Audit and Governance Committee meeting - agenda

28 June 2022

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

10am – 1.15pm

	Agenda item		Time
1.	Welcome, apologies and declaration of interests		10.00am
2.	Minutes of 15 March 2022 [AGC (28/06/22) DO]	for decision	10.05am
3.	Action log [AGC (28/06/22) MA]	for information	10.10am
4.	Internal audit report (inclu. annual opinion) [AGC (28/06/22) JC]	for information	10.15am
5.	Implementation of recommendations [AGC (28/06/22) MA]	for information	10.30am
6.	Annual report and accounts (inclu. annual governance statement) [AGC (28/06/22) RS]	for information	10.40am
7.	External audit completion report [AGC (28/06/22) MP/DG]	for information	10.55am
8.	Strategic risk register and risk system review [AGC (28/06/22) PR/SQ]	for comment	11.10am
9.	Digital Programme update [AGC (28/06/22) KH]	for information	11.25am
10.	Information assurance and security (SIRO report) [AGC (28/06/22) RS]	for comment	11.40am
11.	Resilience & business continuity management [AGC (28/06/22) RC]	for comment	11.50pm
	Break		12.05pm

12.	Counter Fraud strategy **[AGC (28/06/22) MA]**	for comment	12.15pm
13.	Bi-annual human resource report **[AGC (28/06/22) YA]**	for comment	12.25pm
14.	AGC forward plan **[AGC (28/06/22) MA]**	for decision	12.40pm
15.	Items for noting • Whistle blowing • Gifts and hospitality • Contracts and Procurement **[AGC (28/06/22) RS]**	for information	12.50pm
16.	Any other business		12.55pm
17.	Session for members and auditors only		1.00pm
18.	Close		1.15pm
	Lunch		

Next Meeting: Tuesday, 4 October 2022.

Minutes of Audit and Governance Committee meeting 15 March 2022

Details:			
Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Agenda item	2		
Meeting date	28 June 2022		
Author	Debbie Okutubo, Governance Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes of the Audit and Governance Committee meeting held on 15 March 2022 as a true record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes	Action plan from staff survey		

Minutes of the Audit and Governance Committee meeting on 15 March 2022 held via teleconference

Members present	Catharine Seddon - Chair Margaret Gilmore Mark McLaughlin Geoffrey Podger
Apologies	None
External advisers	Mike Surman, National Audit Office – External auditor Mohit Parmar, NAO Joanne Charlton, Internal Auditor – GIAA Rebecca Jones, GIAA Dean Gibbs, KPMG – Audit lead
Observer	Amy Parsons, Department of Health and Social Care – DHSC
Staff in attendance	Peter Thompson, Chief Executive Richard Sydee, Director of Finance and Resources Morounke Akingbola, Head of Finance Clare Ettinghausen, Director of Strategy and Corporate Affairs Rachel Cutting, Director of Compliance and Information Paula Robinson, Head of Planning and Governance Kevin Hudson, Programme Manager Debbie Okutubo, Governance Manager Shabbir Qureshi, Risk and Business Manager Steve Morris, Head of IT Neil McComb, Head of Information

1. Welcome, apologies and declarations of interest

1.1. The Chair welcomed everyone present online and noted that there were no apologies.

1.2. There were no declarations of interest.

2. Minutes of the meeting held on 9 December 2021

2.1. The minutes of the meeting held on 9 December 2021 were agreed as a true record.

3. Matters arising

3.1. It was noted that the link to the ‘responsible for information’ module on Civil Service Learning was not working for some members and this this needed to be resolved.

3.2. Members commented that the IT induction and setting up MFA brief circulated gave a high degree of assurance to all members.

Actions

3.3. The Chair commented that the timetable for the staff survey roll-out action plan was still to be shared with the Committee.

3.4. The Director of Finance and Resources agreed to circulate the summary of other ALBs' experiences of using the DSP Toolkit with members.

Decision

3.5. Members noted the actions from matters arising and the members IT induction document.

4. Internal audit report

4.1. The Chair invited the Internal Auditor to present this item.

4.2. Members were presented with the progress update report for the 2021/22 Internal Audit Plan, the proposed Internal Audit Plan for 2022/23, the GIAA Supplementary Report and the GIAA annual opinion analysis 2020/21.

4.3. Members were advised that as at 4 March 2022, 66% of the internal audit plan had been delivered with the final two reviews in fieldwork stage. The Internal Auditor commented that there was an expectation that the draft report for the two outstanding reviews would be delivered by the end of this financial year.

4.4. In response to a question on the Financial Management: Budgeting audit, members were advised that in some cases, no evidence was presented to demonstrate the operation of certain controls which was the reason for the moderate assurance rating.

4.5. Members asked who ensured that the HFEA was fully compliant and engaging with the findings outlined in the GIAA cross-governmental departments insight report. The Director of Finance and Resources commented that this would fall under his remit and he would keep the committee abreast of areas of concern and actions.

4.6. In response to a query regarding GIAA's Assurance Mapping for smaller customers, as referenced in the 2020/21 Opinion's analysis, the Internal Auditor responded that it was more of a requirement for customers that fall below baseline audit plan size, which was not the case with the HFEA.

Actions

4.7. On the 2022/23 proposed internal audit plan, members requested that the Board should be included in the one on Equality, Diversity and Inclusion.

Decision

4.8. Members **noted** the

- progress update report
- supplementary report and the
- 2020-2021 GIAA opinions analysis paper.

4.9. Members endorsed the proposed audit plan for 2022/23.

5. Implementation of recommendations

5.1. The Head of Finance presented this item. In terms of goodwill letters, it was confirmed that this should be a realistic date as there was more resource in the team. Members commented that

the Director of Compliance and Information should review and update the table with the completion date and bear in mind that this deadline had been pushed back several times and that as result, unnecessary additional resource would need to be allocated.

5.2. Members were advised that the business continuity policy was in the pipeline. Members commented on the rating of it being of low priority and suggested that the RAG status should be reviewed considering current world events.

5.3. For the key performance indicators (KPIs), it was noted that these were usually reviewed on a cyclical basis but with the recent appointment of the Risk and Business Planning Manager, KPIs were being revamped and checks would take place to ensure that data was recorded meaningfully and accurately.

5.4. It was noted that other audit recommendations were in progress with future review dates.

5.5. For the data security and protection toolkit (DSPT), it was noted that the submission was due in June and that staff were currently working on gathering evidence but it was not expected that we would have met all requirements by June. However, we were in a better position than this time last year.

Decision

5.6. Members noted the progress with implementing recommendations.

6. External audit interim feedback

6.1. The External Auditor gave a verbal update. Members were advised that the current NAO External Auditor, Mike Surman was moving on to other business areas in the NAO and that Mohit Parmar will be taking over as the External Auditor for the HFEA.

6.2. Members were informed that detailed handover had happened between them and that because Mike was still at the National Audit Office, if required he would provide assistance.

6.3. Members thanked Mike Surman and welcomed Mohit Parmar, who briefly introduced himself.

6.4. Dean was a lead director at KPMG. He commented that good progress was being made around completion of their PRISM-related work but suggested that further work might need to be completed to ensure revenue has been accurately recorded, if some clinics were still not fully submitting their data via PRISM by the end of this financial year.

6.5. Regarding the implementation of IFRS 16, it was also suggested that adjustments may have to be made around the rent-free period, which should be applied throughout the life of the lease.

Decision

6.6. Members noted the update.

7. Digital projects and PRISM update

7.1. The Chair invited the PRISM Programme Manager to present this item and commented that the committee were now at the stage where they were seeking assurances around the implementation of PRISM following its launch.

7.2. The Programme Manager commented that by the end of February 2022, 37 standalone clinics had submitted data using PRISM and that the quality of the data submitted was extremely good with very low error rates.

7.3. It was noted that some API clinics had also started to submit information into PRISM but there were still some outstanding. Mellowood had nine clinics that were yet to deploy. The CARE group had six clinics yet to deploy. Members were advised that HFEA inspectors were supporting the process by nudging clinics to complete their deployment including any backlog.

7.4. It was noted that 10 Meditex clinics were yet to deploy and even though the end of March was the date given for completion to the API clinics, Meditex had been given additional time to the end of April to complete.

7.5. In terms of error rates for API clinics it was noted that it was at 8.4% which was higher than standalone clinics who were submitting data directly through PRISM. To mitigate this, guidance had been issued to API clinics on how they could access their validation errors through the PRISM Homepage. The Register Team was also working with selected API clinics with high error rates to address these.

7.6. The Programme Manager confirmed that we had written to clinics underlining that deployment was due to finish at the end of March. Therefore, from 1 April 2022, data submission standards for clinics (General Direction 0005) would be re-introduced.

7.7. Members asked what the risk was if many clinics were not on PRISM. The Chief Executive responded that clinics had a statutory duty to send us their data. The immediate risk was to the income generated from clinics but that was being mitigated by making assumptions about billing, which would require a reconciliation later on in the process.

7.8. Members asked if staff were picking up negative feedback from clinics who had fully deployed PRISM. Members also raised concerns about potential reputational damage to the HFEA.

7.9. The Director of Compliance and Information commented that this was part of the inspectors' discussions with a clinic's Persons Responsible (PRs) and that it would be kept under review.

7.10. Members noted that new Choose a Fertility Clinic (CaFC) data would not be published until after November 2022, once the data had been validated. This entailed some risk, since more than 40 verification reports would need to be produced. It was possible, after such a complex migration, that data issues may be found which would require fixing. In addition, the clinics themselves would need to verify their data in the time available. Since this was a new system, they would be given longer than usual to complete this step. However, many clinics had already worked through their data in EDI before it was switched off and had been focused on data quality over a long time period. In addition, future updates to CaFC should be far easier, since the new system encourages 'right first time' data submission, so there is a strong incentive for clinics after the first verification (of pre-PRISM data) under the new system.

7.11. In response to a question, it was confirmed that the potential impact on the Opening the Register function was being considered, since this activity required 100% accurate data. This was a priority to discuss at the Digital Projects Programme Board.

7.12. Members were advised that the months of May and June would be dedicated to handover from contracted staff to in-house staff.

7.13. Members asked if there was a system in place in case in-house staff left once handover had occurred and the contractors were no longer with us. The Chief Executive responded that this was a risk with all staff, but in terms of staff with data knowledge, sufficiently resilient internal expertise was required. We would continue to reflect on this and find the best operating model for IT staff.

7.14. The Director of Compliance and Information also commented that to mitigate the single point of failure risk, plans were in place to recruit additional staff following the approval from the DHSC to raise additional resources. We would therefore be increasing capacity in a number of related teams, including recruiting an additional developer. The current contractor developer had agreed that if required he would assist on an ad hoc basis, if possible.

Decision

7.15. Members noted the:

- progress with PRISM use and API deployment since go-live
- 're-establishment plan' for 2022
- ongoing challenges that are likely to affect PRISM and CaFC
- approach to handover from external contractors to HFEA staff.

8. Draft Annual Governance Statement

8.1. The Director of Finance and Resources presented this item to the committee.

8.2. Members were reminded that this was still in draft form. Therefore, at this stage members were invited to comment on the substance of the statement. It was confirmed that the final report and accounts would be shared with the committee in June.

8.3. It was noted that we were not yet at year end, and therefore some details were yet to be updated including member attendance at meetings.

8.4. Members commented that more assurance could usefully be included around the current environmental risks such as Covid-19, EU exit and the war in Ukraine, and their impact on the HFEA.

8.5. It was suggested that the DSP Toolkit position may require disclosure as to where we were on the improvement journey. Also, that functional standards could be referenced in the governance statement.

8.6. Members commented that there was continuity with previous years, and that the statement was fit for purpose.

8.7. It was noted that the ordering of some sections would be considered and that the statement would be enhanced following the discussion on resilience, business continuity and cyber security later on the agenda.

Actions

8.8. Executives agreed to consider providing more assurance around the current environmental situations such as Covid-19, EU exit and the war in Ukraine, and their impact on the HFEA

8.9. The Director of Finance and Resources to consider disclosing the DSP Toolkit position and where we were on the improvement journey. Functional standards to also be referenced in the governance statement.

Decision

8.10. Members noted the draft annual governance statement and noted that it will be circulated to members in June 2022.

9. Strategic risk register

9.1. The Head of Planning and Governance presented this item.

9.2. The committee noted the update on all risks, controls and scores and made the following points in discussion:

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

9.3. The Committee approved the plan for reviewing the risk policy, the risk register, and risk appetite and tolerances. It would be important to ensure the risk system did not become overly complex and unwieldy, and to focus on ensuring the system was both effective and efficient.

9.4. The idea of surfacing the most active issues in the risk register, and making other improvements to the presentation, was welcomed. Staff were asked to prioritise making it a more dynamic management tool, to guide planning and strategic thinking, and to regularly consider risk tolerances and the effectiveness of current controls. This should include a plan and timeline for bringing risks back into tolerance where they were above tolerance.

9.5. The committee also gave some thoughts on current risks coming over the horizon and welcomed the plan to develop more of a methodology for doing this exercise regularly in the future. Risk factors raised for consideration included:

- Being cognisant of internal and external environmental changes including PRISM, hybrid working, increased cyber security risks, and the war in Ukraine.
- The age of our legislation.
- The impact of high inflation, and financial pressures becoming acute across the health sector due to the end of Covid budgets and a major catching up period on waiting lists.
- Monitoring what the HFEA is doing with the limited resources it has, and whether it may sometimes be necessary to push back on additional requirements.
- How best to use our intelligence in a strategic sense, to effectively lead the ethical debates ahead of fast-moving scientific developments.
- To consider how to reflect public conversations about issues in our inspection regime to ensure we maintain public confidence and patient satisfaction including in following up on the HFEA Ethnic diversity in fertility treatment report which raised some issues for clinics to consider.

