Audit and Governance Committee meeting - agenda

Human Fertilisation & Embryology Authority

05 October 2021

Online

	Agenda item		Page No	Time
1.	Welcome, apologies and declaration of interests			10.00am
2.	Minutes of 22 June 2021 [AGC (05/10/2021) DO]	for decision		10.05am
3.	Matters arising [AGC (05/10/2021) SA]	for information		10.10am
4.	Digital programme update [AGC (05/10/2021) KH]	for decision		10.20am
5.	Internal audit update [AGC (05/10/2021) JC]	for information		10.40am
6.	Implementation of recommendations [AGC (05/10/2021) SA]	for information		10.55am
7.	External audit update [AGC (05/10/2021) MS]	verbal update		11.05am
8.	Reserves policy [AGC (05/10/2021) RS]	for information		11.15am
9.	Strategy & Corporate Affairs directorate update [AGC (05/10/2021) CE]	for decision		11.25am
10.	Legal risks [AGC (05/10/2021) RS]	verbal update		11.40pm 12.05pm
	Break			11.55pm
11.	Strategic risk register [AGC (05/10/2021) HC]	for comment		12.10pm
12.	Resilience & business continuity management [AGC (05/10/2021) RC]	for comment		12.30pm
13.	AGC forward plan [AGC (05/10/2021) SA]	for decision		12.50pm

14.	Items for noting • Gifts and hospitality • Whistle blowing and fraud • Contracts and Procurement **[AGC (05/10/2021) RS]**	for information	12.55pm
15.	Any other business		1.00pm
16.	Session for members and auditors only		
	Short lunch break		(10mins)
17.	AGC committee effectiveness **[AGC (05/10/2021) PR]**	sent separately	
18.	Close		

Next Meeting: Thursday, 9 December 2021, Online

Minutes of Audit and Governance Committee meeting 22 June 2021

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	5 October 2021		
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 22 June 2021 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 22 June 2021 held via teleconference

Members present	Anita Bharucha - Chair Margaret Gilmore Catharine Seddon Alison Marsden Mark McLaughlin Geoffrey Podger
Apologies	None
External advisers	Mike Surman, National Audit Office – External auditor Laura Fawcus, National Audit Office Joanne Charlton, Internal Auditor – GIAA
Observers	Julia Chain, Authority Chair Csenge Gal, Department of Health and Social Care – DHSC Amy Parsons, DHSC
Staff in attendance	Peter Thompson, Chief Executive Richard Sydee, Director of Finance and Resources Clare Ettinghausen, Director of Strategy and Corporate Affairs Rachel Cutting, Director of Compliance and Information Morounke Akingbola, Head of Finance Dan Howard, Chief Information Officer Yvonne Akinmodun, Head of Human Resources Paula Robinson, Head of Planning and Governance Kevin Hudson, Programme Manager Debbie Okutubo, Governance Manager

1. Welcome, apologies and declarations of interest

1.1. The Chair welcomed everyone present online, in particular Alison Marsden as it was her first AGC meeting. Alison joined the Authority in April 2021.

1.2. Alison gave a brief overview of her career to date.

1.3. There were no apologies from members.

1.4. There were no declarations of interest.

2. Minutes of the meeting held 16 March 2021

2.1. The minutes of the meeting held on 16 March 2021 were agreed as a true record and signed by the Chair.

3. Matters arising

3.1. It was noted that the cyber security training for members remained outstanding.

3.2. A lessons' learned report on PRISM was circulated before the meeting. It was suggested that members add their comments and send it back to the Chief Information Officer (CIO) and that it be put on the agenda to be discussed at the 5 October meeting. Members requested that the report should include an updated timeline and the extra resources expended.

3.3. The Director of Finance and Resources requested that the lessons learned report on Covid-19 be circulated outside of the meeting and no longer be presented as a formal agenda item. Members agreed to the request.

3.4. The data security and protection toolkit (DSPT) to be discussed as an agenda item.

4. Digital programme update

4.1. The digital programme update was presented by the Programme Manager. Members were updated on the news received from Mellowood who had requested late in the day a three-month delay to allow them to finish data synchronisation.

4.2. Discussions were held at a senior level and it had been agreed that there would be a six-week delay with a two-week contingency planned in. The Programme Manager commented that at present they had no indications or evidence that Mellowood were on target to meet the new six-week timeline. Members were also advised that Mellowood had declined to pick up the additional costs in this matter. In response to a question, it was noted that the HFEA had no contract or regulatory control over third party fertility system suppliers.

4.3. Members raised their concerns about Mellowood meeting the new timeline and the risk that it might pose to the launching of PRISM and asked staff if they were able to carry out their own due diligence rather than rely on what Mellowood were saying. Members advised staff to find ways in the short term to work with Mellowood to achieve what was needed.

4.4. Members also commented that the rectification plan required more detail and advised staff to let Mellowood know that more information was required.

4.5. The Chair commented that the letter the HFEA sent to the sector was a good and balanced one, which made it clear to the sector that the delay was not the HFEA's fault.

4.6. The Chair reiterated that the committee had confidence in the team but had concerns about the obstacles in the way and asked what levers we had, as Mellowood's lack of readiness and communication was poor. Lastly, that there was a delivery risk to the entire programme and a reputational risk to the Authority.

4.7. The Chief Executive commented that Mellowood's failure would increase the workload of clinics the HFEA regulate, as a significant chunk of the sector use their systems.

4.8. The Programme Manager went on to discuss other third-party suppliers. It was noted that the CARE group were on track. Meditex on the other hand were not on track but we would continue to work with them.

4.9. Members were also advised that the sector had been informed that the six months after the launch of PRISM would be dedicated to embedding the programme so there would be no significant additional changes.

4.10. In terms of progress on other aspects of PRISM it was noted that we had completed retesting and that the data migration team will turn to other activities as listed in the report.

4.11. For the cutover plan it was noted that a modular plan was being drawn up and that a PRISM Oversight meeting may be needed between 7 and 16 July.

4.12. Members commented that we need to manage expectations and even though there is a need for member sign-off we need to be sure of the dates before putting them in calendars. Continuing, members asked what the contingency plan was since July and August were traditionally times when staff took leave.

4.13. The Programme Manager responded that clinics had been surveyed for a July and August cutover date and none of them had said that they could not do those dates. However, the contingency would be to shift the go-live date should there be another delay.

4.14. Members asked the final date when delay was no longer an option and for the advantages and disadvantages of further delay. Staff responded that there were 40 clinics associated with Mellowood and that it would mean additional work for them if we were to require clinics to send their data to us outside of their current API system. The Chief Executive responded that in the long term this could lead to reputational damage.

4.15. Members commented that we need to consider whether we were subsidising failure by allowing Mellowood further time and we therefore needed a contingency plan and that further conversations with Mellowood needed to explore covering at least some of the additional costs incurred by their delay.

4.16. The External Auditor commented that we needed to bear in mind that at a particular level all financial losses would need to be disclosed in the financial statements.

4.17. The representative from the Department of Health and Social Care (DHSC) commented that we should keep them appraised of the situation.

4.18. Members requested that staff should seek advice about having a legal claim against Mellowood.

Decision

4.19. Members noted the progress to date.

4.20. It was noted that the most likely date for PRISM cutover was now 31 July with PRISM going live between 9 and 16 August. Members were asked to consider meeting to sign off PRISM go live in the authorisation window between 7 and 16 July 2021.

4.21. A detailed report would be sent to the 5 October AGC meeting.

5. 2020/21 Internal audit delivery update and 2021/22 proposed internal audit plan

5.1. The Chair invited the Internal Auditor to present the 2020/21 draft annual audit opinion to the committee.

5.2. The Internal Auditor commented that a moderate assurance had been given to the HFEA since it had adequate and effective systems of control, governance and risk management in place for the reporting year 2020-21. Also, that this is consistent with last year's opinion.

5.3. It was noted that this was a positive position despite the impact of Covid-19. There were outstanding audit recommendations, and the Internal Auditor commented that timely implementation of recommendations was crucial.

5.4. The Internal Auditor commented that the planned quarter one audit on staff wellbeing was now underway, and that two data security protection toolkit (DSPT) would also be included in the audit plan (as additions from the originally agreed plan at the start of the year), one was currently underway and related to the 20/21 submission and the second in quarter 4 which was expected to align to the deadlines for the 22/23 submission.

5.5. Members commented on the opinion given for PRISM as it had not met its target to date. Members suggested that the PRISM lessons learned report be circulated to both the internal and external auditors for their awareness and input.

5.6. In response to a question, it was stated that the report on PRISM was written at the point in time when it was being audited. There were controls in place at the time and that was why the opinion at the time was substantial. However, in light of the discussion at this meeting it would be taken back to the GIAA digital team.

5.7. The opinion on the key performance indicators (KPIs) was moderate and a number of recommendations were made.

5.8. Members were content to endorse these two inclusions in the audit plan.

Decision

5.9. Members commented that the opinion seemed appropriate and were content to endorse it.

5.10. Members noted the progress being made with the 2021/22 Internal Audit plan and endorsed the annual audit opinion.

6. Implementation of recommendations

6.1. The Head of Finance presented the summary of the audit recommendations.

6.2. There are two overdue recommendations. Business continuity training had been identified and purchased and training is underway with some Business Continuity staff members having completed the training.

6.3. In terms of the management of capability knowledge and skills gap, this would be completed by the end of the next quarter.

Decision

6.4. Members noted the progress of the recommendations.

7. Information assurance and security (SIRO report)

7.1. The Director of Finance and Resources who is also the Senior Information Risk Officer's (SIRO) presented this item to the committee. It was the annual report to the Accounting Officer and the AGC.

7.2. The SIRO commented that the Information security structure was as strong as it could be.

7.3. Members commented that the cyber security training for members should be made a priority. Members also asked if there were any added risks considering where we were in terms of staff continually working from home, the impact of Covid-19 and the office move.

7.4. The SIRO responded that the one risk identified had been mitigated and that it had to do with hard copy letters being digitalised.

7.5. Members asked about cyber-attacks on our systems. Staff responded that for an organisation our size we do not see any additional attacks. The Chief Information Officer responded that we have industrial levels security on our systems, and we have up to date firewalls that continue to keep us safe.

7.6. In response to a question, it was noted that the internal audit plan was to audit our systems next financial year and a discussion would be held between the Director of Finance and Resources and the Internal Auditor.

Decision

7.7. Members noted and endorsed the SIRO report.

8. Annual report and accounts

8.1. The Director of Finance and Resources presented the draft annual report and accounts for 2020-2021.

8.2. He thanked the Head of Finance and her team for their hard work and commented that this year was particularly difficult due to the pandemic, people working from home and the changes to the audit processes.

8.3. The total operating income was brought to the attention of members. Areas of expenditure that were materially different to those reported in last year's accounts were also highlighted.

8.4. Members felt that the accounts and report were very clear and asked about the change in approach that was mentioned. It was noted that the External Auditor would explain when his report was being presented.

8.5. In terms of the performance analysis members felt that there was scope to champion areas where progress had been made. It was agreed that areas of improvement could be mentioned in the Chief Executive's foreword. Other members felt that the foreword needed to be measured and sensitive to where we were as a nation given the pandemic.

8.6. In terms of the business areas highlighted in the report it was suggested that before submission it should be resolved as to whether it was five or six areas, as only five areas were listed but six areas were referred to. Members agreed to liaise directly with the Director of Finance and Resources in terms of non-material issues in the report.

8.7. There was also a suggestion that the terms of reference of the AGC be included in the report.

8.8. Regarding the risk registers referred to in the report, some members felt that these could not yet be considered as properly dynamic even though they were updated regularly.

8.9. In terms of next steps, the Director of Finance and Resources stated that after signing by the Accounting Officer, the Comptroller and Auditor General will sign the annual report and accounts, which will then be laid before Parliament.

8.10. Members were advised that should an update be necessary the committee would be notified of changes.

8.11. Members thanked the HFEA finance team and the NAO team and commented that they were mindful that the Finance team were doing this for two different organisations at nearly the same time.

Decision

8.12. Subject to the NAO finalising the report, the committee commended the report for the Accounting Officer (Chief Executive) to sign off.

9. External audit completion report

9.1. The External Auditor presented the audit completion reports and the management letter on the 2020-2021 financial statements audit to the committee. He thanked the HFEA Finance team for their assistance and continued engagement during the audit process and commented that this year had seen an increased scrutiny from a regulatory perspective.

9.2. Three areas were identified as part of the audit risks. These were: the management override of controls (it was concluded that there was no indication of management override occurring); revenue recognition and the office relocation to Stratford were both still ongoing.

9.3. In response to a question, the Director of Finance and Resources explained that the IT assets whilst at zero net book value (NBV) were still in use and because we were planning to refresh some of our laptops it was felt that revising the useful economic life (UEL) prior to the year end was not necessary.

9.4. In terms of reviewing the PRISM costs it was noted that this would be done once PRISM was live.

9.5. Regarding accruals the original recommendation remained open as there were some issues found during the audit. It was noted that the accruals review was still under way and a full update would be provided in the final audit completion report for 2021-2022.

