Audit and Governance Committee meeting - agenda

Human Fertilisation & Embryology Authority

08 December 2020

Online

Agenda item			Page No	Time
1.	Welcome, apologies and declaration of interests			10.00am
2.	Minutes of 06 October 2020 [AGC (08/12/2020) DO]	for decision	3	10.05am
3.	Matters arising [AGC (08/12/2020) MA]	for information	12	10.10am
4.	Digital programme update [AGC (08/12/2020) DH]	for information (to follow)		10.15am
5.	Internal audit progress report [AGC (08/12/2020) TS]	for information	14	10.45am
6.	Implementation of recommendations [AGC (08/12/2020) MA]	for information	16	11.00am
7.	External audit planning report [AGC (08/12/2020) MS]	for information	29	11.15am
8.	Lessons learned from Covid-19 management [AGC (08/12/2020) RS]	presentation	54	11.35am
9.	Estates update [AGC (08/12/2020) RS]	verbal update		11.45am
	Break			11.55am
10.	Resilience, business continuity management cyber security training [AGC (08/12/2020) DH]	for information	65	12.05pm
11.	Regulatory and register management [AGC (08/12/2020) RC]	for information	75	12.25pm 12.45pm
12.	Bi-annual HR report [AGC (08/12/2020) YA]	for comment	95	12.40pm
13.	Strategic risk register [AGC (08/12/2020) HC]	for comment	113	1.00pm
14.	AGC forward plan [AGC (08/12/2020) MA]	for decision	161	1.15pm

15.	Gifts and hospitality **[AGC (08/12/2020) MA]**	for information	165	1.20pm
16.	Whistle blowing and fraud **[AGC (08/12/2020) MA]**	verbal update		1.25pm
17.	Contracts and Procurement **[AGC (08/12/2020) MA]**	verbal update		1.30pm
18.	Any other business			1.35pm
	Short lunch break			1.40pm
19.	AGC committee effectiveness **[AGC (08/12/2020) PR]**	for discussion **(attached separately)**		1.50pm
20.	Close			2.10pm
21.	Session for members and auditors only			

Next Meeting: Tuesday, 16 March 2021, Online

Minutes of Audit and Governance Committee meeting 6 October 2020

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:	2
Meeting date:	08 December 2020
Author:	Debbie Okutubo, Governance Manager

Output from this paper

For information or decision?	For decision
Recommendation:	Members are asked to confirm the minutes as a true record of the meeting
Resource implications:	
Implementation date:	
Communication(s):	
Organisational risk:	Low

Minutes of the Audit and Governance meeting on 6 October 2020 held via teleconference

Members present	Anita Bharucha - Chair Margaret Gilmore Mark McLaughlin Geoffrey Podger
Apologies	None
External advisers	Mike Surman, National Audit Office – External auditor Karen Holland, Group Chief Internal Auditor - GIAA Tony Stanley, Internal Auditor – GIAA
Observer	Steve Pugh, Department of Health and Social Care - 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 Kevin Hudson, Programme Manager Paula Robinson, Head of Planning and Governance Helen Crutcher, Risk and Business Planning Manager Debbie Okutubo, Governance Manager

1. Welcome and apologies

1.1. The Chair welcomed everyone present online.

1.2. There were no declarations of interest.

2. Minutes of 23 June 2020

2.1. The minutes of the meeting held on 23 June 2020 were agreed as a true record subject to the inclusion of the omission below in paragraph 10:

> ‘The Committee discussed in detail the update it had received on the programme, and in particular focussed on issues and risks in relation to staffing, programme timetable and resourcing’.

3. Matters arising

3.1. The committee noted the progress on actions from previous meetings and the updates presented at the meeting.

4. Digital programme update

4.1. The digital programme update was presented to members by the Chief Information Officer (CIO). It was noted that both the PRISM homepage and API reporting had been completed and this finalised the PRISM build.

4.2. Members were advised that on 12 October 2020 the release candidate would be shared with all clinics who use EDI and will be migrating to PRISM. The Chief Executive (CE) would then write to persons responsible (PRs) at clinics informing them of the launch and our expectations of the system.

4.3. The clinic engagement and training timetable was shared with AGC members and they were advised that PRISM had passed its functional tests. Integrated testing would be completed on 30 November 2020 and all data migration adjustments would be completed on 23 December 2020.

4.4. Members were informed that from 4 January 2021, a 'live data' release candidate would be shared with clinics to support their final stage of training.

4.5. Choose a fertility clinic (CaFC) verification and the EDI migration timetable was shared with members.

4.6. In terms of the finance and affordability, it was noted that reprofiling brought forward certain works and resulted in additional costs of £230,380 during 2020/21. Around £160k of this has been identified through underspends and the £70k outstanding would be identified during the finance review at the end of October 2020.

4.7. The Chair thanked the CIO for the presentation and suggested the areas that members should focus their questions on were:

- timetable and readiness - what was giving staff this level of confidence
- staff and clinic training
- resources – how accurate are the figures presented and where would the additional funds be sourced
- The register information team app (RITA) and CaFC.

Timetable and readiness

4.8. Members questioned what was giving officers that level of confidence. Staff recognised that previous estimates had not always been accurate, but responded that milestones being met, for example development work and integrated testing, led to greater confidence this time.

Staff and clinic training

4.9. On staff training, the committee heard that the number of HFEA staff to be trained was not large and they were now at the stage of familiarising themselves with the system.

4.10. The embedding of PRISM in clinics would occur in the second phase. How staff would support this would be a focus when it came to engaging with clinics.

4.11. It was noted that clinics had not yet had the release candidate and were instead currently completing the questionnaires they had received. HFEA communication was being deliberately spaced out to avoid overload of information.

4.12. Members commented that it was good to see that the timetable was being adhered to and that the logic in what had been explained seemed plausible.

4.13. In response to a question, it was noted that the Programme Manager post was budgeted to the end of March 2021.

4.14. The Director of Compliance and Information commented that difficulties faced previously by some HFEA register staff was because they were being asked to learn to use PRISM from the back end. This was not their day job and was therefore causing issues as they had not used PRISM in clinical scenarios. The front end was what was normally required of them and they were more familiar with that. It was therefore reasonable to conclude that HFEA staff training would progress more smoothly.

Finance

4.15. It was noted that the additional cost following the reprofiling was £230,380. Staff were confident in the figure because of all the work that had been done - what was left to be done was not substantial. £160,000 had been identified through underspends. £70,000 would be identified through the financial review and other contingencies for the second half of the year.

4.16. There was an agreement with the Department of Health and Social Care (DHSC) to remain within budget but that we had permission to run a deficit position this year.

4.17. Members asked about the impact should we run into a deficit. The Director of Finance and Resources responded that it was an agreement that we had reached with the DHSC and we would get the extra funds from our reserves.

RITA

4.18. Members requested assurance about the delay to elements of RITA until after the PRISM launch.

4.19. The CIO responded that it was originally planned that we would develop and launch RITA (all features) after PRISM. We now plan to develop elements of RITA before launch and the remainder after. After considering options such as development of PRISM and RITA in parallel we concluded that completion of the development of RITA should take place after PRISM to avoid PRISM development taking longer due to both systems being developed at the same time.

4.20. It was noted that phase one of RITA had started, which was mission critical.

4.21. The Chief Executive commented that PRISM will change the nature of the work of current staff as there will be less errors for staff to correct post PRISM. It therefore made sense to complete the development work required for RITA after PRISM had been launched. This approached reduced the risk of developing features in RITA which will not be used.

CaFC

4.22. Members were advised by the Chief Executive (CE) that a potential legal challenge had been stepped down and we were hopeful of an informal resolution.

4.23. The timetable set out for CaFC was similar to previous years therefore not new to clinics.

4.24. In response to a question, the CE commented that the HFEA's working assumption was that as long as clinics are Covid-19 compliant and had a treatment commencement strategy that they were adhering to they would remain open.

4.25. The Director of Compliance and Information commented that clinics continued to review their procedures and we were in close contact with them.

4.26. Members asked what contingencies were in place should it be the case that because of government restrictions we could no longer carry out physical inspections.

4.27. The Director of Compliance and Information responded that there would be a desk based exercise. Also, inspectors were now geographically positioned to reduce travelling to centres too far from their respective base. There was also ongoing work with the Head of Legal and DHSC regarding the constraints placed on the inspection regime by the HFE Act.

4.28. Members commented that there was a challenge with the Care Quality Commission (CQC) for not testing their inspectors for Covid-19 before they attended care homes. The Director of Compliance and Information responded that clinics had said that they were not expecting our inspectors to be tested for Covid-19 to attend for inspections.

4.29. A demonstration of the Patient Register Information System (PRISM) was given.

4.30. The committee congratulated all staff involved.

Decision

4.31. Members requested that a digital programme update meeting be scheduled for November.

4.32. Members requested that for future meetings there should be a running total of spending to date.

5. Internal audit

5.1. The Group Chief Internal Auditor, Karen Holland has now stepped in pending the appointment of a new Internal Auditor.

5.2. Members were advised that the accounts payable would be brought forward to quarter 3.

5.3. The Group Chief Internal Auditor commented that PRISM and some aspects of COVID-19 would be done in quarter 4. Work on inspection process and decision making can be done in the last quarter. The Covid-19 decision making would incorporate governance which would involve Authority members.

5.4. The Director of Compliance and Information commented that the inspection process in quarter 4 was feasible.

5.5. Members suggested that the Executives and Internal auditors meet to agree the way forward.

5.6. The Audit Manager presented the two reports circulated, records management and internal incident handling.

Records management

5.7. It was noted that the objective of the review was to provide assurance that HFEA's records management policies and practises were sufficient to ensure compliance with its statutory obligations.

5.8. Following the audit, some improvements were required to enhance the adequacy and effectiveness of the framework of governance, risk management and control. It was given an overall RAG score of moderate.

5.9. Staff stated that rather than implement the recommendation regarding incident reporting and investigation and having a separate log, instead improvements would be made to provide additional clarity and consistency about the process with respect to data breaches.

5.10. Regarding the hard copy goodwill letters, it was noted that a review will take place and a business case for scanning would be agreed later in the year.

Internal incident handling

5.11. It was noted that the internal incident reporting procedure was a good means of managing and mitigating risks.

5.12. Staff agreed with the internal audit recommendations.

Decision

5.13. Members noted the internal audit report.

6. Implementation of recommendations

6.1. The Head of Finance presented this item. It was noted that there were currently 25 recommendations, of which two were highlighted as amber/red and had not been actioned and the recommendation not accepted.

6.2. Ten had been completed, and 11 had completion dates on or after the October AGC meeting. The remaining four were overdue.

Decision

6.3. Members noted the progress on each recommendation.

7. Strategy and corporate affairs management

7.1. The Director of Strategy and Corporate Affairs presented this item to the committee. It was noted that this was the annual update on the risks and issues in the directorate.

7.2. The shift in the directorate risks from 2016 through to 2019/20 was discussed.

7.3. It was noted that the team was in a good place but a notable risk shared across the directorate was the lack of resilience in all the roles because of the small size of the organisation.

7.4. Members asked what the risk of the office move was for the directorate.

7.5. The Director of Strategy and Corporate Affairs commented that the immediate risk has been lowered due to the move to home working. It was noted that a decision had not yet been made regarding office presence when we move to the new office.

7.6. Members commented that over the last three years since the director joined the organisation the directorate has been in a good place.

7.7. The Director thanked the committee and commented that the next six months would be quite crucial.

7.8. Members asked about the range of data requests we received and whether the HFEA could charge for responding to these requests. The Director responded that we were able to charge for specific data sets that were requested through the Register Research Panel.

7.9. Members commented that the HFEA should consider charging for other data requests.

7.10. The Director of Strategy and Corporate Affairs commented that the Competition and Markets Authority (CMA) were working closely with HFEA on producing guidance for the fertility sector on compliance with UK consumer protection law. The draft guidance was going out to clinics soon at which time it would be shared with AGC members.

7.11. Members were advised that the guidance would be finalised in March 2021.

7.12. The committee thanked the Strategy and Corporate Affairs directorate.

8. Reserves policy

8.1. The Director of Finance and Resources presented the reserves policy.

8.2. Members were advised that having reserves became important during the start of the Covid-19 pandemic when we had to shut down clinics for a short period. The reserves meant we could pay our creditors whilst engaging with the DHSC.

8.3. We have now reached agreement with the DHSC that they will provide additional Grant In Aid (GIA) of £2.4m; in conjunction with sector activity restarting it was now believed that we have sufficient funding to meet our liabilities this financial year, even though we may still report a small deficit which will require the use of our cash reserves.

8.4. Members noted that there was no change to the policy and commented that it was positive that we could spend some of our reserves whilst being in a relatively good position.

8.5. Members noted the reserves policy.

9. Estates update

9.1. The Director of Finance and Resources gave an update on the move. There is a slight delay in our move to the new office and we now have a contingency plan in place for staff who want or need to work in an office setting to go to the CQC building in Victoria.

9.2. It is anticipated that by January 2021 the new office in Stratford will be ready for occupation. To be Covid-19 compliant the office space needs to be re-configured.

9.3. The CE commented that there needed to be a dialogue with staff on the balance of working from home and having an office presence.

9.4. Members commented there was the need to be cautious as things have been known to go wrong in situations where staff work in isolation for long periods of time. Also, it was important to have personal contact, in particular for new staff inductions.

9.5. In response to a question it was noted that approximately ten staff wanted to work from an office setting at this time and will be going to the CQC building on a basis ranging from once a week to once a fortnight.

9.6. Members noted the estates update.

10. Resilience, business continuity management, cyber security training

10.1. The Chief Information Officer presented to the committee. It was noted that the committee received regular and detailed updates on resilience, business continuity management and cyber security.

10.2. The committee noted:

- That our business continuity group had continued to meet to review the HFEA IT issues resulting from Covid-19
- The IT infrastructure work taking place ahead of the move to the new office and the upgrade to business intelligence and finance systems
- The details and timeline relating to the next CaFC refresh
- That staff will be submitting an assessment against the Data Security and Protection Toolkit (DSPT) before 31 March 2021
- Recent improvements and progress made in relation to electronic document management.