Decision

9.6. Members noted the strategic risk register and approved the plan for the forthcoming review of the risk system.

10. Resilience, business continuity and cyber security

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

10.2. Members were updated on the improvements to IT security that had been implemented recently and those that were to be completed shortly. It was noted that the changes would provide greater protection for the HFEA from cyber-attacks such as ransomware. There were two pieces of work that were yet to be completed including HFEA email being accessed from personal mobile phones and devices and the implementation of web filtering.

10.3. Members were informed that the DHSC sent an email in late February requesting a number of immediate actions to mitigate possible risk that could arise from the Russia/Ukraine conflict.

10.4. Members were informed that the Business Continuity Policy was being updated and was awaiting sign off from the senior management team (SMT).

10.5. For the DSP Toolkit the Head of Information commented that last year was the first time that we submitted an end of year annual DSPT return and we were not compliant. For 2022, a new panel consisting of the SIRO, the Head of IT, the Head of Information and the Information Governance Manager had been created and had met to review and assign owners to the recommendations from last year.

10.6. Members were advised that due to the newness of this approach and the lack of knowledge the HFEA had been able to gain from the last submission it was unlikely we would meet all the requirements in the toolkit for June 2022.

10.7. We would however be able to show evidence of improvement and a desire to continue that improvement until we could meet all necessary requirements in future submissions.

10.8. Members acknowledged that significant progress had been made but were disappointed that we still would not meet all the requirements of the DSP Toolkit.

Decision

10.9. Members noted the information about changes to the IT infrastructure and the current position with the DSP Toolkit.

11. Public Interest Disclosure (Whistleblowing policy)

11.1. The Head of Finance presented this item. It was noted that the policy was last brought to the committee in March 2021 and since then a review had taken place, resulting in several amendments.

11.2. Paragraph 5.2, item (b):

> There is possible fraud and corruption.

11.3. Paragraph 7.1, the last sentence had been added:

> This procedure should also be used where there is suspected fraud, bribery, or corruption.

11.4. Paragraph 7.11, referring to section 2-15 within the fraud policy:

> In cases of suspected fraud, the above process in conjunction with the Counter Fraud Policy (sections 2 – 15) should be followed. All cases should be reported to the Director of Finance and Resources in the first instance.

11.5. Paragraph 12 – review period of bi-annually or if changes in law:

> This policy will be reviewed by the Audit and Governance Committee bi-annually or earlier if there are changes in the law that significantly impacts this policy.

Actions

11.6. Members commented that there should be the option to raise cases externally and that this should also be referenced in the annual governance statement.

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

Decision

11.8. Members agreed:

- the changes to the policy and
- endorsed the point that the policy should be brought to the committee once every two years or earlier if there are changes in the law that significantly impacts this policy.

12. Counter Fraud and anti-theft policy

12.1. The Head of Finance presented this item. It was noted that the policy was brought to AGC in March 2021. Since then, a review was undertaken to ensure the policy was still fit for purpose. The policy was reviewed on 24 November 2021.

12.2. Members were advised that there have been no changes to this policy.

13. Finance and Resource management

13.1. The Director of Finance and Resources presented this item. Following discussion at the December 2021 AGC meeting, members were presented with an approach to a deep dive into the Finance function.

13.2. Members were reminded that the HFEA's financial management risk focused on the volatility in income, given the reliance on sector activity (which represented some 80% of total income) and the risk that it could fall below budgeted expectations.

13.3. Members noted the government's deregulation agenda and suggested that staff should be mindful of this.

13.4. Members welcomed the report but felt that covering a directorate's whole set of activities was too broad to enable a deep dive sufficient to give full assurance. Continuing, members suggested that future deep dives should focus on a more concise and specific business element.

13.5. The Director of Finance and Resources commented that this deep dive centred on FV1 – financial viability which was on the strategic risk register and agreed that as such it was quite broad. Going forward, a discussion will be held with the Chair about suitable topics.

13.6. Members welcomed the assurance map and commented that they would like to know that the controls in place were working efficiently.

13.7. The auditors commented that the controls had been pitched at levels to ensure that they were working and measuring what needed to be measured. Also, looking at how consistently the controls have operated was important. They cautioned that capacity in the Finance team needed to be taken into consideration prior to changing the controls or measures already in existence.

13.8. In terms of business areas to deep dive into, members suggested:

- Business areas that require external reviews and evaluation
- Approach to Value for Money (VfM) operations internally across the business
- Cyber security – how resilient are we
- The fees model
- Effectiveness of the Inspectorate
- Examination of previous internal audits and the effectiveness of recommendations implemented
- 12-month evaluation of the planned risk system review (in 2023)
- GDPR update
- Effectiveness of the use of our data.

13.9. The Director of Compliance and Information commented that the Inspectorate had been audited on both the inspection policy and use of the Compliance and Enforcement Policy.

Action

13.10. Areas highlighted above should be areas that the Executive consider for future deep dives.

Decision

13.11. Members noted the deep dive into FV1 – financial viability.

14. Impact of IFRS 16 – New lease

14.1. The Head of Finance presented this item. Members were advised that this new standard amended the accounting for leases as it required recognition of leases which last more than 12 months to be reflected on the balance sheet.

Decision

14.2. Members noted the impact of the implementation of IFRS 16: lease on the balance sheet.

15. AGC forward plan

15.1. The Head of Finance presented this item.

15.2. The Internal Auditor commented that the internal audit annual opinion will be presented at the June 22 meeting.

15.3. It was agreed that the new Risk Management policy will be presented at the October 2022 meeting, as discussed during the item on the risk register and that the Business and Planning Manager would report on progress at the next meeting.

Decision

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

16. Items for noting

16.1. Gifts and hospitality

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

16.2. Contracts and procurement

- An IT contract with BCC group had been signed off. It was noted that the planned new OTR software was also linked to the contract.

17. Any other business

17.1. On behalf of the committee, the Chair thanked Margaret Gilmore, AGC deputy Chair, for her very significant contribution to the work of the committee. This was her last AGC meeting as she was stepping down as an Authority member following two terms as an Authority member and the Deputy Chair of the Authority.

17.2. Margaret thanked everyone for their support and commented that it had been both a pleasure and a privilege to have worked with everyone.

17.3. The Chair also thanked the External Auditor, Mike Surman who was moving on to other projects in the NAO for his challenge and support whilst working with the HFEA.

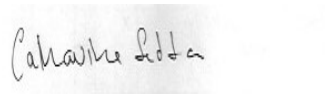
17.4. Mike thanked the entire HFEA team, in particular, the committee, the Director of Finance and Resources and the Head of Finance.

17.5. Following a discussion, it was agreed that the 28 June 2022 AGC meeting will be held in person in the Stratford office at 2 Redman Place.

Chair's signature

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

Signature



Chair: Catharine Seddon

Date: 28 June 2022

AGC Action log

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science, and society

Meeting	Audit and Governance Committee		
Agenda item	3		
Meeting date	28 June 2022		
Author	Morounke Akingbola (Head of Finance)		
Output:			
For information or decision?	For information		
Recommendation	To note and comment on the updates shown for each item.		
Resource implications	To be updated and reviewed at each AGC		
Implementation date	2022/23 business year		
Communication(s)			
Organisational risk	☐ Low	X Medium	☐ High

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

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:	8
Meeting date:	28 June 2022
Author:	Shabbir Qureshi, Risk and Business Planning Manager Paula Robinson, Head of Planning and Governance
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 July.
Organisational risk:	Medium

1. Latest review

1.1. As agreed at the previous AGC and Authority, the Coronavirus risk, CV1, has been discontinued and residual elements have been integrated into the appropriate risks.

1.2. Following several new staff appointments at senior levels, many risk areas will be updated as noted below.

1.3. In summary:

- RF1 (regulatory framework) no significant changes have been made on this occasion.
- I1 (information provision) this risk requires further update now that we have appointed a new head of communication and work on PRISM is in the latter stages of a handover process. The risk remains slightly above tolerance.
- P1 (positioning and influencing) remains unchanged, however with the new appointments, this will be updated.
- FV1 (financial viability) this risk requires further updates as we are in the process of completing year end reports and the impact of estimated fees is assessed.
- C1 (capability) has had minor updates, however with the appointment of new senior staff and Authority members, elements of this risk have reduced.
- C2 (leadership capability) following the appointments of new board members, the inherent risk levels have been reduced.
- CS1 (cyber security) remains unchanged, however the new head of IT will be updating elements of this risk following work on the DSPT toolkit.
- LC1 (legal challenge) – no significant changes have been made on this occasion.

1.4. 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.

2. Recommendation

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

Latest review date – 23/05/2022

Human Fertilisation & Embryology Authority

Strategic risk register 2020-2024

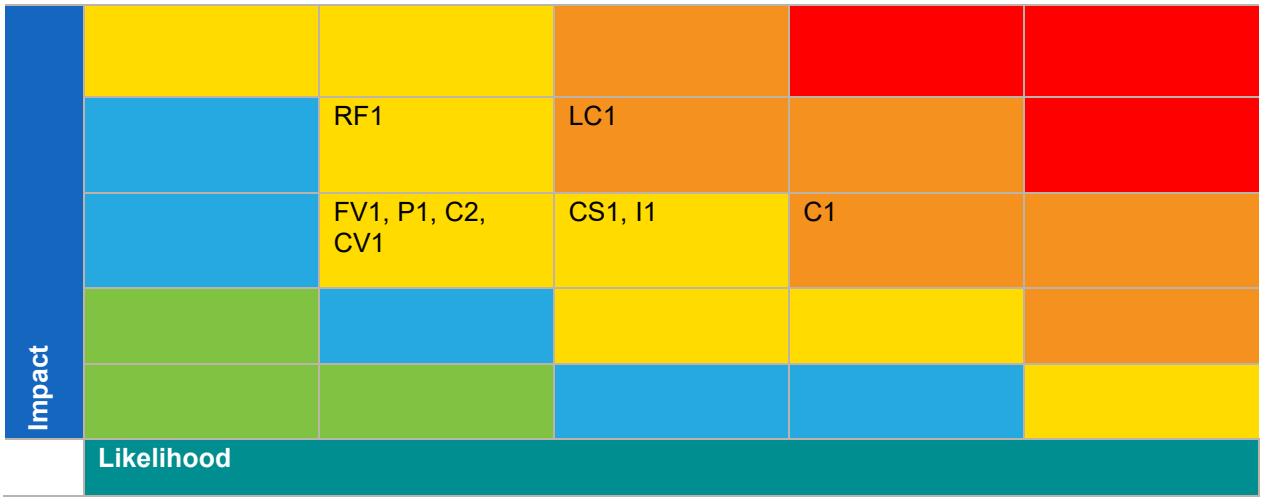
Risk summary: high to low residual risks

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

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

Recent review points: AGC 9 December ⇨ SMT 10 January ⇨ SMT 21 February ⇨ AGC 15 March & Authority 23 March ⇨ SMT 23 May

Summary risk profile – residual risks plotted against each other:



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

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

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

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

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

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

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

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

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

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

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

Commentary

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

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

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

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

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

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

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

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

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

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

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

Commentary
This risk is about us being able to influence effectively to achieve our strategic aims. If we do not ensure we are well placed to do this, we may not be involved in key debates and developments, and our strategic impact may be limited. We have a communications approach, agreed with the Authority in January 2021. This supports our thinking on strategic positioning and will ensure that we are best placed to deliver on the Authority's strategic ambitions. The response to the Covid-19 pandemic required close working with many other organisations and professional bodies, as well as increased engagement with the sector, which has strengthened our strategic positioning. In 2021 we have changed our patient stakeholder organisation group to broaden it's membership and have also established a patient forum to support greater patient involvement in our work. Wider political developments mean that the HFEA has been incorporated into the DHSC 'health family' in a closer way than previously. This has likely improved our connections with the DHSC and other ALBs and enabled us to have greater influence on specific issues.

Causes / sources	Controls	Status/timescale / owner
We do not currently have the range of influence we need to secure our position.	Maintaining and updating our stakeholder engagement plan.	In place, agreed with the Chair and reviewed regularly ongoing – Clare Ettinghausen

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

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

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

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

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

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

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

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

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

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

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

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

Commentary

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Commentary

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

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

Legal challenge poses two key threats:

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

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

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

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

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

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

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

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

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

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

Commentary

Reviews and revisions

SMT review – May 2022:

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

Authority review – 23 March 2022:

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

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

AGC review – 15 March 2022:

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

- I1 – the plan to update this again following further work on the communications strategy was noted. Also agreed to further review the scoring in light of progress towards updating CAFC and the reputational consequences of delays. This is already somewhat mitigated by the communications plan that has been put in place.
- P1 – noted that this risk would also be updated after the communications strategy had been further developed. AGC recommended reflecting on future factors such as increased cross-government

working, shared risks such as cyber security, and the strong government agenda on innovation, sustainability, and digital developments.