9.6. The External Auditor stated that he was considering certifying the 2020-2021 financial statements with an unqualified audit opinion, without modification in respect of both regularity and the true and fair view on the financial statements.

Decision

9.7. Members were content and happy to receive the management letter in writing once it had been finalised.

10. Strategic risk register

10.1. The Head of Planning and Governance presented the strategic risk register.

10.2. The risk dashboard had ten strategic risks listed with one risk above tolerance, five at tolerance and four below tolerance.

10.3. It was noted that the C2 risk - loss of senior leadership had been reframed to include concerns of the committee about the management of risk relating to both the senior executive appointments and Member-related risks. It was noted that this risk was amended to reflect both areas as the mitigations were similar.

10.4. Members suggested that the tolerance threshold be included on the dashboard.

10.5. Members suggested that all planned mitigations be reviewed against the SMART criteria and in particular include timelines for future planned mitigations. Members asked why risks currently below tolerance level remained on the dashboard. The Head of Planning and Governance responded that it was because the risk register was closely aligned with the strategy, and it had been felt that risks to all areas of the strategy should be included. It was suggested that the senior management team consider whether another approach could be adopted.

10.6. In terms of CS1 - cyber security, members suggested that member training should be prioritised.

10.7. In response to a question, it was noted that to mitigate cyber security threats, we undertake regular penetration testing to identify and effectively handle threats. The Chief Information Officer commented that the testing was scheduled to occur throughout the year with different business areas tested at different times.

10.8. Regarding the OM1 - ways of working risk, members suggested that staff should develop a set of principles to make it clearer when face to face meetings needed to occur and also form part of the strategic plan for the new way of working. The Chief Executive responded that this was in hand and the Head of Human Resources also confirmed that it formed part of the hybrid working policy.

10.9. It was noted that all the arms-length bodies (ALBs) working together on the 2nd floor at the Stratford office had formed a small working group to address issues like these.

10.10. Members commented that we could not afford to lose sight that PRISM remained a high reputational and financial risk.

10.11. In terms of horizon scanning, members commented that more work could be done and agreed that legal risks should not be reactive only. The Chief Executive commented that due to the nature of the decisions taken by the HFEA we were open to scrutiny and legal action could happen at any time.

10.12. In response to a question, it was noted in relation to RF1 - regulatory framework, that Covid-19 had forced us to take another direction in terms of our model of regulation, and that learning points were now being incorporated into our future approach.

10.13. Members asked if we were a member of the UK Regulators Network (UKRN). The Director of Strategy and Corporate Affairs responded that we were not formal members but we had access to their newsletters and that we have involvement in other regulators' networks.

Decision

10.14. Members noted the strategic risk register.

11. Bi-annual human resource report

11.1. The Head of Human Resources presented this item. It was noted that the average turnover in the last 12 months was relatively low at 11.5%, but it was anticipated that there would be an increase in turnover as the job market showed signs of recovery.

11.2. In response to a question, it was noted that the staff survey was on an annual basis. Also, that at the last staff survey, staff were broadly happy with the present way of working. In the autumn of this year there would be another survey.

11.3. Members commented that technology would play a role in making hybrid working a success and asked if the HFEA was ready for this. The Head of Human Resources responded that by September we should have the necessary technology and tools to have a blended way of working.

11.4. The Chief Executive commented that we do not want to become a virtual organisation. Discussions were being held with staff and once the current restrictions are over, staff would be expected to attend the office at least one day a week until September, when our future policy would be reviewed.

11.5. In response to a question, it was noted that all the internal meeting rooms would facilitate hybrid meetings once the necessary A/V technology had been installed.

11.6. Members commented on the number of recent resignations and asked if exit interviews had determined why this was the case. The Head of Human Resources responded that nothing specific had been highlighted but there was a common theme that there were more opportunities as the economy was picking up.

11.7. Members also asked how easy it was to recruit to the vacancies and for the new staff members to be socialised. The Head of Human Resources responded that the onboarding of new staff was happening virtually, but in due course we would revert to face to face meetings including interviews.

11.8. The Chair commented that given the pace of change and the uncertainty, the committee would like to hear from the Head of Human Resources should there be any significant changes before the next time that the bi-annual human resource update was due.

Decision

11.9. Members noted the bi-annual human resources report.

12. Resilience, business continuity management

12.1. The Chair invited the Chief Information Officer (CIO) to present this item.

12.2. The CIO reminded the committee that the data security and protection toolkit (DSPT) set both mandatory and non-mandatory requirements. There were 42 detailed requirements and 37 of them were mandatory.

12.3. We assessed ourselves against the 37 mandatory requirements and we were meeting 32 out of the 37 requirements. This meant that our submission, as reported to AGC in March 2021, would be regarded as ‘not met’.

12.4. Members asked what this meant. The CIO responded that this was the first time we were submitting such a report.

12.5. At the request of members, the Internal Auditor agreed to take this away and report back to the committee on how we were ranking against other ALBs.

12.6. Members asked how the IT security review would be conducted and taken forward. The CIO responded that we had a third-party supplier that we were working with and that we would share the outcome with the committee once this was done.

Decision

12.7. Members noted this item.

13. AGC forward plan

13.1. The Head of Finance presented this item.

13.2. It was agreed that the digital programme update will be added to the October meeting forward plan.

13.3. Regarding the board workshop, a discussion would be held with the NAO to agree a date and include this in the forward plan.

Decision

13.4. Members noted the current forward plan and all changes requested.

14. Items for noting

14.1. Gift and hospitality

- The register of gifts and hospitality was presented to the committee. There were no changes.

14.2. Whistle blowing and fraud

- There were no cases of whistle blowing or fraud to report.

14.3. Contracts and procurement

- There were no new contracts or procurements to report.

15. Any other business

15.1. The Chair commented that it was Dan Howard, the Chief Information Officer's last formal AGC meeting and thanked him for his hard work to date especially in relation to PRISM.

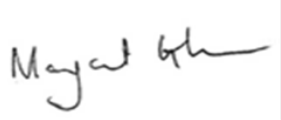
15.2. The CIO responded that he was pleased that PRISM would soon be launched and that he would like to hear when that finally happened.

15.3. The committee echoed the appreciation of the Chair.

Chair's signature

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

Signature



Chair: Margaret Gilmore

Date: 5 October 2021

AGC Matters Arising

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	5 October 2021		
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	2021/22 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 6 October 2020			
13.4 Cyber security training to be confirmed to members	Head of Finance	Dec-20	**Update** – training was provided using the Astute training platform. Reminder to be sent to members before the Christmas break. **Update** – we are still trying to source a training platform

Digital Programme Update – September 2021

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 meeting
Agenda item:	4
Meeting date:	5 October 2021
Author:	Kevin Hudson, Programme Manager
Annexes	None

Output from this paper

For information or decision?	For decision
Recommendation:	1. AGC are asked to note: • The cutover to PRISM and the level of activity currently being experienced. • The work still required to complete the deployment of PRISM. • The ongoing work for post go-live development and re-establishing reporting. • The additional costs of extending key contracts. • Our approach to agreeing a long-term development plan for HFEA IT and information. 2. AGC are asked to agree our approach for reporting lessons learned from PRISM, and to review this at a special ACG meeting during December.
Resource implications:	Contractors costs
Implementation date:	Ongoing
Communication(s):	
Organisational risk:	Medium

1. Introduction and summary

1.1. On 30th July 2021 AGC met to consider whether PRISM should be authorised for go-live.

1.2. AGC agreed that there was sufficient progress with Mellowood and other system suppliers to authorise a go-live for PRISM.

1.3. It was agreed that the cutover from EDI to PRISM would commence from the end of August (rather than mid-August) as this was the data that provided for:

- **Better migration of the risks from third party suppliers:** we would have clearer results on Mellowood's API assurance by the point of switch-over.
- **Better alignment with our internal systems:** an end of month EDI switch off was preferred by both HFEA finance and data migration staff as it made the accounting run more straightforward and allowed for some final refinements.
- **Better fit with staff holiday leave:** both in terms of HFEA and clinic staff. We had a number of requests from clinics not to enact the cutover during August.

1.4. Consequently, the cutover from EDI to PRISM was enacted:

- EDI was switched off on Friday 27th August 2021.
- Thereafter we conducted a detailed cutover exercise which we tested both internally and with selected clinics.
- The cutover was successful, **and PRISM went live at 11.30am on Tuesday 14th September.**

1.5. This paper will outline the progress of:

- The EDI/PRISM cutover.
- The current state of PRISM activity with 'standalone' clinics (i.e., those who enter data directly to PRISM).
- The progress with EPRS suppliers to ensure they complete their API deployments by the end of the agreed deployment window. This has been set for 10th December 2021, 3 months after PRISM go-live.
- Our approach to post go-live PRISM developments and re-establishing reporting.
- Longer term planning for ongoing HFEA IT and information needs.

1.6. In this paper we will also outline the approach we plan to adopt for briefing AGC on 'lessons learned' from PRISM.

2. The cutover from EDI to PRISM

2.1. Following the AGC decision to go-live, we wrote to PRs in the first week of August to advise that EDI would be switched of at the end of that month, specifically on Friday 27th August.

2.2. During August, and particularly the last couple of weeks, there was intense work from our IT support team in ensuring all clinics submitted all records through EDI and were clear of any EDI backlogs.

2.3. In particular, caused by IT issues at the clinics' end, there were a number of technical problems which we managed to solve and ensure these specific clinics were left with no unsubmitted data.

2.4. During cutover we followed the cutover plan developed by Iergo ltd, and HFEA technical, data, development, and register staff partook in daily stand-up calls chaired by Johny Morris.

2.5. The cutover plan also involved a number of staged 'go/no-go meetings' by the programme board which took place on the 24th of August and 7th of September respectively.

2.6. In the first weekend of cutover, we successfully ran the initial 'final ETL' programme which **extracted** all the register data to the end of August, **transformed** it into the PRISM data structure, and then **loaded** it into PRISM. This final ETL programme was the culmination of over two years of data migration preparatory work.

2.7. During the first week of cutover, we then undertook the following:

- **Billing:** The finance team ran the month end billing cycles and records were updated for those that had been invoiced.
- **Cutover testing:** Whilst billing was being run, the development and register teams were working through a template of extensive checks to ensure that the data has been loaded correctly into PRISM and that the live system was running as expected with that data.
- **Fixing cutover issues:** The cutover checks identified seven issues which the development and data migration teams then proceed to fix.

2.8. In the second weekend of cutover, we ran the 'final' final ETL which now included up to date billing flags and the fixes identified by cutover testing.

2.9. On Wednesday 8th September, we invited staff at key test clinics (London Women's Clinic and BMI Priory) to go into the live version of PRISM and work through the same template to confirm PRISM was working as expected. The clinic checking completed on Friday 10th September.

2.10. On Thursday 9th September, standalone clinics were sent detailed go-live notes concerning:

- How to access the live version of PRISM
- Tips for starting out on the system
- A reminder on support materials that are available
- How to get direct support from HFEA and have queries answered
- Details of the live 'known issue' messaging which we have enabled for PRISM
- Information about validation rules and how they will be applied to their data
- Instructions for uploading donor information forms to PRISM and no longer sending them in the post

2.11. On Monday 13th September we conducted our final go/no-go meeting with Peter Thompson where all the progress, risks and issues experienced during the cutover was discussed and recorded in the programme board update for that week.

2.12. At that final go/no-go meeting, approval for go-live of PRISM was given **and PRISM was made live to clinics at 11.30am the following day.**

3. PRISM since go-live

Clinic Activity on PRISM

3.1. In the two weeks since PRISM go-live:

- 29 (out of 36) 'standalone' clinics have logged into PRISM
- They have undertaken 2,985 units of activity, including 865 new registrations, 777 new cycles, 338 new movements, and have made 1015 updates of legacy data.
- There are only 63 validation errors recorded on clinic homepages (2.1% error rate), meaning clinics are correcting most of their information 'live' as they enter.
- We are tracking individual clinic activity using the live data in table 1 below, and over the coming weeks will work with clinics to ensure they are entering all their expected data.