11. Legal risks

11.1. The CE introduced this item. It was noted that there is no active litigation.

12. Strategic risk register

12.1. The Risk and Business Planning Manager presented the strategic risk register. It was noted that two of the ten risks were above tolerance levels.

12.2. Members were advised that lessons learned workshops have been run to review the handling of Covid-19 risks from a business continuity perspective.

12.3. Also, that the board capability score had been reduced as recruitment was underway. Given the assurance of financial cover from the department, the FV1 risk had also been reduced.

12.4. Staff were reminded to prompt board members to do their refresher training on information security, at the agreed time of year.

12.5. Regarding board member recruitment, it was noted that interviews had taken place for four new Authority members and we were waiting for these appointments to be completed by the DHSC. The DHSC representative confirmed that the advert for the appointment of the Chair position was progressing.

12.6. The Deputy Chair of the Authority commented that she was willing and able to step in as Authority Chair should there be a time gap before the new chair is appointed following the departure of the current chair.

12.7. In response to a question, it was noted that operational risks and controls sometimes needed to be included in the strategic risk register where these would have strategic impacts to ensure the completeness of the register. Members asked the executive to ensure that risks related to the Opening the Register service were effectively reflected in the Register and controlled.

13. Audit and Governance Committee forward plan

13.1. The Head of Finance presented the AGC forward workplan to the committee.

13.2. Members asked about the cyber security training listed and when it needed to be done.

13.3. Members noted the forward plan.

Action

13.4. Cyber security training to be confirmed to members.

14. Gifts and hospitality

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

15. Whistle blowing and fraud

15.1. The Head of Finance commented that we submitted our returns to the Cabinet Office. There were no cases of whistle blowing or fraud to report.

16. Contracts and procurement

16.1. There were no contracts or procurements.

17. Any other business

17.1. The Director of Finance and Resources commented that the committee effectiveness exercise would be done after the December meeting.

17.2. The Chair asked that the Head of Planning and Governance join the session to facilitate the review.

Chair's signature

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

Signature

Name

Anita Bharucha

Date

8 December 2020

Matters arising from previous AGC meetings

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		
Details:			
Meeting	Audit and Governance Committee		
Agenda item	3		
Meeting date	8 December 2020		
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	2020/21 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 23 June 2020			
11.2 Lessons learned report from the risk of management of COVID-19 to be brought to the December meeting	Director of Finance and Resources	Dec-20	**Update –** agenda item (presentation)
Matters Arising from the Audit and Governance Committee – actions from 6 October 2020			
4.31 Digital Programme update meeting scheduled for November	Chief Information Office	Nov-20	**Update -** meeting took place 20 November
4.32 Members' kept abreast of spend against the Digital Programme	Chief Information Officer	On-going	**Update -** assurance that spend was on track was given at the PRISM meeting 20-Nov-20
13.4 Cyber security training to be confirmed to members	Head of Finance	Dec-20	**Update –** training provided by astute (new platform). A reminder to undertake the training will be issued to Members' before the Christmas break.

Digital Programme Update – December 2020

1. Introduction and summary

1.1. A paper updating latest progress on PRISM was discussed at an informal AGC meeting on 20th November 2020:

2020-11- 20 AGC PRISM Update

1.2. On 20th November, we advised AGC that by mid-December we would have better clarity on:

- Clinics' response to advance training and their readiness to go-live in late January
- Our progress with the final DQRs on legacy data quality and readiness to complete this by Christmas.
- Whether there have been any technical interruptions – either within HFEA or from clinics.

1.3. We also advised that by mid-December we would hope to have sufficient confidence and assurance to issue a formal notice to clinic that EDI will be switched off and the process of cutover to PRISM will commence.

1.4. Presently, the provisional date for EDI switch off is 13th January 2021 with a PRISM go-live date of 25th January 2021.

1.5. At the time of writing this paper we are not yet in the position where we can commit to final dates, but we are progressing steadily towards achieving that outcome.

1.6. The purpose of this paper is to give an update to AGC, particularly on the topics of technical, data and clinic readiness. We will also update on our system retirement planning which will require completion before we request AGC approval for cutover in early January 2021.

2. Technical Readiness?

Technical Interruptions

2.1. Since the office move there have been no technical interruptions and HFEA staff involved in PRISM have been 100% dedicated to the project.

2.2. However, clinics have been experiencing a low level of technical issues with EDI. As was previously reported to AGC, the extreme age of EDI means that there was a risk that it would be suboptimal with 'the cloud' and this is now proving to be true:

- whilst working, our technical team are having to reboot EDI every 3 hours to ensure it does not unexpectedly fall over.
- each reboot means the system is down for about 5 minutes.
- as EDI is so old, we are not able to receive any performance monitoring statistics as you might expect with newer systems.

Impact on CaFC

2.3. AGC have been provided with a detailed update concerning CaFC in other papers for their 8th December meeting. Some clinics that are behind have asked for an extension citing EDI downtime as the reason. We have therefore extended the CaFC deadline by one week although the EDI downtime experienced by no means amounts to this additional period given to clinics.

2.4. AGC should note that with all CaFC cycles, we have always had some clinics (on average, six per year) that fail to sign off their data on time, and a week's extension is very generous given the relatively small amount of downtime. Moreover, this will not impact on PRISM go live.

2.5. The revised CaFC deadlines for clinics are now to submit their corrected data by 11th December and for PRs to sign this off by 18th December.

Technical Security Actions

2.6. In anticipation of the clinics using the 'live Release Candidate' to review and train on their own data in advance of go-live, we are conducting penetration testing of an additional environment. This testing will take place before Christmas and will cost an additional £7,000 but is deemed necessary because:

- It would be bad practice for clinics to be training and reviewing data in the same space that we are trying to carefully manage the data cutover.
- It allows uninterrupted access for clinics to train on their own data whilst we are working on the cutover.
- The penetration testing involves additional checks to ensure no unauthorised access is possible to a data environment.
- The 'go-live' environment has already been subject to penetration testing, as this is the environment that will hold data for the longer term.
- Whilst the additional environment is the same technical build as 'go-live', and although patient data will only be held here for a short time, further penetration testing is still thought to be a necessary data security precaution.

3. Data Readiness

3.1. On 20th November we previously reported that to manage our data readiness risk, we have put in place processes to bring impact assessments to the PRISM Programme Board which now meets weekly.

3.2. It is our intention to communicate to clinics a definitive date for EDI switch off and go live, once we are certain we have fixed the issues identified in integrated testing or are certain that they will be fixed in time. AGC should also note that the way in which we communicate any definitive date will also need to reference clinic experience of their own 'live training data' in early January and the possible need to pause should that final stage throw up issues (see section 4 below).

Results of further integrated testing and log of clinic facing issues

3.3. We have completed integrated testing of the migrated data for all types of fertility treatment on 30th November.

3.4. Although our original integrated testing plan stated that we should fully test 50 sampled patient records and associated treatments, we have in fact tested 115 registrations including those involving donor gametes, same sex couples, surrogacy, biopsy, storage, and abandoned treatments.

3.5. In all records tested, we were able to match both the patients and their treatments. However, we have identified some 'clinic facing' issues on the quality of data migration which we have collectively logged, and the programme board reviewed and prioritised.

3.6. Currently there are eight logged issues of which four were deemed important to fix before launch, three as 'nice to fix' (but not essential), and one was deemed not required to be fixed as it related to existing legacy data issues unrelated to PRISM.

3.7. There may be further issues added to the log, and each will be reviewed by the weekly programme board, arising from:

- further functional testing in the 'live environment'
- any major issues discovered in the testing of gamete movements that will take place in the next few days
- any issues arising from the PRISM to EDI reconciliation that is being completed by Howard Ryan before he leaves on 15th December
- any business facing issues discovered that do not relate to clinics
- we are also experiencing speed issues with 'live PRISM' (i.e., populated with data) which our technical staff are investigating, but they are confident of fixing this issue.

3.8. This log of issues, as prioritised by the programme board, is now being reviewed by our data migration and PRISM development teams:

- the cause of two of the four 'must be fixed' issue has already been identified
- we expect these issues to be fixed on this weekend's ETL (5th & 6th December)
- we will re-test for these issues on Monday 7th December
- we will be working to resolve the other two 'must be fixed' issues on the week commencing 7th December

Giving notice to clinics of EDI switch off

3.9. Subject to confidence on completion of these issues, and other issues that might be added to the log in the coming days, the programme board will then agree that they are confident of issuing notice of EDI switch off to clinics.

3.10. Ideally, we would want to give two weeks' notice of the switch off which in practice means giving notice before Christmas if we want to switch off EDI on 13th January 2021.

3.11. AGC are asked to approve this approach.

4. Clinic Readiness RITA development and staff support

4.1. On 20th November we previously reported the potential risk that whilst clinics have made a good start on basic training, they may struggle on the more advanced stages and may not be expert by the anticipated time of go live.

4.2. On 23rd November, Peter Thompson wrote to all PRs setting out their responsibilities for being ready for PRISM and an overview of how this will change data submission in the future. AGC may find the text of the letter helpful:

to PR's from Peter Thompson on PRISM

Advanced and Specialist (surrogacy) training

4.3. We also launched the advanced training scenarios on 23rd November. Unfortunately, the response back from the clinics on advanced scenarios has been much less than was received at the start of basic training. This decline in engagement may be due to:

- Clinic's attention on completing their actions for the impending CaFC deadlines.
- For clinics the original launch of the Release Candidate during October was 'new', and they have had many subsequent communications since.

4.4. Clinics are also been finding the advanced training more challenging, particularly around how PRISM deals with same sex couples which is in a different way to EDI. However generally these issues are easily resolved either at the weekly drop-in session or by email exchange.

4.5. We have commenced work on preparing the specialist training module for surrogacy. We expect to release this to affected clinics by 11th December, which is in line with our training plan originally communicated to clinics.

4.6. Weekly clinic drop-in sessions, run by Kevin Hudson and Elizabeth Marrast to address any queries that clinics have on PRISM, are planned to be run until March 2021.

'Live Training' and clinic review of their own data

4.7. Clinics are currently training on a Release Candidate where they need to enter their own fictious registrations for patients, partners and donors.

4.8. From January, and ahead of go-live, we are working to facilitate clinics to train using their own data. This is the training that is 'closest to go-live' that clinics can do ahead of the actual 'go-live'.

4.9. This stage will also serve as a final and definitive check on our data migration, and clinics will be seeing their own data and undoubtedly contacting us if they see any anomalies.

4.10. Even though we would have previously communicated a definitive cut-off date, if major issues are found at even this late stage, it would be preferable to pause the cutover and investigate rather than continue.

4.11. Consequently, any previous communication we give to clinics will be caveated that any switch off on EDI will be after we have assessed any feedback from clinics concerning their data.

4.12. Currently, clinics will have three weeks to train on the 'Live' Release Candidate before go-live on 25th January. They will have seven working days to report any data issues before cutover commences on 13th January.

Will clinics ask for an extension for PRISM to allow longer time for training?

4.13. In total, clinics have been provided with over three months of system availability to prepare, train and rehearse for PRISM go-live. Under any measure that is a reasonable period of time.

4.14. However, given the nature of some clinics and our experience of CaFC and other deadlines that clinics are set, we think that it is likely that some clinics will ask for an extension on PRISM go live whatever deadline we set.

4.15. AGC are asked to comment on how HFEA should respond when it gets these requests. Our current thinking is that our response should largely depend on the number of clinics that are making the request. If a large proportion of the sector are not ready then we should probably pause, whereas we should not hold up launch if a relatively small number are not ready, given the very reasonable timescales that clinics have had for training. Assuming AGC agrees, the programme will need to take that decision at the time if it arises.

4.16. Any small changes we make to the go-live date are unlikely to significantly affect the overall budget as planned post-go live engagement and training will be rescheduled to the period ahead of go-live.

Supplier Engagement for API

4.17. Since the release of the final API there has been a large volume of communication from our developers to system suppliers as they answer supplier questions on the API.

4.18. We are in contact with all the current system suppliers who will be submitting clinic data electronically through the API. Their current status is as follows:

- **Mellowood (IDEAS system) (38 clinics):** We continue to have regular weekly calls. They will be testing the API in coming weeks and preparing for a roll out of their new user interface (UI) from the end of January at a predicted pace of 6 to 10 clinics per week. We have requested further details about how clinics will handle data in the period between EDI switch off and their UI deployment.
- **CARE Group (8 clinics):** have previously confirmed that they will be ready for launch and we will follow up with them in future weeks.
- **Meditex (7 clinics):** have contacted to say that they consider the timescales 'tight' but are working to achieve this deadline. The move to PRISM will involve a site visit to each of their clinics after go-live. Historically this supplier has always been the last to adopt implement system changes so we will be monitoring closely.
- **Silverlink (1 clinic – Aberdeen):** we are responding to their queries but have not yet have confirmation of achievement by the dates required, and the clinic involved has historically expressed concern about their supplier's pace of delivery. We are therefore monitoring closely.

4.19. AGC should note that as previously advised, for all API clinics we are not expecting data to flow immediately after go-live and that there will be gradual increase in data flows into HFEA over the following weeks as API deployments progress. Even if there is a delay in certain clinics submitting treatment data, it is important to note that no data will be lost and any billing issues will simply be recalculated once the late data is submitted, and we are already planning to bill by estimated amounts in the first few months following go-live (see 5.6 below).

4.20. Particularly given the fact that an ex-HFEA inspector is now leading their deployment to clinics, Mellowood have specifically asked for assurance that clinics won't be erroneously contacted if their data is interrupted. We were able to confirm back to them that the wider HFEA teams, including inspectors, have been fully consulted on the PRISM launch as a result of our System Retirement Planning Process.

5. System Retirement Planning

5.1. As previously reported to AGC, there are three stages of sign off for PRISM before we complete the cutover, and the system goes live:

1. **Patient security:** does PRISM properly report patient data and is it safe?
2. **Clinical usability:** does PRISM work and will clinic staff be able to use it?
3. **HFEA business processes:** are all HFEA departments ready for the switch-over?

