Human Fertilisation & Embryology Authority

Authority meeting

Date: 23 March 2022 – 1pm to 4.30pm

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

Agenda item	Time
1. Welcome, apologies and declarations of Interest	1.00pm
2. Minutes of the meeting held 9 February 2022 and matters arising For decision	1.05pm
3. Chair and Chief Executive's report For information	1.10pm
4. Committee Chairs' reports For information	1.25pm
5. Effective governance For decision	1.40pm
6. Performance report For information	2.05pm
7. 2022/23 Budget proposal For decision	2.30pm
Break	2.50pm
8. Next steps in relation to HFEA response to Covid-19 For decision	3.05pm
9. Strategic risk register 2020-2024 For information	3.30pm
10. Add-ons rating system and survey options For decision	4.00pm
11. Any other business	4.25pm
12. Close	4.30pm

Minutes of Authority meeting 9 February 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	23 March 2022		
Author	Debbie Okutubo, Governance Manager		
Output:			
For information or decision?	For decision		
Recommendation	Members are asked to confirm the minutes of the Authority meeting held on 9 February 2022 as a true record of the meeting		
Resource implications			
Implementation date			
Communication(s)			
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes			

Minutes of the Authority meeting on 9 February 2022 held via teleconference

Members present	Julia Chain Margaret Gilmore Anne Lampe Catharine Seddon Jason Kasraie Tim Child	Jonathan Herring Gudrun Moore Ruth Wilde Ermal Kirby Alison Marsden
Apologies	None	
Observers	Steve Pugh (Department of Health and Social Care - DHSC)	
Staff in attendance	Peter Thompson Richard Sydee Clare Ettinghausen Rachel Cutting Catherine Drennan Nora Cooke O'Dowd	Paula Robinson Debbie Okutubo Shabbir Qureshi Joanne Anton

Members

There were 11 members at the meeting – eight lay and three professional members.

1. Welcome and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members, the public and staff present online. The Chair apologised for the meeting not being face to face on this occasion, due to the proximity of the latest government announcements on Covid to the meeting. The March meeting would be face to face in the new office in Stratford.

1.2. The Chair stated that the meeting was audio recorded in line with previous meetings and the recording would be made available on our website to allow members of the public who were not able to listen in during our deliberations to hear it afterwards.

1.3. Declarations of interest were made by:

- Tim Child (PR at a licensed clinic)
- Ruth Wilde (counsellor at licensed clinics)
- Jason Kasraie (PR at a licensed clinic).

2. Minutes of the last meeting

2.1. Members agreed that the minutes of the meeting held on 24 November 2021 were a true record of the meeting and could be signed by the Chair.

2.2. The status of all matters arising was noted.

3. Chair and Chief Executive's report

3.1. The Chair gave an overview of her engagement with key stakeholders and the decision-making committees of the Authority. The Chair spoke at the Progress Educational Trust (PET) conference in December 2021 and at the Fertility 2022 conference in January 2022, where she outlined our plans to bring forward proposals to modernise the HFE Act. A small advisory group will be formed, made up of stakeholders, who will review and advise on our proposed changes to the Act. Detailed proposals will be shared with our sponsors at the Department of Health and Social Care (DHSC) later in the year.

3.2. The Chief Executive provided an update on the key activities that he was involved in since the last Authority meeting. Work was ongoing with the treatment add-ons working group that he chaired.

3.3. The Chief Executive gave a status update on PRISM. Since PRISM went live in September 2021 over 50,000 units of activity has been submitted through PRISM from over 60 clinics. 37 clinics are currently using PRISM directly, while the remainder use third party suppliers to provide an API. The Chief Executive commented that clinics using PRISM directly were showing excellent data quality with error rates of less than 1%. The target for clinics to complete deployment is 31 March 2022.

3.4. There were four system supplier API solutions supporting 60 clinics and three of them had started deployment. There was an API error rate average of 6-8% and the Register Team were working with them to ensure validation errors were addressed and that they achieve the same quality levels that clinics directly inputting into PRISM are achieving.

3.5. Members were advised that a PRISM lessons learned meeting was held with the Audit and Governance Committee (AGC) in December 2021 and the key learning points were shared with the Board:

- Managerial communication and planning – Appointing a technically skilled programme manager who has the ability to act as an interface between technicians and management.
- Governance – Using managerial key performance indicators to better support good governance and be prepared to review the programme once progress slips significantly.
- Design complexity – Ensure the organisation is clear about what is being built and is asking the question 'why' of technical staff and eliciting the technical intelligence needed to inform decision-making.
- Alternatives to PRISM - The future replacement of PRISM would be unlikely to be wholly outsourced given the complexity of the fertility data involved, so we need to maximise the longevity of PRISM and ensure there are always staff in the HFEA that understand the detailed operation of the system.
- Avoiding reliance on single individuals for important pieces of work - So that there is more resilience.
- IT resources required for modern regulation – Understanding the capacity and capabilities needed to support core systems.
- Support from the DHSC – Ask the department how small ALBs can be supported on large IT programmes.

3.6. Members welcomed the fact that PRISM was now being delivered, since it had been a very long journey to this point. Regarding the current error rates, members sought assurance that patients' data would remain secure and that there will be wider sharing of the lessons learned.

3.7. The Chief Executive responded that the security of register data was 100% assured through our cybersecurity measures and secure infrastructure, and that the error rates referred to data sets being submitted from clinics. It was also confirmed that there will be wider sharing of the lessons learned with our sponsors at the DHSC, our external auditors at the National Audit Office (NAO) and with other similar sized ALBs.

Decision

3.8. Members noted the Chair and Chief Executive reports.

4. Committee Chairs' reports

4.1. The Chair invited Committee Chairs to add any other comments to the presented reports.

4.2. The Licence Committee Chair (Alison Marsden) gave an update on the meetings held in November 2021 and January 2022. Members were advised that cases discussed were complex and she thanked the committee staff for their hard work.

4.3. The Statutory Approvals Committee (SAC) Chair (Jonathan Herring) reported that in addition to items approved, there were some tricky ethical and medical issues that were discussed in detail at the meeting.

4.4. The AGC Chair (Catharine Seddon) gave an update on items discussed at the meeting and welcomed the new Risk and Business Manager, Shabbir Qureshi as the December meeting was his first meeting. Authority members were reminded that the NAO led cyber security training invite was open to all members. Also, at the December meeting the committee had the opportunity to say thank you and a fond farewell to Anita Bharucha who was the Chair of the committee for a number of years.

4.5. The Scientific and Clinical Advances Advisory Committee (SCAAC) Chair (Tim Child) gave an update on items discussed at the meeting held on 31 January 2022. Members were informed that the terms of office of some members on the committee was coming to an end which meant that there were four vacancies. Interviews were scheduled to be held in March 2022 with the positions being advertised widely.

Decision

4.6. Members noted Committee Chairs' updates.

5. Performance report

5.1. The Chief Executive commented that due to the timing of this meeting we were presenting three months' worth of data. The good news was that HR1 - sickness levels had decreased, and the previous high sickness rate was not a trend.

5.2. HR2 – turnover remained high at 18%. We continue to recruit successfully to vacancies although some roles had been advertised more than once. However, from discussions with fellow Chief

Executives this was not peculiar to the HFEA as the labour market conditions were also making recruitment very difficult across the board.

