in recruiting a second data analyst to work alongside this individual (see 4.8 below), so whilst it will take time to identify and quantify all the remaining data issues, the time taken to fix these issues should be much faster than otherwise, as there will then be two analysts on the job.

4.6. We also took a management decision for our data analyst to finish his work on the PRISM data reconciliations for inspector books. Where-ever possible we are managing our technical staff with the mantra of 'finishing one task before moving to the next'. These reconciliations are now complete and up to date data feeds being made automatically available for inspectors, and their availability should mean that our data analysts should no longer have to address ad hoc data queries to support current inspections.

4.7. When our data analyst has completed his assessment of total remaining data fixes, we will have clear information on the final timescales for completing the first CaFC and moving OTR to PRISM. The results of this may be favourable or may give additional concern, and we will need to base future resource decisions and planning on these results. As requested, we will inform AGC of the results when they are known and the implications on resources and dates.

Recruitment of a second data analyst

4.8. In March 2022 it was agreed to recruit a second data analyst to support or current member of staff on this work in the same way that we have recruited a second developer for the PRISM system.

4.9. After a number of unsuccessful recruitment attempts for this very specialised post, the second data analyst was successfully recruited and started with HFEA on 12th September. By necessity there will a longer than usual induction, training and data familiarisation for this individual to get up to speed with the complexities of HFEA fertility data.

4.10. However, once up to speed, our second data analyst will be able to significantly augment and back-up our data functions in the same way that our second developer has already provided significant additional capability and resilience for PRISM development.

5. Progress with PRISM Handover to employed HFEA staff

Developer Handover

5.1. In June, we reported to A GC on the detailed PRISM handover programme that took place during May and June 2022 to transfer knowledge on detailed PRISM code and functions from our contracted PRISM developer to our existing employed developer and second developer who was recruited in April.

5.2. That handover completed at the end off June at which time the contract PRISM developer left the HFEA. Since then, our team of employed developers have been further familiarising with the detailed aspects of PRISM code and undertaking longer term code reviews and improvements, particularly in movements and validations. We are very pleased with the progress being made by this team of developers. We believe our development and PRISM coding risks are now mitigated.

5.3. Over the summer, we also updated all the Microsoft Azure user directories for PRISM which has been a necessary upgrade of the underlying code structures of PRISM.

5.4. Since starting in April, our second PRISM developer has progressed very well in both getting up to speed with PRISM code and the complex fertility processes that it supports.

PRISM Operational and Clinic Support

5.5. For the handover of clinic support activities, as previously reported to AGC, we have extended our contracted programme support officer for six months until December 2022, so she can provide more handover support to the newly started Register Team Manager and the register team in general.

5.6. Over the summer, the Register team manager has commenced as the first point of contact for all PRISM queries from clinics, and during September we will be moving the prism support email to the Zoho system so that every clinic query can be ticketed and tracked.

5.7. During the autumn, more work will be required with the Register team to ensure they are fully expert in all aspects of PRISM by the end of December.

5.8. During this time, the HFEA will also need to establish solutions for the detailed development testing of changes to PRISM that is also currently undertaken by the contracted programme support officer.

5.9. Consequently, the decision has been taken to pause recruitment for a vacant IT programme officer post and commence recruitment for a testing analyst that can undertake this essential detailed system testing.

PRISM Programme Management

5.10. In June we reported to AGC that the ongoing requirement for dedicated programme management support of PRISM was still under review by SMT.

5.11. Since then, it has been agreed to extend the contract of the current PRISM programme manager, on a two days per week basis, to primarily cover management of the work to resolve legacy data issues, and to ensure there is a clear path to restoring the first CaFC through PRISM. He is also

covering the ongoing work on movements and validations and will lead the work on PRISM deployment of ARGC.

5.12. The PRISM programme manager contract is currently extended to the end of December. Beyond that date, HFEA's ongoing requirement for dedicated PRISM programme management support will be assessed once the scale of remaining legacy data fixes is clear (see 4.4 to 4.6 above) and there is assurance on the dates for the first CaFC deployment and OTR solely through PRISM.

Financial Impact

5.13. The table below shows the updated contractor costs for PRISM arising from these actions:

Table 4: PRISM contractor costs – development handover and subsequent mitigations

	Costs in first quarter 22/23 to 1st Jul 22	Costs in second and third quarters to 31st Dec 22	
Contracted PRISM developer	£39,866	£0	ends Jun 22
PRISM support officer and system expert	£15,602	£45,435	extend to Dec 22
PRISM programme and data management	£39,843	£36,348	extend to Dec 22
Total contractor costs for the period	£95,311	£81,783	
Total PRISM contractor costs for the year		£177,094	

6. AGC recommendations

6.1. AGC are asked to note:

1. The progress with PRISM use, and the data catch-up that has taken place particularly with Mellowood and Meditex clinics during the summer.
2. The audit undertaken with those 9 large clinics that are still not caught up on PRISM submissions for last financial year as of the end of August 2022, and their stated targets of when they will be caught up.
3. That there is still work to do to enact PRISM deployment with the three ARGC clinics.
4. The improvement in PRISM error rates, but the fact that work still required to address 'variability' and then start the process of backdating these rules for CaFC.
5. The technical work being undertaken to address challenges in PRISM movements.
6. The ongoing work to assess ongoing data fixes required before the first CaFC (and OTR migration to PRISM) can be completed, but that the recruitment of a second analyst will speed up later work on fixing legacy data issues once they are fully up to speed.
7. The progress that our development team have made since the contracted lead developer left in June, and the ongoing work on operational and clinic support for PRISM, testing and PRISM programme management.