5.2. We will be bringing the evidence on these three criteria for when AGC meets to sign off PRISM on Monday 11th January.

5.3. The first two criteria have been reported in the previous sections of this paper.

5.4. To address the final criteria, our data migration lead, Johny Morris from Iergo Ltd, has been supporting HFEA teams and staff through a process of System Retirement Planning which involves multiple meetings to understand the criteria that need to be signed off before they are happy to endorse a go-live with PRISM.

5.5. Arising from this process have been a number of actions, which are generally falling on Kevin Hudson and Johny himself. In addition, there are two key issues emerging:

- Will HFEA billing work correctly through PRISM?
- Will RITA be ready when it is needed?

5.6. **HFEA Billing:** our technical lead for billing (Ian Peacock) also was involved in office move and key data migration work. His work to reconcile billing commences on 7th December and there is an organisational acceptance that during cutover and for month or so thereafter, billing will happen on an estimated basis with a reconciliation happening thereafter.

5.7. **RITA:** development of staff functionality is not happening as quickly as planned because of interruptions to developers either on:

- PRISM issues discovered during integrated testing (which must be fixed before go-live)
- queries from system suppliers on API issues which we are prioritising so as not to cause a delay to their deployments.

5.8. AGC should note that they should not view RITA as a distinct system with a defined start and end date for its build, but rather an evolutionary development of additional PRISM related functionality and reports. This will be informed as both staff and clinics familiarise with PRISM, and how PRISM changes the future of data submission as outlined in Peter Thompson's letter to clinics in section 4.2 of this paper.

5.9. Nevertheless. we also want to make sure that some functionality (as described below) is available by the time staff need them and that we also maximise the benefit of having additional development resource until March.

5.10. Therefore, we are confident that RITA will be ready by the time staff need it as:

- The initial functionality (cross centre searches, viewing donor forms for OTR) are relatively easy to develop.
- As we approach cutover, we expect developers to have far less interruptions.
- For OTR, the RITA functionality will only really be needed once PRISM is populated with significant levels of data, which particularly because of API deployments will not happen immediately from go-live. In the interim, whilst data is building in PRISM, the legacy processes and the 'frozen' final version of EDI' will be the point of reference for the OTR team.
- For the Register Team, we are not currently expecting them to be immediately answering PRISM queries from clinics. Initially, they will need to deal with the final EDI data submissions, and the development team will handle the bulk of initial clinic engagement mirroring the engagement process prior to go live.
- We plan to migrate PRISM support to the Register team as part of the PRISM handover in February and March.

5.11. RITA will also be significantly influenced by any post go-live approach to ongoing organisational-wide reporting and 'off-the-shelf' solutions as we reported to AGC on 20th November.

5.12. As part of the sign off process for cutover authorisation and PRISM go-live, we will be bringing evidence to AGC of the completion of the System Retirement Plan.

6. Next Steps

6.1. As previously stated in this paper, AGC are asked to:

- Approve our approach to formally communicating an EDI switch off date to clinics. This will be once the PRISM programme board are confident that all issues arising from integrated testing will be resolved. This communication is likely to take place in the week before Christmas and will be caveated with regards to subsequent assessment of clinic feedback on their own data.
- Comment on the approach being taken for clinic and supplier readiness and the appropriate HFEA reaction if we get a request from clinics to extend or date of go-live.
- Note, the stages of 'Live training' for clinics in January, and our approach for System Retirement Planning, results of which we will be bringing as part of the sign-off pack for PRISM on 11th January 2021.

Resilience, Business Continuity Management and Cyber Security

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

Details:	
Meeting	Audit and Governance Committee (AGC)
Agenda item	10
Meeting date	8 December 2020
Author	Dan Howard, Chief Information Officer
Output:	
For information or decision?	For information
Recommendation	The Committee is asked to note: • That infrastructure upgrade work associated with the move to the new office has concluded. IT services are running as expected from our new office in Redman Place. • We have agreed a contract for secure IT equipment destruction. Around 500kg of redundant server and IT equipment has been removed from Spring Gardens. • Progress relating to the resolution of errors ahead of the refresh of the Choose a Fertility Clinic website. • That we have convened a review group to create and monitor progress ahead of our DSPT self-assessment submission in June 2021.
Resource implications	Within budget
Implementation date	Ongoing
Communication(s)	Regular, range of mechanisms
Organisational risk	☐ Low ☒ Medium ☐ High
Annexes:	None

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. Our infrastructure upgrade work associated with the move to the new office has concluded and IT services are running as expected from our new office in Redman Place.

1.3. We have agreed a contract for IT equipment destruction which exceeds industry standards for secure destruction. Around 500kg of redundant server and IT equipment was removed from Spring Gardens in November.

1.4. Our work with clinics to resolve errors associated with our Choose a Fertility Clinic (CaFC) refresh is nearing conclusion. Clinics have completed 92% of the work to resolve errors and submit missing data. To compensate for workload pressures and some EDI downtime, we have agreed a short extension of one week to the deadline. Despite the extension a small number of clinics will be unable to sign off their reports. Further details are below.

1.5. A review group has been convened to create and monitor our Data Security and Protection Toolkit assessment action plan.

2. Infrastructure improvements

2.1. Our IT infrastructure work associated with the move to the new office has concluded. This is the culmination of around two years' work on HFEA system updates and associated migration to Microsoft Azure.

2.2. It includes upgrade work to our finance system, document management system, VPN (Virtual Private Network) system, Email system, Licensing system (Epicentre), telephony system (MS Teams) and legacy data submission system (EDI).

2.3. The EDI migration to Azure completed successfully in November and without significant issue. There are some minor performance issues resulting from running an old system on Azure infrastructure. To ensure stability an automatic reboot takes place periodically, resulting a few minutes of downtime per day. All data is queued and no data can be lost. EDI will be fully decommissioned once we have launched PRISM with migrated data in January 2021.

2.4. All infrastructure services are now running as expected from Redman Place, to include network, firewall and telephony.

2.5. There is no server or other IT equipment remaining in Spring Gardens.

3. Secure IT hardware destruction

3.1. In October we agreed a contract with Stone Computers for the destruction of our redundant hardware (servers, laptops and other data-bearing items).

3.2. The service is offered at no cost to customers and is based around data erasure / refurbishment of units which are sold on through various channels. The HFEA may receive a small rebate on these items.

3.3. Data bearing items are subject to secure data erasure to HMG Information Assurance Standard number 5 (HMG level 5) using market-leading Blancco software which is

approved by the Communication Electronics Security Group (CESG) as well as 15+ governing bodies.

3.4. A WEEE (Waste Electrical and Electronic Equipment) recycling certificate is supplied along with a full Asset Management Report (AMR).

3.5. On 18 November 2020 around 500kg of server/IT equipment was collected from Spring Gardens and we have received certification that data will be destroyed and the items will be repurposed or securely destroyed shortly.

4. Choose a Fertility Clinic refresh

4.1. In early October we provided PRs with the usual CaFC verification reports. The reports are refreshed regularly as data is updated. The register team have provided support to clinics with any queries from those reports. The team have responded to around 1100 emails (each containing multiple enquiries) since the start of the process.

4.2. We have communicated regularly with clinics and they have made good progress in submitting missing information and resolving errors. Sector wide progress is in line with previous years.

4.3. At the start of the process there were 6363 errors requiring resolution across 2018 and 2019 data. On 30 November there are 513 errors remaining which suggests that clinics are 92% through their work resolving errors.

4.4. To accommodate workload pressures and some EDI downtime and report access issues we have agreed to extend the data submission and PR sign off deadlines by one week.

4.5. Clinics therefore have until Friday 11 December to submit any missing data or to resolve any errors. The deadline for PRs to sign off their reports is Friday 18 December 2020.

4.6. It is usual that a very small number of clinics will be unable to sign off their reports. Even with the extension it is expected that fewer than 5 clinics will not be in a position to sign off their data. As usual, we will agree caveats to be published on the CaFC website for the clinics this applies to.

4.7. Following PR sign-off and Corporate Management Group approval to proceed, we will then refresh the CaFC information on our website.

4.8. Given resource constraints, it is expected that the CaFC website update will take place in February 2021, once PRISM has gone live.

5. Data Security and Protection Toolkit (DSPT)

5.1. The Data Security and Protection Toolkit is an online self-assessment tool that allows organisations to measure their performance against the National Data Guardian's ten data security standards. It is typically completed by organisations that process NHS data and is completed annually. As set out to AGC in October, NHSX and DHSC have now decided that the HFEA should complete a DSPT for the first time.

5.2. NHSX have confirmed that the 2020/2021 DSPT self-assessment is due by 30 June 2021 which provides a 3 month extension against the original deadline of 30 March 2021.

5.3. We have convened a review group consisting of the Director of Finance and Resources (SIRO - Senior Information Risk Officer), Chief Information Officer, IT Systems Manager and Information Governance/Records Manager to develop and monitor our action plan. The group will report as necessary to SMT and CMG.

5.4. Completion of the DSPT is a significant amount of work. The initial review against the 145 requirements will be complete in mid-December. That includes an assessment of available evidence and expected readiness ahead of the June 2021 submission deadline. Additional support may be available from NHSX for our first submission only.

5.5. Given the quantity of work and our very small team there is a risk that we will not fully meet the standard when we make our first submission in June 2021. There may be an associated reputation risk of a 'not satisfied' submission from our partners, stakeholders and the clinics we regulate.

5.6. We will keep AGC updated on progress and ask AGC to sign off our DSPT assessment ahead of its submission.

6. Recommendation

The Committee is asked to note:

- That infrastructure upgrade work associated with the move to the new office has concluded. IT services are running as expected from our new office in Redman Place.
- We have agreed a contract for secure IT equipment destruction. Around 500kg of redundant server and IT equipment has been removed from Spring Gardens.
- Progress relating to the resolution of errors ahead of the refresh of the Choose a Fertility Clinic website.
- That we have convened a review group to create and monitor progress ahead of our DSPT self-assessment submission in June 2021.

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Regulatory and Register Management

Rachel Cutting MBE
Director of Compliance and Information

www.hfea.gov.uk

State of the Sector Report 2019/2020

- > 80,000 IVF and DI cycles
- 106 active licences
- Two-thirds stand alone clinics / third owned by groups
- Of the 106 licensed clinics, 62 clinics (58%) are privately owned
- Just over a quarter of clinics offering fertility treatment are based in London (30 clinics), followed by the South East (11 clinics).

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Team structures

Chief Information Officer

Six teams

1. Opening the Register
2. Register Management
3. IT System Management
4. Software Development
5. Information Governance
6. PRISM / Data submission

Chief Inspector

x5 Senior Inspectors (1 senior seconded to EU Exit work)
x10.5 Inspectors

x1 Clinical Governance lead
x0.5 CG support

x2 Business Support (1 vacant post)

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Strategic and Operational Risk

Strategic:

- Regulatory Framework: At tolerance
- Cyber Security: At tolerance

Operational:

- Compliance
  - Risk of patient expectations of our complaints service exceed our ability to act
  - Risk of being unable to inspect renewal licence applications where the centre already has a five-year licence
- Information and IT – all managed through prioritisation
  - Workload focussed on project work and continuing to support ‘business as usual’ but some planned work has had to be delayed
  - Limited 3rd party support ‘days’ are left this FY. Prioritising urgent fixes
  - The increase in OTR requests following restarting is stretching the service but currently managing and will review capacity in the team

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Impact of Covid-19

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On the sector

Stopping and restarting services

- Decision to suspend treatment was taken by the HFEA on 23 March 2020 in response to the government lockdown, suspension of elective treatments by NHS England and professional advice.
- Clinics instructed to wind down services in an orderly manner, ceasing all new treatments by 15 April, with exception of fertility preservation services for cancer patients (59 clinics, mix of NHS and Private, offer this service).
- HFEA worked closely with professional associations during March – May to understand how services could be offered safely during the pandemic.
- Revised professional guidelines issued late April / early May.
- HFEA took decision on 30 April to allow fertility clinics to apply for permission to restart treatment from w/c 11 May - provided they met standards (HFEA General Directions 0014 v.2). All clinic applications assessed by HFEA inspectors against criteria.

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Providing safe fertility treatment

HFEA General Direction 0014 v.2 requires licensed clinics to follow specified professional guidelines

- Clinics need to adopt a local risk based approach – e.g. phone consultations, clinics ensure social distancing in waiting rooms, staff rotas, extra time for procedures, restrictions on partners.
- Clinics required to adopt screening procedures and adopt testing as soon as reliable serological test available.
- Precautionary PPE for procedures with close physical proximity e.g. blood samples, egg collection or embryo transfer.
- Changes to laboratory working arrangements.
- HFEA inspectors use an audit tool to ensure compliance with professional guidelines.
- Taken together, such measures should provide a safe way of delivering services even if some degree of restrictions, including local lockdowns, remain in place.