5.3. In response to a question, the Chief Executive commented that further retention measures that might be possible now that we share office space with other ALBs were not yet possible due to the present situation. The gradual transition back to more office-based working may provide an opportunity to develop those links.

5.4. Also, civil service pay had been frozen for a long time and we still do not know what the pay increase might be in 2022. Should there be an increase in pay, ideally it should be fully funded by the Treasury rather than individual organisations needing to make other budget cuts to plug the pay gap themselves.

Strategy and Corporate Affairs

5.5. The Director of Strategy and Corporate Affairs presented this item. The multiple births report was recently published and thanks to the collaborative work both from the HFEA, licensed clinics and our stakeholders, the multiple birth rate was down to an average of 6% and there was an increase in success rates from fertility treatment over this time.

5.6. The Director thanked the Intelligence team for their work on using the data we hold for public use to inform policy makers, clinics, patients and researchers. She also thanked the Communications team for positively changing how the information looked on our website and social media infographics to accompany the report.

5.7. As with previous meetings, an update was given on the actions following the publication in March 2021 of the Ethnic Diversity in Fertility Treatment report. We are reviewing the patient survey results and follow-up actions would be planned where relevant with others, including our patient engagement forum. Members were advised that there were two clinic workshops coming up, one in March looking at donor availability and multiple births and in June on success rates and access to treatment. We would also be exploring whether there might be opportunities linked to the Government's forthcoming Women's Health Strategy.

5.8. The National Institute for Health and Care Excellence (NICE) are reviewing their guidelines on fertility treatment and one of the resources they will refer to is our Ethnic Diversity in Fertility Treatment report.

5.9. The work on treatment add-ons continues, which will be coming back to the Authority later in the year with proposals for evolving the presentation of the rating system and we will be discussing the evidence base with SCAAC during this year.

Compliance and Information

5.10. The Director of Compliance and Information presented to the Authority. Members were informed that the inspection team were busy with desk-based assessments in preparation for inspections. In terms of numbers, eight inspections were carried out in January, 12 are scheduled for February and 11 for March.

5.11. Members were informed that pre Covid approximately 100 inspections occurred per year. By April 2022, approximately 122 inspections will have been undertaken.

5.12. Regarding IT, members were advised that we are working to improve our security protection from ransomware and other attacks. A number of changes have already been implemented such as

further use of multi factor authentication, preventing the use of non HFEA laptops and changes to how emails can be accessed from personal devices.

5.13. It was noted that access to websites that present a technical threat to the HFEA would be blocked and that this was to prevent malware being downloaded onto HFEA laptops. Going forward, it would only be possible to access the HFEA's IT systems from within the UK. Temporary exceptions could be requested from the Information Governance Manager.

5.14. Members were advised that changes were being made to how Authority members could exchange and receive emails with the HFEA. These changes had been agreed with the Authority Chair.

5.15. On training, a session on information governance was arranged for staff in January 2022 and there was a high turnout from staff.

5.16. For the OTR service, there are currently 682 applicants waiting for information and we are currently averaging 52 new applications per month. Over the past few months, the team has been fully staffed, and we were now responding to more applications than we were receiving.

5.17. The number of OTR responses to be sent out in the next few months will increase when the Senior Donor Information Officer starts to close OTRs. Due to the amount of experience needed to be responsible for releasing Register information, there is a long lead-in period for this aspect of the role. At present the Team manager is the only one who can do the final check.

5.18. The manager is also heavily involved in the 2023 OTR service development project which is progressing.

5.19. Members will recollect that extra staff were taken on to support the OTR service as a temporary measure. The permanent posts have now been advertised and we will have four permanent members in the team very shortly.

5.20. The Chair commented that the increasing volumes of OTR had put a huge burden on the Executive but they were rising to the challenge. The Deputy Chair (Catherine Seddon) had agreed to be the lead board member providing support and assurance on this matter to the Authority.

Finance and Resources

5.21. The Director of Finance and Resources informed members that the budget was showing a significant underspend but that a lot of this resulted from non-cash costs. At present, our income position was an estimate because of the impact of the PRISM roll-out on clinics ability to submit data; once the reconciliation was done we would see the actual costs.

5.22. Members were reminded that when they approved the increasing fee to clinics it was subject to DHSC and HM Treasury approval. Both had now agreed in principle to the increase from 1 April 2022 and that a letter will be going out to licensed clinics to that effect.

5.23. The Chair thanked the Finance team for all their hard work.

Returning to the office

5.24. The Chief Executive commented that we had adopted a policy to allow office-based staff to work in the office for a minimum of one day a week. The Corporate Management Group (CMG) were

currently working on a new home working policy which the Senior Management Team would review and cascade to staff shortly. Members will be kept informed of further developments.

5.25. The Chair thanked the Chief Executive for the update and commented that there were social and cultural benefits to being in the office.

Decision

5.26. Members noted the performance report.

6. Covid-19 update

6.1. The Director of Compliance and Information presented the update.

6.2. Members were advised that just before Christmas we became aware that there was a temporary deferral of fertility treatments for unvaccinated patients in Scotland and that we were not so far aware that this policy had changed.

6.3. When centres reopened in May 2020, after the temporary suspension of licensed treatments, we asked all PRs to report any hospital admissions and all OHSS cases as an incident to the HFEA. This was because at the time it was critical that any treatment offered did not result in referrals to NHS emergency care. It was therefore important for this to be monitored.

6.4. We were also monitoring closely the impact of Covid-19 on fertility treatment rates and therefore also asked PRs to report positive Covid-19 cases.

6.5. As restrictions have eased and hospital admissions have fallen, and as treatment numbers are now at good levels, with centres managing staff absences at a local level, we felt this extra reporting burden on clinic staff was no longer required. We therefore emailed during the week commencing 7 February to tell PRs that they no longer need to do this.

Decision

6.6. Members noted the Covid-19 update.

7. Gamete and embryo storage

7.1. The Head of Policy presented this item. It was noted that the HFE Act currently sets out the storage limit as a maximum of 10 years. In 2009 the limit was extended to a maximum of 55 years, but only where a patient was or was likely to become prematurely infertile in the written opinion of a medical practitioner.

7.2. Members were advised that changes to the storage and consent regime were being considered by Parliament via amendments to the Health and Care Bill.

7.3. It was noted that over the next six months this piece of work will be a priority for a number of teams.

7.4. Members commented that they were glad that this was now on the political agenda and sought confirmation that the gametes and embryos included sperm and not just eggs.

7.5. In response to a question, members were informed that the Executive were developing guidance that will map out various storage scenarios and what steps clinics will need to take and when. However this document cannot be finalised as the amendments are still subject to the

parliamentary process. This document will be provided to clinics and would also be useful for the inspection team. We have also engaged an embryologist and an external lawyer who have both been seconded to work with us on this project and will be looking at the different consent forms.

7.6. In response to a question, the Head of Legal commented that imported gametes would also benefit from the 55-year statutory storage period, provided gamete providers had consented to that period of time and in certain circumstances Special Directions would be needed for such imports. She also noted that whilst it appears to be a relatively straightforward shift to storage for up to 55 years, the practical implementation was more complex.