Table 1: Clinic activity since PRISM go-live

PRISM system activity and error report 27/09/2021

Activity>>	*29*	*21*	*12*	*17*	*1*	*21*	*23*	*13*	*2*	*25*		
Totals since go-live>>		**777**	**55**	**338**	**1**	**932**	**855**	**83**	**7**	**2,985**	**63**	**2.1%**
Week 2 (21/9 - 27/9)		**458**	**38**	**168**	**1**	**389**	**358**	**51**	-	**1,424**	39	2.7%
Week 1 (14/9 - 20/9)		**319**	**17**	**170**	-	**543**	**497**	**32**	**7**	**1,561**	24	1.5%

Centre	First Logged On	New Cycles	Cycle Errors	New Move-ments	Move-ment errors	Upd. Legacy Cycles	New Reg.	Upd. Legacy Reg.	Reg. Errors	Total 'Activity'	Total Errors	Error Rate
0005 Fertility Exeter	14/09/2021	14	0	3	0	9	25	0	6	**51**	6	11.8%
0011 London Sperm Bank	14/09/2021	0	0	103	0	0	0	1	0	**104**	0	0.0%
0013 Centre for Reproductive Medicine, Coventr	16/09/2021	35	3	4	0	65	29	0	0	**133**	3	2.3%
0015 Sussex Downs Fertility Centre	14/09/2021	0	0	0	0	0	0	0	0	-	0	0.0%
0017 Newcastle Fertility Centre at Life	14/09/2021	61	4	15	0	76	103	20	0	**275**	4	1.5%
0021 Hull & East Riding Fertility	14/09/2021	14	0	11	0	35	19	4	0	**83**	0	0.0%
0026 BMI The Priory Hospital	16/09/2021	23	2	0	0	3	8	0	0	**34**	2	5.9%
0031 Assisted Reproduction Unit (ARU), Universi	14/09/2021	0	0	0	0	0	0	0	0	-	0	0.0%
0049 Wales Fertility Institute, Cardiff	14/09/2021	1	0	0	0	1	10	0	0	**12**	0	0.0%
0067 St Mary's Hospital	14/09/2021	45	1	11	0	80	87	0	1	**223**	2	0.9%
0070 London Sperm Bank (LSB) London Bridge	14/09/2021	0	0	0	0	0	11	0	0	**11**	0	0.0%
0075 London Women's Clinic, Darlington	14/09/2021	38	0	27	0	62	59	1	0	**187**	0	0.0%
0086 Kent Fertility Centre	15/09/2021	14	0	2	0	23	2	0	0	**41**	0	0.0%
0094 Barts Health Centre for Reproductive Medi	14/09/2021	72	2	67	0	54	62	16	0	**271**	2	0.7%
0102 Guys Hospital	14/09/2021	10	1	11	0	44	14	3	0	**82**	1	1.2%
0105 London Women's Clinic	14/09/2021	224	23	55	1	191	232	9	0	**711**	24	3.4%
0119 Birmingham Women's Hospital	14/09/2021	25	0	3	0	27	24	0	0	**79**	0	0.0%
0148 Shropshire and Mid-Wales Fertility Centre	14/09/2021	7	2	0	0	24	4	1	0	**36**	2	5.6%
0157 Assisted Reproduction and Gynaecology Ce	20/09/2021	0	0	0	0	0	0	0	0	-	0	0.0%
0179 Centre for Reproduction and Gynaecology	15/09/2021	1	0	0	0	1	2	0	0	**4**	0	0.0%
0201 Edinburgh Fertility Centre	15/09/2021	74	8	3	0	25	64	1	0	**167**	8	4.8%
0295 Bristol Centre for Reproductive Medicine	21/09/2021	0	0	0	0	0	1	0	0	**1**	0	0.0%
0301 London Women's Clinic, Wales	14/09/2021	28	6	1	0	134	41	7	0	**211**	6	2.8%
0322 Brighton Fertility Associates	21/09/2021	0	0	0	0	0	0	0	0	-	0	0.0%
0329 Wales Fertility Institute ? Neath	14/09/2021	22	0	11	0	26	21	1	0	**81**	0	0.0%
0341 The Fertility & Gynaecology Academy	14/09/2021	22	1	5	0	6	15	1	0	**49**	1	2.0%
0342 Concept Fertility	14/09/2021	15	0	0	0	45	2	0	0	**62**	0	0.0%
0354 IVI London (Wimpole Street)	20/09/2021	32	2	6	0	1	20	0	0	**59**	2	3.4%
0356 European Sperm Bank UK Ltd	14/09/2021	0	0	0	0	0	0	18	0	**18**	0	0.0%

3.2. In relation to the individual clinic activity, we are observing the following:

- LWC group (5 clinics with whom we worked closely in testing before launch) are submitting well across their sites with 1,224 units of activity in total.
- A number of clinics including Newcastle, Barts and Edinburgh are submitting very well with very little engagement from HFEA.
- St Mary's Manchester has made a good switch to being a standalone clinic despite being an API clinic with EDI (their system Acubase chose not to migrate to PRISM)
- However, some clinics are submitting volumes less that expected (specifically Guys, ARGC and Bristol) and we will be engaging further with these clinics in coming weeks.

Go-live issues and resolving clinic queries

3.3. All standalone clinics have been advised to contact, Kevin Hudson, the PRISM programme manager, directly if they have any issues with entering data into PRISM.

3.4. This is to ensure the programme manager can be immediately and fully aware of all issues arising with PRISM, and also so that the clinics can receive quick acknowledgement of their issues, and that their queries do not appear to go to an 'anonymous' in-box.

3.5. Overall, since go-live, the number of queries received by standalone clinics has been less than originally expected by the development and register teams. This is a good thing, and is demonstrating that, on the whole, PRISM is intuitive and easy to use for clinics.

3.6. When he receives a query Kevin Hudson either immediately responds or triages it to other members of HFEA staff, as well as logging the issues which allows trends to be identified. Major issues and common queries since go-live have so far included:

- Missing registrations if the patient was registered but had not treatments. This was a data migration rule brought in to ensure we did not take across the large number of patient details for whom there were never any treatments. However, this also captured more recent and legitimate registrations without treatments. On 23rd September, our data migration staff added this information back into PRISM and this issue was fixed.
- Clinic surprise that PRISM was collecting less data than was previously collected in EDI. This is as a result of the data dictionary agreed some years ago with the senior representatives in the sector and communicated to the sector previously. Whilst it is not possible to make major changes to the data dictionary immediately as it would have a major impact on EPRS suppliers, we are recording all feedback on these topics so that this can be reviewed as and when we come to considering expanding the data dictionary.
- A number of technical issues relating to clinic portal access and IP address whitelisting which have been dealt with by the appropriate HFEA teams.
- Clinic queries (particularly from the London Sperm Bank) about how to mark gametes as destroyed or donated if the donor is registered at a different clinic. We are making a rapid change request to give clinics this additional functionality as we think it will be helpful for clinic operations.

3.7. Once the level of clinic queries has levelled off and clinics are entering data into PRISM with ongoing confidence, we will change the method of requesting support from a direct contact to Kevin Hudson to a generic HFEA email address and ticketing system.

4. Progress with EPRS suppliers

The 'deployment window'

4.1. On 23rd August 2021, and as per the cutover plan, we wrote to all clinic PRs and system suppliers to advise them of the PRISM deployment window. This entailed:

- A recognition that for a period after PRISM go-live, not all clinics will be submitting data together, particularly API clinics that would be part of a system supplier's deployment.
- Acknowledging that standalone clinics will also need a period of time to get up to speed with PRISM data entry.
- Advising that during this time, we would be relaxing the data submission standards detailed in General Directive 005.
- But that this had a definitive end date, namely 10th December 2021 by which all clinics (API or standalone) would be expected to be submitting data to the HFEA in time.
- We also advised that HFEA's own data during the deployment window would be incomplete. Consequently, we would only report data to the end of August 2021 and clinics had to make additional mitigations concerning such rules as the 10-family limit.

We also communicated this to EPRS suppliers and advised that their deployments must complete by 10th December 2021. We are tracking progress of each system supplier:

Mellowood (40 clinics)

4.2. Mellowood are on track to deploy within the deployment window:

- We are expecting to finish the assurance process with Mellowood by the end of September.
- Thereafter during October, deployment will commence at a rate of six clinics per week and this should complete before the end of November.

CARE (11 clinics)

4.3. CARE are on track to deploy within the deployment window:

- We are expecting to finish the assurance process with CARE by mid-October
- Once approved, we expect all CARE clinics to deploy at once.
- CARE have expanded their data validation resource and will be active users of the API reporting functionality developed in PRISM to improve the quality of their data.

Meditex (8 clinics)

4.4. As previously reported to AGC, it is the view that most supplier risk lies with Meditex and there are doubts as to whether they will deploy within the deployment window:

- Whilst Meditex have stared the assurance process, we do not expect them to complete until mid-October at the earlier.
- They have advised they will deploy at one clinic per week. Unless they can accelerate the deployment rate, this will mean they will not fully deploy by the 10th of December.

- Our programme approach is firstly to confirm with Meditex that their API solution works (historically there have been issues here), and then to have conversations, with the relevant PRs included if required, about increasing the pace of deployment.
- October will be a critical month for Meditex and their clinics. If Mellowood and CARE successfully start deployment whilst Meditex still are not near accreditation, then we will need to start compliance action in advance of a likely breach of the deployment window.
- At this stage the practical solution with Meditex will be to put further pressure on them through their clinics, rather than to advise clinics that they need to switch to manual entry – which we will need to insist upon if it becomes clear that Meditex are unable to deliver.

Silverlink (1 clinic)

4.5. Silverlink are on track, and we expect to agree a deployment date that fits within our developer resource requirements to ensure Mellowood, CARE and Meditex deploy within the window.

Prospective Suppliers

4.6. We continue to be in dialogue with prospective suppliers (OXDH Health and Baby Sentry Pro) who wish to bring their new API solutions for standalone clinics that already submitting data directly to PRISM.

4.7. We continue to advise these suppliers that it will be six months from go-live before we can consider their accreditation. This is because:

- Our business imperative must be to complete the deployment of current clinics before allowing clinics to change the way they submit data.
- It is particularly labour intensive for our technical staff to accredit new suppliers. The level of scrutiny that we must give a new supplier is higher than for a supplier that has a history of successfully sending information to HFEA.
- We will need to build specific ‘backport’ functionality to facilitate any new system supplier or a standalone clinic that wishes to move to an API solution (see next section).

5. Post go-live development and re-establishing reporting

Post Go-live Development

5.1. We have previously advised AGC concerning the PRISM topics where there is an ongoing need for further development. This includes:

- Logged usability amendments to PRISM as advised by clinics and approved by the Programme Board.
- Creating a more loose-fitting validation approach to recording cycles if there is a groundswell from clinics that PRISM is too restrictive in terms of process accuracy.
- Additional printing functionality as requested by clinics.
- RITA Phase 2: Functionality required by staff but not essential for go-live.
- Adding functionality for Mitochondrial Donation Therapies (MDT).
- Amending PRISM to accommodate transgender patients.

- Managing manual access to PRISM on API clinics so it permits essential data updating but does not corrupt the API process.
- Dealing with 'deprecated code': parts of the PRISM code where it is not clear what function they perform (this has arisen because of the longevity of the project and the different number of developers working on it).
- Creating a 'backport facility' so that system suppliers can move clinics from manual data entry to API. This will need to mirror the process previously available in EDI.
- Expanding the API accreditation process so that new system suppliers can provide API solutions for their clinics.

5.2. Whilst our development focus during the deployment window remains to ensure EPRS system suppliers are properly supported to complete their API solutions, in conjunction with the programme board, we will commence a programme of work for our developers to address these topics.

5.3. There are some topics in this total list of PRISM developments that are of higher priority than others. We will be concentrating first on the backport facility, MDT therapies, manual updating of data from API clinics and RITA Phase 2.

Re-establishing Reporting

5.4. Our data migration team are the key staff that will re-establish HFEA reporting after go-live. Their programme of work includes re-establishing:

- HFEA billing processes by the end of October.
- Inspector's books by the end of November.
- A reporting database for the HFEA Intelligence team by the end of December.
- RBAT and CaFC processes – for which there is currently no fixed delivery date.

5.5. In order to consider options for RBAT and CaFC, during July and August, we commissioned the external business intelligence company Stalis, to conduct an assessment of options for CaFC.

5.6. The report we received focused more on the infrastructure aspects of how to store data rather than the analytical aspects of how to extract and report data.

5.7. We are in the process of considering the next steps for Stalis. It is the programme opinion that:

- from dealing with Stalis…
- and also, from trying to engage other external experts in health analytics…
- and given the increasing pressures that organisations such as NHS England are likely to place for their own support to ensure the wider post-COVID NHS recovery on routes to expert external organisations such as the NHS Health System Support Framework…
- … that it is likely to be increasingly difficult to source appropriately expert external companies to support the smaller and very specialist requirements of HFEA for its detailed analytical needs.

Contracted Resources

5.8. We have extended our existing contracted resources to the end of December.

5.9. Our senior contracted PRISM developer, Ola Akewsoula, has now worked for HFEA for several years and has good business knowledge of fertility and HFEA business processes as well as detailed knowledge of PRISM. In the months to December, we will focus Ola on:

- Supporting EPRS suppliers to ensure we complete deployment.
- Starting to address the post go-live development requirements in 5.1 above.
- Conducting a handover to Gavin Ward, HFEA's employed developer.
- Considering how we can use Ola for wider HFEA development needs, particularly in relation to re-establishing HFEA reporting.

5.10. Elizabeth Marrast, our contracted support assistant, will continue to support Ola and Gavin in ongoing developments and will also continue to support clinics and the register team concerning the details aspects of PRISM use.

5.11. Kevin Hudson, the contracted programme manager, will continue to oversee the programme through deployment, and also address the planning for ongoing HFEA requirements (see next section) and address a 'lessons learned' exercise for PRISM.

5.12. Now that the data migration has completed, Iergo ltd have spend 2 days after go-live to archive and hand over the DQR process and ongoing tasks from the System Retirement Plan. Their involvement with HFEA has now ceased. We have been very pleased with the support they provided during cutover.