- C1 – noted that the suggestion of using the proximity of other ALBs to help with staff development and career paths was not yet in place, since the different ALBs occupying 2 Redman Place are returning to the office at different rates. Th executive were encouraged to consider other ways of ensuring staff benefit from things like secondment opportunities, since it was unlikely that a full return to office working would take place.
- CS1 – cyber security was recognised as a major issue for all organisations, especially give the war in Ukraine and a probability of increased attacks in the future. The committee welcomed the additional training on cyber security that they would be attending that afternoon. The executive was encouraged to consider the possibility of the HFEA experiencing outages as a result of collateral damage from wider attacks (for instance if London's power network were targeted). It was also possible that an attack on a smaller body like the HFEA could be used to undermine bigger parts of government.
- CV1 – agreed with the proposal to discontinue this risk from June onwards and fold any outstanding risk elements into other relevant risks such as C1, capacity. A lessons learned exercise should be conducted to identify useful learning points.

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

SMT review – 21 February 2022:

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

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

SMT review – 14 January 2022:

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

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

- CS1 to be referred to the Head of IT for review following recent work on device security.

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

AGC review – December 2021:

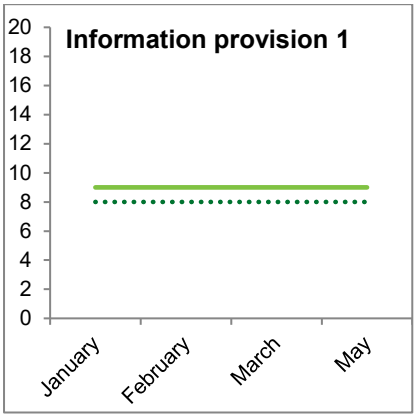
AGC noted a report and presentation including an update on all risks, controls and scores and made the following points in discussion:

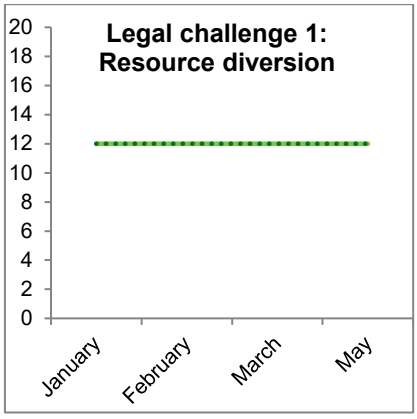
- The plan for reviewing the risk system in line with earlier input was noted. An outline plan and timetable should come to the next AGC meeting.
- RF1 – may need to be reframed to reflect that our work on the Act may see us seeking new powers. A question was also raised about whether the impact of the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

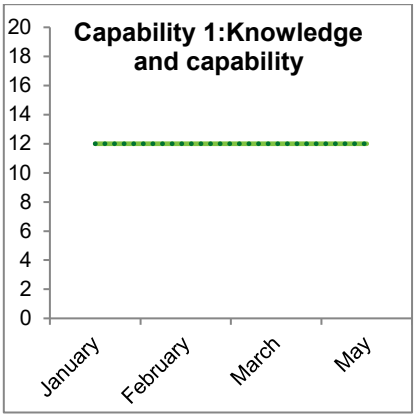
Risk trend graphs (February 2022)

Key:

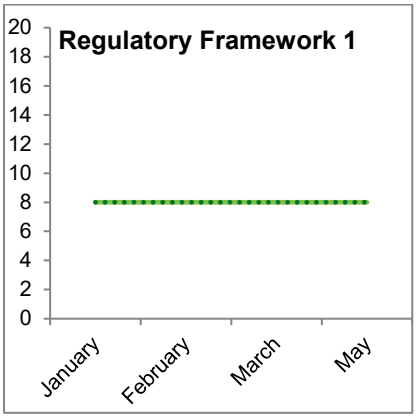
High and above tolerance risks

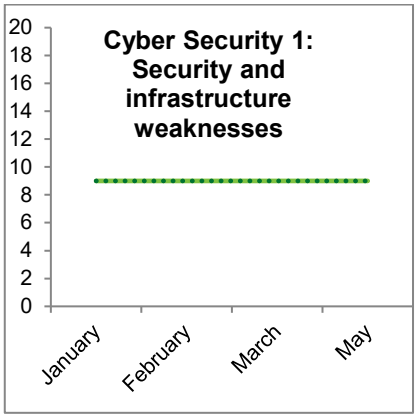


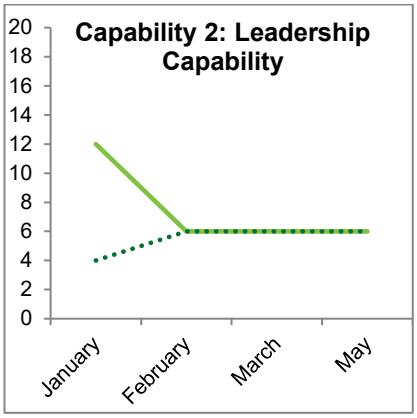


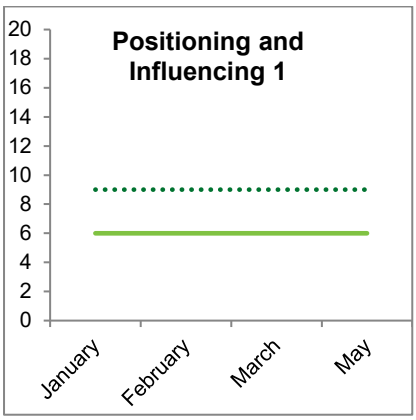


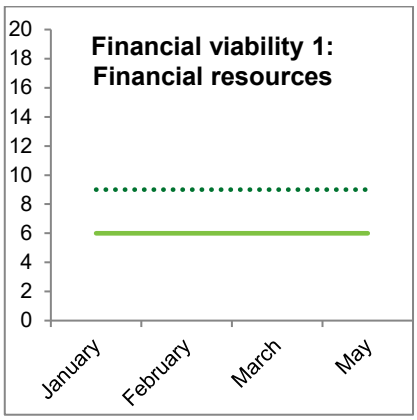
Lower and below tolerance risks











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.

HFEA Risk Management review update

1. Overview

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

1.2. A review plan was submitted to AGC in June 2021, this was subsequently updated for AGC on 15 March 2022.

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

2. Plan for the risk review

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

Month	Proposed plan	June update
March	Support the internal audit of our risk systems and begin to consider recommendations once the report is ready.	Completed. Final report within paper set.
April	Review of best practice guidance and other organisational approaches with reference to the revised Orange Book and risk improvement groups (DHSC and Cross-government). Consideration of how to feed latest best practice into a revised version of our risk policy.	Completed. Work to align the HFEA risk management policy to the revised Orange book has commenced, adapting the structure of the policy to match the Orange book to aid future updates. As per audit feedback, the separate 'Risk Champions' policy will be combined into the main risk management policy with the roles of the champions defined.
May	Commence review of operational risk management practices and identification and mitigation of weaknesses, in line with	In progress. See notes below for detail.

	recommendations arising from the current audit, and our own observations about current team practices. Redrafting of policy to begin. Consideration of content/structure changes in the strategic risk register, to surface the most active issues and improve presentation. Feedback for AGC on progress to date to be drafted in readiness for the June meeting.	
June-September	Design and implementation of rolling improvement plans for operational risk management. Ongoing work on the revised risk policy and risk register. Consideration of how to frame the discussion on our overall risk appetite and the setting of tolerances for individual risks. Design of a horizon scanning methodology.	In progress. See notes below for detail.
October	Revised draft of risk policy and risk register completed and presented to AGC for consideration. Discussion on risk appetite and tolerance levels.	No change.
November	Agreement of risk appetite with Authority alongside their periodic review of the risk register.	No change.
December	Finalisation and launch of the revised risk policy and feedback to AGC on the Authority's discussion on risk appetite.	No change.

3. Policy changes

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

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

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

3.4. The new policy will address the following, using both Orange book principles and audit feedback:

- Adopt the structure of the Orange book, sectioning the policy in a similar format.
- Incorporate the role and responsibilities of the 'Risk Champions' into the main policy.
- Build in both continuous improvement and horizon scanning into the policy and associated documents.
- Provide specific guidance to aid with the assessment of the impact of risk; taking into account the legal, financial, regulatory and reputational risks.
- Frame the policy, strategic risk register and departmental risk registers using the causes/ events/ consequences system.
- Include guidance on selecting the top three risks to bring to CMG and the process of escalating risks to the Strategic Risk Register.
- The risk appetite concept to be referenced at all levels, highlighting the differences between current/ tolerable/ optimal risk positions.
- Add specific sections on horizon scanning, include future risk identification and using this to identify opportunities, and focussing on making risks both dynamic and time-framed where appropriate.
- Further develop the 'deep dives' concept to incorporate risk assurance mapping and assess the effectiveness of the mitigations, taking into account resource limitations.
- Demonstrate and build the links between risk management, service delivery plans and performance management.
- Reference will also be made to the 'Risk Management Skills and Capability Framework' which will include risk inductions and the requirements of both informal and formal risk training depending on roles.

4. Operational risk registers

4.1. The GIAA audit findings are: "The HFEA do not have a standardised template in place for recording operational risk across teams and this has resulted in variations in the quality and completeness of information collected in respect of operational risk."

4.2. The 'Project Risk Registers' were identified in the audit as having some good practice elements and these have been adopted into the new template.

4.3. A new draft Excel template has been created (Annex 2 has screenshots). This has incorporated the following:

- A standardised template for all teams to use.
- All teams will have a tab on a single sheet so they can compare each other's risks.
- Teams will be able to 'tag' other teams that may impact their own identified risks.
- Risks will have an 'Open/ Closed/ Future' system to make risks dynamic.
- The sheet has automation built in, so calculations and colours are selected automatically.

4.4. Guidance on completing risk registers along with 'best practice' examples will be developed.

4.5. These changes will allow more rigorous and consistent reviews of risk registers at CMG.

5. Performance reporting

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

- Tabs for each team to aid navigation.
- The sheet is 'locked' to prevent formulas and formatting to be restricted.
- All RAG ratings are automated.

5.2. All teams have reviewed their KPIs; some are still under review, with Comms KPIs the most challenging as some indicators are not available with the systems HFEA currently use. The new Compliance KPIs will not provide meaningful data until August as the tracking systems have been recently put in place and the cycle tracked takes up to five months.

5.3. The first 'dip check' (recommended at the last audit) to scrutinise data is planned for July. The process for this will be incorporated into the new policy.

6. Service delivery plans

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

6.2. A standardised Excel template for SDPs will be created and referenced within the new risk policy. Where possible, in line with the performance reports and risk registers, this will be a single document with each team having their own tabs. However, as there are significant differences between how teams articulate delivery, there will need to be scope to adapt the template to suit each team.

7. Internal incidents

7.1. The current policy and documentation for internal incidents are being reviewed.

7.2. Annex 3 shows screenshots of options being considered to move away from completing a Word document to recording incidents in a web-based form which will be more user-friendly and allow for more automation as the data captured from the form will be available for immediate export into an Excel document to aid tracking.

7.3. The plan is to have internal incident reporting available on the intranet homepage to allow for greater visibility of the process. We can also use this to highlight learning, promote best practice and compliance.

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

7.5. The KPIs used for internal incidents are also under review.

7.6. The review is planned to be completed and the new systems launched along with the new risk policy.

8. Training and development

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

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

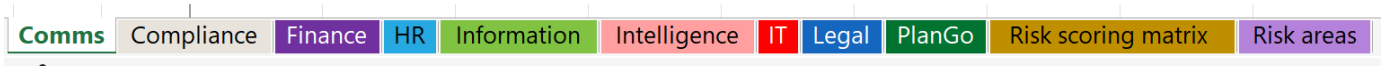
8.3. Formal training needs will be assessed, and plans put in place during July, for the Risk and Business Planning Manager and the Head of Planning and Governance.