7.7. Members asked what onus would be on clinics in terms of ethical considerations for longer storage. The Head of Legal responded that already the law required licensed clinics to provide relevant information to patients and the offer of counselling, prior to giving consent and that the information already needs to be tailored to the patients' needs. Our new guidance to clinics on what information needs to be provided to patients in these circumstances will need to be clear. The new provisions will require clinics to provide relevant information and the offer of counselling to patients before every renewal of consent to storage.

7.8. Members asked if clinics are likely to charge patients more for longer periods of storage and were concerned that this would increase disparity between people who could afford to pay and those who could not. Professional members commented that private clinics are likely to charge extra for longer storage, and patients who receive NHS funding for storage generally only had two or three years storage covered. Members noted that decisions around storage fees and NHS funding for storage was outside of the HFEA's remit.

7.9. It was agreed that the Executive would provide regular updates to the Authority on the progress of this work.

7.10. The Director of Strategy and Corporate Affairs commented that a collective effort had progressed the work to this stage and thanked the DHSC sponsor team colleagues for their work. PET and the Fertility Network were also thanked for their input into this campaign.

Decision

7.11. The Executive agreed to consult with Authority members to seek advice, review documents and provide input where necessary, between February and May 2022.

7.12. Approval and sign-off of key documents was delegated to the Chair for any new or revised General Direction(s), Licence conditions, guidance, and other material necessary for the implementation of the proposed amendments.

7.13. Regular updates would be shared with the Authority on the progress of this work.

8. Business planning 2022/23

8.1. The Head of Planning and Governance presented this item. Members were advised that the Corporate Management Group (CMG) met in January 2022 to consider how best we could deliver key elements of our strategy in the coming year, bearing in mind current and new pressures on our capacity.

8.2. During the discussion top priorities were identified, and also work that could be delayed or scaled down in order to ensure that the activities with the most practical and strategic benefit could be done successfully.

8.3. Members were advised that the majority of our resource would always be expended on core statutory work including:

- Inspection and licensing regime
- Opening the Register requests
- Maintaining the Register
- Information for researchers
- Annual horizon scanning and maintenance of the Code of Practice
- Information provision (including CAFC update)
- Information requests
- Fulfilling wider DHSC or healthcare system requests
- Meeting external legal requirements, for example responding to statutory information requests.

8.4. In addition to the statutory work, activities which had the highest strategic priority were also identified:

Best care

- Completing the review of the treatment add-ons traffic lights and evidence base.
- Engagement with NICE on their fertility guidelines review.

Right information

- Work following the launch, in 2021, of PRISM and our new register of treatments. This work is necessary to ensure that PRISM is fully operational for clinics, and that various internal systems that were linked to the old register, are now linked to the new register to restore full functionality.
- Linked to this, working towards a fresh publication of our CaFC data in 2022.
- Clearing the backlog of OTR requests that built up as a result of clinic closures during the first Covid lockdown, combined with increased volumes of requests.
- Reviewing our communication activities to ensure we are getting the most impact with the tools and resources we have

Shaping the future work

- Our Donor Information Service Development Project, which will help us to prepare for future, higher, levels of demand.
- Continued preparatory work to present our ideas for modernisation of the HFE Act.
- Other work relating to more imminent legislative developments, such as changes to gamete and embryo storage limits.
- A review of our fee regime (agreed previously with the DHSC and HM Treasury).

8.5. Work that had been deprioritised or scaled down included:

- The project on reducing clinic variation (although we have retained some of the intended components of that project, such as work on transparency in regulation, and work on our intelligence dashboards).
- A review of guidance on the ten-family limit – we intend to resume scoping of this work in 2023.
- Active review of donor egg availability (beyond encouraging clinics to present up to date information on the Portal).
- Large-scale work with GPs on information provision to patients – however we will do targeted work, where we are able, to improve GPs' access to information.
- Further work on our guidance for clinics on conditional donation.
- Further work on encouraging responsible innovation and ensuring clinics assess innovative treatments (apart from some already planned work on authorising new processes, which has been scheduled for the second half of the coming business year).
- Guidance and information particularly focused on partners – this had been reduced in scope to a review of our website information and social media activity. Further work in this area may however arise from the Government's Women's Health Strategy, when it is published.

8.6. In terms of the deprioritised areas, members asked about donor egg availability, particularly for ethnic minority patients and if there was any scope in reviewing the Scottish government's recent campaign. The Director of Strategy and Corporate Affairs commented that the Scottish campaign had started in the summer and we had not heard since then, but this will be followed up.

8.7. In response to a comment on the OTR service, members were advised that the counselling service was separate from the OTR service. The counselling service had a three-year contract and now that the contract was nearing its end it was being reviewed. A proposal would be brought to the Authority for consideration in the future, and meanwhile it was possible to extend the current contract pending resolution.

8.8. In terms of right information, members asked if the review of the communications activity was looking at the most effective ways of raising awareness about our work. This would also apply to the planned targeted work with GPs on access to fertility information for patients.

8.9. Members felt that it was essential that diversity and inclusion are built into our corporate DNA and our ways of working. The Chief Executive responded that when patients from black and minority ethnic groups have had inadequate experiences these could be seen as 'lead indicators' that provide insight into the wider experience of all patients.

8.10. The Chair commented specific work needed to be done around black and minority ethnic groups as it was important that we mainstream diversity and inclusion in everything we do and ensure it becomes part of our daily conversations.

8.11. Members echoed what was said and agreed that actions around diversity and inclusion should be made clear.

Decision

8.12. Members approved the draft business plan and agreed that senior staff and the Chair would reflect on the points made about diversity and inclusion.

9. Modernising fertility regulation: a plan for legislative change

9.1. The Director of Strategy and Corporate Affairs presented this item. The outline of what took place in 2021 and key plans for 2022 on how we intend to engage with key professionals, patient groups, licensed clinics in our proposals for legislative reform was discussed with the Authority.

9.2. It was noted that in 2021 we marked the 30th anniversary of the HFEA with a series of activities Including events and blogs. The events were held online due to Covid-19 restrictions.

9.3. Members were also reminded that throughout 2021 we developed our thinking about elements of the Act that were in need of modernisation to keep pace with changes in the fertility market, science and society.

9.4. The then health minister, Lord Bethell, had agreed that modernisation was needed and the HFEA should work with the DHSC on an agreed way forward. The plan in 2022 is to bring some worked-up proposals back to the Authority later this year for discussion and approval. Following this, we will then present to the DHSC a set of proposals by the end of 2022.

9.5. Members were also advised that a small expert advisory group would be set up to gather views and discuss ideas. In addition, we would undertake a mix of engagement work which would include our standing stakeholder groups and getting feedback from licensed clinics and patients.

9.6. Members raised a concern on consent being described as overly complicated. Staff confirmed that this was not a comment on the central importance of consent, but rather about the administrative complexity entailed for clinics in obtaining the correct consents from patients.

9.7. Members commented further that Authority members should be part of the stakeholder group to be consulted and agreed that republishing blogs was a good idea to maximise awareness.

9.8. In terms of the patient protection section, members asked how detailed we wanted it to be and if we would also be offering solutions. Staff responded that we would.

Decision

9.9. Members noted the outline of activities that took place during 2021 and approved plans for developing proposals for reform of the HFE Act during 2022.