5.13. Development work that we are unable to complete whilst we have the additional resource will feed into the longer-term three-year planning activity which is described in the next section.

6. Longer Term planning for HFEA IT and information needs

A definitive end to the PRISM programme and wider planning requirements

6.1. It is possible to describe a definitive end to the PRISM programme and this is helpful for considering HFEA's requirement for long term resource. That 'definitive end' can be described as the point in time when the following tasks are completed:

- Completion of the deployment to all clinics.
- Re-establishment of HFEA reporting processes.
- Clinics undertaking a CaFC verification process using PRISM.
- Calculating and calibrating a CaFC report from PRISM that can be shared with the sector and demonstrate continuity and consistency with past reporting.

6.2. There still remains an ambition to publish an annual CaFC despite the switch to PRISM. The last CaFC was published in March 2021.

6.3. During August, the wider HFEA planning exercise has identified the following objectives for IT and information over the next three years:

- Establish PRISM and complete activities.
- RITA Phase 2.
- A New CaFC from PRISM.

- Improved Register Analytical Tools.
- Updating the Clinic Portal.
- A replacement or long-term solutions for Epicentre.
- HFEA departmental individual IT requirements ('departmental Top 3's').

Replacements for Dan Howard, Chief Information Officer

6.4. As previously advised to ACG, the Chief Information Officer role held by Dan Howard, has been split into two functions: Chief Technology Officer and Head of Information.

6.5. Neil McComb, previously Register Information Manager, successfully applied for the Head of Information role and commenced this position on the 1st of September 2021.

6.6. Although external recruitment for Chief Technology Officer was unsuccessful, Steve Morris, previously HFEA IT Manger, has agreed to step up to role of Interim Head of IT. He stated in this role from 21st September 2021

Agreeing the long-term plan for HFEA information and IT development

6.7. During October and November, Steve Morris, Neil McComb, and Kevin Hudson will work with Rachel Cutting, Peter Thompson and wider HFEA stakeholders to agree the approach. Prioritisation and resources to complete the PRISM programme (as outlined in 6.1 above) and the wider three-year HFEA requirements (6.2 above). In thinking about future requirements our aim will be to avoid large scale bespoke IT development and instead utilise 'off the shelf' solutions wherever possible.

6.8. The results of this planning will be shared at a future AGC meeting.

7. Financial Impacts

7.1. The financial impact of extending contracts to the end of December is outlined in table 2 below.

Table 2: Additional costs arising from contract extensions to December

	Costs to extend contracts to end of December 2021
Programme Manager costs (Kevin Hudson)	£41,940
Lead PRISM Developer (Ola Akewsoula)	£38,580
PRISM support officer (Elizabeth Marrast)	£15,098
Total additional direct costs	£95,618

7.2. As previously reported by Richard Sydee to AGC, funding for these additional costs will need to be sourced from savings elsewhere in the organisation. Richard Sydee will update AGC concerning the source of funds for these costs.

8. Lessons Learned

8.1. During October and November, we will undertake a process to explore the lessons learned from PRISM.

8.2. Particularly given the requirements to move forward on the post PRISM work described in section 5 and 6 above, our approach will be to focus on priority areas and key questions that we know will be important for any future work, namely:

- What were the circumstances that led us to erroneously advise AGC in late 2019 that PRISM was ready to launch, and how can we make sure we avoid such a governance breach with any future projects?
- Were there any viable alternatives to an in-house development of PRISM?
- How in the future can we avoid reliance on single individuals for important pieces of work?

8.3. As part of this exercise, we will also collect together the key messages for future programmes of work so that they can be reviewed by staff in advance of commencing any future IT work.

8.4. We will aim to complete a paper that provides evidence on these issues by the end of November that can be discussed at a special AGC meeting during December.

9. AGC recommendations

9.1. AGC are asked to note:

- The cutover to PRISM and the level of activity currently being experienced.
- The work still required to complete the deployment of PRISM.
- The ongoing work for post go-live development and re-establishing reporting.
- The additional costs of extending key contracts.
- Our approach to agreeing a long-term development plan for HFEA IT and information.

9.2. AGC are asked to agree our approach for reporting lessons learned from PRISM, and to review this at a special ACG meeting during December.

Reserves Policy

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	8		
Meeting date	5 October 2021		
Author	Morounke Akingbola (Head of Finance)		
Output:			
For information or decision?	For decision		
Recommendation	The Committee are requested to approve the Reserves Policy		
Resource implications			
Implementation date	2021/22 business year		
Communication(s)			
Organisational risk	☐ Low	X Medium	☐ High

Background

For several years up to 2016, the HFEA has posted surpluses which has led to a considerable cash reserve. We have tried to reduce our cash reserves by diverting funds towards our development projects and have also maintained licence fees levels.

In 2020/21 during the COVID-19 pandemic, we anticipated that the pandemic would impact on our cash reserves where clinic activities were reduced and in turn their ability to pay their licence fees.

We secured funding from the DHSC (£2.4m) to plug any gaps and only drawing down £1.3m of grant in aid at the end of the financial year. Our closing cash position at the 31 March 2021 was £3.3m, £0.7m more than a target that was set over four years ago.

In January 2021 we relocated to new offices which resulted in lower accommodation costs. Factoring this into our reserves policy and reviewing the other fixed costs that would need to be paid regardless of unforeseen difficulties has resulted in a small reduction in our minimum reserves from £1.4m to £1.3m.

Discussions have been had with DHSC Finance and we received soft agreement that we can effectively go into deficit (over our budget) by utilising our cash reserves. This could mean that the current balance could be reduced from the £3.3m closer to our target.

For ease, the amendments to the policy are:

- Para 11 accommodation costs for two month (£730k)
- Para 12 other commitments (£119k)
- Para 13 contingency (£849k)

The Committee are requested to review and approve the enclosed Reserves policy.

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 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	October 2022
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

Human Fertilisation & Embryology Authority

Strategy and Corporate Affairs update

Clare Ettinghausen
Director of Strategy and Corporate Affairs
October 5 2021

www.hfea.gov.uk

The 'Stratcad' directorate

Planning and Governance
Head: Paula Robinson
- Licensing
- Corporate governance
- Strategic and Business planning
- Risk management
- Programme management
- Performance Monitoring

Research and Intelligence
Head: Nora Cooke O'Dowd
- Information access
- Data analysis
- Intelligence reports
- Data research governance
- FOIs and PQs

Engagement and Communications
Head: Jo Triggs
- Patient information/enquiries
- Internal communications
- Media, campaigns, reports
- Digital and social media
- Communications with clinics
- Stakeholder engagement

Policy
Head: Laura Riley/Joanne Anton
- Standards and guidance
- Public enquiries
- Stakeholder engagement
- Scientific horizon scanning
- Policy project across and outside organisation

Human Fertilisation & Embryology Authority

Directorate risks: 2020/21

- Resilience within directorate – one person/one role
- Staff turnover/impact of office move
- Poor internal comms leading to miscommunication
- Capacity to achieve strategic objectives and BAU
- Capitalising on data opportunities
- Processing around Register Research Panel requirements
- Capacity of other teams to support our work e.g. IT
- Realising changes in Clinic practice e.g. treatment add-ons
- Matching ambition with resource – having a joined up approach across the organisation
- Core standards and processes being adhered to across the organisation
- Other data providers and our response

Human Fertilisation & Embryology Authority

Directorate risks: 2021/2022

- Resilience within directorate – one person/one role – harder to recruit as one person doing multiple roles
- Staff turnover/impact of office move/recovery from pandemic impact/new staff embedding (all areas)/demands from eg DHSC on each area
- Cultural re-build following pandemic
- Capacity to deliver BAU - stretched for anything else
- Capitalising on data opportunities including RRP requirements
- Capacity of other teams and systems to support our work e.g. IT; new register outputs
- Achieving change with limited regulatory powers and use of publication as a regulatory tool
- Matching ambition with resource – capacity to be agile while supporting institutional knowledge and staff L and D and support

Human Fertilisation & Embryology Authority

Human Fertilisation & Embryology Authority

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Strategic risk register 2020-2024

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society
Meeting:	Audit and Governance Committee
Agenda item:	11
Meeting date:	5 October 2021
Author:	Helen Crutcher, Risk and Business Planning Manager
Annexes	Annex 1: Strategic risk register 2020-2024

Output from this paper

For information or decision?	For information and comment
Recommendation:	AGC is asked to note the latest edition of the risk register, set out in the annex.
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	Feedback from AGC will inform the next SMT review and Authority in November.
Organisational risk:	Medium

1. Latest reviews

1.1. SMT reviewed the register at its meeting on 20 September 2021. SMT reviewed all risks, controls and scores.

1.2. SMT's comments are summarised in the commentary for each risk and at the end of the register, which is attached at Annex 1. The annex also includes a graphical overview of residual risk scores plotted against risk tolerances.

1.3. One of the ten risks is above tolerance.

2. Risk management system review

2.1. As AGC members will recall, in early June when we reported last, we were hoping to begin a risk review over the course of the summer. However, subsequently, the Risk and Business Planning Manager handed in her notice and to date we have been unable to recruit to the role. We will be managing a gap from 7 October. Discussions are underway about how to manage this.

2.2. Because of the need to balance handover tasks and record keeping against BAU delivery, across a number of areas, not only risk, the decision was taken that it would be unwise to progress the risk review as planned. Since the organisation will be managing a gap in this key risk system supporting role, the substantive review, which would have included the Strategic Risk Register, did not seem appropriate, since there will be no resource to support and embed changes and mature the culture to establish this effectively.

2.3. Prior to leaving, the Risk and Business Planning Manager has reviewed the risk policy against guidance and updated internal supportive processes as well as briefing an internal auditor on the HFEA risk system. The Head of Planning and Governance will oversee risk management during the recruitment gap, ensuring that the periodic Authority review of risk appetite and tolerance occurs, and will discuss how and when best to take forward the intended review. However, this will be alongside her existing workload, so there will be more limited support capacity for a period.

3. Recommendation

3.1. AGC is asked to note the above and comment on the strategic risk register.

Latest review date – 20/09/2021

Human Fertilisation & Embryology Authority

Strategic risk register 2020-2024

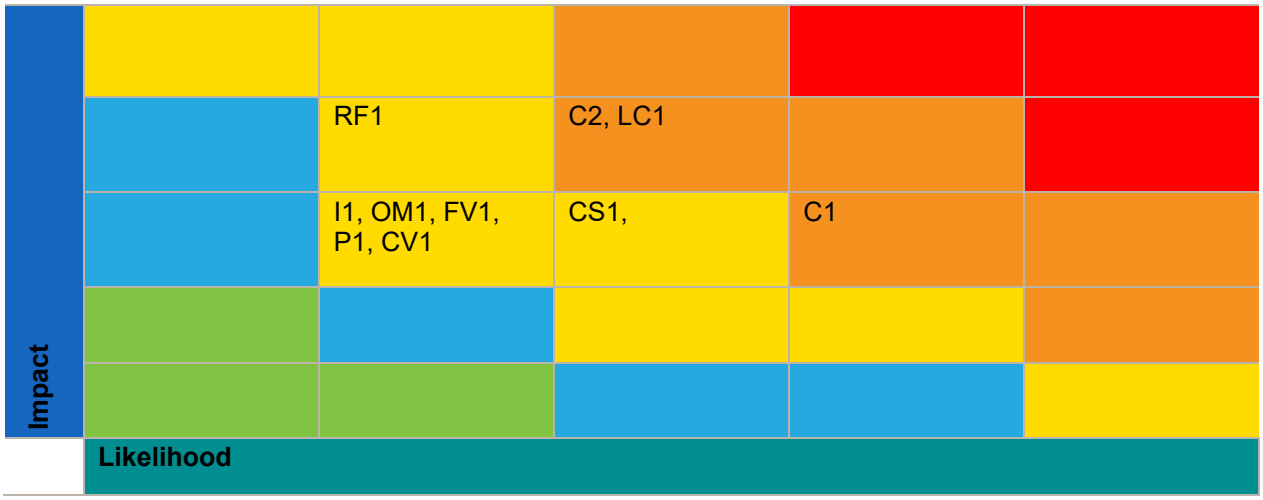
Risk summary: high to low residual risks

Risk ID	Strategy link	Tolerance	Residual risk	Status	Trend*
C2: Leadership capability	Generic risk – whole strategy	4 - Low	**12 – High**	Above 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	⇔⇔⇔⇔
OM1: Operating Model	Whole strategy	6 – Medium	**6 – Medium**	At tolerance	⇔⇔⇔⇔
FV1: Financial viability	Generic risk – whole strategy	9 – Medium	**6 – Medium**	Below tolerance	⇔⇔⇔⇩
I1 – Information provision	The right information	8 – Medium	**6 – Medium**	Below tolerance	⇔⇔⇔⇔
P1 – Positioning and influencing	Shaping the future (and whole strategy)	9 – Medium	**6 – Medium**	Below tolerance	⇔⇔⇔⇔
CV1 - Coronavirus	Whole strategy	12 - High	**6 – Medium**	Below tolerance	⇔⇔⇔⇔