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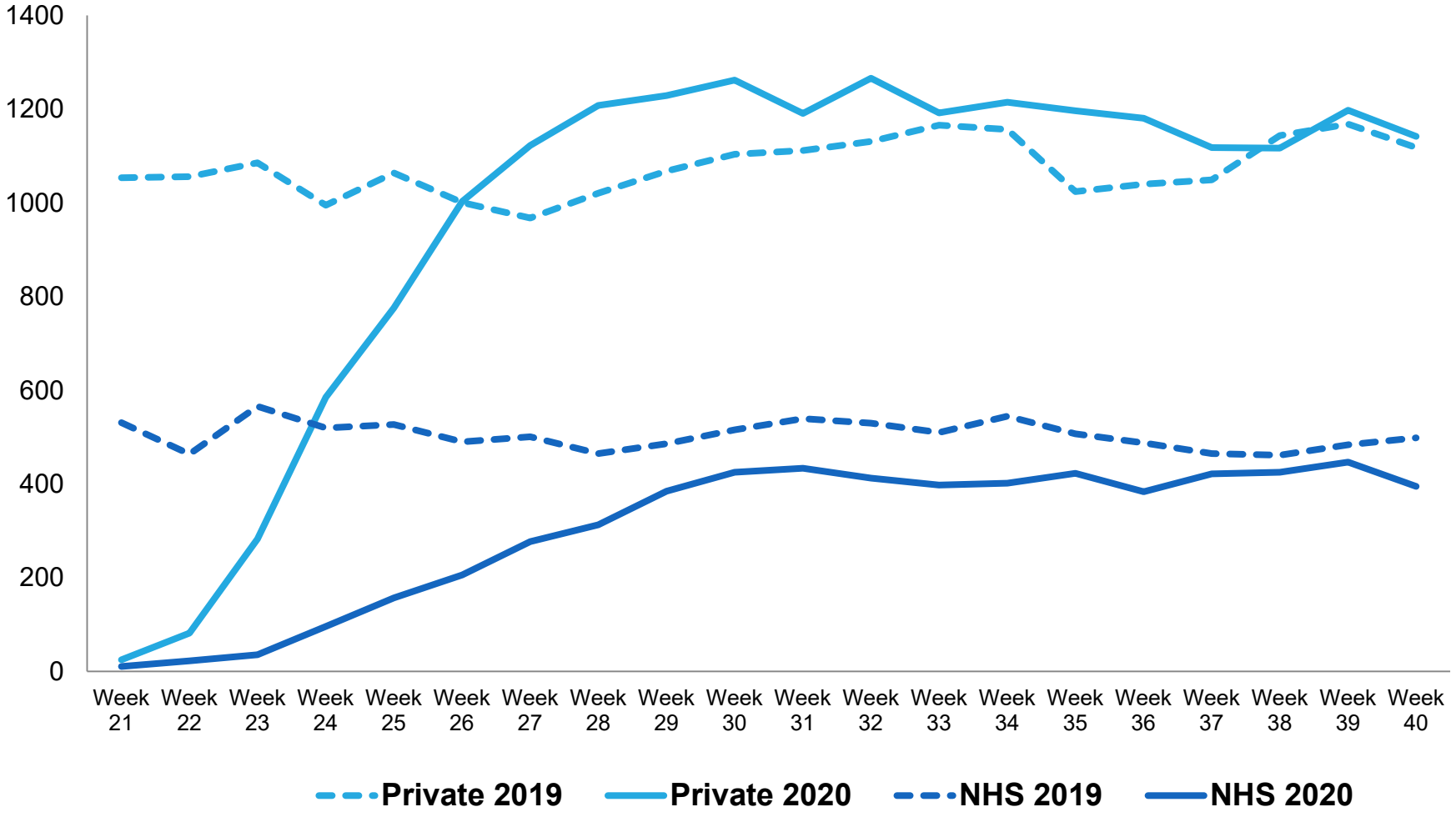
All cycles taking place by week in UK, Week 21 – 40 in 2019 compared to 2020, by funding type



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Current position

- In response to the second lockdown Peter Thompson issued a position statement on 02 11
    - we acknowledged that clinics have robust procedures in place to be covid-19 secure
    - we expect clinics to promptly review their policies and procedures
    - we expect all clinics to demonstrate how their service can be safely maintained and how they can minimise any possible further impact on the wider NHS
    - we will closely monitor the situation and request that any referrals made by licensed clinics to an NHS facility other than their own clinic be reported through the HFEA incident reporting system
    - a further national closure of clinics shouldn't be necessary

- Well received from clinic staff and patients

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Impact on the HFEA: Compliance

Authority approved cessation of inspections during lockdown a1 and to resume inspections from November 2020

- Key points:
  - The HFEA has a statutory duty to inspect licensed premises every 2 years
  - Covid-19 was unprecedented and was a justifiable reason to suspend onsite inspections during lockdown 1
  - Lockdown 2 restrictions less strict so appropriate to recommence inspections

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How inspections were conducted pre Covid-19 and during lockdown

The Inspection cycle involves 3 types of inspection with most clinics being issued with a 4 year licence

- Pre Covid-19:
  - Initial and renewal inspections involve a review of compliance against all requirements
  - Interim inspections conducted at the half way point of a licence and unannounced
- During Lockdown:
  - Initial inspections conducted through a DBA and virtual inspection
  - Centres with 4 year licences with no concerns had their licences extended to 5 years (maximum licence length)
  - Centres with less than a 4 year licence or with concerns a DBA was conducted to determine whether licence could be extended or an inspection scheduled as soon as possible
  - Interim inspections cancelled for those with no concerns. Those clinics with concerns require an inspection scheduled as soon as possible

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Number of inspections affected by Covid-19

March 2020-October 2020

- T&S Renewals (deferred): 21 (2 licences revoked)
- Research Renewals (done as DBA-no physical visit): 5
- T&S Interims (cancelled or deferred-if concerns): 23 (but 1 licence revoked)
- Research Interims (cancelled): 7
- Focussed/Targeted: 5 (2 deferred, 2 executive summary and 1 licence revoked)
- Variation to premises (done by DBA-no physical visit): 3
- Initial (done by DBA): 1

Total: 65

How inspections will be conducted during the continued pandemic

Modified process developed and implemented

- A greater use of DBA and tools to allow for off-site review of compliance
- A more focussed and shorter time spent at licenced centres, prioritising clinics with greater risks of non compliance
- Individual risk assessment of inspectors and clinics with inspections being geographically distributed between inspectors to reduce travel distance
- A cancellation of unannounced inspection – interim inspections to continue with notice given

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Impact on the HFEA: OTR

Closing and opening the service

- Service suspended in March 2020
- Resumed again on 20th October
- In first 2 weeks of opening number of OTRs = 109
- Usually on average 43 per month
- SMT has taken the decision that given this increased pressure, for the next few months we will be unable to perform, and review performance, against our target of 95% of applications fully processed within 30 working days. It is still our intention to respond to applicants as quickly as possible, with effective support and accurate data.
- We will keep this situation under review and discuss with the Authority when this changes.

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Achievements

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Development of a new C&E policy

Current policy was approved by Authority in 2016

The new policy incorporates several improvements to:

- ensure the escalation of concerns are undertaken through a process which is managed consistently, fairly, and transparently
- define the process inspectors follow when deciding what recommendations to make to Licence Committee
- mitigate the risk that centres feel they have been treated unfairly or disproportionately
- provide a robust framework when we are faced with legal challenge

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The new policy

The proposed policy is robust, risk based and has 5 detailed steps to follow:

- assessing likelihood
- assessing impact
- using the defined levels of likelihood and impact to determine the risk score
- working through a series of mitigating and aggravating factors, or at least those relevant in the particular circumstances, as well as consideration of the role the PR has played, to determine whether the initial risk score reflects the broader context in which the clinic operates *(this ensures the policy is not too rigid and allows inspectors to draw on their experience and knowledge to ensure a proportionate decision is made)*
- determine what regulatory action should be recommended by using the Regulatory Action table (RAT)

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Aims of the Compliance and Enforcement Policy

To provide a public statement of *when* and *how* regulatory action will be taken:

- in cases where regulatory action is necessary, it provides a clear statement of what action clinics can expect us to take
- to provide a clear framework to guide the compliance team in all circumstances including when difficult decisions need to be made when non-compliances found on inspection or from incidents, or indeed that might arise in other circumstances, raise concern
- reflects the principles of best regulatory practice under which regulatory activities should be transparent, accountable, proportionate, consistent, and targeted only at cases in which action is needed

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Next steps

- Authority approved the revised draft version of the Compliance and Enforcement Policy to go out for consultation

- Authority agreed to provide comments and advice on the new policy

- Authority approve the proposed timeline for the consultation and implementation
  - 4 week consultation in January 2012
    - Clinic focus
    - Licenced Centres panel
    - Professional stakeholders

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Information: Achievements

- **PRISM**
  - Release candidate now in clinics for training
- **New developer in post**
- **Choose a Fertility Clinic information refresh**
  - Better information for patients
- **Improvements to Policies**
  - Information Governance and IT Security
- **Improvements made to IT infrastructure**
  - Key systems to the cloud (servers now removed from Spring Gardens)

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Looking forward: Post PRISM

- **Register:** Better strategic use of our Register – for regulation, CaFC, research and performance improvement.
- **Data Quality:** New Data Quality strategy – targeted work by Register team based on risk, geography, NHS/private sector, treatment types.
- **OTR and DCR:** Address the OTR backlog and ongoing management, continual improvement of the DCR service in partnership with Hewitt and Kings, planning for 2023 changes and development of new service model.
- **Software development:** Specialist system review such as Epicentre, smaller bespoke applications – using off the shelf systems as appropriate
- **IT:** System upgrades as necessary, policies and procedures review

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Thank you

Bi-annual Human Resources update 2020

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 & Governance Committee
Agenda item:	12
Meeting date:	08 December 2020
Author:	Yvonne Akinmodun, Head of Human Resources
Annexes	Annex 1: Name Annex 2: Name

Output from this paper

For information or decision?	For information
Recommendation:	The Committee is asked to note and comment on the: a. The results from the recent all staff survey (section 4) b. Executive update on employee wellbeing (section 5) c. Update on Equality & Diversity in the workplace
Resource implications:	
Implementation date:	
Communication(s):	
Organisational risk:	Medium

1. Introduction

1.1. This paper sets out some of the key activities the organisation has been working on since the last HR presentation to AGC in December 2019. Many of the activities have taken place against a backdrop of COVID restrictions and changes to ways of working. We also want to take this opportunity to share some of the actions that will inform the next phase of our People HR Strategy in the coming months.

2. Staff survey

2.1. The HFEA has long conducted a staff survey, usually on an annual basis. The last comprehensive staff survey took place in June 2020. We engaged the services of an external survey company to help with the creation of the survey questions and the provision of benchmarking data.

2.2. Our survey results were compared with other around 200 public sector bodies. Below is a selection of the types of organisations against which our results were benchmarked:

- HSIB (Healthcare safety bureau)
- Various universities (e.g. Open University)
- Multiple fire & rescue services
- GPhC – General pharmaceutical council
- Royal College of Surgeons
- Francis Crick Institute

2.3. The results of this latest survey (Appendix 1) shows significant improvement in a number of key areas when measured against the previous survey in 2018. The top themes with the highest and lowest score are shown below.

Top 5 highest scoring areas in 2020 were:

- Senior Leaders make the effort to listen
- The purpose of the HFEA makes me feel good about my work
- Senior leaders provide an overall clear vision of the overall direction of the organisation
- I understand the aims of the organisation (purpose)
- I have the equipment and resources I need to do my work properly

Top 5 low scoring areas were:

- People communicate openly regardless of level or position
- My job makes the best use of the skills and abilities that I have
- If I had a concern about returning to work, I know I can raise it
- My career aspirations at the HFEA are being met

- Your plans for the future – I would still like to be working at the HFEA in two years time

2.4. The survey also provides an open text option for staff to respond on an issue of their choice. The key themes that emerged from the responses included:

- Staff like the fact that the organisation offers good work-life balance
- Many felt that relationships within teams is good, but could be improved between teams
- Some expressed concern about returning to work and the office move, and hoped that the organisation would be flexible in its approach
- Concerns over how fit for purpose IT resources was mentioned by a few
- Concerns about management of poor performance management were expressed

2.5. Some of the key actions put in place following the survey include the launch of a staff survey action planning group. This small group met and agreed the following actions:

- Communications - group members will seek views at team level on what on what actions can be put in place to help increase team collaboration.
- Career development - a review of our PDP process to include opportunities for career development conversations to take place
- Support - we will continue to seek views from staff on what more can be put in place to support staff during the pandemic.

3. Key measures of organisational health

3.1. Sickness and turnover are two key indicators of the health of any organisation. Over the last 12 months, both measures suggest that the HFEA is in good health, despite the pandemic.

3.2. On sickness our currently rate stands at 1.5%, which is below the target of 2.5%

3.3. We have seen a significant decline in staff turnover over the last 12 months. Turnover currently stands at 12%. That may be due, in part at least, to the impact of Covid-19 on the number of job opportunities generally.

3.4. While turnover is now below our target of 15%, we will continue to monitor turnover and conduct exit interviews with those who are leaving the organisation to understand what lessons can be learned to help us continually improve engagement in the workplace.

4. Equality and Inclusion

4.1. At the September Authority, we presented a paper setting out our goals for ensuring we continue to develop a more inclusive workplace. Since the September meeting we have put the following measures in place:

4.2. **Awareness and unconscious bias sessions:** We have since set up online unconscious bias training for all staff as part of our menu of mandatory training programs.

4.3. **Induction:** We are currently also developing equality and inclusion training for new starters as part of their induction

4.4. **Recruitment:** we are currently exploring ways to work with organisations who specialise in reaching a wider section of the community when advertising our job and board vacancies

We are working through the requirements needed to sign up for the Race at Work Charter, which are:

a) Appoint an Executive Sponsor for race

b) Capture ethnicity data and publicise progress

c) Commit at Board level to zero tolerance of harassment and bullying

d) Make clear that supporting equality in the workplace is the responsibility of all leaders and managers

e) Take action that supports ethnic minority career progression

One of the actions we have put in place is to appoint the Director of Strategy and Corporate Affairs as our senior equality and diversity sponsor.

5. Wellbeing

5.1. We are now 9 months into the pandemic and staff have been working at home since March 2020. As a caring employer, we have tried putting in place a number of measures to support our staff in this difficult time.

5.2. We conducted a short pulse survey of staff in May 2020 to find out how they were coping with lockdown. Feedback suggested they were broadly coping with the changes to ways of working.

5.3. We also asked staff if they had any concerns about working in lockdown as part of the comprehensive staff survey in June (see paragraph 2.1 above). 84% of staff stated that they felt they would be comfortable telling their manager if they had any concerns about home working.

5.4. A further 15% indicated that they would prefer to work from the office as soon as they were able. We have since been able to provide staff who wish to work from the office access the CQC office in Victoria, pending the full set up of our Stratford office.

5.5. Anecdotal evidence since the summer suggests that most staff continue to cope with working from home though it is also clear that as this situation continues some staff are finding this more difficult

5.6. Other measures we have put in place over the past few months include:

- Weekly quizzes to encourage team building
- Quarterly wellbeing sessions delivered by our mental health first aiders
- Weekly all staff meetings led by the CEO
- Weekly team check in meetings led by Heads with their staff
- In addition, all staff have access to counselling services through our employee assistance service which is promoted on our intranet.