10. Annual report on the Register Research Panel (RRP)

10.1. The Head of Research and Intelligence presented this item. Members were reminded that the HFEA holds a statutory Register of all patients, partners, donors, treatments and children born as a result of fertility treatment. It is believed to be the largest database of assisted reproduction treatment in the world.

10.2. The Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 state that the Authority may grant authorisation to a research establishment for the processing of disclosable protected information from the Register.

10.3. The launch of PRISM and the new Register means that there will be greater opportunities to do more with the data we hold in the longer term, with potential benefits for the efficacy of treatment and patient outcomes.

10.4. However, this causes short-term issues and members were advised that as a result, the Register Research Panel was suspended in September 2021 and only one research project was approved. However work has continued and the team has engaged with 14 new researchers and continued to develop legal and administrative processes for the panel. The backlog of previously requested data extracts was also cleared.

10.5. It was noted that the vast majority of people seeking to access the data in the register request anonymised data. This is released in our data publications and in response to parliamentary questions, Freedom of Information requests and public enquiries. An updated version of the anonymised register is now available on the HFEA website that researchers can access without applying for permission.

10.6. Post-PRISM reporting and infrastructure work is being undertaken in 2022 and as a result Fertility Trends report cannot be published this year. A report of unvalidated treatment data will be published in 2022 looking at the Covid period.

10.7. Members asked when to expect the next Fertility Trends, and the Head of Research and Intelligence responded that as soon as we had validated data, this would be possible again. It was anticipated that the next Fertility Trends will be published in the first half of 2023.

10.8. In response to the question on pending research applications, the Head of Research and Intelligence responded that we remain in conversation with all applicants and continue to encourage researchers to stay in touch with us, as a lot of preparatory work is involved before the data can be made available to the research project.

Decision

10.9. Members noted the Register Research Panel annual report.

11. Any other business

11.1. The Chair requested that every effort be made (Covid-19 restrictions permitting) to hold the Authority meeting scheduled for 23 March Authority meeting in person at the new Stratford offices.

Chair's signature

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

Signature

Chair: Julia Chain

Date: 23 March 2022

Authority meeting

Matters Arising

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science, and society		
Meeting	Authority meeting		
Agenda item	2		
Meeting date	23 March 2022		
Author	Debbie Okutubo, Governance Manager		
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 Authority meeting		
Implementation date	2022/23 business year		
Communication(s)			
Organisational risk	x Low	☐Medium	☐ High

ACTION	RESPONSIBILITY	DUE DATE	PROGRESS TO DATE
Matters arising from the Authority – actions from 7 July 2021			
5.7 PGT-M being out of target of the 75 working days	Director of Compliance and Information	July 22	This will be kept under review and will be reported to a future Authority meeting.
8.14 Fertility trends - Multiple birth – A report publishing our data on multiple births.	Head of Research and Intelligence	July 22	A paper on multiple births to be published February 2022. On track – due to be published 8 February 2022. Completed
Matters arising from the Authority meeting – actions from 23 September 2021			
5.18 Backlog on OTR	Director of Compliance and Information	March 22	Staff are gaining competence and there is a significant increase in the amount of OTRs being processed. An improved way of reporting the performance indicator is being discussed and will be introduced as an increased amount of applications in the backlog are now being worked on.
9.15 Discussion to be held with multiple birth outliers	Director of Compliance and Information	September 22	To be raised at inspection
Matters arising from the Authority meeting – actions from 9 February 2022			
7.11 The Executive to consult with members for input on gamete and embryo storage until May 2022.	Director of Strategy and Corporate Affairs	May 2022	Consultation will occur as and when required.

Chair and Chief Executive's report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	3
Meeting date:	23 March 2022
Author:	Julia Chain, Chair and Peter Thompson, Chief Executive
Annexes	N/a

Output from this paper

For information or decision?	For information
Recommendation:	The Authority is asked to note the activities undertaken since the last meeting.
Resource implications:	N/a
Implementation date:	N/a
Communication(s):	N/a
Organisational risk:	N/a

1. Introduction

1.1. The paper sets out the range of meetings and activities undertaken since the last Authority meeting in February 2022.

1.2. Although the paper is primarily intended to be a public record, members are of course welcome to ask questions.

2. Activities

2.1. The Chair has continued to engage with the decision-making functions of the Authority and with key external stakeholders, as covid restrictions allowed:

- 15 February – introductory meeting with Angela Pericleous-Smith, BICA
- 17 February – Introductory meeting with Jackson Kirkman-Brown, Birmingham Womens Clinic and Chair of ARCS
- 4 March – interview with Bloomberg; same day shortlisting of new members for SCAAC with Tim Child and Andy Greenfield
- 9 March – attended 1st meeting of the Ethnic diversity working group for donor availability and Multiple Births
- 14 March – Peter and I had introductory meeting with Fiona Fox, Science Media Centre
- 15 March – attended the Science Media week launch; on the same day also attended the CQC – Health & Care: learning from the past building for the future

2.2. The Chief Executive has continued to support the Chair and taken part in the following externally facing activities:

- 1 March – introductory meeting with Sam Roberts, CEO of NICE
- 7 March – DHSC/HFEA Quarterly accountability meeting with our sponsor team and other members of SMT
- 8 &15 March – interview panel for the Head of Communications role

- 11 March – attended launch of Public Policy Projects report ‘A Women’s Health Agenda: Redressing the Balance’
- 15 March – attended our Audit and Governance Committee meeting

Committee Chairs' reports

Details about this paper

Area(s) of strategy this paper relates to:	The best care/The right information/Shaping the future
Meeting:	Authority
Item number:	4
Meeting date:	23 March 2022
Author:	Paula Robinson, Head of Planning and Governance
Annexes	-

Output from this paper

For information or decision?	For information
Recommendation:	The Authority is invited to note this report, and Chairs are invited to comment on their Committees.
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	None
Organisational risk:	Low

1. Committee reports

1.1 The information presented below summarises Committees' work since the last report.

2. Recent committee items considered

2.1 The table below sets out the recent items to each committee:

Meetings held	Items considered	Outcomes
Licence Committee:		
2 March 2022	1 Initial Licence Application 1 Interim 1 Variation 1 Executive Update 1 Special Direction Application	The minutes from this meeting have not yet been finalised.
Other comments:	The May meeting will be our first with a largely new membership. Legal training is being arranged for the new members	
Executive Licensing Panel:		
8 February	2 Renewals 2 Interims 1 Extension of Licence 1 Change of Person Responsible 1 Executive Update	All granted/approved
22 February	2 Renewals 3 Interims 2 Change of Person Responsible 1 Executive Update	All granted/approved
8 March	3 Interims 1 Variation of Premises 1 Change of Person Responsible	All granted/approved
Other comments:	The volume of items continues to be high at most meetings.	
Licensing Officer decisions:		
	ITE Certificates - 26 Change of Centre Name - 13 Change of Licence Holder -1	All granted/approved
Other comments:	12 Care centres varied their licensed names.	