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

Recent review points: AGC 22 June ⇨ SMT 5 July ⇨ SMT 2 August ⇨ SMT 20 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	**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 we 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. We are undertaking more on-site inspections, and reaching 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 changes. The Authority endorsed this approach. There is a higher resource requirement for these new processes, particularly 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 mean there is 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 regulators is effective in areas where we do not have effective powers	In progress - Clare Ettinghausen

Causes / sources	Controls	Timescale / owner of control(s)
	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. We are developing a business case for further work and will initiate the first stage of a multi-year project in 2022-2023.	Ad Hoc ongoing - Catherine Drennan Pre-business case project planning in progress - Joanne Anton, Catherine Drennan
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 To 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, review project underway with next update October 2021 – Joanne Anton Revised version of the policy launched 1 June 2021– Catherine Drennan, Rachel Cutting In place and review ongoing – Paula Robinson In place - Peter Thompson
The revised inspection approach (including fully remote and hybrid inspections due to Covid-19, introduced November 2020) requires greater resources from the inspection team. This will affect ongoing delivery if it continues for a sustained period. 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.	In progress with overview and ongoing plan returning to the Authority in September 2021 – Sharon Fensome Rimmer, Rachel Cutting

Causes / sources	Controls	Timescale / owner of control(s)
	Continued extensions to some licences where appropriate (ie, low risk clinics with good compliance) to manage the pressure on inspection delivery workload.	
Some changes can be very fast meaning our understanding of the implications is limited, affecting our ability to adequately prepare, respond and take a nuanced approach	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: • 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 are 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 it 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 September 2021, development on the first phase	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 needs to be prioritised against other development work. We will set up a new group to prioritise and oversee development from October 2021.	Ongoing – Rachel Cutting (pending recruitment to Chief Technology Officer post) Prioritisation of remaining development as delivery

Causes / sources	Controls	Timescale / owner of control(s)
has completed and this risk is decreasing.		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. 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.	In place – Joanne Anton Audit tool launched in clinics from Autumn 2020 - Rachel Cutting Detailed planning to follow and first meeting likely to be held in Q4 2021/2022 – 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 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

I1: There is a risk that 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	**2**	**3**	**6- Medium**
Tolerance threshold:					**8- Medium**
Status: **Below 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. Ongoing communication with applicants and centres has been clear, to ensure they understand, 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 of September 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 for this, set against other development, before agreeing a plan. If we were unable to update CaFC by summer 2022 this risk would rise sharply.

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.	In place and ongoing - Jo Triggs

Causes / sources	Controls	Status / timescale / owner
	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 aren't in the places that people look for information meaning they do not find us. In some cases, this is because we have decided not to be, for instance on some social media platforms.	We are developing relationships with key influencers to ensure that we have an indirect presence on social media or forums.	In place and ongoing - Jo Triggs
We do not have effective relationships with key strategic stakeholders and so cannot tailor our information to them.	Ensure a strategic stakeholder engagement plan is agreed and revisited frequently. Active work taking place to expand our regular stakeholder contacts (patient organisation stakeholder group, formerly AFPO). This will be evaluated a year after launching. Stakeholder engagement plans considered as part of project planning to ensure this is effective.	In place with ongoing review – Clare Ettinghausen Recruitment underway – plan to launch revised group in Autumn 2021. Ongoing – Paula Robinson
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. Review our information and distribution mechanisms on an ongoing basis to ensure relevance.	In place and ongoing - Jo Triggs In place and ongoing - Jo Triggs
We are currently working off a snapshot of the Register and our access to live Register data is restricted. This will continue until the new Register goes live and we implement new data tools and a reporting database. This may hamper our ability to provide the right data in a timely way when responding to ad-hoc requests.	A reporting version of the Register was captured in December 2020 to enable us to do planned reporting such as the trends report, meaning there will be no impact on such standing information provision. For other requests, such as ad hoc FOIs and PQs, we also use this snapshot but there is a risk that we could receive a question about a variable that is not included in the snapshot. This would require assistance from a key staff member in the Register team and may not be possible at short notice.	Register snapshot captured December 2020. Understanding of potential need for cross team support in place and ongoing – Nora Cooke O'Dowd

Causes / sources	Controls	Status / timescale / owner
	The implementation of these new tools and systems will be prioritised, to ensure that impact and this 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 etc.) to ensure relevant data is available.	In place - Rachel Cutting (pending recruitment to Chief Technology Officer (CTO) post), Sharon Fensome-Rimmer
Until more development is done on reporting from the new Register, we will be unable to update data on Choose a Fertility Clinic. Over time it will stop delivering on its unique selling point, to be a source of independent, timely, accurate information to inform patients' treatment choices.	We updated the data available on CaFC ahead of the Register migration, to ensure that 2019 treatment data can be accessed, bringing this up to date. This will delay CaFC becoming out of date but does not close the risk. Ongoing controls need to be agreed, but conversations are underway about next steps and approaches we may take, so that we can plan any control activities into business plans for 2021/22 or 2022/23 as needed.	Completed February 2021 – Neil McComb Discussions about future mitigation plans underway item at CMG scheduled September 2021 – Peter Thompson
There are gaps in key strategic information flows on our website, for instance after treatment, resulting in missed opportunities to share information.	Digital Communications Board with membership from across the organisation in place to discuss information available and identify any gaps and what to do to fill these.	In place and ongoing - Jo Triggs
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 - Jo Triggs In place and ongoing – Joanne Anton Future measure – Peter Thompson
Our OTR workload will increase and change in 2021/2023 (when children born after donor anonymity was lifted begin to turn 16 and 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. Business case for service development project approved July 2021. Delivery to begin Autumn 2021. Temporary additional resource in place (April and July 2021) to help mitigate increasing demands on the service in the short-term. Training is underway.	Future control – project will begin delivery Autumn - Neil McComb

Causes / sources	Controls	Status / timescale / owner
The OTR service may be negatively impacted by an influx of applications following reopening after being paused, with demand outstripping our ability to respond. Note, this is being managed as a live issue as of September 2021.	Our focus is on accuracy and effective support for applicants; therefore, we have temporarily ceased reporting against our usual KPI, during the period 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.	Additional resource in place (from April and July 2021) and being trained– 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 the centres' 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 underway to identify future improvements to inspection reports. This will be delivered alongside other transparency work. Consideration of further changes to the information we publish in discussions on 'regulation and transparency' at Authority meetings. We do provide patient and inspector ratings on CaFC to provide some additional insight into clinics.	Early work underway, but likely to complete 2022 – Rachel Cutting In place – Rachel Cutting
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	**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, 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, and reviewed ongoing. This supports our thinking on strategic positioning and will ensure that we are best placed to deliver on the Authority's strategic ambitions. 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.

Causes / sources	**Controls**	**Status/timescale / owner**
We do not currently have the range of influence we need to secure our position.	Maintaining and updating our stakeholder engagement plan. Chair and Authority members acting as ambassadors to expand the reach and influence of the organisation's messages and work.	In place, agreed with the Chair and reviewed regularly ongoing – Clare Ettinghausen In place but will need to continue to engage on this as Board membership changes. Authority

Causes / sources	Controls	Status/timescale / owner
	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.	members - Peter Thompson and Clare Ettinghausen In place - Paula Robinson
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
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.	In place - Joanne Anton In place - Joanne Anton

Causes / sources	Controls	Status/timescale / owner
	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.	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
Covid-19 and the implementation of GD0014 caused reduced treatment activity during 2020-2021 meaning this risk became a live issue. We are now assured about our budget for 2021-2022, and in September SMT reduced the risk score accordingly, however uncertainty remains about resources in future years. In September 2021 the Authority have agreed that the Executive should pursue additional resources for 2022-23. This would either take the form of access to reserves, or an increase to our licence fees. The Executive will explore these options with Treasury and the Department, returning to Authority in November.

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. Following agreement by Authority, options for access to additional resources in 2022-23 (through access to reserves or an increase to fees) being explored as of September. 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. We will refresh this model quarterly internally and review at least annually with AGC.	CMG monthly and Authority when required – Peter Thompson Discussions underway – Peter Thompson and Richard Sydee Regular review to resume following outcomes of discussions for 2022-23 – Richard Sydee

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 review 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.	Finance staff member present at Programme Board. 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 Programme Board 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: Further Covid-19 impacts on HFEA income. As of September 2021, this is considered a small risk but there is uncertainty about autumn/winter covid impacts.	The final contingency for all our financial risks is to seek additional cash and/or funding from the DHSC.	Ongoing - Richard Sydee
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. Annual budget has been agreed with DHSC Finance team. GIA funding has been agreed through to 2021 and discussions about SR21 are underway to set out funding for the next three years.	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.

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.

As of September 2021, turnover is increasing above tolerance putting strain on staff generally while covering gaps, inducting new starters, and managing knowledge transfer. Moreover, recruitment is getting more difficult, with typically fewer high-quality applicants per post advertised, which increases the risk of a post not being appointed to. The civil service pay freeze is not helping and the increase for the NHS increases the likelihood that HFEA staff might choose to move to those health ALBs on NHS T&Cs. Though overall high turnover has cumulative effects across the whole organisation, high turnover at team level can feel particularly acute. This has been the case in the Policy team particularly. Regular conversations about resources at CMG ensures that we are aware of and can, where possible, plan mitigations for both.

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 have extended an existing contractor and asked another staff member to act up to cover for our inability to recruit to the Chief Technology Officer post and are considering our approach once this temporary cover comes to an end. 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 ensure that we continue to attract a wide range of candidates to our roles.

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. As of September, this has been required, see below for current controls.	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.	Taking an alternative approach to covering the Chief Technology Officer role in the interim. Reviewing our approach to longer-term recruitment. Looking for alternative ways to allocate skills and resources for hard-to-fill roles to cover gaps.	In place Rachel Cutting 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. 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	In place, ongoing – Peter Thompson In place – Jo Triggs In place, general staff survey occurring October 2021 with wellbeing pulse survey September and quarterly thereafter– Yvonne Akinmodun In place and review planned

Causes / sources	Mitigations	Status/Timescale / owner
	package offered by the HFEA. This may boost good morale.	in 2021 - 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. 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 Programme Board and CMG meetings. 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 to be 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 underway as of September 2021 – 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
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
In-common risk Covid-19 (Coronavirus) may 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

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**
4	4	16- High	**3**	**4**	**12 - High**
Tolerance threshold:					**4 - Low**
Status: **Above 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 as 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 low. Between now and April 2022 we need to recruit seven new Board members. The public appointments timetable is tight and unpredictable and DHSC plan to approach Ministers to see whether short extensions of 3 months might be offered should decisions not be made in time. Wholly new members have long onboarding times and plans to bridge any gaps will necessarily rely on existing Member's flexibility and goodwill. This will not be sustainable longer-term and may make maintaining effective Licensing and governance challenging in 2022.

Causes / sources	Mitigations	Status/times cale / owner
A precipitous reduction in available members (due to member terms ending) would put at risk our ability to meet our statutory responsibilities to licence fertility clinics and research centres and authorise treatment for serious inherited illnesses.	Membership of licensing committees has been actively managed to ensure that formal decision-making can continue unimpeded by the recent board vacancies. However, there is no guarantee that this would be possible for future vacancies, especially if there were several at once and bearing in mind that a lay/professional balance must be maintained for some committees. This is being actively discussed for upcoming possible vacancies.	In place, ongoing - Paula Robinson
The loss of a member of the senior leadership team (for instance through retirement,	Note: We cannot mitigate the cause of this risk, since staff may choose to leave the organisation	

Causes / sources	Mitigations	Status/times cale / owner
leaving the organisation for a new role etc) creates a leadership/knowledge gap.	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 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. More explicit succession planning is being considered but must be balanced with a free and fair recruitment process. Clear, documented plans to enable more straightforward management of such a situation when it occurs.	In place – Peter Thompson 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 Future control – to be implemented during Q3 – Peter Thompson Future control to be implemented during Q3 – – Peter Thompson
Any member recruitment often takes some time and 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 have taken some time which may create additional challenges for planning (the annual report from the commission for public appointments suggests	We have focussed on streamlining induction to ensure that the Members who joined the HFEA this year are brought up to speed as quickly as practicable (see risks below). This risk cause remains for future recruitment, and we remain in discussion on the ongoing management of this.	Underway- Peter Thompson,

Causes / sources	Mitigations	Status/timescale / owner
appointments take on average five months).		
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
Several current Board members are on their second and third terms in office, which expire within the same period (December 2021- April 2022).	Contingency plan in place for managing committees when the upcoming members' terms end in case we are carrying vacancies however this control relies heavily on the goodwill of other members and ability to maintain quoracy.	In progress, ongoing - Peter Thompson, Paula Robinson
The induction time of new members (including bespoke legal training) can be significant, particularly for those sitting on licensing committees, which may lead to a loss of collective knowledge and potentially an impact on the quality of decision-making. Evidence from current members suggests that it can take up to a year for members to feel fully confident.	The Governance team has reviewed recruitment information and member induction to ensure that this is as smooth as possible. Targeted extensions to some existing members, bridged the period of learning for those members who joined in Spring 2021 and provided support new members.	In place and ongoing - Paula Robinson
Induction of new members to licensing and other committees, requires a significant amount of internal staff resource and could reduce the ability of the governance and other teams to support effective decision-making.	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
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	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/times cale / owner
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.		
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 very 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. Annual cyber security training in place to ensure that Authority are appropriately aware of cyber risks and responsibilities. We are continuing to	In place – Steve Morris In place - Peter Thompson Last undertaken January 2020. New course for Authority