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

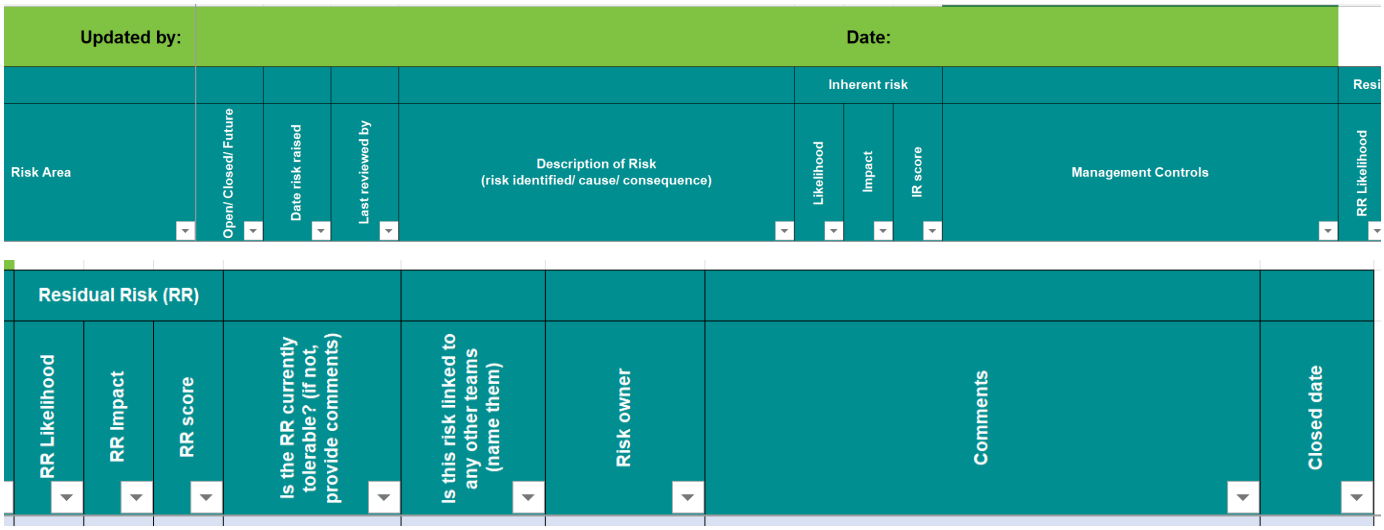
9. Recommendation

9.1. AGC is asked to note the above and comment on this plan.

Annex 2 – Draft operational risk register

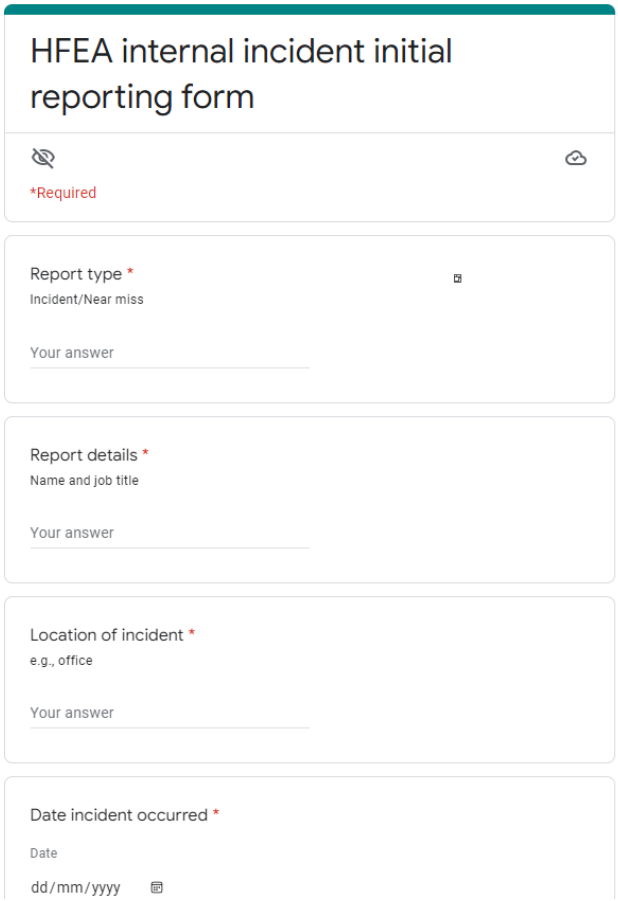


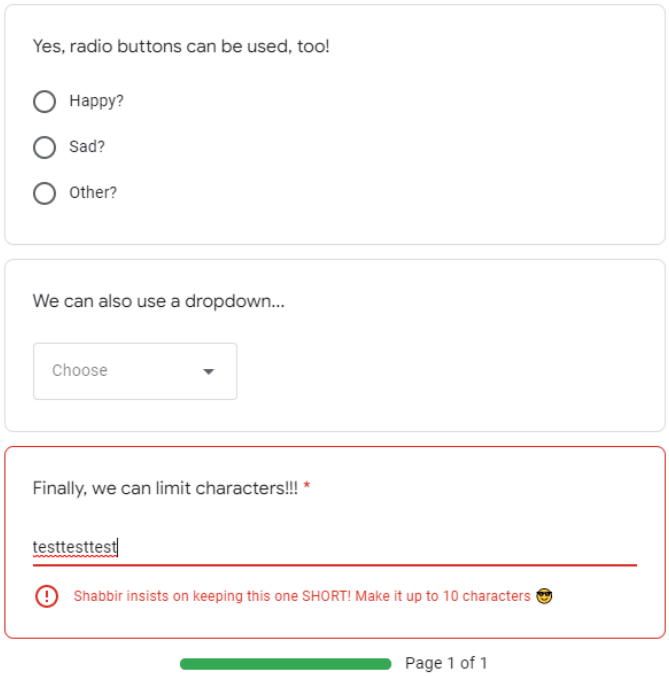
- This shows the tabs for each team



- These are the current draft column headers. The total scores are automatically calculated, and colour coded accordingly.
- ‘Closed’ risks will be greyed out but remain on the sheet and can be made ‘live’ again if required.
- Other teams will be ‘tagged’ and each team will be able to check if they have been identified in other teams’ registers and add those risks to their own where required.

Annex 3 – Internal incidents web-based reporting





- This is an initial sample form to complete. The questions can have a mixture of free text, calendars, drop downs, radio buttons and character limited text.
- This allows considerably greater control on information submitted and also making certain fields mandatory.

ID	Start time	Completion time	Email	Name	Report type	Reporter details	Location of incident	Date of event	Question 1	Question 2
1	6/8/22 13:39:52	6/8/22 13:39:59	Philipp.Bolloev@HFEA.GOV.UK	Philipp Bolloev	Incident	test	test	01/06/22	Test answer 1	Test answer 2
2	6/8/22 13:40:46	6/8/22 13:40:53	Philipp.Bolloev@HFEA.GOV.UK	Philipp Bolloev	Near miss	test 2	test 2	01/06/22	Test answer 1	Test answer 2
3	6/8/22 13:42:31	6/8/22 13:42:37	Shabbir.Qureshi@HFEA.GOV.UK	Shabbir Qureshi	TBC	test 3	test 3	01/06/22	Test answer 1	Test answer 2

- This is the report on Excel created based on the answers provided on the web form.
- The system records all the historical reports and this data can be copied and pasted onto the internal incident management recording system.

Digital Projects / PRISM Update June 2022

Details about this paper

Area(s) of strategy this paper relates to:	The right information – to ensure that people can access the right information at the right time
Meeting:	Audit and Governance Committee
Agenda item:	9
Meeting date:	28 June 2022
Author:	Kevin Hudson, PRISM Programme Manager
Annexes	

Output from this paper

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

1. Introduction and summary

1.1. PRISM went live on 14th September 2021. Since then, some clinics have been using PRISM directly, and other clinics have been deployed to PRISM by their system supplier through an API solution.

1.2. From 1st April 2022 we published a new version of General Direction (0005) outlining the standards to which clinics must adhere when entering PRISM.

1.3. At the ACG meeting on 15th March 2022, we reported the following:

- As of the end of February, 68,794 units of activity had been submitted into PRISM from 73 standalone (direct entry) and API (third-party system supplier) clinics.
- There remained 25 clinics that had so far not used PRISM. These were all API clinics still awaiting deployment from their third-party system supplier.
- Validation error rates for standalone (direct entry) clinic were very low at an average of 0.8% although API error rates were higher at 8.4%.
- We outlined an early plan for restoring reporting through PRISM and delivering CaFC and detailed a large number of risks around gamete movements, quality metrics and legacy data issues that we were needing to address.
- We outlined our approach for a handover from contractors to HFEA staff and the recruitment of additional system developers and data developers.

1.4. As of the end of May 2022, 161,045 units of activity have been submitted into PRISM from 100 clinics. All system suppliers are now fully deployed with the exception of the 3 ARGC clinics which require a special deployment arrangement with Meditex.

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

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

2. Progress on PRISM deployment

Standalone Clinics (entering information directly to PRISM)

2.1. By the end of May 2022, 52,727 units of activity have been submitted by 40 standalone clinics. These clinics commenced on 14th September 2021 and have been using PRISM continuously since that date.

2.2. As previously reported, the quality of data submissions from standalone clinics continues to be excellent. These clinics have 404 outstanding validation errors in total, representing 0.8% of activity.

2.3. Again, as previously reported, we believe the reason for this exceptionally low error rate is that in PRISM, data errors are automatically presented in the clinic's PRISM Homepage. This serves as a strong and visible prompt to the clinic to fix the error there and then.

API clinics (submitting information automatically through a third-party system)

2.4. **Mellowood:** 37 clinics using the IDEAS system have submitted 60,792 units of activity into PRISM. They are now fully deployed. The last clinic (Inovo Belfast) was deployed on 31st May 2022. During May we had to resolve a number of technical issues that were preventing the last few Mellowood clinics submitting to PRISM.

2.5. There are still a number of Mellowood clinics that need to catch up on their data. We are also observing that the number of movements submitted by Mellowood clinics is half the expected level if compared to standalone clinics. Our developers are working with Mellowood developers, particularly on movements. Mellowood issued a 'new build' of their API solution to their clinics in late April and a further new build is due to be deployed on 13th June. These will help fix issues that IDEAS clinics are reporting with their systems.

2.6. We have continued to speak with Mellowood every week, both to ensure the final clinics get deployed and also to work with them to improve the quality of their API solution.

2.7. The error rate for Mellowood is 6.4%. It has been reducing slowly (from 8.2% in February and 10.9% in December). There is wide variation with the error rates of Mellowood clinics. TFP Oxford is reporting 0.4% errors from 4,619 submissions and Kings Fertility 1.9% from 6,120 submissions. Conversely there are 7 clinics with error rates over 10%. The variation in error rates suggests the primary issue is user compliance rather than a system wide issue.

2.8. **CARE Group:** 12 clinics from this group have submitted 32,371 units of activity to PRISM. They were fully deployed by 31st March and fully caught up on their data by 31st May.

2.9. Their error rate is 7.4%. We are now working with the CARE clinics as a group to reduce their errors to the level of standalone clinics.

2.10. **Meditex:** As reported in previous AGC updates, the programme team have encountered challenges with the Meditex API solution. We also previously reported that:

- In December, we accredited their submissions using test data and Meditex undertook a pilot with 0030 Herts and Essex to ensure their solution also worked with real clinic data, particularly to ensure it synchronised with legacy data and that no duplicate records were submitted to the Register.
- The Meditex pilot incurred a number of technical and data synchronisation issues. During January and February, the programme team liaised closely with Meditex. As of the end of February, 0030 Herts and Essex have submitted 785 units of activity, which HFEA staff have fully tested. We were therefore confident in the quality of these submissions to progress to a full Meditex deployment.

2.11. Meditex started their deployment in April 2022. As of the end of May they have deployed 11 clinics who have submitted 15,155 units of data. These clinics are still in process of 'catching up' on data submissions.

2.12. The reported error rate for Meditex is high at 22.2%. However, we believe many of these are caused by technical issues within the Meditex API solution. When our data developer

'revalidates' the Meditex submitted data a large number of these errors are removed, indicating they do not represent user errors at the clinic. We are still investigating the cause of these 'error spikes' and once they are fully understood, will advise Meditex on corrections that need to be made to their API solution.

2.13. Meditex is not yet fully deployed. There remain the 3 ARGC clinics to deploy. These are the last clinics to use PRISM. It was agreed in November 2021 that ARGC would use the Meditex API solution and Meditex confirmed they would deploy to ARGC after deployment to their other clinics.

2.14. In April 2022, Meditex advised that they needed a bulk-backport for ARGC, a record of all previous submissions that the clinic had made to HFEA so that the system supplier knows which records have been submitted to HFEA and which remain to be submitted. Consequently, in May we diverted our data analysts away from data work to build this functionality as we did not want the deployment of the ARGC clinics to become 'adrift' from other deployments. (It is important to note that while the timing of the work on the bulk backport was not ideal, this is work we would need to undertake at some time to enable new API suppliers to enter the market.)

2.15. This backport was completed at the end of May and we have submitted to Meditex. This backport solution was pre-tested with the CARE group and our staff believe this is best solution for the sector and is very similar to previous backports we provided to Meditex. However, Meditex have asked for some further bespoke solutions just for them, but we do not think these we will work, PRISM already provides them with the information they've requested, and we have signposted this again to them. We have advised Meditex that they must adopt the HFEA solution (rather than use HFEA development resource to provide a different one to them) and we are currently awaiting a response from them.

2.16. We have also been recently advised that Meditex will have no development capability during July and August as staff are taking extended leave. This has the risk to delay ARGC deployment until September. Meditex are a very small IT company, based in Germany, with only 400 users of their system worldwide.

2.17. It is the HFEA position that maintaining a single technical standard of processes with system suppliers is important. Moreover, ARGC would not be the first Meditex clinic that experienced a significant delay in submissions to HFEA. Another Meditex clinic (Evewell) was unable to submit to HFEA during 2020 and 2021 due to technical reasons. These were resolved ahead of PRISM go-live, and the clinic was able to catch up with a large backlog of data in the last two weeks of August 2021. Therefore, whilst any delay to ARGC deployment will be frustrating, we believe the impact will be manageable.

New API deployments and migrations

2.18. On 1st April 2022, we published new guidance to the sector regarding the process for any clinic or system supplier wishing to deploy an API solution for PRISM. This guidance outlines the:

- Requirement for a sponsoring clinic to lead this process, rather than a system supplier.
- Resources required by clinic, system supplier and HFEA.
- Assurance process to ensure a new API solution properly deals with fertility scenarios.
- Assurance process to ensure that the API deals properly deals with legacy HFEA data.
- API deployment process co-ordinated with the system supplier, clinic and the HFEA.

2.19. Within this guidance, HFEA retains the right to refuse an API migration if there are insufficient resources, or other issues with the clinics, or if the system supplier has not completed their deployments elsewhere in the sector. It requires the clinic PR to formally initiate the process.