Meetings held	Items considered	Outcomes
Statutory Approvals Committee:		
27 January 2022	6 PGT-M applications 1 Special Direction application	5 PGT-Ms and Special Direction approved 1 PGT-M refused
24 February 2022	1 Mitochondrial Donation application 5 PGT-M applications 2 Special Direction applications	The minutes from this meeting have not yet been finalised
Other comments:	None.	
Audit and Governance Committee:		
15 March 2022	Main agenda items: Internal audit reports External audit interim feedback Digital projects/PRISM update Draft Annual Governance Statement Strategic risk register Resilience and business continuity management and cyber security Strategic risk deep dive – finance Implementation of IFRS16 - leases	The meeting was held the day before the Authority papers were circulated.
Other comments:	None.	
Scientific and Clinical Advances Advisory Committee:		
The next SCAAC meeting will be held on 6 June 2022.		

3. Recommendation

3.1 The Authority is invited to note this report. Comments are invited, particularly from the committee Chairs.

Effective governance

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:	Authority
Agenda item:	5
Meeting date:	23 March 2022
Author:	Debbie Okutubo, Governance Manager
Annex:	Annex 1 – Standing Orders

Output from this paper

For information or decision:	For decision
Recommendation:	• Note the annual reviews of committee effectiveness and the action points for each committee. • Agree the proposed changes to Standing Orders, effective from 1 April 2022 (vote required).
Resource implications:	In budget
Implementation date:	1 April 2022
Communication(s):	The Standing Orders are published on our website and on the staff Hub. They are also included in the standard licensing pack, which will be updated.
Organisational risk:	Low

1. Introduction

1.1. The HFEA has a number of committees established by the Act or under Standing Orders. High-quality decision-making processes are essential to maintain trust in us as a regulator and to everyone affected by fertility treatment including clinics, patients and the wider public.

1.2. This paper is intended to provide assurance over the effectiveness of the decision-making structures established by the Authority and that the activities of the HFEA are aligned with its responsibilities and objectives.

1.3. It also brings together different updates and recommendations related to the governance of the Authority, which is committed to an annual review of our governance arrangements consisting of a review of each committee's effectiveness and of standing orders.

2. Annual review of committee effectiveness

2.1. On an annual basis all committees are required to review their own effectiveness using a standard framework. Between September 2021 and January 2022 this exercise was conducted by the Licence Committee, Statutory Approvals Committee, Executive Licensing Panel and the Scientific and Clinical Advances Advisory Committee.

2.2. The National Audit Office has produced a specific effectiveness tool for Audit Committees that the Audit and Governance Committee used for its review.

2.3. The Register Research Panel was temporarily suspended in September 2021 and therefore did not carry out their annual committee effectiveness assessment this year.

2.4. Generally, the feedback from committees has been positive. The table below summarises the feedback from each committee.

Committees	Positives	Areas to note or for improvement
Audit and Governance Committee	There is constant dialogue with the external auditor which yields better understanding at meetings. Discussions have taken place with the internal auditor on proportionality and size of the organisation in relation to audit recommendations. A number of management issues are discussed at AGC meetings. PRISM exposed a lot of issues and a lessons learned exercise has been conducted.	It is worth considering the Civil Service College introductory audit training, particularly when new members join. Terms of reference to be looked at by the new Chair in terms of skills mix. Non-Authority AGC members to be sent Board papers and minutes for background. It is important that the relationship with management is such that appropriate challenge can continue to occur. 360 feedback on an anonymous basis (from both sets of auditors) would be helpful to include next year in the committee effectiveness exercise. It was also noted that the NAO is planning a revision of this form. Use of assurance mapping to be introduced gradually as resources permit. This should

Committees	Positives	Areas to note or for improvement
	The independent perspective from non-Authority members is very useful.	clarify how the areas of greatest risk are targeted by the internal auditors. (Since this review, we have commenced a programme of risk 'deep dives' to AGC.)
Licence Committee (LC)	The Chair has continued to take forward discussions regarding having further information in inspection reports and the role of precedents. Committee papers include indexing tabs, for ease of reference. New committee members should be told about this specifically to make them aware. Microsoft Teams meetings work well and the committee have developed confidence working this way since the start of the pandemic.	Consider creating a unique induction process for new LC members. For example, by observing more than one meeting and/or buddying up with existing members (in addition to legal training). Consider, where possible, expediting reports with critical non-compliances that relate directly to patient safety, to ensure they are considered by LC as quickly as possible. Licensing Manager and Committee to consider how issues noted for future discussion can be better tracked. (Since the review, a system has been set up for this.) Consider future legislative changes we could recommend to DHSC that would be helpful in licensing decisions. Consider raising such issues as part of the committee chair's updates at Authority, as this would open them up for wider discussion, and would be captured in minutes. Endeavour to retain a broad range of expertise among committee members, including research and legal expertise.
Executive Licensing Panel (ELP)	ELP works very well and is well supported. Virtual meetings to continue. Items coming to the Panel are getting more complex. Members feel that they are able to deal with these as and when they come in. New members and Head of Policy returning to the rota should help to even out the workload.	Schedule annual meeting with Chair of Licence Committee, the Director of Strategy and Corporate Affairs and the Director of Finance and Resources who both chair ELP meetings.
Statutory Approvals Committee	Meetings being held via Microsoft Teams is working well.	Ensure minutes of any private briefings are shared.

Committees	Positives	Areas to note or for improvement
	Legal and specialist/expert advisers are useful and welcomed at meetings. Having extra briefing items with relevant HFEA staff is useful, when appropriate. The amount of business is manageable for the committee and they would be happy to see more items, within the possibilities of HFEA staff resources, to ensure that patients do not have to wait unnecessarily for decisions.	The Licensing Manager is exploring the practicality of using SharePoint to approve minutes (work in progress). The Committee also suggests that Executive Summaries work best when they summarise the papers, including the application form and peer review, rather than cut and paste large sections from them.
Scientific and Clinical Advances Advisory Committee	The committee engages with the right issues, in an effective way. The committee discusses contemporary and relevant issues. The scope of the committee is very good but it could usefully include a big data scientist with knowledge of epidemiology databases and utilisation of biobanks. It is always helpful to have members of the Authority on hand to offer advice about specific regulation and due process.	There are some 'dominant narratives' that would ideally be challenged more often, but that requires more members to be prepared to challenge. The business can seem too much for some meetings and has required some truncation of discussions. There is probably the need to go back to four meetings a year or have longer meetings. Some members were of the strong opinion that at least one of the meetings should be face to face. Zoom conferencing is very time efficient but full reliance on it felt that they were missing out on collaborative working opportunities and wider conversations. Members of the Scientific and Clinical Advances Advisory Committee shall usually be appointed for a term of three years. Expert advisers may be appointed for a period of one, two or three years.
Remuneration, Appointments, Oversight committees and the Register Research Panel	*Formal reviews not undertaken due to infrequency of meetings.*	

2.5. Members are asked to note the summary of the annual reviews of committee effectiveness.

3. Review of Standing Orders

3.1. In addition to the review of committee effectiveness we are proposing several changes to Standing Orders.

3.2. The Authority is asked to review and approve the proposed changes to Standing Orders, as set out below (sections 4-8). If approved, the new Standing Orders would come into effect on 1 April 2022.

4. Appointments Committee

4.1. We currently have an Appointments Committee as one of the additional standing committees. The purpose of the Appointments Committee is to oversee the appointment of external members contributing to the work of the committees and working groups.