Causes / sources	Controls	Timescale / owner
	investigate cyber security courses to identify the most appropriate one for Authority members.	members to be implemented Autumn 2021. – Steve Morris
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. Regular review of cyber / network security policies to ensure they are appropriate and in line with other guidance. Policies currently under review, for completion by end of 2021-2022. Further review of cyber security scheduled to CMG in October 2021. We undertake independent review and test our cyber controls, to assure us that these are appropriate. Regular review of business continuity plan to ensure that this is fit for purpose for appropriate handling cyber security incidents to minimise their impact. Additional online Business Continuity training for Business Continuity Group.	Undertaken by staff October/November 2020 – Steve Morris Update agreed at CMG in June 2020– Steve Morris In place, next full review to be complete by December 2021 – Steve Morris In place, CMG considered this in April 2021 – Steve Morris In place and being completed by end July 2021 – Steve Morris
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.	Testing is undertaken regularly, – next cycle of testing for completion by December 2021– Steve Morris In place, reviewed in summer 2020 and fit for purpose – Neil McComb

Causes / sources	Controls	Timescale / owner
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 – Steve Morris
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 security alerts and action the high priority ones when they arrive.	Ongoing– Steve Morris
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. We regularly review and if necessary, upgrade software to improve security controls for telephony. We are also currently reviewing whether to redevelop our centres database, Epicentre, in the coming year, since some elements of it are old and out of support.	Ongoing, next round of testing to complete by December 2021– Steve Morris In place – Steve Morris Ongoing (Upgrade to Pulse RAS system completed during summer 2021) – Steve Morris Ongoing – Steve Morris
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.	Ongoing (regular reminders sent to staff with security best practice) – Steve Morris
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. We have an effective permission matrix and password policy. Our web configuration limits the service to 20 requests at any one time. The new Register is under the tightest security in the cloud.	In place – Steve Morris To be decided Autumn 2021 – Steve Morris

Causes / sources	Controls	Timescale / owner
	Proposals will be brought to CMG in October 2021 to further reduce risks from remote access	
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None. Cyber-security is an 'in-common' risk across the Department and its ALBs.		

OM1: There is a risk that the HFEA fails to capitalise on or respond effectively to changes affecting the organisation and its ways of working (including related to office working and Covid-19) hampering strategic and statutory delivery.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	4	20 –Very High	**2**	**3**	**6- Medium**
Tolerance threshold:					**6- Medium**
Status: **At tolerance**					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Operating Model OM1: Management of changes to HFEA operating model	Peter Thompson Chief Executive	Whole strategy.	⇔⇔⇔⇔

Commentary
This risk draws various key causes of ongoing change to the HFEA operating model into a single risk. This risk will be reviewed carefully to ensure that it fully reflects emergent risks, and appropriate granularity, including reflecting risks arising from new ways of working brought in by PRISM once it launches. Looking ahead, a key aspect of managing this risk will be being alert to what other organisations are doing; maintaining our relative flexibility while meeting our organisational needs is likely to be a way of attracting and retaining staff ongoing. As of September, discussions with CMG are advancing and proposals on homeworking and principles for using the office space are being drafted. More engagement with Staff on these issues is planned both through and following the upcoming staff survey, in October 2021.

Causes / sources	Controls	Status/Timescale / owner
The facilities provided in the Stratford office may not fulfil all HFEA requirements and desired benefits, such as ability to host key corporate meetings. Note: Covid-19 may have altered the requirements of the HFEA, and we have not yet returned to a new office based working arrangement, meaning that although the move has competed this risk remains.	HFEA requirements were specified up front and feedback given on all proposed designs. Outline plans were in line with HFEA needs and we had staff on the working groups set up to define the detail. Our requirements and ways of working are being revisited in the light of the changed circumstances we are in due to Covid-19. AV equipment is not yet fully installed as of September 2021. If lower-priority requirements are unable to be fulfilled, conversations will take place about alternative arrangements to ensure HFEA delivery is not adversely affected.	Done – Richard Sydee Ongoing as part of Covid-19 management – Richard Sydee Contingency if required – Richard Sydee

Causes / sources	Controls	Status/Timescale / owner
Stratford is a less desirable location for some current staff due to: • 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 as staff choose to leave following the move.	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). 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.	In place – Yvonne Akinmodun, 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 factor these into planning our future operating model and alienate staff by not considering their views, for instance on flexible working.	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 is being planned, to inform any policy reviews.	Ongoing with survey in October prior to more of a return to the office – Peter Thompson
The need to operate with revised arrangements during Covid-19 and social distancing 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.	Clarity provided to staff that current arrangements for working from home will continue until at least end June 2021. CMG to balance staff desire for certainty about post-Covid-19 arrangements with need for flexibility of response during a period of ongoing change. CMG to discuss likely policies that will be applicable following social-distancing arrangements to provide assurance, for instance about maximum office attendance requirements.	Discussions in progress Ongoing with specific culture discussion in September – Peter Thompson
Current staff may not yet feel informed about the facilities in the new office, leading to anxiety and lower morale.	Conversations about ways of working occurred throughout the office move project, to ensure that the project team and HFEA staff were an active part of the discussions and development of relevant policies and have a chance to raise questions, information was cascaded, and staff could visit the site. Staff engagement group was in place to ensure wide engagement as we approached the move.	Ongoing – Richard Sydee

Causes / sources	Controls	Status/Timescale / owner
	Management of ongoing ways of working tasks and engagement with staff being done through CMG as part of HFEA move project closure and post-project oversight. As the situation relating to the pandemic evolves, we are seeking clarity on the availability of facilities, so that this can be communicated to staff.	
The move to a new office and Covid-19 arrangements will lead to ways of working changes we may be unprepared for.	CMG has been discussing ways of working in the aftermath of Covid-19 and in relation the office move, to ensure that these changes happen by design rather than by default. Policies related to ways of working have been agreed and circulated. Staff have and will continue to be involved and updated as appropriate.	Discussions each month at CMG until we move back to the office – Richard Sydee Done and to continue as these are reviewed in light of Covid-19 - Richard Sydee, Yvonne Akinmodun
There is still uncertainty about arrangements around meetings in Redman Place including: • availability of physical meeting spaces • implications of any ongoing social distancing • AV/VC arrangements and readiness for use • shared desk arrangements • booking procedures If these are not managed effectively or do not work well this will lead to disruption to core business.	Throughout Covid-19 remote working, the organisation has effectively run meetings remotely and could continue to do so for as long as is necessary, to ensure that required meetings can continue. Ongoing FM group in place for Redman Place, to coordinate and communicate about arrangements and ensure that these run smoothly.	Ongoing – Peter Thompson In place following central programme closure – Richard Sydee
There are different cultures and working practices in the organisations moving, so there may be perceived inequity about the policy changes made.	During the Redman Place Programme, a formal working group was in place including all the organisations who are moving to Stratford with us, to ensure that messaging around ways of working has been consistent across organisations, while reflecting the individual cultures and requirements of these. We will communicate about any differences, so that staff understand any	Ways of working group work completed, follow on communications being coordinated across all

Causes / sources	Controls	Status/Timescale / owner
	differences in practice and that the intention is not to homogenise practices. Ongoing working groups in place following programme closure in March 2021.	organisations – Richard Sydee
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
NICE/CQC/HRA/HTA – IT, facilities, 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

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.

In May, we were served with a Judicial Review claim. We filed our summary grounds of resistance and both the claim, and our summary grounds were considered by a judge, who refused permission to proceed with the Judicial Review claim. It is a good sign that permission was robustly refused, however, the Civil Procedure rules make provision for the claimant to renew their application by way of an oral hearing. A hearing is listed for 12 October.

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 decisions taken about their licence.	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 possible position to make out a robust case and defend any challenge.	In place – Peter Thompson
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

Causes / sources	Mitigations	Timescale / owner
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-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.	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. 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).	Ongoing – Catherine Drennan In place – Catherine Drennan 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	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	In place new version launched June 2021– Rachel Cutting, Catherine Drennan In place – Sharon Fensome-Rimmer

Causes / sources	Mitigations	Timescale / owner
consistency and avoid process failings, so we are in the best position for when we are challenged, therefore reducing the impact of such challenges.	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: • 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.	In place – Peter Thompson Since Spring 2018 and 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, Joanne Triggs 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

Causes / sources	Mitigations	Timescale / owner
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. Departmental/ministerial sign-off for key documents such as the Code of Practice in place.	In place – Peter Thompson
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

CV1: There is a risk that we are unable to undertake our statutory functions and strategic delivery because of the impact of the Covid-19 Coronavirus.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16 – High	**2**	**3**	**6- Medium**
Tolerance threshold:					**12- High**
Status: **Below tolerance**					

Risk area	**Risk owner**	**Links to which strategic objectives?**	**Trend**
Business Continuity CV1: Coronavirus	Peter Thompson Chief Executive	Whole strategy.	⇔⇔⇔⇔

Commentary
Risk management of these risk causes has been our organisational priority since the beginning of the pandemic. All staff have been working from home (though now returning to the office at least one day per week) and a strategy to manage inspections is in place. Communications to the sector and patients are in place and ongoing. A business continuity group meets regularly to consider risks and ensure an effective response is developed and maintained. We would revisit and revise our plans as circumstances change, as is likely in the autumn and winter. Our revised inspection processes are effective and include comprehensive risk assessment and controls; we are assured that we can effectively maintain this regulatory function. Licensing has continued effectively remotely. SMT considered the risk score in March and decided that the effective inspection methodology reduced the impact of this risk, as the controls ensured we can continue to undertake this statutory function, bringing the score down. The implementation of the methodology has caused a secondary risk, while it beds in, but that is being managed and is captured under RF1. While the implementation has now bedded in well, any increase in infection rates later in the year is likely to impact the inspection team so we will monitor the effects on our delivery approach and review this if required.

Causes / sources	**Controls**	**Status/Timescale / owner**
Risk of providing incorrect, inconsistent, or non-responsive advice to clinics or patients as guidance and circumstances change (ie, not updating our information in a timely manner) and this leading to criticism and undermining our authoritative position as regulator.	Business continuity group (including SMT, Communications, HR, and IT) meeting frequently to discuss changes or circumstances and planning timely responses to these. Out of hours media monitoring being undertaken, to ensure that we respond to anything occurring at weekends or evenings in a timely manner. Close communication with key sector professional organisations to ensure we are ready to react to	In place, ongoing – Richard Sydee In place - SMT and communications team In place and ongoing –

Causes / sources	Controls	Status/Timescale / owner
	any developments led by them (such as guidance updates). Proactive handling of clinic enquiries and close communication with them. Careful monitoring of the need to update information and proactive handling of updates. Public enquiries about Coronavirus are being triaged, with tailored responses in place. Enquirers are being directed to information on our website, to ensure that there is a single source of truth, and this is up to date. Enquiries team have additional support from Managers and Directors. We have reviewed our approach regularly to ensure that this is fit for purpose. Close monitoring of media (including social) to identify and respond to any perceived criticism to ensure our position is clear. Regular review of communications activities to ensure they are relevant and effective.	Clare Ettinghausen In place and ongoing – Sharon Fensome-Rimmer, Rachel Cutting Joanne Triggs – in place In place and under regular review – Joanne Anton In place – Jo Triggs
Risk of being challenged publicly or legally about the HFEA response, resulting in reputational damage or legal challenge. (This risk also therefore relates directly to LC1 above)	As above – ensuring approach is appropriate. As above – continuing to liaise with professional bodies. We may choose to put out a press release in case of public challenge. Legal advice was sought to ensure that HFEA actions were in line with legislative powers. Further advice available for future decisions. Ability to further engage legal advisors from our established panel if we are challenged. Framework for decision making around removing GD0014 in place and Directions kept under periodic review.	In place – Richard Sydee Ongoing - Rachel Cutting If required - Joanne Triggs Done – Peter Thompson If required – Peter Thompson, Catherine Drennan In place – Rachel Cutting and Catherine Drennan
Gaps in HFEA staffing due to sickness, caring responsibilities etc	Possible capability gaps have been reviewed by teams to ensure that these are identified and managed. Other mitigations as described under the C1 risk.	In place – Yvonne Akinmodun