2.20. So far, we have had no requests from clinics to initiate this process, although we are expecting some in the coming months. Mellowood have advised they wish to devote resource to improving the current API solution rather than support their clinics from moving to standalone to API.

General Direction (GD) 0005 on data submission standards for clinics.

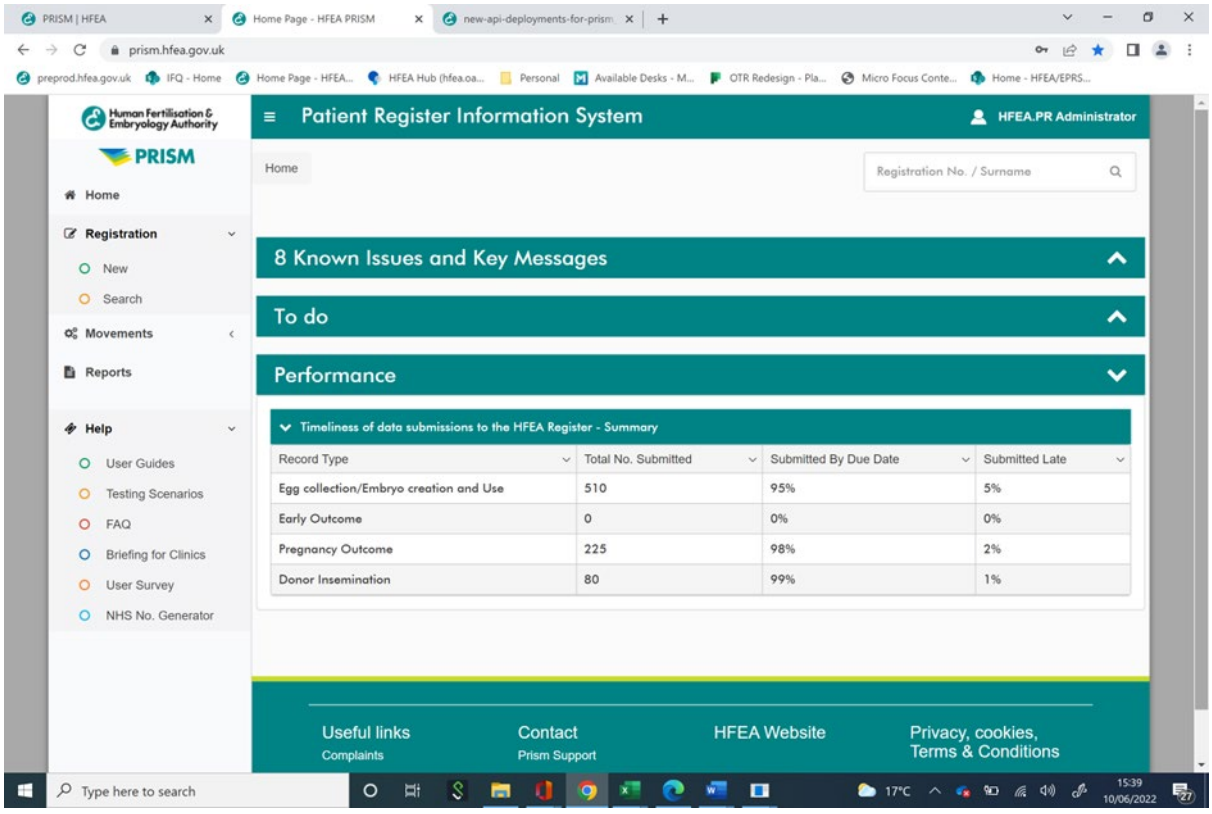
2.21. During March, the HFEA completed the new version of GD0005 after significant input from HFEA inspectors and the legal team. We also consulted clinics on the PRISM user group who had advance sight of a draft copy.

2.22. The General Direction outlines the timescales that clinics must adhere to when submitting data. It also requires clinics to rectify errors within four weeks of the error being incurred, and that clinics set up standard operating procedures to ensure they are regularly checking errors. For API clinics this also means accessing the PRISM Homepage and we have provided guidance on how to do this.

2.23. All PRISM documentation for clinics and suppliers is now in a dedicated area on the Clinic Portal.

2.24. We have also created timeliness reports within PRISM so clinics can assess their submission performance statistics, and this information is also provided as a live dashboard on their PRISM Homepage.

Figure 1: Current example of the performance dashboard of a high submitting standalone clinic (data is as of 10th June 2022 and represents all submissions since 1st April 2022)



2.25. As an organisation we have not yet started to enforce compliance with GD0005, but it is the expectation that all clinics that have deployed will be caught up on data submission backlogs by June, after which time we will work with clinics and the HFEA compliance teams to improve data submission quality in line with our published GD0005, particularly in relation to correcting errors.

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

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

3.2. In the future the process should be far more straightforward, both because it is re-established, and because it is increasingly using PRISM submitted data. Ultimately onerous clinic verifications exercises will not be needed if clinic errors can be eliminated at source as demonstrated by those 40 clinics entering data directly to PRISM.

3.3. Re-establishing the 2022 CaFC is essentially a six-stage process that will be undertaken by a two-person team - our data analyst and our data developer.:

1. Re-establishing Quality Metrics, the flags built into HFEA data to identify certain report types which are also needed for billing and inspectors' books as well as CaFC.
2. Address any legacy data issues that arise during the process. CaFC, like OTR, analyses data down to a very fine level of detail.
3. Ensuring that PRISM validation rules can effectively report against EDI submitted data. (Once we are fully reporting from PRISM submitted data, this won't apply. But the first CaFC is essentially an EDI/PRISM hybrid).
4. Building 40+ verification reports that clinics can use to check and correct the accuracy of their submitted data for CaFC purposes.
5. Supporting clinics on a verification period to check and correct two years of data, undertaken by our data analyst and the register team.
6. Receiving the verified data back into PRISM and building a new CaFC reporting mechanism.

3.4. **Quality Metrics:** In the run to Easter the data team made good progress re-establishing the quality metrics, first for billing and inspectors' books and then for CaFC. However, since Easter we have had to divert our analyst to construct the backport for ARGC (see 2.14 above) and he completed this work at the end of May.

3.5. **Legacy Data Issues:** Our data analyst is working through a number of legacy data challenges (i.e., EDI data that was migrated into PRISM), which are larger and more diverse that we previously expected. These issues are primarily about how legacy data is linked together in

PRISM in a different way compared to EDI, rather than omissions in how data has been historically sent to HFEA.

3.6. Whilst these legacy data linkage issues exist in PRISM, this is also affecting OTR. The OTR team currently check all work against EDI which increases the time to respond. Moreover, developing new reports through PRISM will allow the OTR team to further improve its productivity in dealing with OTR responses.

3.7. Therefore, this is affecting both how CaFC and OTR might be reported through PRISM. Consequently, (in our data analyst's own words) our approach is: *"a two pronged [CaFC and OTR] simultaneous attack on the same problem, where the entire problem can be quantified and monitored, fixed in house where possible, and more importantly for clinics, handed over to them in large tranches of work instead of a drip feed approach".*

3.8. Unfortunately, we do not think there are any quick wins when it comes to fixing the remaining legacy data linkage issues in PRISM. The quick wins with migrated data were addressed in November when our analysts spent a few weeks fixing data issues before moving to Quality Metrics. However, these legacy linkages issues do need to be fixed otherwise the CaFC and OTR reporting will be incomplete, and it will also mean we will have far greater assurance on the accuracy of verification actions that we later send to clinics.

3.9. Trying to 'reconfigure the systems' to report at a more 'simplistic level' for CaFC would take longer than simply 'working through the detail'. Moreover, OTR requires us to achieve this level of detail, and whilst there are potential for inaccuracies in the legacy data in PRISM, the OTR team need to double check all results in EDI.

3.10. Our data analyst is now focussed on legacy data issues until at least August. Towards the end of July, we will know how much work needs to be completed on these areas, and therefore would be able to make a prediction on the delivery dates for CaFC and 'OTR solely through PRISM' that are reliant on this work.

3.11. **Validation Rules and Verification Reports:** Our data developer is currently working through ensuring all PRISM validation rules correctly report against historic EDI data. Once this is assured, he will then move to generating the verification reports.

3.12. **Clinic engagement on CaFC:** We have not yet engaged with clinics about a CaFC verification through PRISM. We anticipate that many will be nervous about this and at present some are still trying to catch up or get to grips with PRISM. As mentioned in 3.8 above, the legacy data work will require some input from some clinics to advise on certain elements of their data. This will essentially serve as a 'CaFC pre-verification'. We will advise clinics on this when we know the scale of what we need to ask them to fix.

3.13. Discussions with SMT are ongoing on the implications of the requirement to address legacy data linkage issues, including how we communicate to the sector whilst our technical staff are working through the detail, and how we prepare clinics for the forthcoming task of verification. AGC should note that we are out for recruitment on a second data analyst that can support this team and interviews are taking place this month.

4. PRISM Handover to employed HFEA staff

New starters for HFEA

4.1. Our new Register Team Manager and our second data developer both commenced employment with HFEA on 11th April. During the rest of that month, they underwent induction and training.

4.2. Our new Head of IT (to replace Steve Morris who retired at the end of May), commenced on the 9th May. He took a handover from Steve during the rest of May and has participated in all the PRISM handovers sessions.

4.3. We are currently recruiting for a second data analyst to support the data team. Interviews are taking place in June.

PRISM handover to employed staff

4.4. During April, the contracted PRISM programme manager developed a full handover plan to last the 8 weeks of May and June, starting on 11th May. This would involve a handover of:

1. PRISM programme management from contracted PRISM programme manager to the newly appointed Head of IT who commenced in early May.
2. PRISM support activities from contracted PRISM co-ordinator and system expert to the newly appointed Register Team Manager who started in April.
3. A full development handover of the PRISM code from the contracted PRISM developer to the employed system developer and the second system developer who started in April.
4. [Note: There will need to be a further 'analytical and data handover' when our contracted 'back-end' data developer leaves in March 2023 to the HFEA data analyst and the newly employed data developer]

4.5. As part of the handover plan, a set of 'Assurance Questions' were developed that could test whether receiving staff were confident on the 'tricky areas' of PRISM. Once those questions were agreed with both staff and contractors, a set of daily handover workshops were initiated to address those topics:

- 11th May: Data dictionary
- 12th May: PRISM registration types.
- 16th May: PRISM code structure & schema
- 17th May: Validation Engine
- 18th May: Editing PRISM
- 19th May: Gamete Inventory
- 20th May: Accreditation and authentication
- 25th May: Movements and Donors
- 26th May: Shared Motherhood, swap role and change of role
- 27th May: Surrogacy
- 30th May: API endpoints
- 31st May: API data synchronisation
- 1st June: Technical queries from system suppliers
- 6th June: Distinguishing clinic issues - data, bug, EPRS, or training
- 7th June: Donor Usage Report and Reports
- 8th June: Standing data in PRISM
- 9th June: Historic validation rules and reducing API errors
- 10th June: Areas where clinics are not submitting data

4.6. Each workshop involved all contractors and all staff from development and register teams as well as the Head of IT and Head of Information. All sessions were recorded, notes written up and are shared in SharePoint folders that all can access.

4.7. The handover was planned as a hybrid approach – workshops on dedicated topics around which staff can do further exercises on these topics and undertake helpful PRISM related tasks such as bug fixing and responding to clinic queries. Generally, we have been successful in keeping this as wholly protected time for HFEA staff to familiarise on PRISM.

4.8. There are three weeks of the handover to go. The focus will now turn to more practical work on PRISM although there may be some further follow up workshops in the last two weeks.

4.9. On the 8th June, SMT undertook a review of the handover to date, and the following mitigations were taken:

4.10. **The development handover (it's primary purpose) was working well**:

- The new developer was getting up to speed quickly and there was good collection of knowledge.
- We are also benefitting from having one employed developer who has already worked on PRISM for 18 months.
- Most challenges were not 'IT technical' but related to complex fertility topics and it has highlighted a need for ongoing, formalised fertility training for all staff.
- The new development team will need to bed in during the Summer, but it was not felt that any further extension to our contracted developer was needed.
- He has however agreed to the option of returning for occasional days if the team need to ask further questions.

4.11. **The handover of support activities was more challenging:**

- It was recognised that our new Register team manager (who started on the 11th April and had no prior fertility knowledge) needed an extended handover before she could become expert in PRISM and lead the support functions.
- Moreover, the team are under capacity due to register team staff being diverted to support OTR.
- We also received some emails from clinics citing concern about the imminent loss of this individual who is providing extensive support to them.
- Therefore, SMT made the decision to extend the contract of contracted programme support officer for a further six months so that she could provide ongoing support to the register team.
- We are making a DHSC application under the new delegated spending controls to this effect.

4.12. **The handover of programme management is still under review by SMT:**

- The new Head of IT has been involved in PRISM development operations since he started in May, and it is anticipated he will be able to oversee the running of the PRISM development team from July.

- Discussions are ongoing with SMT concerning whether there will be benefit to the HFEA in receiving ongoing support from the contracted programme manager for a further time on areas of PRISM outside of development.
- If required, this will include extended programme support and short-term continuity for the Head of IT, continued monitoring for PRISM issues including clinic error rates, and particularly support for the data side of PRISM as outlined in section 3 in relation to CaFC and OTR.
- If more time is needed, it will only be on a part time basis (2 days a weeks) as the contracted programme manager has advised that he is looking to reduce his hours.
- We will update AGC at the meeting on the decision made by SMT.