We will continue to review and monitor our wellbeing activities to ensure we are providing staff with as much support as possible.

6. Recommendation

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

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:	13
Meeting date:	8 December 2020
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 in January.
Organisational risk:	Medium

1. Latest reviews

1.1. SMT reviewed the register at its meeting on 25 November. 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. Ongoing handling of residual move-related risk

2.1. Our physical office move has now occurred, though staff will not routinely return to office working until at least April 2020, and even then, it may be in a reduced form, due to Covid-19. It is clear the remaining risk of disruption to HFEA delivery due directly to the move has significantly reduced, now that the physical move has successfully taken place and HFEA staff continue to work effectively from home.

2.2. This does not mean all the risks captured cease to be concerns, but SMT reflected that these largely amount to broader organisational change risks. Some of these may be ongoing for some time. Given this, SMT agreed that we should reconsider these risks in 2021 and formulate a new organisational change risk.

3. Recommendation

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

Latest review date – 25/11/2020

Strategic risk register 2020-2024

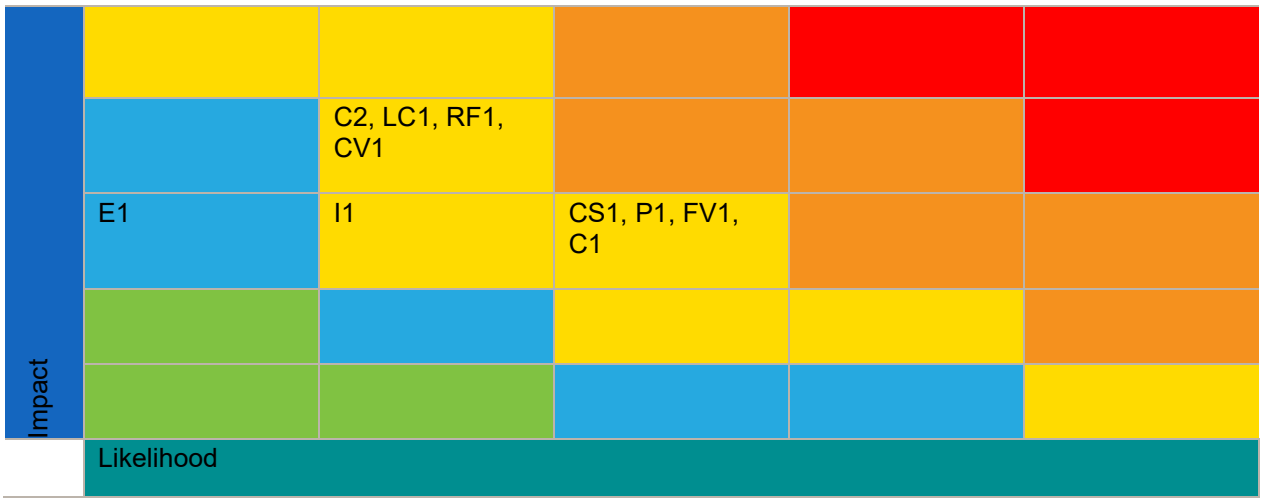
Risk summary: high to low residual risks

Risk ID	Strategy link	Residual risk	Status	Trend*
FV1: Financial viability	Generic risk – whole strategy	**9 – Medium**	At tolerance	⇔⇔⇔⇔
P1 – Positioning and influencing	Shaping the future (and whole strategy)	**9 - Medium**	At tolerance	⇔⇔⇔⇔
CS1: Cyber security	Generic risk – whole strategy	**9 – Medium**	At tolerance	⇔⇔⇔⇔
C1: Capability	Generic risk – whole strategy	**9 – Medium**	Below tolerance	⇔⇔⇔⇔
CV1 - Coronavirus	Whole strategy	**8 – Medium**	Below tolerance	⇔⇔⇔⇩
C2: Board capability	Generic risk – whole strategy	**8 – Medium**	Above tolerance	⇔⇔⇔⇔
RF1 – Regulatory framework	The best care (and whole strategy)	**8 - Medium**	At tolerance	⇔⇔⇔⇔
LC1: Legal challenge	Generic risk – whole strategy	**8 – Medium**	Below tolerance	⇔⇔⇔⇔
I1 – Information provision	The right information	**6 - Medium**	Below tolerance	⇔⇔⇔⇔
E1: Relocation of HFEA offices in 2020	Generic risk – whole strategy	**3 – Low**	Below tolerance	⇔⇔⇔⇩

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

Recent review points: AGC 6 October 2020⇨SMT 21 October⇨ Authority 11 November⇨25 November 2020

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 is 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.

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 artificial intelligence).	We are strengthening or seeking to build connections with relevant partners who do have powers in such areas (for instance, the CMA in relation to pricing of treatments). 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.	In progress - Clare Ettinghausen Ongoing - Catherine Drennan In progress - Laura Riley, Joanne Anton, Catherine Drennan
We may have ineffective tools, systems, or regulatory interventions available which are	Regular review processes for all regulatory tools such as:	

Causes / sources	Controls	Timescale / owner of control(s)
too rigid and cannot be adapted to changes.	• Code of Practice. • Compliance and enforcement policy (Draft revised policy agreed by Authority in November 2020 with consultation to follow) • Licensing SOPs and decision trees To enable us to revise these and prevent them from becoming ineffective or outdated.	In place, next update 2021 – Laura Riley, Joanne Anton Currently under review as at November (delivery extended due to Covid-19) – Catherine Drennan, Rachel Cutting In place and review ongoing – Paula Robinson
Change may be too fast for us to adequately respond to if we do not understand the nature of the changes arising. Resulting in us being under-prepared or taking an insufficiently 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 have to wait for some changes to be clearer in order 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 – Laura Riley, Joanne Anton In place - Peter Thompson
We may focus on 'pet projects' or ephemeral interests, being influenced by personal preferences or biases.	Strategic aims have been clearly articulated; all projects must be aligned to these aims to ensure that our work is focused on delivering these objectives. We ensure this by consideration at Corporate Management Group.	Ongoing – 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
We may have a lack of staffing expertise or capability in the areas developments occur in.	As developments occur, Heads consider what the gaps are in our expertise and whether there is training available to our staff.	Ongoing - Relevant Head/Director

Causes / sources	Controls	Timescale / owner of control(s)
	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.	with Yvonne Akinmodun
If RITA (the register information team app – used to review submissions to the Register) 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. Note: as at December 2020 we are actively discussing risk management, as we continue to develop RITA.	Launch date of PRISM delayed due to Covid-19. RITA will be built sequentially after PRISM. Development has been split into phase 1 (essential) and phase 2 (nice-to-have). While RITA development has not started, it is expected that essential phase 1 RITA development (relating to functionality to support the OTR and Register teams) will be complete before the team need to support a fully launched PRISM. 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 or providing clinic support. If additional development work is required to complete RITA phase 1 development in a timely way, we will consider options for providing the necessary resource. However, this control may impact on our ability to support or develop other internal applications.	Plans in place – Dan Howard Ongoing – Dan Under review as plans develop - Dan
We may not have all the right data from the sector (from inspections or the Register) to make informed interventions, for instance on add-ons.	As part of planning and delivering the add-ons project we will look at the evidence available and consider whether we can access other information if we do not have this already. Revising 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 data on the Register and adding fields when required.	In place - Laura Riley Audit tool launched in clinics from Autumn 2020 - Rachel Cutting Within 2020/2021 business year - Dan Howard
We may face barriers to adding fields to the Register, preventing us from collecting the right data to reflect changes in the sector. This might reduce the evidence available to inform regulatory interventions and maintain	Process to be established for reviewing data on the Register and adding fields when required.	Within 2020/2021 business year - Dan Howard

Causes / sources	Controls	Timescale / owner of control(s)
patient safety as the sector changes.		
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 are managing this carefully 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.

Causes / sources	Controls	Status / timescale / owner
People don't find us/our information, meaning we are unable to get clear and unbiased information to patients, donors and others.	Knowledge of key searches and work to improve search engine optimisation to ensure that we will be found. We have a rolling bi-annual cycle to review website content and can revise website content to ensure this is optimised for search if necessary. We undertake activities to raise awareness of our information, such as using social and traditional media. We maintain connections with other organisations to ensure that others link to us appropriately, and so we increase the chance of people finding us.	In place and ongoing - Jo Triggs

Causes / sources	Controls	Status / timescale / owner
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.	Ensure a strategic stakeholder engagement plan is agreed and revisited frequently. This will be part of the new Communications strategy, to be agreed with the Authority in January 2021. Stakeholder engagement plans considered as part of project planning to ensure this is effective.	Early work done but development needed, future control – Clare Ettinghausen 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, or clinics post their own data.	Monitoring of clinic websites at the renewal inspection point to ensure that the data there is accurate and in line with guidance. A review of all centre websites undertaken during summer 2020. 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.	In place and all clinic websites reviewed during summer 2020 - Rachel Cutting, Sharon Fensome Rimmer In place and ongoing - Jo Triggs
There is a risk that Choose a Fertility Clinic stops delivering on its unique selling point, to be a source of independent, timely, accurate information to inform patient's treatment choices, if we are unable to update it from the new Register, or provide the information in an alternative manner.	We are updating the data available on CaFC ahead of the Register migration, to ensure that 2019 birth data can be accessed, bringing this up to date. This will delay CaFC becoming out of date. Ongoing controls need to be agreed, but early conversations are underway about next steps and approaches we may take, so that we can plan any control activities into business plans for 2021/2022 as needed.	Underway as at November 2020 – Dan Howard Discussions about mitigation plans underway – 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

Causes / sources	Controls	Status / timescale / owner
We may not signpost effectively elsewhere resulting in us trying to reinvent the wheel and stepping on other organisation's toes rather than targeting our resources.	We have an ongoing partnership with NHS.UK to get information to patients early in their fertility journey and signpost them to HFEA guidance and information. Links to other specialist organisations in place as relevant on the website (ie, Fertility Network UK, BICA, BFS, Endometriosis UK etc).	In place and ongoing - Jo Triggs
We may provide too much information, leading to information overload and lack of clarity about what information we provide and how.	Regular review cycle for website ensures that the information provided is relevant.	In place and ongoing - Jo Triggs
We may provide inaccurate information to the media or public enquiries. Though we have well established and effective working practices and controls, we must continue to be aware of and mitigate this risk.	Regular communication between relevant teams. Information provided in enquiries is checked within teams and by legal or at a more senior level if needed. Briefings when key reports etc are issued to ensure others know the key issues, statistics etc.	In place and ongoing - Jo Triggs, Joanne Anton In place and ongoing – Nora Cooke O'Dowd
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. Developed links with DNA testing organisations to ensure that they provide information to those using direct to consumer tests about the possible implications.	In place and ongoing - Jo Triggs In place and ongoing - Laura Riley
Our OTR workload will increase and change in 2021/2023 (when children born after anonymity was lifted turn 16 and 18) and we may lack the capability to deal sensitivity with donor issues.	Plans to undertake service redesign work to review resourcing and other requirements for OTR to ensure these are fit for purpose.	Future control – to be started in Q3/4 2020/2021 - Dan Howard
The OTR service may be negatively impacted by an influx of applications following reopening after being paused, with demand outstripping our ability to respond.	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 provided some temporary additional administrative resource to support he OTR team to process applications.	From October 2020 – Dan Howard

Causes / sources	Controls	Status / timescale / owner
Ineffective media management may mean we don't correct incorrect information available elsewhere or signpost our own.	Media monitoring service in place that is checked daily to identify items where a decision should be taken about need to correct information or not. We review the contract for our media monitoring service annually to ensure that it is fit for purpose. We would choose an alternate provider if this was not working effectively. Relationship with the media ensures that we are asked for comment and that we have internal processes in place to provide the comment in an effective way.	In place and ongoing - Jo Triggs In place - Jo Triggs Jo Triggs – Last reviewed January 2020
Risk that key regulatory information will be missed if Clinic focus, Clinic Portal or emails are not being read.	There is a statutory duty for PRs to stay abreast of updates. 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 when they need it regardless of additional communicated updates. We are implementing a formal annual catch-up between clinics and an inspector.	In place – Rachel Cutting In place – Laura Riley, Joanne Anton Being scheduled as at November – Rachel Cutting
We don't provide tangible insights for patients in inspection reports to inform their decision making.	Review of inspection reports is underway to identify future improvements to inspection reports. We do provide patient and inspector ratings on CaFC to provide some additional insight into clinics.	Underway, likely to complete mid-2021 – Rachel cutting In place – Rachel Cutting
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None.		

P1: There is a risk that we don't 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	**3**	**3**	**9 - Medium**
Tolerance threshold:					**9 - Medium**
Status: At 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 in a position 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, others will not present the HFEA perspective, meaning we may be voiceless, or our strategic impact may be limited. Work is being undertaken to update Authority on the communications strategy, for consideration in January 2021. This supports our thinking on strategic positioning and will ensure that we are best placed to deliver on the Authority's strategic ambitions.