Causes / sources	Controls	Status/Timescale / owner
Risk of disproportionate impact of coronavirus on staff from black and ethnic minority backgrounds. Note: we do not have evidence of this being an issue within the HFEA.	Decision taken to delay routine return to the office subject to government guidance, reducing work-related risk. We are engaging with other similar organisations to consider possible approaches to managing this risk. We have considered the impact as part of planning for the return to inspections and office working, including individual risk assessments for inspection staff, performed before each inspection.	In progress – Yvonne Akinmodun In place – Sharon Fensome-Rimmer
Clinics stop activity during the epidemic and so we are unable to inspect them within the necessary statutory timeframes.	Extending of licences (noted above) should remove this risk by ensuring that the licence status of clinics is maintained.	In place - Paula Robinson
Precipitous decrease in funding due to large reductions in treatment undertaken because of Coronavirus. Note: this risk may be both short and longer-term if clinics close as a result.	As per FV1 risk - We have sufficient cash reserves to function normally for a period of several months if there was a steep drop-off in activity. The final contingency would be to seek additional cash and/or funding from the Department.	In place – Richard Sydee Ongoing discussions if needed as ongoing impact becomes clearer – Richard Sydee
Negative effects on staff wellbeing (both health and safety and mental health) caused by extended working from home (WFH), may mean that they are unable to work effectively, reducing overall staff capacity.	Provided equipment for staff who must WFH without suitable arrangements in place. Ability of staff unable to work from home to work in Covid-19 secure office. Mental Health resources provided to staff, such as employee assistance programme and links to other organisations' resources. Mental Health First Aiders in place to increase awareness of need to care for mental health. Available to discuss mental health concerns confidentially with staff. Regular check-ins in place between staff and managers at all levels, to support staff, monitor effectiveness of controls and identify need for any corrective actions. Additional support for Managers in place. Corrective actions could include discussions about workload, equipment, reallocation of work or resource dependent on circumstance. Pulse wellbeing survey to assess impact.	In place – Richard Sydee In place – Yvonne Akinmodun In place – Yvonne Akinmodun In place and ongoing – Yvonne Akinmodun September 2021 and reoccurring quarterly –

Causes / sources	Controls	Status/Timescale / owner
		Yvonne Akinmodun
Inability of staff to return to office working may negatively impact organisational culture, reduce collaboration, or hamper working dynamics and productivity. Note: This risk will affect the organisation for some time including when we return to the office, while social distancing is in place and office working is significantly reduced due to Covid-19 restrictions. The ongoing consideration of this risk is reflected within the OM1 risk.	Discussion about return to office working at CMG to ensure that this is planned effectively, and impacts considered. This is occurring on a month-by-month basis in the run up to returning to the office. Online solutions to maintain collaboration and engagement, such as informal team engagement and 'teas', Microsoft Teams etc.	Ongoing – Peter Thompson In place – Heads
Risk that we miss posted financial, OTR or other correspondence.	Arrangement in place to securely store, collect and distribute post. Updated website info to ask people to contact us via email and phone. We notified all suppliers about the change in arrangements. Although this is unlikely to stop all post as some have automated systems.	In place– Richard Sydee In place – Jo Triggs In place – Morounke Akingbola
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
In common risk		
DHSC: HFEA costs exceed annual income because of reduced treatment volumes.	Use of cash reserves, up to appropriate contingency level available. The final contingency would be to seek additional cash and/or funding from the Department. (Additional Grant in Aid was provided for the 2020/2021 business year).	Richard Sydee

Reviews and revisions

20/09/2021 – SMT review – September 2021

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

- SMT noted some updates to control owners because of staff leaving the HFEA.
- RF1 depending on the outcome of a discussion with Authority on the effectiveness of the revised inspection regime, this risk is likely to reduce.
- I1 – SMT noted that discussions were still underway regarding plans for updating CaFC. If it were not able to be updated by July 2022 (more than a year since the previous data) this risk would rise.
- P1 – No significant updates.
- FV1 – SMT agreed that the immediate pressure on HFEA finances had reduced and agreed to reduce the risk score. Discussions were underway with Authority and DHSC about controls for future years.
- C1 – SMT noted that the risk had been reviewed with the Head of HR and discussed the impact of turnover and management thereof. Further work would be done to understand the causes and possible further controls. Though 20% may be the performance point that turnover became particularly problematic, the pain of this could be much more acute at a team level and needs careful management.
- C2 – SMT noted that though early indications on recruitment were positive, Board recruitment and the process around appointments had seemed to become more politicised. Contingency plans were in place to manage potential gaps but relied on current members' goodwill to enable core regulatory functions.
- CS1 – SMT noted this risk should be reviewed by the staff covering the role of CTO. An initial update took place, though this risk will need a full review in the light of IT prioritisation and work planned in the autumn.
- OM1 – SMT noted the upcoming conversation with CMG and agreed that this risk should reflect the work underway with CMG on developing principles for using the office strategically.
- LC1 - SMT noted that the Head of Legal had reviewed the risk in full and agreed no change to the score was required.
- CV1 – no major updates but this risk would be under close review over the autumn and winter, especially in relation to Covid approach.

02/08/2021 – SMT review – August 2021

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

- RF1 – Steps had been taken to ensure the new inspection approach was proportionate. The risk in this area is likely to reduce and can be reviewed in the autumn.
- I1 – SMT agreed that this risk was likely to rise soon due to the need to update the reporting tools for the new Register before we are next able to publish a revised Choose a Fertility Clinic. A paper would follow to CMG in September at which point we could understand implications and reconsider the score of the risk. Training of additional staff was reducing the provision of information to OTR applicants, but this was likely to be temporary, we had been clear with applicants, and this will ultimately result in higher processing capability.
- FV1 – SMT agreed that this risk should be considered separately by the Director of Finance and Resources to consider if income was now stable enough to further reduce the risk but did not yet reduce the score.
- C1 – SMT discussed some challenges in relation to key recruitment including the Chief Technology Officer role. Though plans were in place to manage gaps as required, this posed pressures to teams and increased the likelihood level of this risk (from 3 to 4). This raised the score to 12, at tolerance.
- C2 – SMT discussed the latest position in relation to member recruitment. Although recruitment had begun and contingency planning is underway for managing member terms of office, much will rely on reallocation of existing members to committees to ensure that business can be managed. This will be sustainable indefinitely. Any long delays to recruitment could become problematic, especially given the long onboarding period for new members.
- CS1 – SMT discussed some planned work on further data security enhancements and upgrading systems, to occur in the autumn and noted that ultimately these should reduce the cyber security risk further. Risk related to EDI would cease with cut-over to PRISM.

- No updates required to CV1, LC1, P1 (updated in advance with Director of Strategy and Corporate affairs), OM1.

05/07/2021 – SMT review – July 2021 (with update to PI1 risk with Director of Strategy and Corporate Affairs 20/07/21)

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

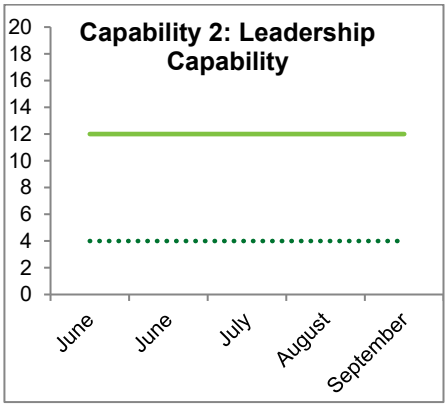
- SMT noted that risks owned by the CIO had been reviewed with him prior to his departure from the HFEA. SMT agreed that the Director of Compliance and information would take on ownership of all CIO risks pending the appointments of a Head of Information (HOI) and Chief Technology Officer (CTO).
- SMT discussed AGC's comments and noted early steps taken to respond to AGC recommendation to make all planned mitigations SMART. These would be reviewed with owners over the coming months ahead of October AGC. SMT noted the addition of tolerances to the dashboard per AGC request.
- C1 – SMT discussed further controls and whether more could be done with the Head of HR on benefits. A management conversation should occur on the possibility of offering homeworking contracts if it were considered beneficial to improving recruitment and retention of staff. Follow up to occur with Head of HR and CMG.
- C2 – SMT discussed the status of proposals for board memberships which were with the Government, arrangements were still uncertain. SMT agreed that although it was not yet time to raise the score, we may need to do so soon and to write again if there was no progress before September.
- OM1 – Plans were being drawn up to explore how the new office space would work when the organisation returned. There would be more certainty on mitigations by September.
- RF1 – SMT agreed the risk reflected the current position. Some extensions to licences would be required ongoing for a period to manage the ongoing backlog of inspections, and we would need to be clear about this. Overall, we now had an opportunity, to take forward our learning and the best outcomes from Covid-19 related changes, to improve our regulation ongoing.
- P1 - This risk and controls were reviewed separately with the Director of Strategy and Corporate Affairs.
- LC1 – SMT discussed AGC comments about being more proactive in managing legal risk. SMT agreed that key to this was taking decisions well, but much legal risk is necessarily managed when it arises (reactively).
- FV1 – SMT agreed to review and potentially reduce the score following finalisation of Q1 financial data which may lift concerns about income. What was left may be a capacity rather than financial risk.
- CV1 – SMT agreed not to revise this risk score given the uncertainty of the impact of the releasing of restrictions, however, by autumn the ongoing impact of Covid-19 variants etc was likely to be clearer and we should look afresh at the risk at that time.
- SMT requested the Risk and Business Planning Manager draw up a plan for what revisions to risk management documentation and approaches were reasonable before her departure from the organisation in October.

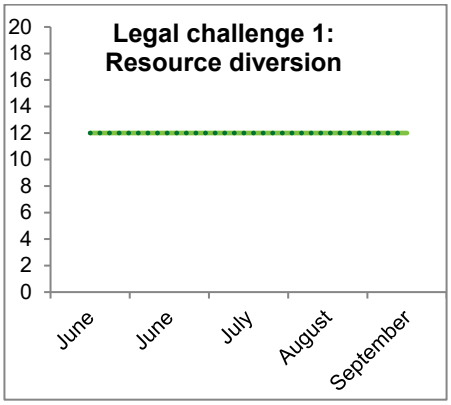
Risk trend graphs (last updated September 2021)

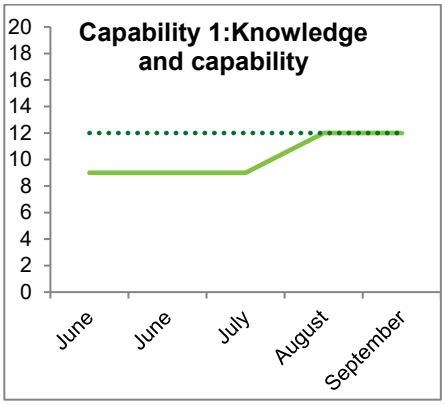
Key:

Residual Risk
Tolerance

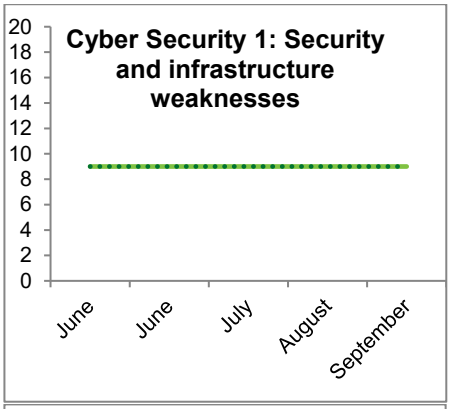
High and above tolerance risks

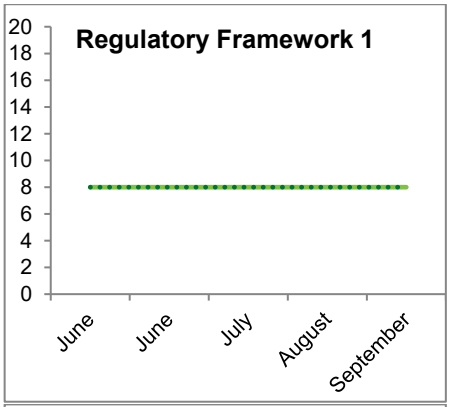


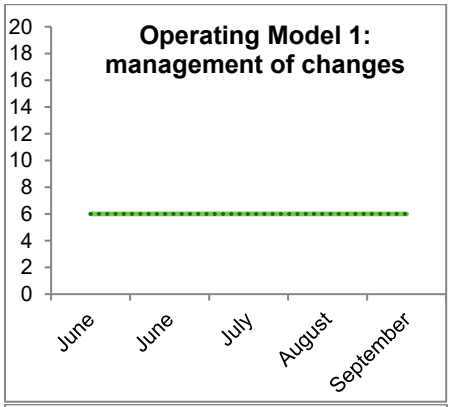


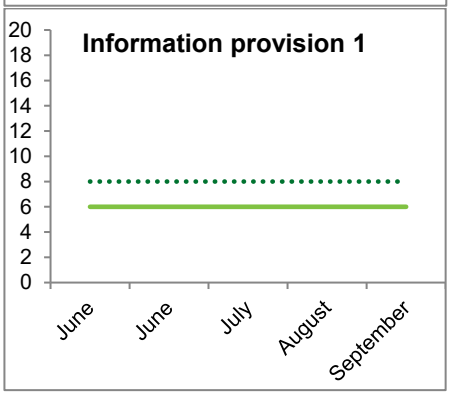


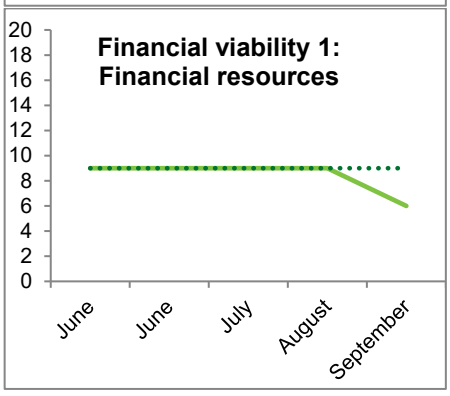
Lower and below tolerance risks

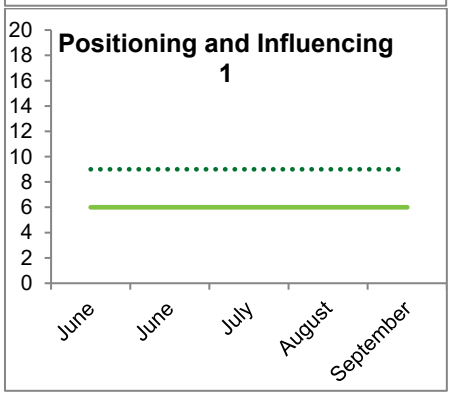


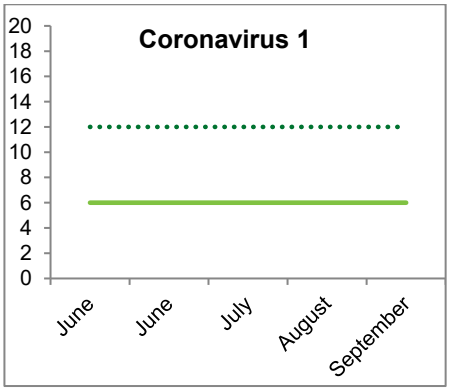












Criteria for inclusion of risks

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.