5. Finance

5.1. The current financial implications of the handover mitigations outline in section 4 above shown in table 1. We will update these figures at the meeting if there are any changes arising from point 4.12 above.

Table 1: PRISM contractor costs – costs to date during handover and subsequent mitigations

	Costs in first quarter 22/23 to 1st Jul 22	Subsequent costs in 22/23 to 31st Mar 23	
Contracted PRISM developer	£39,866	£0	ends Jun 22
PRISM support officer and system expert	£15,602	£40,892	extend to Dec 22
PRISM programme and data management	£39,843	tbc	
Total contractor costs for the period	£95,311	£40,892	
Total PRISM contractor costs for the year		£136,202	

6. AGC recommendations

6.1. AGC are asked to note:

1. The progress with PRISM use, and that with the exception of one clinic group (ARGC), PRISM deployment is complete.
2. The challenges that still exist with Meditex for deployment of ARGC.
3. The legacy data challenges that our data team are addressing ahead of the PRISM data being wholly usable for CaFC and OTR.
4. The approach taken for the PRISM handover to HFEA staff.

5. The handover mitigations that SMT have agreed.

SIRO Report

Strategic delivery:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Details:			
Meeting	Audit and Governance Committee		
Agenda item	10		
Meeting date	28 June 2022		
Author	Richard Sydee, Director of Resources		
Output:			
For information or decision?	For information		
Recommendation	N/A		
Resource implications	N/A		
Implementation date	N/A		
Communication(s)	N/A		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes			

1. Background

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

1.2. This report is my annual report to the Accounting Officer and AGC.

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

2. Report

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

2.2. The HFEA has historically held and processed personal data and records and maintained robust controls and security protocols around all data relating to fertility treatments, which it is required to hold under the HFE Act.

2.3. In recent years we have also responded to changes in legislation relating to the broader personal data we hold in relation to our staff, clinic staff and members of the pubic who may have contacted us. We have introduced several changes to our policies and procedures to ensure we comply with the General Data Protection Regulation and the Data Protection Act.

2.4. Throughout the year we undertake scheduled activity to ensure we comply with our policies; this work Is overseen by the HFEA's Information Governance Manager who makes periodic reports to the Corporate Management Group. In particular:

- During the year we have prepared and updated a number of information governance and IT security papers.
- We continue to regularly reviews our Information asset register, ensuring all assets have owners who are reviewing the assets held, there purpose and use. We have protocols to ensure documents that have reached the end of their retention period are reviewed and either deleted or the retention period extended.
- We have updated the information risk training we are using and have made this mandatory across the organisation

2.5. This provides an overview of our approach to RM and specifically the roles and responsibilities of staff across the organisation as well as our approach to record retention and deletion.

2.6. We continue to review our process for assessing our approach to capturing the level of information risk and our tolerance of it. Given the size of the HFEA there is limited resource to provide continuous oversight of this issue, as such our approach is proportionate and looks to embed the consideration of information risks within the broader assessment of organisational risks.

2.7. Our self-assessment against the DSPT for the 2021 submission was one of general compliance with the DSPT mandatory assertions. In terms of the required audit of our evidence, required by the toolkit to be independent of the HFEA and undertaken by our Internal Auditors, this led to an opinion of unsatisfactory, with issues acknowledged in relation to the breadth and detail of the evidence provided to support our assessment.

2.8. I am confident that progress has been made in the HFEA's approach to the DSPT for the June 2022 submission. The number of assertions that our IA colleagues are assessing has increased, but we have developed a more robust approach to sourcing and cataloguing evidence for our positively assessed assertions.

2.9. Our internal assessment is that the HFEA will still not meet the requirements of the 2022/23 mandatory assertions. We are currently working with GIAA colleagues to assess the substance of our evidence for this. We expect to submit our assessment in line with the 30 June 2022 deadline and the AGC will receive the findings from the internal audit review at the October 2022 meeting.

2.10. Overall, we have a low tolerance of risk for information on our Register database, that which falls within the auspices of GDPR and is commercially sensitive or business critical. The focus of our resource will continue to be the secure and compliant storage of these records.

2.11. In terms of the security of our data the HFEA has appropriate cyber security polices in place. AGC regularly receive updates on cyber security and I am assured that the HFEA's approach to cyber security provides significant protection of our information assets and that there is active monitoring of cyber security with appropriate action taken to improve the level of protection against new and emerging cyber threats.

2.12. I have considered the HFEAs compliance with the mandatory requirements set out in the SPF, see Security policy framework - Publications - GOV.UK. The requirements were last updated in July 2014 and focus on eight areas (governance, culture, risk management, information, technology, personnel, physical security, responding to incidents) with three types of consideration for each of those (information, physical and people). The requirements have been applied proportionately and matched to the HFEA's organisational risks. Not all of the areas apply to the HFEA. This is contained at Appendix A to this document.

2.13. In line with the Office of the Government SIRO handbook I have also considered a number of the factors that underpin the management of the HFEA's information risks.

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

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

Annex A - Assessment of the HFEAs compliance with the Security Policy Framework 2014 (As at 31 March 2022)

	Mandatory Requirement	Compliance	Further actions required
1	Departments and Agencies must establish an appropriate security organisation (suitably staffed and trained) with clear lines of responsibility and accountability at all levels of the organisation. This must include a Board-level lead with authority to influence investment decisions and agree the organisation's overall approach to security.	Director of Resources is SIRO, Chief Information Officer has day to day responsibility of information security.	Ongoing review and refresher training as required.
2	Departments and Agencies must: * Adopt a holistic risk management approach covering all areas of protective security across their organisation. * Develop their own security policies, tailoring the standards and guidelines set out in this framework to the particular business needs, threat profile and risk appetite of their organisation and its delivery partners.	Risks identified as part of routine operational and strategic risk management as well as detailed on the information asset register Policies are in place and reviewed annually.	Ongoing review and development of the information asset register.
3	Departments and Agencies must ensure that all staff are aware of Departmental security policies and understand their personal responsibilities for safeguarding assets and the potential consequences of breaching security rules.	All staff and Authority members are informed of policies and given guidance. Annual training is undertaken by all	Ongoing reminders and awareness raising with staff.

		through Civil Service Learning.	
4	Departments and Agencies must have robust and well tested policies, procedures and management arrangements in place to respond to, investigate and recover from security incidents or other disruptions to core business.	System in place for detecting security breaches and business continuity arrangements in place.	None.
5	Departments and Agencies must have an effective system of assurance in place to satisfy their Accounting Officer / Head of Department and Management Board that the organisation's security arrangements are fit for purpose, that information risks are appropriately managed, and that any significant control weaknesses are explicitly acknowledged and regularly reviewed.	System in place and SIRO reports annually - any weaknesses identified in Governance Statement (none). Response to GDPR and Records management audits during 2018/19 have also been reflected in HFEA processes	None.
6	Departments and Agencies must have an information security policy setting out how they and any delivery partners and suppliers will protect any information assets they hold, store or process (including electronic and paper formats and online services) to prevent unauthorised access, disclosure or loss. The policies and procedures must be regularly reviewed to ensure currency.	Policies and procedures are in place and reviewed annually.	None.
7	Departments and Agencies must ensure that information assets are valued, handled, shared and protected in line with the standards and procedures set out in the Government Security Classifications	The HFEA's assets are all classified OFFICIAL and are appropriately controlled.	None.

	Policy (including any special handling arrangements) and the associated technical guidance supporting this framework.		
8	All ICT systems that handle, store and process HMG classified information or business critical data, or that are interconnected to cross-government networks or services (e.g. the Public Services Network, PSN), must undergo a formal risk assessment to identify and understand relevant technical risks; and must undergo a proportionate accreditation process to ensure that the risks to the confidentiality, integrity and availability of the data, system and/or service are properly managed.	ICT systems are risk assessed as part of the overall operational risk register. IT security was reviewed by Internal Audit in 2017/18	None
9	Departments and Agencies must put in place an appropriate range of technical controls for all ICT systems, proportionate to the value, importance and sensitivity of the information held and the requirements of any interconnected systems.	Patching and firewalls in place. Assurance reports received and reviewed regularly with suppliers. Portable devices and removable media is secured.	None.
10	Departments and Agencies must implement appropriate procedural controls for all ICT (or paper-based) systems or services to prevent unauthorised access and modification, or misuse by authorised users.	Policies and staff induction in place, to clarify proper use and implications of breaches.	None.
11	Departments and Agencies must ensure that the security arrangements among their wider family of delivery partners and third-	Contracts include required conditions and where appropriate third	None.

	party suppliers are appropriate to the information concerned and the level of risk to the parent organisation. This must include appropriate governance and management arrangements to manage risk, monitor compliance and respond effectively to any incidents. Any site where third party suppliers manage assets at SECRET or above must be accredited to List X standards.	parties are given copies of the HFEA's system policies. Changes to arrangements and incident monitoring and results are reviewed at quarterly meetings with suppliers.	
12	Departments and Agencies must have clear policies and processes for reporting, managing and resolving Information Security Breaches and ICT security incidents.	Policies have been revised and are in place.	None.
13	Departments must ensure that personnel security risks are effectively managed by applying rigorous recruitment controls, and a proportionate and robust personnel security regime that determines what other checks (e.g. national security vetting) and ongoing personnel security controls should be applied.	Recruitment and references provide assurance. No vetting in place as very little sensitive data.	None.
14	Departments and Agencies must have in place an appropriate level of ongoing personnel security management, including formal reviews of national security vetting clearances, and arrangements for vetted staff to report changes in circumstances that might be relevant to their suitability to hold a security clearance.	N/a.	
15	Departments must make provision for an internal appeal process for existing employees wishing to challenge National Security Vetting	N/a.	

	decisions and inform Cabinet Office Government Security Secretariat should an individual initiate a legal challenge against a National Security Vetting decision.		
16	Departments and Agencies must undertake regular security risk assessments for all sites in their estate and put in place appropriate physical security controls to prevent, detect and respond to security incidents.	Assessment and sufficient controls provided by building management.	None.
17	Departments and Agencies must implement appropriate internal security controls to ensure that critical, sensitive or classified assets are protected against both surreptitious and forced attack and are only available to those with a genuine “need to know". Physical security measures must be proportionate to the level of threat, integrated with other protective security controls, and applied on the basis of the “defence in depth" principle.	Visitor and entry controls provided by building management. Lockable furniture provided for storage. Clear desk and clear screen requirements reinforced through training, checks and reminders.	None.
18	Departments and Agencies must put in place appropriate physical security controls to prevent unauthorised access to their estate, reduce the vulnerability of establishments to terrorism or other physical attacks, and facilitate a quick and effective response to security incidents. Selected controls must be proportionate to the level of threat, appropriate to the needs of the business and based on the “defence in depth" principle.	Sufficient controls around access and mail provided by building management.	None.

19	Departments and Agencies must ensure that all establishments in their estate put in place effective and well tested arrangements to respond to physical security incidents, including appropriate contingency plans and the ability to immediately implement additional security controls following a rise in the Government Response Level.	Building management provide the lead on incidents. HFEA have contingency plans in place that are reviewed annually, and incident management processes were utilised in 2018 in relation to a power outage	None.
20	Departments and Agencies must be resilient in the face of physical security incidents, including terrorist attacks, applying identified security measures, and implementing incident management contingency arrangements and plans with immediate effect following a change to the Government Response Level.	Building management provide the lead on incidents. HFEA have contingency plans in place that are reviewed annually, and incident management processes were utilised in 2018 in relation to a power outage	

Resilience, Business Continuity Management and Cyber Security

Strategic delivery:	
Details:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society
Meeting	Audit and Governance Committee (AGC)
Agenda item	11
Meeting date	28 June 2022
Authors	Martin Cranefield, Head of IT and Neil McComb, Head of Information
Output:	
For information or decision?	For information

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

Resource implications	Within budget		
Implementation date	Ongoing		
Communication(s)	Regular, range of mechanisms		
Organisational risk	☐ Low	☒ Medium	☐ High

1. Introduction and background

1.1. In recent months, AGC has received regular and detailed updates on Resilience, Business Continuity Management and Cyber Security, in line with the strategic risk register.

1.2. This paper provides an update on IT infrastructure and cyber security in a number of areas.

1.3. It also includes an update on our current approach to submitting evidence for next year's Data Security and Protection Toolkit

2. Infrastructure improvements

IT security changes

2.1. As part of the monitoring services provided by National Cyber Security Centre (NCSC), we have two advisories from the NCSC Mail Check service relating to MTA-STS and TLS-RPT not being configured on the hfea.gov.uk domain. Configuring this makes email less vulnerable to middleperson attacks and allows the receiving email service to enforce encryption, without the risk of delivery failing. We have instructed Alscient to start configuring this in testing mode initially so we can review the telemetry before activating.

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

- HFEA staff to be prevented from accessing HFEA's instance of Office365 (incl. email) from non-HFEA laptops.
- Preventing emails being auto-forwarded from HFEA mailboxes to external accounts. Individual emails can be forwarded.
- Changes to how HFEA email can be accessed from personal mobile phones. Work on this has not yet commenced.
- Implementation of web filtering (aka 'net nanny') to prevent access from HFEA laptops to known malware and phishing web sites was installed and configured. However, a subsequent issue has resulted in local DNS issues on laptops which is causing connection problems for users. We have had to inactivate the protection for the time being and the issue has been escalated to the supplier for further troubleshooting.