4.2. The membership of the Appointments committee consists of three members, the Chair, deputy Chair and the Chair of the Audit and Governance committee.

4.3. The appointment process for external members is now thorough, with the full involvement of the Chair and deputy Chair at interview and selection stages. This means two of the three members are already involved from the beginning of the recruitment process.

4.4. This makes Appointment Committee meetings essentially redundant as it means they meet only to ratify appointments that a majority of them approved previously after following a robust recruitment process.

4.5. We are therefore proposing that the current section 5 in Standing Orders - Appointments Committee, be deleted and that the Chair formally signs off all external member appointments as part of her delegated powers from the Authority, following a formal recruitment process.

4.6. The main change (other than the deletion of the terms of reference) is shown in 3.3.1(i) under particular responsibilities of the Chair of the Authority, but in addition several other paragraphs require to be edited, as follows:

- 3.3.1(i) The appointment of external members and advisers to committees or working groups, and the oversight of associated selection processes.
- 7.2.3 The Chair of the HFEA shall only appoint persons who are not Authority members to a committee or working group where it has been agreed during the recruitment and interview process that such persons are suitable for appointment.
- 7.3.3 (c) where appropriate, sign the minutes of any previous meetings with any agreed amendments that may be necessary; except in the case of the Remuneration Committee, whose minutes should be signed off by the Chair as soon as they have been agreed by members following the most recent meeting, and

4.7. Annex A – 1.5 The Authority shall maintain the following additional committees:

a) Audit and Governance Committee

b) Statutory Approvals Committee

c) Remuneration Committee

d) Scientific and Clinical Advances Advisory Committee, and

e) Oversight Committee.

5. The Statutory Approvals Committee

5.1. The Statutory Approvals Committee (SAC) currently operate from a pool of up to seven members with no more than five members attending each meeting.

5.2. We are recommending that to give the Committee more resilience, given the frequency of meetings and the time commitments entailed for members, that the committee should operate from a pool of up to 10 members with no more than five members attending each meeting going forward.

5.3. The proposed change is in section 3.4:

- The Statutory Approvals Committee shall operate from a pool of up to 10 members, with no more than five members attending each meeting.

And in the section immediately below that says 'the membership shall include':

- c) up to eight other Authority members.

5.4. A further minor change is proposed to the list of persons who will usually attend the meetings 3.11(c), simply to include the correct up to date job title of the Licensing Manager (formerly called the Senior Governance Manager).

6. Remuneration Committee

6.1. The Remuneration Committee currently consists of three members, the Authority Chair, deputy Chair and the Chair of the Audit and Governance Committee (AGC).

6.2. We are recommending that in the event that the Deputy Chair of the Authority and the Chair of the AGC are one and the same person, the Authority Chair shall appoint another Authority member to the third place on the committee.

6.3. This requires the addition of a new section 4.5:

- In the event that the Deputy Chair of the Authority and the Chair of the Audit and Governance Committee are the same person, the Chair of the Authority shall appoint another Authority member to the third place on the Committee.

7. Scientific and Clinical Advances Advisory committee (SCAAC)

7.1. During the current and next calendar year, there will be a change in membership on the committee.

7.2. To enable this be managed and to ensure a good skill mix it is proposed that expert advisers of SCAAC be appointed for a maximum of two terms, with a term lasting for one, two or three years.

7.3. Authority members on SCAAC remain as appointed by the HFEA Chair.

7.4. The changes proposed would be reflected in paragraph 6.7 in the original document, which will become 5.7 if the above removal of the Appointments Committee is agreed:

- Members of the Scientific and Clinical Advances Advisory Committee shall usually be appointed for a term of three years. Expert advisers may be appointed for a maximum of two terms, with a period of one, two or three years.

8. Licence Committee

8.1. The current terms of reference of the Licence Committee, set out in Annex D of Standing Orders, prevents most staff from observing a Licence Committee meeting. This makes it difficult for new inspectors and some other staff whose work involves directly or indirectly supporting licensing matters to gain first-hand experience and insight into the Licence Committee's needs and processes.

8.2. For this reason we are recommending that the limitations of paragraph 5.3 of Annex D be eased slightly so as to allow new inspectors and those with other relevant roles to observe a meeting of the committee as part of their induction into the organisation, or if needed for training purposes.

8.3. The proposed changes below are in paragraph 5.3 of Annex D:

- Members of the Licence Committee, or employees who have been appointed to the Executive Licensing Panel, members of the inspectorate requiring induction or training, or those with other relevant roles, may attend a meeting of the committee as observers, as part of their induction or training. However, such observers shall not take any part in the discussion or deliberation of the committee and are not entitled to vote.

9. Recommendation

9.1. The Authority is asked invited to:

- Note the feedback from the annual reviews of committee effectiveness and the action points for each committee
- Approve by a majority vote, revised Standing Orders (see section 1.3 in Standing Orders), to come into effect from 1 April 2022.

Human Fertilisation & Embryology Authority

Annex 1

Standing orders

From 1 April 2022~~1~~

Version control

Reviewed and approved by Authority on 9 December 2009.

Amendments approved by Authority on 20 January 2010 and 12 May 2010.

Typographical corrections made on 4 August 2010

Reviewed and amendments approved by Authority via written resolution (issued 12 November 2010) and decision noted at Authority meeting on 8 December 2010.

Reviewed and amended in light of new equalities legislation and approved by Authority on 23 March 2011.

Reviewed, amended and approved by Authority on 7 December 2011.

Amendments approved by Authority on 12 September 2012.

Amendments approved by Authority on 23 January 2013.

Reviewed, amended and approved by Authority on 20 March 2013.

Amendments approved by Authority on 13 November 2013.

Reviewed, amended and approved by Authority on 5 March 2014.

Reviewed, amended and approved by Authority on 11 March 2015.

Reviewed, amended and approved by Authority on 17 September 2015.

Reviewed, amended and approved by Authority on 9 March 2016.

Reviewed, amended and approved by Authority on 15 March 2017.

Reviewed, amended and approved by Authority on 14 March 2018.

Reviewed, amended and approved by Authority on 30 January 2019.

Reviewed, amended and approved by Authority on 24 March 2021.

Reviewed, amended and approved by Authority on 23 March 2022 [if approved].