Resilience, Business Continuity Management and Cyber Security

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 (AGC)		
Agenda item	11		
Meeting date	04 October 2022		
Authors	Martin Cranefield, Head of IT and Neil McComb, Head of Information		
Output:			
For information or decision?	For information		

Recommendation	The Committee is asked to note:
	• Infrastructure improvements
	  ◦ Improvements to IT security that have been implemented and those yet to be completed.
	  ◦ Data Backup review
	  ◦ Infrastructure penetration test
	• Current position on Data Security and Protection Toolkit		

Resource implications	Within budget		
Implementation date	Ongoing		
Communication(s)	Regular, range of mechanisms		
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. Infrastructure improvements

IT security changes

2.1. As part of the audit and NCSC's recommendations, we were advised to enable DMARC (**Domain-based Message Authentication Reporting & Conformance)** setting on our domain name hfea.gov.uk to prevent unauthorised email servers on the internet from sending out malicious emails purporting to be from HFEA. We already have SPF policy in place, which is widely used across the internet, however enabling DMARC will further strengthen our security. We have been testing this setting for the past two months and results are promising with a large % of our emails that send emails from @hfea.gov.uk passing DMARC, however there are still some failures to address before we set our policy to 'quarantine' or 'reject' emails should DMARC checks fail.

2.2. The local DNS issues on laptops when enabling the web filtering service has been resolved and we have subsequently reactivated the service.

2.3. We have disabled the ability to share OneDrive files to external email addresses as this posed a security risk.

2.4. We are evaluating an email security service (Mimecast) who offer extensive email security services. Mimecast offers the ability to send large files to external parties with tight security controls when required on an ad-hoc basis. Their service also offers email phishing training to end users by simulating phishing attacks and can identify users which are more prone to fall prey to malicious emails and subsequently target them for further training.

2.5. The following items were agreed previously at CMG on 20th October and have not yet been completed.

- HFEA staff to be prevented from accessing HFEA's instance of Office365 (incl. email) from non-HFEA laptops. Work on this has not yet commenced.
- Changes to how HFEA email can be accessed from personal mobile phones. Work on this has not yet commenced.

Data Backup review

2.6. We had an initial discovery call with MTI, a supplier recommended by NHS Digital to provide independent assessments on data backups. We have some prep work to do prior to our next call with them in October.

2.7. We have successfully evaluated a specialist third-party solution to backup HFEA's Office365 environment. We will place an order and set this up in our live environment in October to further strengthen our data backup resilience.

Infrastructure Penetration Test

2.8. Our supplier conducted the test as scheduled the week of 12th September. A verbal update will be given during AGC meeting as their report will be delivered within two weeks post testing. It was agreed they would raise any high-level risks immediately should they be discovered during testing however none were received.

3. Data Security and Protection Toolkit (DSPT)

Background

3.1. AGC will recall that the Data Security and Protection Toolkit (DSPT) is an online self-assessment tool that allows organisations to measure their performance against the National Data Guardian's ten data security standards. We have completed our submission for 2020/21 and are now preparing for 2022/23.

3.2. This will be our second submission and we expect our experience of last year to proof helpful in this year's performance.

3.3. In 2020/21 the HFEA the HFEA was in category 2 of the list of organisations who completed the DSPT. This year NHS digital have raised the bar and moved the HFEA into category alongside NHS trusts and CCGs.

3.4. This means that there are now 113 mandatory evidence items out of 133 in total to complete. This is over 20 more than last year and will require a significant amount of work for the IG manager and Head of IT.

3.5. In a recent webinar, NHS Digital said that they will increase the work year-on-year as they re-categorise non-mandatory items as mandatory. This may have resourcing implication in the future.

Next steps

3.6. The new IG and Security Steering Group has been set up and will meet for the first time on 13/10/2022. They will consider the mandatory items and the owners of those items.

3.7. With the future re-categorisation of non-mandatory requirements in mind we will also consider the non-mandatory items to understand the toolkit standards more holistically. Where new processes need to be planned to meet mandatory requirement it may be possible to create them in a way that meet future requirements.