Data Backup review

2.3. Martin Cranefield has carried out an initial assessment of the data backup configuration since joining the HFEA in May. He has noted:

- Data backups of servers are stored within the Microsoft ecosystem and not backed up to a third-party environment.
- Office365 environment is not being backed up at all (emails, OneDrive files and SharePoint). We are currently evaluating options and backup suppliers who specialise in backing up Office365 data.

Martin was aware DHSC had previously communicated to Arms-Length Bodies in February offering a free independent review of an organisation's data backups by a

specialist supplier recommended by DHSC. He has reached out to DHSC and NHS Digital to secure a review as soon as possible.

Infrastructure Penetration Test

2.4. We have sent all the requested information to the supplier that will be carrying out the infrastructure penetration test and expect to start this exercise in July.

EDRM upgrade (electronic document and records management system)

2.5. The upgrade of the EDRM server was updated from version 9.3 to 10.0. There is a further update to install which will support the Microsoft Office integration with CM. Karl is working on this update and is expected to rollout in the coming weeks.

3. Data Security and Protection Toolkit (DSPT)

Background

3.1. AGC will recall that the Data Security and Protection Toolkit (DSPT) is an online self-assessment tool that allows organisations to measure their performance against the National Data Guardian's ten data security standards. It was the first time we have submitted an end of year annual DSPT return.

3.2. The DSPT sets both mandatory and non-mandatory requirements. There are 42 detailed requirements and 37 of them are mandatory. We chose to assess ourselves against the 37 mandatory requirements only.

3.3. Each requirement has multiple questions for which we need to provide evidence and explanation, the total number of evidence items across the 37 mandatory requirements is 88.

3.4. AGC will recall that we submitted our mid-year interim assessment in February 2021 and at the time we forecast that we would not be fully compliant with the mandatory DSPT requirements for the annual submission in June 2021.

Final Report

3.5. The final DSPT report found the HFEA to have an overall rating of 'unsatisfactory'.

3.6. They noted that:

"HFEA do not have a structured evidence submission process or the benefit of experience from previous years to draw upon and have not had sufficient time to develop one. HFEA have been transparent in their decision to focus on mandatory assertions only however, documentary evidence to support the assertions have not been uploaded into the toolkit by HFEA and we have not been provided with the suite of off-line evidence on which we can provide assurance that assertions are accurate and fully supported."

3.7. They also provided a number of recommendations to accelerate knowledge and experience to avoid future evidence provision weaknesses and to offer greater assurance that data security and protection controls are operating and are effective.

Recommendation 1	HFEA should develop a structured approach to future Toolkit population with a nominated Toolkit lead and line of business representatives specifically tasked with acquiring

	tangible evidence of the actual controls employed to manage data security and protection.
Recommendation 2	HFEA to re-examine the evidential needs of the Toolkit and use this to re-evaluate and re-design where appropriate all of their information and security management processes.
Recommendation 3	Conduct a lessons-learned exercise to support the development of the framework described in recommendation 1.
Recommendation 4	To reach out to similar organisations deemed more mature in the process of the Toolkit completion to learn from their experience, process and techniques.

Follow up

3.8. The HFEA have already conducted a lessons learned review during a meeting with the SIRO, Director of Compliance and Information and the new Head of Information.

- It was agreed that the recommendations should be actioned.
- It was noted that the failings in the Toolkit submission was due to staff inexperience with the process rather the quality of security practices.
- It was noted that the failings mentioned in the report were not linked to failings in HFEA data security, but rather in the evidencing of them.
- It was agreed to quickly reach out to colleagues in the HRA to learn from their experiences

3.9. On meeting with representatives from the HRA it became clear that they had a much more robust process to address all the necessary assertions in the toolkit, clear lines of responsibility for evidencing those assertions and processes by which that documentation could be collected.

3.10. Since the last paper to AGC, CMG has agreed our new approach to collecting evidence for submission to the toolkit. A new panel consisting of the SIRO, the Head of I.T, the head of information and the IG manager has been created and has already met for the first time.

3.11. This panel has assigned owners to each of the requirements in the toolkit and the IG manager has set up meetings with these owners to explain the documentation they need to provide as evidence. This will be kept in a log and presented at further meetings of the panel with the SIRO having the final say on whether the supplied information is sufficient for the toolkit requirement.

3.12. The next meeting of this panel will take place on 17th June 2022 and it is likely that this meeting will sign off our final submission before the deadline of 30th June 2022.

3.13. Due to the newness of this approach and the lack of knowledge we have been able to gain from the last submission it is unlikely we will meet all the requirements in the Toolkit for 2022. We will however be able to show evidence of improvement and a desire to continue that improvement until we can meet all necessary requirements in future submissions.

Counter-Fraud Strategy

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:	12
Meeting date:	28 June 2022
Author:	Morounke Akingbola, Head of Finance
Annexes	Annex 1: Counter-Fraud Strategy

Output from this paper

For information or decision?	For information
Recommendation:	AGC are requested to review/comment
Resource implications:	None
Implementation date:	Ongoing
Communication(s):	via the 'Hub'
Organisational risk:	Medium

1. Purpose

1.1. The Counter-fraud Strategy was developed as part of the HFEA's commitment to tackling fraud, bribery and corruption and is a key aspect of the Government Functional Standard GovS 013 Counter Fraud. The strategy was developed in October 2019 when it was shared with the Committee at the 8 October 2019 meeting.

1.2. The strategy has been reviewed and has not change, however updates have been provided against actions detailed in the Action plan.

2. Action

2.1. The Committee are requested to note the strategy and to discuss and comment on the high-level action plan. In particular the Committee are requested to note that work around fraud awareness has been limited due to resource issues.

2.2. Any suggestions as to how further awareness and keeping counter-fraud alive would be very much appreciated.

Counter-Fraud Strategy

Purpose of the Counter Fraud Strategy

1. The HFEA is a small organisation with a less public-facing role than some other regulators; nevertheless, our activities can expose us to inherent risk of fraud from both external and internal sources. Our commissioning and procurement of goods and services also presents inherent risks of corruption and bribery.

2. As well as financial loss, fraud and corruption also detrimentally impacts service provision, morale and undermines confidence in the HFEA and public bodies more generally.

3. There is little evidence that these risks ('fraud risk') are a material risk for the HFEA. This may be due to the established counter fraud arrangements as set out in the 'Counter Fraud Policy and Procedures', although such evidence can, of course, only be based on what is known. There is, however, strong evidence that overall, fraud risk in the public sector is increasing, due to more sophisticated methods of fraud but also different ways of delivering service and revised management arrangements.

4. It is therefore essential that the HFEA regularly assesses its exposure to fraud risk and ensures that its counter fraud arrangements and the resources allocated to managing the risks – the controls are effective and aligned to best practice. Overall, the Counter Fraud Policy commits the HFEA to achieving an anti-fraud and theft culture that promotes honesty, openness, integrity and vigilance in order to minimise fraud, theft and its cost to the HFEA.

5. This Strategy therefore sets out what the HFEA will need to do over the period 2021 to 2024 to successfully fulfil this commitment.

6. Many controls to manage fraud risk are already in place but these need to be maintained and where necessary, improved to help keep pace with the risk. There are also other controls which either are needed or may be needed, depending on the overall assessment of fraud risk and the resources available.

7. Implementation of the Strategy will help the HFEA to achieve its strategic objective of 'improving standards through intelligence and meet the Cabinet Office Functional Standards released in 2018.

Scope – What is covered by this Strategy

8. All references to fraud within this Strategy include all types of fraud-related offence, i.e., theft, corruption, and bribery.

9. The Strategy covers all business, activities and transactions undertaken by the HFEA or on its behalf, and therefore applies to all Members and all who work for the HFEA[1].

Basis – What has informed this Strategy

10. The HFEA's counter-fraud arrangements are based on the Cabinet Office Government Functional Standard for Counter Fraud. These Standards set the expectations for the management of Fraud, bribery and corruption risk in all government organisations.

11. This standard sets out key principles:

Strategic Governance	Accountabilities and responsibilities for managing fraud, bribery and corruption risks are defined across all levels of the organisation
Inform and Involve	Staff have the skills, awareness and capability to protect the organisation against fraud
Prevent and deter	Policies, procedures and controls are in place to mitigate fraud, bribery and corruption risks and are regularly reviewed to meet evolving threats
Investigate and sanction	Thoroughly investigate allegations of fraud and seek redress
Continuously review and hold to account	Systems in place to record all reports of suspected fraud, bribery and corruption are reviewed; intelligence feeds into the wider landscape

12. This Strategy has been informed by a detailed assessment against these principles using the Functional Standards Maturity model. The HFEA assessed itself as being non-compliant against the standard in autumn of 2019. Since then we have been working with the standards and the DHSC Counter Fraud Laison Group to improve our compliance.

13. The basis of this Strategy is therefore to address those areas of the standard that must be met and developed in order that the HFEA can move towards embedding the counter-fraud culture envisaged by the functional standards.

14. Not all areas of the standard are relevant to the HFEA as the standard applies to organisations of varying sizes and type within the UK, and not all recommendations are therefore proportionate to the risks faced.

[1] Employees including casual staff and agency staff, consultants, contractors, and partners.

Key risks and challenges

15. In an effort to understand and mitigate areas of fraud, bribery and corruption, a risk assessment was conducted prior to development of this strategy and then bi-annually.

16. The result of these assessments highlighted the following fraud risks:

- Expense fraud;
- Procurement fraud and
- Inappropriate use/sharing of data.

17. Cyber fraud whilst not listed above is still a risk and is held within the operational and strategic risk registers and managed.

Objectives – Where the HFEA needs to be

18. Based on the five principles of the Counter Fraud Functional Standards (11 above), the objectives below set out what the HFEA will need to be achieving by 2023 in order to fully have met the standard.

- Conduct fraud risk assessment of existing and new fraud threats to ensure appropriate actions are taken to mitigate identified risks;
- Creation of a counter-fraud culture across the organisation through training and communication;
- Maintain effective systems, controls, and procedures to facilitate the prevention and detection of fraudulent and corrupt activity;
- Effective response and investigation of suspected cases of fraud and corruption and pursue redress and effective sanctions, including legal action against people committing fraud;
- Implement reporting of counter-fraud performance by establishing key metrics for reporting on counter-fraud activity and fraud cases.

Implementation

19. Implementation of this Strategy takes account of the controls that are already in place to mitigate fraud risk. Actions (high-level) to achieve the above objectives are at Annex A.

Accountability

20. The Director of Resources is the SMT member responsible for counter fraud and has delegated responsibility for maintaining, reviewing and implementing this Strategy to the Head of Finance.

21. Additionally, all other Directors and Heads of Directorates are responsible for ensuring that the Strategy is applied within their areas of accountability and for working with the Head of Finance in its implementation. All employees and Authority Members have a responsibility to work in line with this strategy and support its effective implementation. Details of responsibilities are set out in the Counter-Fraud Policy.

22. Progress on implementing this Strategy will be provided to the Audit and Governance Committee (AGC) in addition to the Department of Health and Social Care Anti-Fraud Unit (DHSC AFU).

23. The effectiveness of counter fraud controls is assessed in part by Internal Audit reviews, and an overview of the effectiveness of our mitigating controls are contained in the Internal Audit reports submitted to AGC. Any strategic concerns could be raised in these reports.

Measures of success

24. The successful implementation of this strategy will be measured by:

- successful implementation of the actions contained within the strategy;
- increased awareness of fraud and corruption risks amongst members, managers and employees;
- evidence that fraud risks are being actively managed across the organisation;
- increased fraud risk resilience across the organisation to protect the HFEA's assets and resources;
- an anti-fraud culture where employees feel able to identify and report concerns relating to potential fraud and corruption.

Reporting and review

25. The HFEA's approach to suspected fraud can be demonstrated in its Fraud Response Plan contained in the Counter-fraud and Anti-theft Policy

26. The responsibility for the prevention and detection of fraud rests with all staff, but Directors and Managers have a primary responsibility given their delegated contractual and financial authority. If anyone believes that someone is committing a fraud, or suspects corrupt practices, these concerns should be raised in the first instance directly with line management or a member of SMT then the Chair of the Audit and Governance Committee.

27. The Chief Executive and the Director of Finance and Resources has responsibility for ensuring the HFEA has a robust anti-fraud and corruption response.

28. The Audit and Governance Committee will ensure the continuous review and amendment to this Strategy and the Action Plan contained within it, to ensure that it remains compliant with good practice national public sector standards, primarily Cabinet Office Functional Standards: Counter-fraud.