Causes / sources	Controls	Status/timescale / owner
We may not engage widely enough or have the contacts and reach we need to undertake key work, meaning aspects of the strategy are too big to complete within our resources.	Ensure a stakeholder engagement plan is agreed and revisited frequently. 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.	Early work done, Communications strategy to be considered by Authority in January 2021– Clare Ettinghausen In place - Paula Robinson
We may be 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

Causes / sources	Controls	Status/timescale / owner
The sector may disagree with HFEA about key strategic terms and principles, such as 'ethical care' creating negative publicity for us and reputational damage.	We have clearly communicated our intentions, to ensure that these are not misunderstood or misinterpreted and will continue to engage with our established stakeholder groups.	In place - Clare Ettinghausen
The sector may take a different view on the evidence HFEA provides in relation to Add-ons and so we may be ignored.	The working group for the add-ons project will focus 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 and having an open dialogue with the sector on add-ons.	Ongoing - Laura Riley
In relation to changes, HFEA and sector interests may be in conflict, damaging our reputation. This may particularly be the case in relation to Covid-19 and the use and removal of General Directions 0014 (GD0014).	Decisions taken within the legal framework of the Act and supported by appropriate evidence, which would ensure these are clear and defensible. Framework for decision making around removing GD0014 drawn up following Authority discussion.	In place - Peter Thompson In place – Rachel Cutting
We may not engage with early adopters or initiators of new treatments/innovations or changes in the sector.	Regular engagement with SCAAC enables developments to be flagged for follow up by compliance/policy teams. Routine discussion on innovation and developments at Policy/Compliance meetings to ensure we consider developments in a timely way. Inspectors feed back on new technologies, for instance when attending ESHRE, so that the wider organisation can consider the impact of these. We are investigating holding an annual meeting with key innovators (in industry).	In place - Laura Riley/Joanne Anton In place - Laura Riley/Joanne Anton In place and ongoing – Sharon Fensome-Rimmer Future control, delayed due to Covid-19 but to be reviewed in Q4 - 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

Causes / sources	Controls	Status/timescale / owner
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 taken into account.	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**
4	4	16–High	**3**	**3**	**9– Medium**
Tolerance threshold:					**9 - Medium**
Status: At 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
Due to Covid-19 and the suspension of clinic treatment activities in March and April this is a live issue for 2020/2021 since we have limited income for as long as GD0014 (version 2) is in place. Although almost all clinics have now resumed treatment, it is clear that it will take many months for activity to return to normal levels. Moreover, capacity constraints with GPs mean that many potential patients are not being referred to fertility clinics. Taken together, this means that our income will be lower than planned for the remainder of this business year at least. We have had assurance of financial cover from the Department for the remainder of this financial year. There remains significant uncertainty about the 2021/2022 financial year. We will continue to monitor sector activity very closely. SMT reduced the score of this risk from 15 to 9 in September 2020 to reflect this, but noted that given wider uncertainties (about grant-in-aid and treatment volumes) for the 2021/2022 financial year, this risk score may rise over the coming months, the risk would need to be carefully managed and monitored. An initial options appraisal for a fee review project went to the Authority in May 2020. A consultation and modelling for the new income model will follow in 2021/2022, with the intention to launch this in 2022/2023, subject to Authority agreement. This should ensure that the income model is fit for purpose and reflects the changing nature of sector activity, and set the HFEA up for the future.

Causes / sources	Controls	Timescale / owner
There is uncertainty about the annual recovery of treatment fee income – this may not cover our annual spending. This is a live issue for 2020/2021 as we have reduced income for as long as GD0014 (version 2) is in place. Although clinics have reopened it will take some time	Heads see quarterly finance figures and would consider what work to deprioritise or reduce should income fall below projected expenditure. We would discuss with the Authority if key strategic work needed to be delayed or changed. We have a model for forecasting treatment fee income, and this reduces the risk of significant variance, by utilising historic data and future population projections. We will refresh this model	CMG monthly and Authority when required – Peter Thompson Quarterly, ongoing, with AGC model review at least annually

Causes / sources	Controls	Timescale / owner
for activity to return to 'normal' levels.	quarterly internally and review at least annually with AGC. We are undertaking a fee review project in 2021/2022 to ensure that the income model is fit for purpose and reflects the changing nature of sector activity. We are discussing with the Department of Health and Social Care how this issue will be managed from 2021/2022.	(conversation planned in March) - Richard Sydee Planning underway – Peter Thompson and Richard Sydee
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. As at November 2020 we have reduced income due to the deployment of GD0014 in response to Covid-19 and the subsequent reopening of the sector.	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. The reserves policy was reviewed by AGC in October 2020. 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. **Note**: we have decided not to employ this control in the light of the significant impact of Covid-19 on the sector (clinics are not working at historic levels). We will look to review this risk and controls on a quarterly basis depending on the level of activity underway across the sector.	Given the Covid-19 related drop in income, we have actively employed this control – 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.	Quarterly meetings (on-going) – Morounke Akingbola Ongoing – Richard Sydee
Additional funds have been required for the completion of the data migration work and this will constrain HFEA finances and may affect other planned and ad hoc work.	The most cost-effective approach was taken to procure external support to reduce costs and the resulting impact. Ongoing monitoring and reporting against control totals to ensure we do not overspend. Funding was received from the Department to complete the PRISM programme. Additional funding has been allocated from underspends elsewhere in order to cover budget needed to complete the project following impact of Covid-19 delays, while minimising the impact on the wider organisation.	In place – Richard Sydee Ongoing, – Richard Sydee October 2020 – Richard Sydee

Causes / sources	Controls	Timescale / owner
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 financial autonomy or goodwill for securing future funding.	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. 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).	Continuous - Richard Sydee Annually and as required – Morounke Akingbola
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: Covid-19 impacts on HFEA income.	The final contingency for all our financial risks is to seek additional cash and/or funding from the DHSC and we are in ongoing discussions with the Department about this issue for the 2021/2022 business year having received confirmation from them for cover in 2020/2021.	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.	Quarterly accountability meetings (on-going) – Richard Sydee December/January annually,

Causes / sources	Controls	Timescale / owner
	Annual budget has been agreed with DHSC Finance team. GIA funding has been agreed through to 2021.	– 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	**3**	**3**	**9- Medium**
Tolerance threshold:					**12 - High**
Status: **Below 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. For 2019/2020 Turnover was 12.2% (in 2018/19 this was 26.8%). This reduction in turnover suggests that we are currently in a more stable situation and this will naturally strengthen our capabilities as staff develop more experience in their roles. We have also often been able to recruit internally which has assisted in reducing turnover as staff have been able to develop their careers within the HFEA. We have taken steps to improve retention, focussing on things that we can control like learning and development. AGC receive 6-monthly updates on capability risk 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. We have three Authority member vacancies which create Board capability gaps, these risks are captured in the separate C2 risk, below. Although we reduced our assessment of this risk score in May 2020, we are aware that ongoing impacts of Covid-19 may affect capability in future months, and we are considering approaches to manage this as the situation develops.

Causes / sources	Mitigations	Status/Timescale / owner
High turnover, sick leave etc., leading to temporary knowledge loss and capability gaps.	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 if appropriate.	In place – Yvonne Akinmodun In place – Peter Thompson In place – Relevant Director alongside managers
Poor morale could lead 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 package offered by the HFEA. This may boost good morale.	In place, ongoing – Peter Thompson In place – Jo Triggs In place, staff survey undertaken June 2020 – Yvonne Akinmodun In place - Peter Thompson
Work unexpectedly arises or increases for which we do not have relevant capabilities.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG – standing item on planning and resources at monthly meetings. 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.	In place – Paula Robinson In place – Paula Robinson In place – Paula Robinson

Causes / sources	Mitigations	Status/Timescale / owner
	Review of 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.	Ongoing review in progress 2020-2021– Paula Robinson In place until project ends – Dan Howard
The future office move may not meet the needs of staff (for instance location), meaning staff decide to leave sooner than this, leading to a significant spike in turnover, resulting in capability gaps.	See separate E1 risk for full assessment of risk causes and controls.	Engagement with staff and other organisations underway and ongoing – Richard Sydee
Possible capability benefits of colocation with other organisations, arising out of the office move, such as the ability to create career pathways and closer working may not be realised.	Active engagement with other organisations early on. 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.	Ongoing – Richard Sydee Early progress, ongoing – Yvonne Akinmodun
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
Government/DHSC The UK leaving the EU may have unexpected operational consequences for the HFEA for which we do not have the relevant capabilities.	We continue to work closely with the Department to ensure that we are prepared and can provide detailed guidance to the sector at the earliest opportunity, to limit any impact on patients. We have provided ongoing updates to the sector. Since December 2018, we have run an EU exit project to ensure that we fully consider implications and are able to build enough knowledge and capability to handle the effects of the UK's exit from the EU. We have progressed this project through the transition period. We continue to engage with DHSC and clinics to prepare for the end of the transition period. Actions will depend on the progress of the UK/EU talks. Authority and AGC are also updated at their meetings, as appropriate.	Communications ongoing – Clare Ettinghausen/Andy Leonard
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 have reviewed our business continuity plan to ensure it is fit for purpose.	Ongoing - Peter Thompson

C2: Failure to appoint new or reappoint current Authority members within an appropriate timescale leads to loss of knowledge and may impact formal decision-making.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	4	12- High	**2**	**4**	**8 - Med**
Tolerance threshold:					**4 - Low**
Status: Above tolerance					

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

Commentary

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.

Out of a current Board membership of 14, we have three vacancies, bringing the Board membership down to eleven. The Chair's term expires on 31 March 2021. Four other senior Authority members' terms also end on that date, although we understand that short extensions for two members are expected. If the DHSC is unable to recruit to all these positions, the membership would be reduced to six. This would pose a significant challenge to robust statutory decision-making and knowledge management.

The Department are in the latter stages of recruitment to four posts, which we hope will be completed by the end of 2020. The advert for the Chair issued in October, although the final timing of a new appointment is uncertain. We remain in contact with the Department on these matters. SMT reduced the risk score from 16 to 8 in September 2020 to reflect the progress made on recruitment, although the risk remains above tolerance. Contingency plans will be put in place from January 2021 to ensure that there is a smooth transition from the current Chair to the Deputy Chair should a new Chair not be in place by end March 2021.

Causes / sources	Mitigations	Status/timescale / owner
As at November 2020, we have three member vacancies. The reduction of available members that is possible by March 2021, including the Chair, would put at risk our ability to meet our statutory responsibilities to licence fertility	Membership of licensing committees has been actively managed to ensure that formal decision-making can continue unimpeded by the current 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.	In place, ongoing - Paula Robinson

Causes / sources	Mitigations	Status/timescale / owner
clinics and research centres and authorise treatment for serious inherited illnesses.		
The uncertainty about Chair reappointment may result in a gap in leadership and direction for the Authority. The Chair's term has been extended until March 2021, which gives more time to consider controls, though it only changes the proximity of this risk.	The Department is actively considering extending certain Board appointments to ensure a smooth transition.	Further controls to be considered - Peter Thompson
Any member recruitment may take 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 appointments take on average five months).	Recruitment is underway for four Board posts. This is being run by the Department of Health and Social Care (DHSC) and is expected to complete in 2020.	In progress as at November, with plan to appoint by end of 2020- Peter Thompson
Several current Board members are on their second terms in office, which expire within the same period (five Members of the Board by March 2021, in addition to the three pre-existing vacancies).	We are discussing options with the Department for managing the cycle of appointments, in order to reduce the impact of this.	In progress, ongoing - Peter Thompson
The induction time of new members (including bespoke legal training), particularly those sitting on licensing committees, 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 may take up to a year for members to feel fully confident.	The Governance team are reviewing recruitment information and member induction to ensure that this will be as smooth as possible once it starts.	In progress, ongoing - Paula Robinson

Causes / sources	Mitigations	Status/timescale / owner
Induction of new members to licensing and other committees, will require a significant amount of internal staff resource and could reduce the ability of the governance and other teams to support effective decision-making.	We will be mindful of this resource requirement when planning other work, in order to limit the impact of induction on other priorities.	In progress, as timescales become clear - 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.	CEO letter to DHSC Permanent Secretary on 10 December to clarify this risk interdependency and recommend that member appointments should be added to Departmental risk register. Recruitment, led by the Department, is in progress as at November.	Raised December 2019 - Peter Thompson
Government/DHSC DHSC is responsible for having an effective arm's length body in place to regulate ART. If it does not ensure this by effectively managing HFEA Board recruitment, it will be breaching its own legal responsibilities.	CEO letter to DHSC Permanent Secretary on 10 December to clarify this risk interdependency and recommend that member appointments should be added to Departmental risk register. Recruitment, led by the Department, is in progress as at November.	Raised December 2019 - Peter Thompson
Government/DHSC HFEA operates in a sensitive area of public policy, meaning there may be interest from central government in the appointments process. We are unsure of the intended approach of any future government. This may impact any planned approach and risk mitigations and give rise to further risk.	CEO letter to DHSC Permanent Secretary on 10 December to clarify this risk interdependency and recommend that member appointments should be added to Departmental risk register. Recruitment, led by the Department, is in progress as at November.	Raised December 2019 - 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.

Delays to PRISM delivery necessitate the continued use of EDI in clinics. Many clinics use older server technology to run our EDI gateway within their clinic or organisation resulting in an increased cyber risk while that technology is in use. We supported many to upgrade their infrastructure to reduce the likelihood of a cyber incident. The related cyber risk concerns an attack on the clinic's infrastructure – and all have local logical and physical security controls in place. We are aware of the related cyber risk. All submission data is encrypted in transit. We continue to work with clinics to support the upgrade of their server infrastructure.

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	In place – Dan Howard

Causes / sources	Controls	Timescale / owner
	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.	In place - Peter Thompson Last undertaken January 2020, plans for roll out of next training underway – Dan Howard
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. 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 – Dan Howard Update agreed at CMG in June 2020– Dan Howard In place, review to occur January 2020 – Dan Howard In place, and to be reviewed in the light of the office move, CMG to consider this in February 2021 – Dan Howard To be rolled out by end May 2021 – Dan Howard
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. 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.	Done, with further testing in January 2021 – Dan Howard In place – Dan Howard

Causes / sources	Controls	Timescale / owner
The IT support function 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.	Contract in place until May 2021 with option to extend until May 2023 – Dan Howard
We may not effectively mitigate emerging or developing cyber security threats if we are not aware of these.	We maintain external linkages with other organisations to learn from others in relation to cyber risk.	Ongoing (such as ALB CIO network) – Dan Howard
We may have technical or system weaknesses which 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. Our third-party IT supplier undertakes daily checks on our server infrastructure to monitor for any errors and to monitor for any security issues or increased 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	Ongoing, next testing in January 2021 – Dan Howard In place – Dan Howard In place – Dan Howard Ongoing (eg, upgrade to Pulse RAS system) – Dan Howard Ongoing (Eg, upgrade to Microsoft Teams system) – Dan Howard
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) in order to implement encryption	Ongoing (regular reminders sent to staff with security best practice) – Dan Howard
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 will be under the tightest security when this is migrated to the cloud.	In place – Dan Howard In place – Dan Howard In place – Dan Howard

Causes / sources	Controls	Timescale / owner
		To be implemented – Dan Howard
The continued use of EDI by clinics during the extended delivery of PRISM means the end of life server version used for the EDI gateway application (which processes data from EDI or 3rd party servers into the HFEA Register) continues to be used. This may therefore be more vulnerable to attack as it becomes unsupported.	Data submitted through the EDI gateway application is encrypted in transit, which reduces the likelihood of sensitive information being accessed.	In place – Dan Howard
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None. Cyber-security is an 'in-common' risk across the Department and its ALBs.		