3.8. We will however still be prioritising the completion of mandatory requirements.

Cover paper – Reserves Policy

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	11		
Meeting date	4 October 2022		
Author	Morounke Akingbola, Head of Finance		
Output:			
For information or decision?	For information		
Recommendation	Members are asked to note the policy which we are proposing not to change. There is also the outstanding issue of utilisation of reserves which the Director of Finance and Resources will revisit with DHSC during the last half of this business year.		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes			

Background

For several years the HFEA has posted surpluses which has lead to considerable cash reserves. We have tried to reduce our cash reserves by diverting funds towards our development projects and have also up until March 2022 maintained licence fee levels.

In 2020/21 we reviewed our reserves and reduced our minimum reserves from £1.4m to £1.3m in the wake of the COVID-19 pandemic where we expected our income to reduce and secured funding from the DHSC.

Post relocation to new offices has impacted upon our accommodation cost based (lower rent costs) which in turn resulted in a reduction in our fixed costs.

We are proposing that the reserve levels agreed by the Committee in October 2021 remain unchanged and are:

Contingency	£0.8m
Cash reserves	£1.3m

Reserves Policy

Introduction

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;
    - 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. The HFEA experiences negative cashflow (more payments than receipts) in some months but overall, there is a net positive position. Based on a review of our cashflows over the last few years we see on average net cash outflows over the last quarter of c£300k, with the range being between £100k and £400k. In order to ensure that there is always a positive cash balance we would wish to maintain a working capital cash balance of £400k, based on our most unfavourable outflow in the last 4 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 69% 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 £365k, accommodation costs have decreased since the relocation to 2 Redman Place in January 2021. A reserve of two months for these two elements would therefore be £730k.

12. A further reserve for other commitments for two months is estimated to be £119k.

Minimum reserves

13. The HFEA's minimum level of reserves will be maintained at a level that enables positive cashflow (£400k), provides £849k for contingency. The minimum level of cash reserves required is therefore £1.3m (rounded). 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 able to 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	CMG
Next review date	September 2023
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

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	☐Shaping the future – to embrace and engage with changes in the law, science and society
Details:			
Meeting	Audit & Governance Committee Forward Plan		
Agenda item	12		
Meeting date	4 October 2022		
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:	4 Oct 2022	8 Dec 2022	14 Mar 2023	27 Jun 2023
Following Authority Date:	16 Nov 2022	28 Jan 23	22 Mar 2023	12 July 2023
Meeting 'Theme/s'	Strategy & Corporate Affairs, AGC review	Register and Compliance, Business Continuity	Finance and Resources	Annual Reports, Information Governance, People
Reporting Officers	Director of Strategy and Corporate Affairs	Director of Compliance and Information	Director of Finance & Resources	Director of Finance & Resources
Strategic Risk Register	Yes	Yes	Yes	Yes
Horizon scanning				
Deep dives				
Risk Management Policy[1]	Risk Management Policy/update on review of systems conducted			
Digital Programme Update	Yes	Yes		Yes
Annual Report & Accounts (including Annual Governance Statement)				Yes – For approval
External audit (NAO) strategy & work		Audit Planning Report	Interim Feedback	Audit Completion Report
Information Assurance & Security				Yes, plus SIRO Report
Internal Audit Recommendations Follow-up	Yes	Yes	Yes	Yes

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

AGC Items Date:	4 Oct 2022	8 Dec 2022	14 Mar 2023	27 Jun 2023
Internal Audit	Update	Update	Update	Results, annual opinion approve draft plan
Whistle Blowing, fraud (report of any incidents)	Update as necessary	Update as necessary	Update as necessary	Update as necessary
Public Interest Disclosure (Whistleblowing) policy			Reviewed bi-annually	
Anti-Fraud, Bribery and Corruption policy			Reviewed and presented bi-annually	
Counter-fraud Strategy and progress of Action Plan	Fraud Risk Assessment			Counter Fraud Strategy; Action plan
Contracts & Procurement including SLA management	Update as necessary	Update as necessary	Update as necessary	Update as necessary
HR, People Planning & Processes		Bi-annual HR report		Bi-annual HR report
Strategy & Corporate Affairs management	Yes			
Regulatory & Register management		Yes		
Training			Yes	
Resilience & Business Continuity Management	Yes	Yes	Yes	Yes
Finance and Resources management			Yes	
Reserves policy	Yes			
Estates	Yes	Yes		Yes

AGC Items Date:	4 Oct 2022	8 Dec 2022	14 Mar 2023	27 Jun 2023
Review of AGC activities, terms of reference		Yes		
Legal Risks	Yes			
AGC Forward Plan	Yes	Yes	Yes	Yes
Session for Members and auditors	Yes	Yes	Yes	Yes

Suggested training for Committee Members

- Understanding good governance
- Risk Management
- Counter fraud
- Reviewing financial statements
- External Audit – Knowledge of the role/functions of the external auditor/key reports and assurances

Suggested deep dive topics as agreed at the 4 October 2022 meeting