Annex A: Strategic Action plan 2022-23

Strategic Governance						
Action	**Description**	**Core Discipline**	**Due date**	**Outcome**	**Owner**	**Update**
Roles and responsibilities	Assign accountable individual responsible for delivery of counter-fraud strategy, senior lead for counter-fraud activity	Leadership, Management and Strategy	June 2019	Director of Finance and Resources assigned as accountable individual	Head of Finance	Accountable individual was assigned at the June 2019 AGC meeting. **COMPLETE**
Strategy	Detail our arrangements for managing fraud, bribery and corruption.	Leadership, Management and Strategy	July 2019, reviewed annually	A shared understanding of the management of the risk of fraud, bribery and corruption	Director of Finance and Resources	Strategy developed. **COMPLETE**
Action Plan	Develop annual action plan which details the activities needed to manage areas of fraud risk	Prevent	July 2019 then annually	Increased awareness; additional controls implemented	Head of Finance	Action plan last reviewed in August 2021 and has been updated. Next review July 2022

Inform and Involve						
Action	**Description**	**Core Discipline**	**Due date**	**Outcome**	**Owner**	**Update**
Risk Assessment	Identify and assess HFEA's fraud risk exposure affecting principle activities in order to fully understand changing patterns in fraud and corruption threats and potential harmful consequences to the authority	Risk Assessment	Bi-annually July November	Controls implemented for fraud risks identified	Head of Finance	Fraud Risk Assessment was created and shared with CMG on: 16/12/20 No new risks were added
Awareness	Raise awareness of fraud and corruption by running awareness campaigns	Culture	Ongoing throughout the duration of the strategy	Improved staff awareness	Head of Finance	Fraud page has been created on the Intranet ('the Hub)
Training	Actively seek to increase the HFEA's resilience to fraud and corruption through fraud awareness by ensuring that all existing and new employees in all directorates undertake a fraud and corruption e-learning course	Culture	July annually	100% of staff undertake mandatory training	Head of Finance/Head of HR	Staff undertook fraud awareness training: in Q4 2020/21

Prevent and Deter						
Action	**Description**	**Core Discipline**	**Due date**	**Outcome**	**Owner**	**Update**
Policies	Refresh and promote the HFEA's suite of anti-fraud related policies and procedures to ensure that they continue to be relevant to current guidance.	Leadership, Management and Strategy	Annually, each April	Updated policies.	Head of Finance	Anti-Fraud policy reviewed Jan-21
Internal Audit	Use of Internal Audit review to identify further weaknesses	Prevent	Feb-21 Mar-22	Assurance to AGC	Director of Finance and Resources	Payables and Receivables audit conducted in Feb-21 Budgetary Process audit conducted in May-22
Intelligence	Use of information and intelligence from external sources to identify anomalies that may indicate fraud	Prevent	End of 2022/23	Increased awareness; additional controls implemented	Head of Finance	Earliest submission of data is Jan-23.

Investigate and sanction						
Action	**Description**	**Core Discipline**	**Due date**	**Outcome**	**Owner**	**Update**
Reporting	Produce fraud investigation outcome reports for management which highlight the action taken to investigate the fraud risks, the outcome of investigations e.g., sanction and recommendations to minimise future risk of fraud	Leadership, Management and Strategy	November, then quarterly as standing item on AGC agenda	Management feel assured and sighted on any actual fraud and resulting investigations	Director of Finance and Resources	No instance of fraud, thus investigations have been conducted.
Recording	System for recording of and progress of cases of fraud to be utilised where practicable	Leadership, Management and Strategy	On-going, HFEA has access to DHSC AFU	Database of intelligence that feeds into DHSC AFU's benchmarking data	Director of Finance and Resources	No cases to update

Review and held to account						
Action	**Description**	**Core Discipline**	**Due date**	**Outcome**	**Owner**	**Update**
Embedding the standard (GovS 013)	Maintaining staff awareness through consistent sharing of information.	Culture	On-going	100% of staff complete fraud training	Head of Finance	HR to confirm number of staff who complete training
Sharing	Reporting quarterly to Cabinet Office' Consolidated Data Requests	Leadership, Management and Strategy	September 2019 and quarterly	Basic to maturing standard met	Director of Finance and Resources	CDR return completed April-22 for Q4 2021/22 and submitted.

Human Resources update 2022

Details:	
Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society
Agenda item	13
Meeting date	28 June 2022
Author	Yvonne Akinmodun, Head of Human Resources
Output:	
For information or decision?	For information
Recommendation	The Committee is asked to note and comment on the: a. The exit interview summary b. Update on Equality & Diversity in the workplace c. Staff survey action plan
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	☐ Low ☒ Medium ☐ High
Annex	Action plan from the staff survey

1. Introduction

1.1. This paper sets out some of the key HR activities the organisation has been working on. 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.

1.2. The paper uses data from two key sources:

- Employee exit interviews
- Equality and inclusion which includes a presentation in annex 1

2. Employee Exit Interviews

2.1. The HR team capture and record information following staff resignations in order to gain a better understanding of why staff leave and to help identify any themes or areas of concern that need to be addressed.

2.2. The information is gathered through the use of exit interview forms. Where possible, the forms are completed following a face-to-face meeting with the exiting employee. The completion of an exit interview form is entirely voluntary and whilst the vast majority of staff are happy to conduct an interview, there are some who have been unwilling to provide information about their reason for leaving.

3. Key findings from exit data

3.1. Between January to June 2022, 10 people exited the organisation. Of the 10 exits, 7 were voluntary resignations with a further 3 taking place involuntary, for reasons such as end of contract terms.

3.2. **Top 3 reasons for leaving included:**

- Lack of opportunity for progression
- Personal reasons
- Pay

Two of the top three reasons for leaving remain the same as previous years. The exception with the current data is around those who cited personal reasons as the cause for leaving. Previous exit interviews have also indicated a lack of training and development as a reason for leaving. This has not been indicated in this set of data.

3.3. **Lack of opportunities for progression:** Three of the 10 staff cited a lack of opportunity for progression as the main reason for leaving. Most recognised that owing to the size of

the organisation, opportunities for progression would be somewhat limited. They had therefore chosen to leave to explore development opportunities in other organisations.

3.4. **Personal reasons:** A further 3 left for personal reasons, which ranged from retirement to seeking a career change.

3.5. **Pay:** Although pay was mentioned as a reason for leaving, it was not cited as the main reason for leaving.

4. Summary

4.1. We will continue to conduct exit interviews to gain useful insights into any further changes the organisation might need to make to help boost engagement and reduce turnover.

5. Equality and Inclusion

5.1. The executive committed in 2021 to providing AGC with key highlights and information about equality and inclusion activity within the HFEA. In addition to presenting some key equality and diversity data, below is a brief overview of the key activities that we have put in place to support our journey.

5.2. Awareness and unconscious bias sessions: In addition to running online inclusion awareness sessions, we also ran a mandatory organisation wide session in May.

5.3. Equality and diversity survey: We conducted an organisation wide confidential survey on equality and diversity, using an external facilitator. The key highlights from the survey will be presented to CMG and also used to inform future actions and activities around equality and diversity.

5.4. Leadership development: We will be running an equality and diversity session for the leadership team , (CMG). The session will enable further discussion around actions to support our equality and diversity agenda.

5.5. 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.

5.6. Equality and Inclusion Group: In May 2022, we joined with other ALBs within Redman Place to form an equality and inclusion group, chaired by the CEO of the HTA. One of the outcomes from the first meeting is an agreement to work collectively towards the creation of a mentoring arrangement between the 5 ALBs. The program will be aimed at mid-level managers who might be seeking a mentor as part of their career development and progression. Fuller details of the program and how it will work in practice are still to be determined.

6. Staff survey action plan

6.1. The annual all staff survey ran in the autumn of 2021. The results from the survey were presented to AGC in December 2021 at which a commitment to create a staff survey

action plan was agreed. A planning group made up of members of staff from all areas of the organisation was set up in early January.

6.2. The planning group put forward suggestions, which formed the basis for a staff survey action plan. Copy attached at annex 2.

6.3. The action plan along with progress to date has been shared with staff. Most actions from the plan have now been completed and we continue to work through the remaining actions as we prepare for this year's survey.

7. Recommendations

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

Action plan from staff survey

Themes	Concerns	Action	Owner	Comments/Updates
Purpose	1. Although staff work well within their own teams, many feel we do not work well across teams	1. Reconstitute the social club to help with organising social activities across the organisation 2. Regular updates on key areas e.g. PRISM 3. Reinstate the monthly team 'show and tell' sessions where a nominated team does an update on a key area of their work 4. Run cultural web session in which we seek volunteers who share their views on what it is like working at the HFEA and how we can improve working across teams	Staff survey action group IT CMG HR	So far there have been no volunteers to take this action forward IT to follow up CMG to sign off on this action This action is being addressed through the work starting on 'Lived experiences - a focus group/survey for all staff
Autonomy	2. No concerns within this area raised			
Leadership	3. Some staff do not feel their manager provides sufficient feedback and coaching to help with their career development	1. Run a 'managers as coaches' workshop to help manager develop the tools to have coaching conversations with their team members	'HR	HR to organise this within the training for the new financial year
Enablement – Tools for the job	4.Some staff don't feel the organisation does enough to help with managing their wellbeing	1. Update and launch a new policy on the provision of equipment 2. Promote the wellbeing portal within the Hub and offer a range of wellbeing tools for staff to access 3. Run a workshop for managers on how to manage and work with hybrid teams. This	IT/Finance HR/Internal communications HR	Done Done Done

		will include how to oversee the wellbeing of your team members 4. Continue to run quarterly wellbeing pulse surveys. The next one will take place in January 2022 5. Provide a guide on the intranet for staff, in particular new staff to help to make it easier for them to navigate the Hub	HR Communications	In progress Not started
Reward/Fairness	5, When roles are advertised and the starting salary is the same as the salary they have worked up to gradually over many years, that's dispiriting and seems unfair.	1. It is our policy to advertise all roles at the starting salary, which in most cases should be lower than that of existing employees within the organisation. 2 .We are a public body and are therefore restricted in when and how we review pay. There is also the issue of affordability. SMT will need to determine, given these constraints if it is possible and appropriate to conduct a review of pay and grading later this year	SMT	A review of government guidance on pay for 22/23 is underway
	6.Fair treatment – some concerns were raised around fairness in relation to diversity and inclusion	1. Explore diversity and inclusion awareness training for all staff, starting with senior managers within the organisation 2. Explore mentoring support for all our mid-level managers 3. Explore specific training around leadership for women of colour. 4. Advertise our roles in diversity press as a way of reaching a wider section of our community so that they can be more represented at senior level within the HFEA	HR HR HR HR	Done Raised with ALBs. Final decision pending Done. In addition, This action is also being addressed through the work on 'Lived experiences - a focus group/survey for all staff Have promoted a few roles in diversity press. Will continue to review

Audit and Governance Committee Forward Plan

Strategic delivery:	☐The best care – effective and ethical care for everyone	☐The right information – to ensure that people can access the right information	☐Shaping the future – to embrace and engage with changes in the law, science and society
Details:			
Meeting	Audit & Governance Committee		
Agenda item	14		
Meeting date	28 June 2022		
Author	Morounke Akingbola, Head of Finance		
Output:			
For information or decision?	Decision		
Recommendation	The Committee is asked to review and make any further suggestions and comments and agree the Forward Plan. *Receive confirmation of bi-annual review of Fraud/Whistleblowing policies.*		
Resource implications	None		
Implementation date	N/A		
Organisational risk	☒ Low Not to have a plan risks incomplete assurance, inadequate coverage or unavailability key officers or information	☐ Medium	☐ High
Annexes	N/A		

Audit & Governance Committee Forward Plan

AGC Items Date:	15 Mar 2022	28 Jun 2022	5 Oct 2022	8 Dec 2022
Following Authority Date:	23 Mar 2022	6 July 2022	16 Nov 2022	28 Jan 23
Meeting 'Theme/s'	Finance and Resources	Annual Reports, Information Governance, People	Strategy & Corporate Affairs, AGC review	Register and Compliance, Business Continuity
Reporting Officers	Director of Finance & Resources	Director of Finance & Resources	Director of Strategy and Corporate Affairs	Director of Compliance and Information
Strategic Risk Register	Yes	Yes	Yes	Yes
Risk Management Policy[1]			Risk Management Policy/update on review of systems conducted	
Digital Programme Update	Yes	Yes		
Annual Report & Accounts (inc Annual Governance Statement)	Draft Annual Governance Statement –	Yes – For approval		
External audit (NAO) strategy & work	Interim Feedback	Audit Completion Report		Audit Planning Report
Information Assurance & Security		Yes, plus SIRO Report		
Internal Audit Recommendations Follow-up	Yes	Yes	Yes	Yes
Internal Audit	Update	Results, annual opinion approve draft plan	Update	Update

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

AGC Items Date:	15 Mar 2022	28 Jun 2022	5 Oct 2022	8 Dec 2022
Whistle Blowing, fraud (report of any incidents)	Update as necessary	Update as necessary	Update as necessary	Update as necessary
Public Interest Disclosure (Whistleblowing) policy	Reviewed bi-annually thereafter			
Anti-Fraud, Bribery and Corruption policy	Reviewed and presented bi-annually thereafter			
Counter-fraud Strategy and progress of Action Plan		Counter Fraud Strategy; Action plan		
Contracts & Procurement including SLA management	Update as necessary	Update as necessary	Update as necessary	Update as necessary
HR, People Planning & Processes		Bi-annual HR report		Bi-annual HR report
Strategy & Corporate Affairs management			Yes	
Regulatory & Register management				Yes
Cyber Security Training			Yes	
Resilience & Business Continuity Management	Yes	Yes	Yes	Yes
Finance and Resources management	Yes – deep dive			
Reserves policy			Yes	
Estates	Yes	Yes	Yes	Yes
Review of AGC activities, terms of reference				Yes
Legal Risks			Yes	
AGC Forward Plan	Yes	Yes	Yes	Yes

AGC Items Date:	15 Mar 2022	28 Jun 2022	5 Oct 2022	8 Dec 2022
Session for Members and auditors	Yes	Yes	Yes	Yes

Suggested training for Committee Members

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