E1: There is a risk that the HFEA's office relocation leads to disruption to operational activities and delivery of our strategic objectives.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
2	4	8 - Medium	**1**	**3**	**3 - Low**
Tolerance threshold:					**8 - Medium**
Status: **Below tolerance**					

Risk area	Risk owner	Links to which strategic objectives?	Trend
Estates E1: Relocation of HFEA offices	Richard Sydee Director of Finance and Resources	Whole strategy.	⇔⇔⇔⇩

Commentary
An internal project is in place to prepare for the office move, handle the direct impacts of the move on the organisation and ensure that we actively prepare and mitigate associated risks. This feeds into a larger programme managed by DHSC. We have made progress in reviewing working practices and policies and have launched several of these. Several cross-ALB working groups have actively defined requirements and solutions and these have fed into the HFEA internal project. As at end November 2020, the handover of the building to DHSC has taken place, we have moved all HFEA possessions out of Spring Gardens and our official address change was 30 November. Virtual induction packs will be circulated to staff in December, this is being coordinated by the central programme. We anticipate that the office will be ready for occupation in January, though staff working in the new office will be contingent on the Covid-19 regulations at the time. CMG has agreed that we will plan to continue to work from home until April, with those who need to access an office, able to do so in Stratford from January. New policies are being drafted and will be discussed with staff in advance, including a revised flexible working policy from April. SMT agreed to reduce this risk in November following the effective completion of the physical move, but suggested we should reconsider the remaining risks and pick these up with a new organisational change/ways of working risk, which would also capture any ongoing impact of Covid-19 changes.

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.	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 have been revisited in the light of the changed circumstances we are in due to Covid-19.	Ongoing – Richard Sydee Ongoing as part of Covid-19 management

Causes / sources	Controls	Status/Timescale / owner
	If lower-priority requirements are unable to be fulfilled, conversations will take place about alternative arrangements to ensure HFEA delivery is not adversely affected. Arrangements need to be put in place to ensure that costs and access are shared equitably.	– Richard Sydee Contingency if required – Richard Sydee Discussions still underway as at November – Richard Sydee
We may be unable to recruit staff as they do not see the HFEA as an attractive central London organisation. Note: Move to Stratford noted in all job adverts. Recruitment data to date suggests we are not seeing an impact on recruitment. We will continue to monitor this to consider whether other mitigations are needed/possible.	We will continue to offer desirable staff benefits and policies, such as flexible working, and have reviewed and updated these to ensure that they support staff recruitment and retention. Other civil service and government departments are also being moved out of central London, so this is less likely to impact recruitment of those moving within the public sector.	Completed (however as per above control we will revisit in the light of Covid-19) – Yvonne Akinmodun
Stratford may be 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 before the move.	We will review the excess fares policy to define the length of time and mechanism to compensate those who will be paying more following the move to Stratford. 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.	Begun but to be completed (this is now subject to Covid-19 developments) – Yvonne Akinmodun, Richard Sydee Done - Yvonne Akinmodun,
The Stratford office may cost more than the current office, once all facilities and shared elements are considered, leading to opportunity costs.	Costs for Redman Place (the Stratford building) will be allocated on a usage basis which will ensure that we do not pay for more than we need or use. The longer, ten-year lease at Redman Place will provide greater financial stability, allowing us to forecast costs over a longer period and adjust	Ongoing but we await confirmation of overarching procurement arrangements from central

Causes / sources	Controls	Status/Timescale / owner
The Finance and procurement strand of the project has been delayed; we await final estimates of the cost to HFEA, though have been assured that calculations have been completed.	other expenditure, and if necessary, fees, accordingly, to ensure that our work and running costs are effectively financed. The accommodation at Redman Place should allow us to reduce some other costs, such as the use of external meeting rooms, as we will have access to larger internal conference space not available at Spring Gardens.	programme - Richard Sydee
The move to a new office will lead to ways of working changes that 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 significantly before the move, to ensure that there is time for these to bed in and be accepted ahead of the physical move. Staff have and will continue to be been involved and updated as appropriate.	Discussions at each CMG until we move back to the office – Richard Sydee Done and to continue as these are reviewed following Covid-19 - Richard Sydee, Yvonne Akinmodun
Owing to the different cultures and working practices of the organisations moving, there may be perceived inequity about the policy changes made.	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 differences in practice and that the intention is not to homogenise practices.	Ways of working group work completed, follow on communications being coordinated across all organisations – Richard Sydee
Current staff may not feel involved in the conversations about the move, leading to a feeling of being 'done to' and lower morale.	Conversations about ways of working occurring throughout the project, to ensure that the project team and HFEA staff are an active part of the discussions and development of relevant policies and have a chance to raise questions. An open approach is being taken to ensure that information is cascaded effectively, and staff can voice their views and participate. We have a separate area on the intranet and Q&A functionality where all information is being shared. Staff have had the opportunity to visit the site ahead of time so that they feel prepared.	Ongoing – Richard Sydee

Causes / sources	Controls	Status/Timescale / owner
	Staff engagement group in place to ensure wide engagement as we approach the move.	
The internal move project may be ineffectively managed, leading to oversights, poor dependency management and ineffective use of resources.	Regular reporting to Programme Board and CMG to ensure that effective project processes and approaches are followed. Assurance will be provided by regular reporting to AGC and Authority. The Director of Finance and Resources is Sponsoring the project meaning it has appropriate senior, strategic guidance. Dedicated part-time external project manager brought in to undertake ongoing project management, to ensure sufficient and effective resourcing of this as the project moves into a more advanced phase of delivery. Other key staff such as HR and representatives from other teams involved in the internal HFEA Project team.	In place – Richard Sydee
Necessary changes to IT systems and operations may not work effectively, leading to disruption to HFEA delivery.	Communications between HFEA and other organisations' IT teams to determine IT requirements, allowing more time to resolve these. Infrastructure has largely been migrated to the cloud, which facilitated the move and reduced related risk to IT systems. It will also mean the HFEA should be able to function even if there are IT issues affecting other systems on-site.	In place - Ongoing - Steve Morris, Dan Howard In place - Steve Morris, Dan Howard
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
British Council – lead on physical build – may not understand or take HFEA needs into account.	DHSC liaising directly with the British Council and managing this relationship on behalf of the other organisations, with feedback through the DHSC project board, on which the Director of Finance and Resources sits.	In place – Richard Sydee, DHSC
DHSC – Lead on the whole overarching project, entering into contracts on behalf of HFEA and others – HFEA requirements may not be considered/met.	Regular external programme meetings attended by the Director of Finance and Resources as HFEA Project Sponsor and other HFEA staff when delegation required.	In place – Richard Sydee
NICE/CQC/HRA/HTA – IT, facilities, ways of working interdependencies.	Regular DHSC programme meeting involving all regulators. Sub-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	**2**	**4**	**8 - Medium**
Tolerance threshold:					**12 - High**
Status: **Below 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 by clinics (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.

We have not been directly involved in any litigation since October 2018.

Causes / sources	Mitigations	Timescale / owner
We may face legal challenge about the way we have executed our core regulatory functions of inspection and licensing. For instance, clinics	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 defend any challenge.	In place – Peter Thompson

Causes / sources	Mitigations	Timescale / owner
challenging decisions taken about their licence.		
We may be legally challenged if new science or technology emerges that may not be 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 in order 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
Our policies may be legally challenged if 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.	Evidence-based and transparent policymaking, with risks considered whenever a new approach or policy is being developed. 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 taken into account 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 – Laura Riley/Joanne Anton with appropriate input from Catherine Drennan Ongoing - Laura Riley, Joanne Anton In place – Richard Sydee Ongoing - Laura Riley, Joanne Anton
We may face 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 ongoing examples. The	We undertake good record keeping, to allow us to identify and access old versions of guidance, and other key documentation, which may be relevant to cases or enquiries and enable us to see how we have historically interpreted the law. Through constructive and proactive engagement with third parties, the in-house legal function serves to anticipate issues of this sort and prevent challenges. This strengthens our ability to find solutions that do not require legal action.	Ongoing – Catherine Drennan In place – Catherine Drennan

Causes / sources	Mitigations	Timescale / owner
case by case nature of the Courts' approach to matters means resource demands are unpredictable when these arise.	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. Some amendments were made to guidance in the Code of Practice dealing with consent to storage and extension of storage, this was launched in January 2019. This guidance will go some way to supporting clinics to be clearer about the legal requirements. Additional amendments will be made in the next update. Storage consent has been covered in the revision of the PR entry Programme (PREP).	In place – Peter Thompson Done in 2018/19 – Catherine Drennan Revised guidance will be provided where appropriate to clinics in 2021– Catherine Drennan PREP launched January 2020 – Catherine Drennan/ Laura Riley, Joanne Anton
Committee decisions or our decision-making processes may be contested. ie, Licensing appeals and/or Judicial Reviews. Challenge of compliance and licensing decisions is a core part of the regulatory framework and we expect these challenges even if decisions are entirely well founded and supported. Controls therefore include measures to ensure consistency and avoid process failings, so we are in the best position for when we are challenged, therefore reducing the impact of such challenges.	Compliance and Enforcement policy and related procedures to ensure that the Compliance team acts consistently according to agreed processes. Well-evidenced recommendations in inspection reports mean that licensing decisions are adequately supported and defensible. The Compliance team monitors the number and complexity of management reviews and stay in close communication with the Head of Legal to ensure that it is clear if legal involvement is required, to allow for appropriate involvement and effective planning of work. Panel of legal advisors in place to advise committees on questions of law and to help achieve consistency of decision-making processes.	In place but a review of the policy undertaken Autumn 2020 with consultation to follow – Rachel Cutting, Catherine Drennan In place – Sharon Fensome-Rimmer In place – Sharon Fensome-Rimmer In place – Peter Thompson

Causes / sources	Mitigations	Timescale / owner
	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.	Since Spring 2018 and ongoing – Catherine Drennan In place – Paula Robinson
Any of the key legal risks may escalate into high-profile legal challenges which may result in significant resource diversion and reputational consequences for the HFEA which risk undermining the robustness of the regulatory regime. We are aware of endeavours to put some test storage consent cases to the courts which may make HFEA involvement more likely.	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: HFEA could face unexpected high legal costs or damages which it could not fund. This is an interdependent risk as the Department must ensure the ability to maintain the regulatory regime.	If this risk was to become an issue then discussion with the Department of Health and Social Care would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also an interdependent risk because DHSC would be involved in resolving it.	In place – Peter Thompson
DHSC: We rely upon the Department for any legislative changes in response to legal risks or impacts.	Our regular communications channels with the Department would ensure we were aware of any planned change at the earliest stage. Joint working arrangements would then be put in place as needed, depending on the scale of the change. If necessary, this would include agreeing any associated implementation budget.	In place – Peter Thompson

Causes / sources	Mitigations	Timescale / owner
	Departmental/ministerial sign-off for key documents such as the Code of Practice in place.	
DHSC: The Department may be a co-defendant for handling legal risk when cases arise.	We work closely with colleagues at the Department to ensure that the approach of all parties is clear and is coordinated wherever possible.	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**	**4**	**8 - 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 necessarily become our organisational priority. All staff are working from home and a strategy to manage inspections was put 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. The Coronavirus risk has had a cascading effect across the whole risk register and will do for the foreseeable future. Where there are specific risk causes related to other core risks these are signposted as relevant. The organisation was incredibly flexible to rapidly adapt to changed ways of working, the next step is to ensure this is sustainable and we take a flexible and appropriate response as restrictions change. A Covid-19 risk management review was undertaken in autumn 2020 to reflect on lessons learned during the first phase of the pandemic response. These lessons will be used to consider effectiveness of controls and a report will be presented to AGC in December. SMT reduced the risk score from 12 to 8 in November, to reflect that we had effectively resumed inspections. The revised inspection processes were effective and included risk assessment and controls (including PPE, alternative inspection teams, reduction of time on site) at each stage (from planning to execution), meaning that we are assured that we can effectively maintain this regulatory function, reducing the residual likelihood of the risk.