Contents

5: Reservation of powers to the Authority

6: Arrangements for the exercise of functions by delegation

7: Committees, working groups and advisory groups

8: Sealing and execution of documents

Foreword[1]

1. The Human Fertilisation and Embryology Authority (HFEA) is an executive non-departmental public body sponsored by the Department of Health. The HFEA is a body corporate, established by Section 5 of the Human Fertilisation and Embryology Act 1990 (as amended) (the Act). In accordance with Schedule 1 to that Act, the Chair and members of the Authority are appointed by the Secretary of State for Health.
2. The HFEA is the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos. The HFEA sets standards for, and issues licences to, centres. It provides authoritative information for the public, in particular for people seeking treatment, donor-conceived people and donors. The HFEA determines the policy framework for fertility issues, which are sometimes ethically and clinically complex.
3. The HFEA is committed to adopting best practice in corporate governance. These standing orders form part of the corporate governance framework with which the HFEA must comply, and which includes:
    - the Act
    - regulations issued by the Secretary of State for Health or the HFEA
    - the framework agreement between the HFEA and the Department of Health, or any other memorandum of understanding (MoU) or other agreement
    - standing financial instructions adopted by the HFEA, and
    - financial procedures for procurement and payment of goods and services, budget management and travel and subsistence.
4. As a public body, the HFEA is also required to comply with applicable legislation including that relating to human rights, equalities, freedom of information, environment information and data protection; and with relevant government policies on information assurance and data security. In addition, the HFEA is expected to comply with the statutory code of practice for regulators ('The regulators' code').
5. In accordance with the Act (under Section 8) the HFEA shall:
    i. keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this act, and advise the Secretary of State, if he/she asks it to do so, about these matters
    ii. publicise the services provided to the public by the HFEA or provided in pursuance of licences
    iii. provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use for the purpose of activities governed by the Act, or may wish to do so
    iv. maintain a statement of the general principles which it considers should be followed in the carrying–on of activities governed by the Act, and in the carrying-out of its functions in relation to such activities
    v. promote, in relation to activities governed by this act, compliance with requirements imposed by or under this act, and the Code of Practice under Section 25 of the Act, and
    vi. perform such other functions as may be specified in regulations.

[1] This foreword is not part of the standing orders.

6. In accordance with the Act (under Section 8ZA) the HFEA must carry out its functions effectively, efficiently and economically and, so far as relevant, have regard to the principles of best regulatory practice.
7. These standing orders take account of the relevant Cabinet Office guidance for public bodies which is intended to secure the public service values of impartiality, integrity, objectivity, openness and accountability, and to ensure that value for money is optimised.
8. These standing orders primarily govern the procedures for meetings of the Authority and the committees established by the Authority.
9. In the conduct of operational activities, Authority members and employees are also expected to comply with the HFEA's published principles and policies approved by the Authority and employees of the HFEA are, in addition, expected to comply with the requirements set out in the employee handbook.

Standing orders

Current version 1 April 2022~~1~~

1. Use of standing orders

1.1. Power to make standing orders

1.1.1. These standing orders are made in accordance with the powers of the HFEA:

a) under paragraph 9 of Schedule 1 to the Act, to regulate its own proceedings and to make such arrangements as it considers appropriate for the discharge of its functions, and

b) under section 9A of the Act, to establish committees and to delegate functions to committees, Authority members and employees.

1.1.2. These standing orders shall govern the proceedings of the Authority and its committees and working groups.

1.2. Commencement

1.2.1. These standing orders were adopted by the Authority at its public meeting on 9 December 2009, and first came into force on 1 January 2010.

1.3. Variation and amendment of standing orders

1.3.1. These standing orders can be amended by the Authority, provided that:

- a notice of motion has been given, and
- no fewer than half of the Authority members at the meeting vote in favour of amendment, and
- at least two-thirds of the Authority members are present, and
- the variation proposed does not contravene any statutory provision, or a direction made by the Secretary of State.

1.4. Standing orders to be given to Authority members, committee members and officers

1.4.1. It shall be the duty of the Chief Executive to ensure that:

a) existing Authority members, committee members and officers and all new appointees are provided with a copy of these standing orders and informed of their obligation to comply with these standing orders; and

b) a copy of these standing orders is published on the Authority's website.

1.5. Non-compliance with standing orders

1.5.1. All Authority members, committee members, officers and employees shall have a duty to disclose any non-compliance with these standing orders to the Chair of the HFEA or Chief Executive.

1.5.2. If for any reason these standing orders are not complied with, details of the non-compliance and any justification for non-compliance shall be reported to the next formal meeting of the Authority for action or ratification.

1.6. Review of standing orders

1.6.1. These standing orders shall be reviewed at least annually by the Authority. The scope or extent of such a review can be agreed in advance by the Chair, with input from the executive and committee chairs, where relevant.

2. Interpretation

2.1. Role of Chair of the Authority

2.1.1. The Chair of the HFEA shall be the final authority on the interpretation of these standing orders.

2.2. Definition of terms

2.2.1. The following terms are used in these standing orders:

'The Act' means the Human and Fertilisation and Embryology Act 1990 (as amended).

'Adviser' means persons appointed to provide advice to the Authority, its committees or working groups.

'Advisory group' means a group of persons appointed to provide advice to the Authority, its committees or working groups.

'Chair of the HFEA' means the person appointed by the Secretary of State for Health to chair the HFEA and shall be deemed to include the Deputy Chair of the Authority, if the Chair is absent from the meeting or is otherwise unavailable.

'Chief Executive' means the person appointed by the HFEA to act as Chief Officer and Accounting Officer of the Authority.

'Committee' means a committee established by the HFEA (under s.9A(2)of the Act).

'Committee members' means persons formally appointed by the Chair of the HFEA to sit on or to chair specific committees.

'Corporate Management Group' (CMG) means the executive management group established by the Chief Executive for effective management of the HFEA.

'Deputy Chair of the HFEA' means the HFEA member appointed by the Secretary of State to take on the Chair's duties if the Chair of the HFEA is absent for any reason.

'Lay member' means a member of the Authority, who is not, nor has been:

- a medical practitioner registered under the Medical Act 1983,
- concerned with keeping or using gametes or embryos outside the body, or
- directly concerned with commissioning or funding any research involving such keeping or use, or actively participated in any decision to do so.

'Officer' means a member of the CMG.

'Secretary of State' means the Secretary of State for Health.

'Working group' means a non-standing committee of the HFEA, established and maintained for a specific purpose.

'Working group members' means persons formally appointed by the Chair of the HFEA to sit on or to chair specific working groups.

3. The Authority

3.1. Responsibilities of Authority members

3.1.1. Authority members shall, at all times, act in accordance with the provisions of the Act and with the provisions of the Code of conduct for Authority members annexed to these standing orders.

3.1.2. Authority members shall not give the Chief Executive instructions which conflict with his/her duties as the Authority's accounting officer.

3.1.3. No Authority member shall solicit for any person any appointment as a member or employee of the Authority, or recommend any person for such appointment.

3.1.4. Authority members shall, as soon as possible, disclose to the Chief Executive any relationship between them and a candidate of whose candidature they become aware. It shall be the duty of the Chief Executive to report to the Authority any such disclosure made.

3.1.5. Authority members shall, in the conduct of Authority business, have regard to the functions and duties of the Authority set out in sections 8 and 8ZA of the Act.

3.1.6. Authority members shall, in the conduct of Authority business, comply with all relevant legislation applying to public bodies and with government policies on information assurance and data security. In addition, Authority members shall have proper regard to the principles set out in the statutory code of practice for regulators ('The regulators' code').

3.1.7. Authority members shall ensure that the financial transactions of the Authority are carried out in accordance with the standing financial instructions and other financial procedures adopted by the Authority.

3.1.8. The Authority shall appoint an Authority member to act as equality champion, who will promote compliance with equalities legislation and from time-to-time report to the Authority on it.

3.2. Responsibilities of Authority members, committee members and employees

3.2.1. In the conduct of operational activities, Authority members and employees shall comply with applicable policies approved by the HFEA.

3.2.2. Authority members, committee members and employees shall ensure compliance with the financial procedures for procurement and payment of goods and services, budget management and travel and subsistence adopted by the Authority.