Resilience, Business Continuity Management and Cyber Security

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 Shaping the future – to embrace and engage with changes in the law, science and society
Meeting:	Audit and Governance Committee (AGC)
Agenda item:	13
Meeting date:	5 October 2021
Author:	Rachel Cutting Director of Compliance and Information Steve Morris Interim Head of IT
Annexes	None

Output from this paper

For information or decision?	For information
Recommendation:	The Committee is asked to note: • The interim measures put in place for the management of the IT team • That our annual internal IT security review took place in July • The upgrade of our electronic management system commenced • A service redesign project has commenced to address the lengthy waiting times for OTR applications and to ensure readiness for 2023. • A more detailed report will be presented at the next AGC once staffing changes have been embedded.
Resource implications:	Within budget
Implementation date:	Ongoing
Communication(s):	Regular, range of mechanisms
Organisational risk:	Medium

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 explains the interim plans put in place following the resignation of Dan Howard, our Chief Information Officer and failure to recruit to the Chief Technology Officer (CTO) role.

1.3. This paper provides an update on IT infrastructure and cyber security relating to the upgrade to our electronic management system and IT security review.

1.4. We have commenced a service redesign project for the Opening the Register (OTR) service in light of the recent increase in demand, the backlog of applications and expected increase in 2023/2024 as a result of the removal of donor anonymity in 2005

2. IT Interim Structure and Management

2.1. In July 2021 our Chief Information Officer resigned from his post and left the organisation. In light of the breadth of this position's remit and job description it was decided to separate this role into the Head of Information (HOI) and the CTO role. The HOI was successfully recruited to in August.

2.2. The CTO role was advertised but only attracted 2 applications, who were shortlisted for interview, but neither were appointable.

2.3. On reflection after the interviews, it was realised that recruitment to a CTO role with the salary we could offer would be challenging. With PRISM being successfully managed by Kevin Hudson it was decided to look at the wider IT challenge from a different perspective and consider the outcomes and deliverables we may need in the future. Therefore, an interim IT structure was agreed by SMT to give stability and management whilst options for the future are considered.

2.4. Steve Morris who was in the post of Systems Manager has taken the role as the Interim Head of IT until May 2022 when he retires. His vacant post is out for advert currently and recruitment to this position whilst Steve Morris is in the interim head role will enable a detailed and beneficial hand over period.

3. IT Structure update and Document Management system upgrade

3.1. We commenced upgrading our electronic document management system (Content Manager) to an updated version (v10) in July 2021. Testing has successfully been completed on the core build on the CM server.

3.2. It was hoped that staff would be able to access CM through a browser interface, but testing has shown this lacks some of the functionality that many users need. A decision has been made to provide full client access to all users, but that requires an upgrade of the client on all laptops.

3.3. The client upgrade will be completed asap, but this is additional work and resource pressures and therefore it will have to follow on after the PRISM launch is largely bedded in, probably October 2021. Once the client rollout is complete it will take no more than 2 weeks to switch the server version and fully complete the upgrade work.

4. IT Security Review

IT security review

4.1. All IT staff met on 14th July to review security across the entire IT estate in HFEA. Highlights from this

- It was confirmed that the method used by HFEA to backup IT systems means that we can recover from a ransomware attack with minimal data loss.
- IT security risks often materialise through malware attacks directed at staff through websites and email. A continual process of training and reminders is needed to maintain awareness.
- Further technical changes can be made to tighten up on IT security, but in some cases these may have an impact on user functionality or ease of access. A paper will be taken to CMG in October to reach agreement on how to proceed.
- HFEA laptops currently run Windows 10. We need to review Windows 11 (recently available) and plan a roll-out such that HFEA security is enhanced rather than eroded.

5. Opening the Register (OTR)

5.1. AGC will be aware that demand on the donor information team increased substantially in the months following the suspension of the service from March 2020 to October 2020. The number of OTR requests received increased from around 40 per month (before the 2020 service pause) to an average of 106 per months in the subsequent months following reopening. The number of applications whilst have declined are still slightly higher from the number received per month pre pandemic. The increase in requests since October 2020 is primarily due to the backlog as a result of the 2020 service pause. There have also been several donor sperm stories in the media which is also associated with an increase in applications.

5.2. We have updated the information on our website to let potential applicants know about the delay and we also provide an honest and transparent estimation of the time it will take to process when we receive requests.

5.3. Processing an OTR request is a very detailed and time consuming task and we cannot risk making an error. We search the register and check information held with clinics, our electronic document management system and our licensing system. The process requires a final check by a second member of the team.

5.4. The impact of the removal of donor anonymity will further increase demand on the team. Donor anonymity was removed in 2005 and donor conceived individuals will soon reach the age of 18. The changes will impact the HFEA from around December 2023 / January 2024 and the change will further increase the number of requests we receive.

5.5. We have taken immediate steps to manage the increased workload and we have successfully recruited 3 members of staff to fixed term contracts, two as donor information officers and one as a senior donor information officer. Whilst the number of applications being processed is still quite low once training is complete the number of applications processed each month will rise to levels to clear the backlog.

5.6. To address the recent increase in demand and expected further increase in 2023/24, we will have commenced a service redesign project.

5.7. The project will include:

- Staffing redesign to ensure resource meets the future demand on the service
- Policy development, to include defining and clarifying the boundaries of the new information service
- Legal advice, guidance and training to ensure the team provides appropriate and correct advice and guidance
- Integration of new processes and IT investment to streamline the process, increase efficiencies, and provide a better level of customer service.

5.8. We will report progress to AGC on this service redesign project.

6. Recommendation

The Committee is asked to note:

- The interim measures put in place to ensure our IT team and service can function effectively whilst allowing time to consider options for our future management requirements.
- The CM upgrade unexpectedly requires a client rollout to all laptops. This will delay completion until October.
- The IT security review provided reassurance on recovery from ransomware. Other technical changes may have a user impact and will be discussed in detail at CMG.
- A service redesign project for the Opening the Register (OTR) service in light of the recent increase in demand and expected increase in 2023/2024 as a result of the removal of donor anonymity in 2005 has commenced and measures have been put in place to clear the backlog of applications and reduce waiting time.

Audit and Governance Committee Forward Plan

Strategic delivery:	☐Safe, ethical, effective treatment	☐Consistent outcomes and support	☒Improving standards through intelligence
Details:			
Meeting	Audit & Governance Committee Forward Plan		
Agenda item	13		
Meeting date	5 October 2021		
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:	5 Oct 2021	9 Dec 2021	15 Mar 2022	28 Jun 2022
Following Authority Date:	17 Nov 2021	9 Feb 2022	23 Mar 2022	6 July 2022
Meeting 'Theme/s'	Strategy & Corporate Affairs, AGC review	Register and Compliance, Business Continuity	Finance and Resources (deferred to June)	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
Risk Management Policy[1]		Yes		
Digital Programme Update	Yes	Yes	Yes	Yes
Annual Report & Accounts (inc Annual Governance Statement)			Draft 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
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

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

AGC Items Date:	5 Oct 2021	9 Dec 2021	15 Mar 2022	28 Jun 2022
Public Interest Disclosure (Whistleblowing) policy			Reviewed annually thereafter	
Anti-Fraud, Bribery and Corruption policy			Reviewed and presented annually thereafter GovS: 013 Counter Fraud	
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		Yes Including bi-annual HR report
Strategy & Corporate Affairs management	Yes			
Regulatory & Register management		Yes		
Cyber Security Training	Yes – update on whether annual training undertaken			
Resilience & Business Continuity Management	Yes	Yes	Yes	Yes
Finance and Resources management			Yes	
Reserves policy	Yes			
Estates	Yes	Yes	Yes	Yes
Review of AGC activities & effectiveness, terms of reference	Yes			
Legal Risks	Yes			
AGC Forward Plan	Yes	Yes	Yes	Yes

AGC Items Date:	5 Oct 2021	9 Dec 2021	15 Mar 2022	28 Jun 2022
Session for Members and auditors	Yes	Yes	Yes	Yes

Gifts and Hospitality Register

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	15		
Meeting date	5 October 2021		
Author	Morounke Akingbola (Head of Finance)		
Output:			
For information or decision?	For information		
Recommendation	Committee is asked to note ***that there have been no new items added to the register***. The Committee are requested to accept that if there are no new entries, a copy of the register is not required.		
Resource implications			
Implementation date	2021/22 business year		
Communication(s)			
Organisational risk	☐ Low	X Medium	☐ High

Register of Gifts / Hospitality Received and Provided/Declined

Version: HFEAG0001
Oct-21

DIVISION / DEPARTMENT: HFEA
FINANCIAL YEAR: 2019/20

	Details of the Gift or Hospitality						Provider Details			Recipient Details	
Type	**Brief Description of Item**	**Reason for Gift or Hospitality**	**Date(s) of provision**	**Value of Item(s)**	**Location where Provided**	**Action on Gifts Received**	**Name of Person or Body**	**Contact Name**	**Relationship to Department**	**Name of Person(s) or Body**	**Contact Name**
Either 'Provision' or 'Receipt'	*Give a brief description of the gift or hospitality recorded*	*Summarize the reason or occasion for the gift or hospitality*	*Give the date(s) on which it was provided or offered*	*Give the known or estimated value - if unknown then state 'unknown' and explain further under the 'Reason for Gift' column.*	*Give the name of the venue or location at which the gift or hospitality was provided*	*For Gifts Received only, specify what happened to the item(s) after it was received*	*Give the name of the individual or organization providing or offering the gift / hospitality*	*Give a contact name if an individual is not specified as the provider - otherwise leave blank*	*Specify the relationship of the provider to the Department (e.g. 'supplier', 'sponsor', etc.) - if the Department is the provider then leave blank*	*Give the name of the individual(s) or organisation receiving the gift / hospitality - if there are multiple recipients, specify each on a separate line*	*Give a contact name if an individual is not specified as the recipient - otherwise leave blank*
Receipt	Lunch invitation	To introduce to Legal Trainers	10/08/2017	£ -	Not known	Lunch accepted	Old Square Chambers	Eleena Misra	Legal Consultancy	HFEA	C Drennan
Receipt	Lunch invitation	Introduce Clients to new lawyers	01/11/2017	£ -	Not known	Lunch accepted	Blackstone Chambers	Catherin Callaghan	Legal Consultancy	HFEA	C Drennan
Receipt	Breakfast invitatoin	Breakfast meeting	08/02/2018	£ -	Not known	Breakfast accepted	Fieldfisher	Mathew Lohn	Legal Consultancy	HFEA	P Thompson
Receipt	Invitation to Silk Party	Informing Clients of a change (to QC)	22/03/2018	£ -	Not known	Invitation accpeted	Blackstone Chambers	Catherin Callaghan	Legal Consultancy	HFEA	C Drennan
Receipt	Lunch provided	Lunch provided prior to a review meeting	24/07/2019	£ 20.00	Not known	Lunch accepted	Alsicent		IT Support supplier	HFEA	D Howard
Receipt	Chocolates	Recruitment agency meeting	16/12/2019	£ -	Not known	Shared in office	Covent garden Bureau	Charlotte Saberter	Recruitment agency	HFEA	J Hegarty
Receipt	Lunch invitation	Interactive Workshops	11/12/2019	£	Central London	Lunch accepted	Interactive Workshop	Anna Beer	Training	HFEA	Y Akinmodun
Receipt	Cheque received	Book Review conducted	14/02/2020	£ 50.00	Not known	Cheque cashed donated to charity	Literary Review		None	HFEA	M Gilmore