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	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.	In place, ongoing – Richard Sydee In place - SMT and communications team

Causes / sources	Controls	Status/Timescale / owner
undermining our authoritative position as regulator.	Close communication with key sector professional organisations to ensure we are ready to react to 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.	In place and ongoing – Clare Ettinghausen In place and ongoing – Sharon Fensome-Rimmer, Rachel Cutting Joanne Triggs – in place In place and under regular review – Laura Riley 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 has been sought to ensure that HFEA actions are 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.	In place – Richard Sydee Ongoing - Rachel Cutting If required - Joanne Triggs Done – Peter Thompson If required – Peter Thompson, 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
Risk of disproportionate impact of coronavirus on staff from	Decision taken to delay routine return to the office until April 2021, reducing work-related risk. We are engaging with other similar organisations to	In progress – Yvonne Akinmodun

Causes / sources	Controls	Status/Timescale / owner
black and ethnic minority backgrounds.	consider possible approaches to managing this risk. We have considered the impact as part of planning for a return to inspections and office working, including individual risk assessments for inspection staff, performed before each inspection.	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
Ineffective oversight of those clinics that are continuing to practice as clinics may not abide by professional body and HFEA guidance. Since GD0014 version 2 was issued, clinics have been able to reopen where it is safe to do so.	HFEA restarted physical inspections from November. This reduces the potential oversight gap. We put in place a new General Directions for clinics to follow. Clinics who do not follow General Directions 0014 would be subject to serious regulatory action. Inspection team are in active communication with all of their clinics to ensure oversight and understanding of risks. Activity of centres is being monitored through the Register submission system. Effective desk-based approach to oversight of clinics. Those clinics (who have resumed treatment services and/or are open) where Interim inspections were due during the period of no inspections were asked to complete the Self-Assessment Questionnaire, in the same way that they would have done before an inspection. This gives us oversight of all areas of practice. A methodology for a wholly virtual inspection has been developed. Agreed approach with the Department for managing any exceptional breaches in statutory duty to physically visit licensed premises every two years if this were impossible (for instance if future Covid-19 restrictions make this unworkable), to ensure that centres remain appropriately inspected and licensed.	In place – Rachel Cutting In place – Sharon Fensome-Rimmer In place – Sharon Fensome-Rimmer, Rachel Cutting Agreed November 2020 – Rachel Cutting, Catherine Drennan
Precipitous decrease in funding due to large reductions in treatment undertaken because of Coronavirus. Note: as per FV1 this is a live issue. Note: this risk may be both short and longer-term if clinics close down 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, we have agreed support for the remainder of 2020/21, and we will resume discussions about the likely impact on us in 2021/22 in the coming months.	In place – Richard Sydee Ongoing discussions as impact becomes clearer – Richard Sydee

Causes / sources	Controls	Status/Timescale / owner
We have had to cancel events and meetings and cannot run them as planned which may delay some strategic delivery.	Conversations ongoing with Authority and Corporate Management about options for management of individual risk impacts and review key milestones where needed. Routine stakeholder meetings occurring virtually and revised arrangements to allow for virtual meetings and committees.	In place – Peter Thompson
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 have to WFH without suitable arrangements in place. Temporary use of desks at another ALB's office site from October – December. 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.	In place – Richard Sydee In place – Yvonne Akinmodun In place – Yvonne Akinmodun In place and ongoing – 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.	Discussion about return to work at CMG to ensure that this is planned effectively, and impacts considered. This will occur 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. Though we need to review this in light of our completed move to Stratford. Updated website info to ask people to contact us via email and phone.	In place but to be reviewed December 2020– Richard Sydee In place – Jo Triggs

Causes / sources	Controls	Status/Timescale / owner
	We notified all suppliers about the change in arrangements. Although this is unlikely to stop all post as some have automated systems.	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. Live issue as at November – captured under FV1	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 has been provided for the 2020/2021 business year).	Richard Sydee

Reviews and revisions

25/11/2020 – SMT review - November 2020

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

- C2 – SMT noted that we expected DHSC to have made the four appointments by end December. Chair recruitment was underway.
- P1 – SMT considered whether there may be a case for reducing the score of this risk and reflected that the risk was closely related to the appointment of a new Chair, which may have a significant impact on our strategic positioning. SMT agreed to reconsider the score of this risk in the new year
- CV1 – SMT noted the significant progress made adjusting our inspection processes for Covid-19. Inspections had been carried out effectively using the new processes, PPE and risk assessments were in place. Controls were in place to manage any staff absence and inspections by Desk Based Analysis were also proving effective. Since we were now assured that we could continue to complete this core aspect of our regulatory functions, despite the necessary Covid-19 control measures, SMT was of the view that the overall risk to HFEA functioning arising from Covid-19 had therefore reduced. SMT noted business continuity conversations were required to ensure processes were in still place to distribute post effectively following the move to Redman Place.
- SMT discussed the E1 risk and noted that the successful move of HFEA physical assets to Stratford reduced the likelihood of disruption significantly. Any risk remaining was in relation to ways of working and arose both from the move and also Covid-19. Covid-19 necessitating medium-term homeworking, actually reduced the likelihood of further disruption. Staff would largely not return to the office until April 2020. SMT reflected that the remaining risk may now be better managed as part of a newly formed ways of working/culture risk. SMT would consider the nature of this in January.
- FV1 – SMT discussed the financial viability risk at length. Although things were stable for 2020/2021 due to the financial cover we had received from DHSC, there were no guarantees about the position for 2021/2022. We anticipated further discussions with DHSC late December/early January, at which time we may have more certainty about the position and ongoing risks. Wider conversations were needed with CMG about which changes to ways of working, emerging from Covid-19, may be able to continue and provide ongoing savings. This could tie in with business planning conversations in January.

11/11/2020 – Authority review – October 2020

Authority noted the risk register, but did not change any risks, controls or scores at that time. The following points were made in discussion:

- The Chair stressed the importance of the executive reviewing the Board Capability risk and its controls and potentially increasing its score if we did not get clarity soon on appointments.
- Members raised concerns about risk management of RITA risks and effectively maintaining an OTR service.

21/10/2020 – SMT review - October 2020

SMT discussed points raised by AGC, reviewed all risks, controls and scores and made the following points:

- C2 – SMT discussed recent Board recruitment progress and agreed to consider any necessary contingency actions in November depending on developments.
- I1 – following the AGC discussion, SMT agreed to reflect the risk and controls relating to the reopening of the OTR service.
- SMT reflected that none of the updates necessitated a change in the score of any of the risks at this time.

06/10/2020 – AGC review – October 2020

AGC reviewed all risks, controls and scores and made the following points:

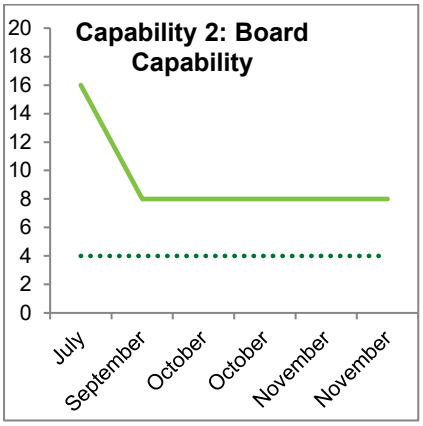
- AGC discussed board member recruitment, noting that interviews had taken place for four new Authority members and we were waiting for these appointments to be completed by the DHSC. The

DHSC representative confirmed that the advert for the appointment of the Chair position was progressing.

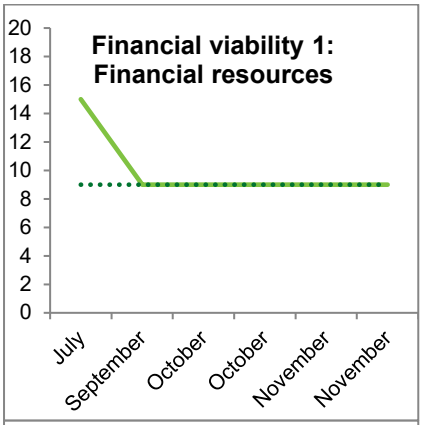
- The Deputy Chair of the Authority commented that she was willing and able to step in as Authority Chair should there be a gap before the new chair is appointed following the departure of the current Chair.
- Members asked the executive to ensure that risks related to the Opening the Register service were effectively reflected in the Register and controlled.

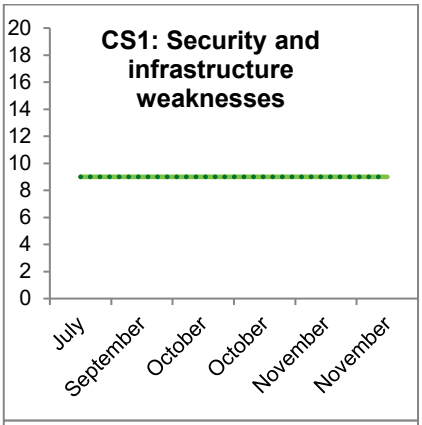
Risk trend graphs (last updated November 2020)

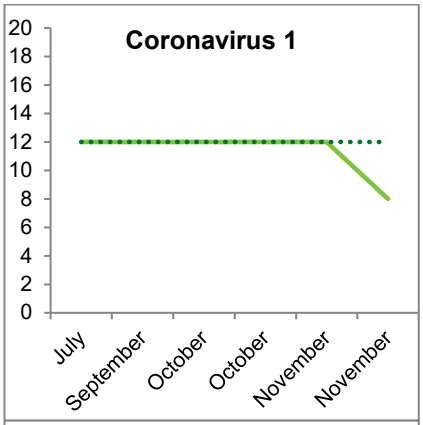
High and above tolerance risks

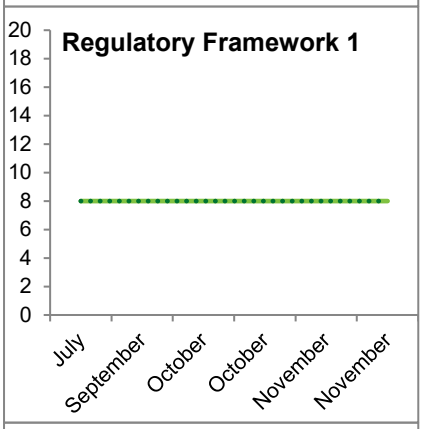


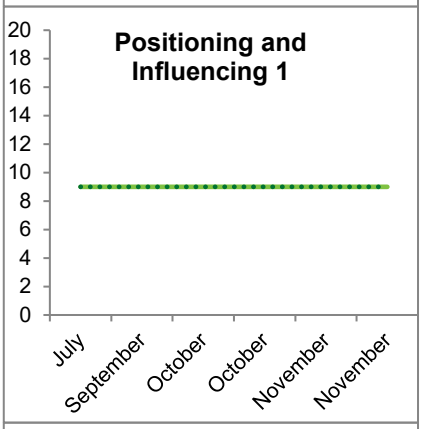
Lower and below tolerance risks

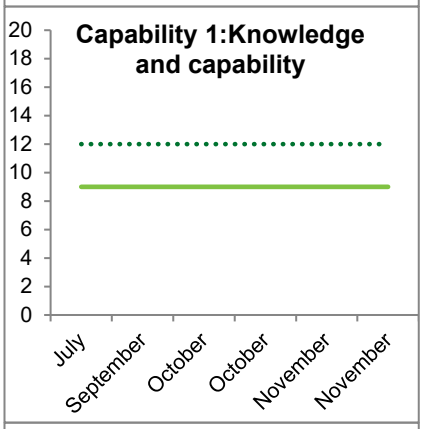


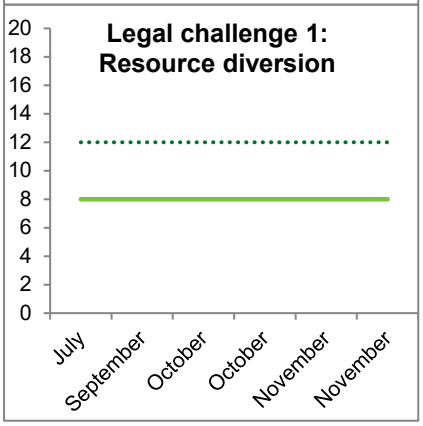


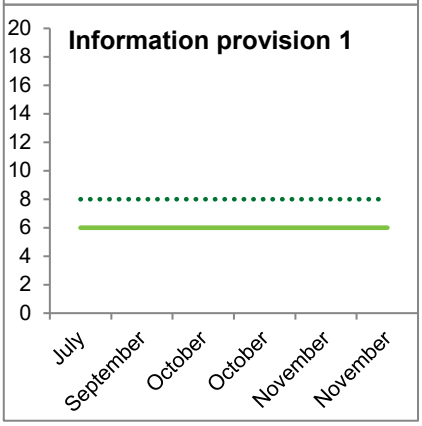


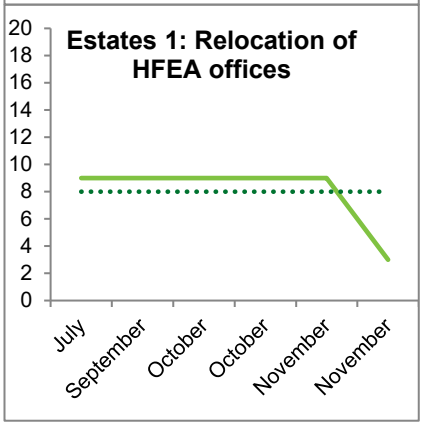












Criteria for inclusion of risks

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.

Audit and Governance Committee Forward Plan

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

Details:	
Meeting	Audit & Governance Committee Forward Plan
Agenda item	14
Meeting date	8 December 2020
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:	8 Dec 2020	16 Mar 2021	22 Jun 2021	5 Oct 2021
Following Authority Date:	27 Jan 2021	24 Mar 2021	7 July 2021	17 Nov 2021
Meeting 'Theme/s'	Register and Compliance, Business Continuity	Finance and Resources	Annual Reports, Information Governance, People	Strategy & Corporate Affairs, AGC review
Reporting Officers	Director of Compliance and Information	Director of Finance & Resources	Director of Finance & Resources	Director of Strategy and Corporate Affairs
Strategic Risk Register	Yes	Yes	Yes	Yes
Digital Programme Update	Yes	Yes	Yes (delete if PRISM has gone live)	Yes (delete if PRISM has gone live)
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	Results, annual opinion approve draft plan	Update
Whistle Blowing, fraud (report of any incidents)	Update as necessary	Update as necessary	Update as necessary	Update as necessary

AGC Items Date:	8 Dec 2020	16 Mar 2021	22 Jun 2021	5 Oct 2021
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	Yes		
Cyber Security Training				Yes – this is an update on whether all Members have undertaken annual training
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			

AGC Items Date:	8 Dec 2020	16 Mar 2021	22 Jun 2021	5 Oct 2021
Legal Risks				Yes
AGC Forward Plan	Yes	Yes	Yes	Yes
Session for Members and auditors	Yes	Yes	Yes	Yes

Register of Gifts and Hospitality

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

Details:			
Meeting	AGC		
Agenda item	15		
Meeting date	08 December 2020		
Author	Morounke Akingbola (Head of Finance)		
Output:			
For information or decision?	For information		
Recommendation	Attached is the latest Gifts and Hospitality Register. Since the last meeting, no items have been added. Members are asked to note.		
Resource implications			
Implementation date	2020/21 business year		
Communication(s)			
Organisational risk	☐ Low	X Medium	☐ High

Register of Gifts / Hospitality Received and Provided/Declined

Version: HFEAG0001
Dec-20

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