3.3. Particular responsibilities of Chair of the Authority

3.3.1. The Chair of the HFEA shall in addition to the responsibilities shared by all Authority members have particular responsibility for:

a) approving the agenda for meetings of the Authority

b) chairing meetings of the Authority

c) signing minutes of Authority meetings

d) briefing Authority members

e) ensuring that these standing orders are complied with

f) the appraisal of Authority members

g) the appraisal of the Chief Executive

h) the appointment of members to committees or working groups

~~h)~~i) the appointment of external members and advisers to committees or working groups, and the oversight of associated selection processes

~~i)~~j) taking decisions on litigation

~~j)~~k) ensuring a log of whistle blowing incidents is maintained

~~k)~~l) liaison with the Secretary of State for Health and other relevant Ministers on behalf of the Authority

~~l)~~m) representing the HFEA to the public, and

~~m)~~n) issuing 'Chair's letters' to licensed centres setting out changes of policy, the issuing of new directions under the Act, or any other important messages.

3.3.2. The Chair of the HFEA may consult with two or more Authority members as appropriate before discharging the particular responsibilities set out above or before undertaking any action on behalf of the Authority.

3.4. Particular responsibilities of Deputy Chair of the Authority

3.4.1. Where the Chair of the HFEA has died or has ceased to hold office, or where he/she has been unable to perform his/her duties as Chair owing to illness, absence from the UK or any other cause, the Deputy Chair shall act as chair until a new Chair is appointed or the existing Chair resumes his/her duties, as the case may be; and reference to the Chair in these standing orders shall, so long as there is no Chair able to perform his/her duties, be taken to include references to the Deputy Chair.

3.5. Particular responsibilities of the Chief Executive

3.5.1. The Chief Executive is the HFEA's designated accounting officer and, as such, is accountable to Parliament and the Secretary of State for:

a) safeguarding the public funds for which he/she has been charged

b) handling those public funds, ensuring propriety and regularity when doing so

c) day-to-day operations and management of the HFEA.

3.5.2. The Chief Executive shall establish the Corporate Management Group to ensure:

a) effective management of the HFEA's business and operational activities

b) achievement of the HFEA's strategic and statutory objectives

c) continuous improvement within the HFEA, and

d) monitoring of compliance with applicable legislation, and oversight of executive working groups on particular subjects.

3.5.3. The Chief Executive shall determine the membership and terms of reference of the Corporate Management Group.

3.6. Registers of interests and hospitality

3.6.1. The HFEA shall maintain and publish a register of interests and a register of hospitality, formally to record declarations of Authority members and employees.

3.7. Declarations of interest and potential conflicts

3.7.1. At every meeting of the Authority or of a committee, members shall be required to declare any interests they may have.

3.7.2. Authority members and committee members shall identify any potential conflicts as soon as possible after receipt of papers in advance of any meeting of the Authority or of a committee.

3.7.3. Where a potential for a conflict of interests is identified, Authority members and committee members shall consult and follow the 'Guidance for Authority and committee members on handling conflicts of interest'.

3.8. Access to external legal advice by Authority members

3.8.1. All external legal advice must usually be commissioned through the Authority's legal advisers and no advice can be commissioned without the approval of the Chair of the HFEA or the Chief Executive.

3.9. Register of policies

3.9.1. The Authority shall maintain a register of all policies approved by it and relating to the effective running of the Authority, and shall review all such policies at regular intervals.

4. Meetings

4.1. Ordinary meetings

4.1.1. Members of the Authority shall usually meet as a full Authority no fewer than six times in each calendar year, and such meetings shall be held at such intervals and venues as the Chair may determine.

4.1.2. All ordinary meetings of the Authority will be open to members of the public to attend.

4.1.3. All ordinary meetings may begin with a private session of the Authority (which may, at the Chair's discretion, be attended by officers, advisers, auditors or Department of Health representatives), at which may normally be discussed:

a) any legal update

b) any commercially sensitive matters, and

c) any other business that the Chair judges is reasonable to be conducted in private.

4.2. Extraordinary meetings

4.2.1. In addition to the fixed ordinary meetings, extraordinary meetings of the Authority may be called:

a) at any time by the Chair, and

b) subject to paragraph 4.2.2, at the request of any Authority member.

4.2.2. An extraordinary meeting requested by an Authority member shall only be held if:

a) the request is made in writing to the Chair of the Authority, specifying the item(s) to be considered at the meeting

b) the written request is signed by at least one-third of the Authority members, and

c) the written request sets out the need for an extraordinary meeting and the reason why the matters to be considered should not be considered at the next ordinary meeting of the Authority.

4.2.3. It will be for the Chair to decide whether the extraordinary meeting is held in public or in private.

4.3. Written resolutions

4.3.1. A written resolution shall be as valid and effectual as if it had been passed at a full meeting of the Authority provided that:

a) the resolution is circulated by email to all Authority members

b) Authority members shall have at least three days to respond to the resolution

c) no fewer than one-third of the Authority members respond, and

d) the majority of those responding are in favour of, and approve, the resolution.

4.4. Notice of meetings and written resolutions

4.4.1. Other than in exceptional circumstances, the Chair of the HFEA shall notify Authority members of the dates of the ordinary meetings of the Authority in any calendar year at least one month before the beginning of that year.

4.4.2. Failure to serve notice on any Authority member shall not affect the validity of an ordinary meeting.

4.4.3. The Chair of the HFEA shall notify Authority members of the date of an extraordinary meeting or written resolution to be considered by the Authority and shall provide Authority members with such notice as is reasonable in the circumstances.

4.5. Agendas

4.5.1. The Chair of the Authority, in consultation with the Chief Executive, shall determine the agenda for all meetings of the full Authority.

4.5.2. An Authority member desiring a matter to be included on an agenda shall make his/her request to the Chair at least 10 working days before the meeting, and should include appropriate supporting information. Requests made less than 10 days before a meeting may be included on the agenda at the discretion of the Chair.

4.5.3. Papers may be tabled at a meeting of the full Authority only with the permission of the Chair and no business other than that set out in the agenda shall be considered at a meeting of the Authority, except where the Chair considers that the nature or urgency of the matter is such that it would be desirable to consider the matter at that meeting.

4.5.4. Agenda items which are not considered at a meeting may be carried forward for consideration at an appropriate later ordinary meeting, or at an extraordinary meeting.

4.6. Distribution of papers

4.6.1. The Chief Executive shall endeavour to ensure that agendas and supporting papers (where possible) are sent to Authority members in good time before an Authority meeting, and shall usually send out such papers five working days before the meeting.

4.6.2. Agendas and papers may be distributed by such method as the Chief Executive considers appropriate, including by email.

4.6.3. Agendas and papers for a meeting, including those sent by email, shall be deemed to have been received on the day following the day they were sent.

4.6.4. Provided that the agenda and/or papers for a meeting have been sent to Authority members in accordance with this standing order, their non-receipt by any Authority member shall not invalidate the business transacted at that meeting.

4.6.5. Papers for consideration by the full Authority or by a committee shall be presented in the standard template approved by the Chief Executive.

4.6.6. The papers considered by Authority members at a meeting of the Authority and the minutes of the meetings of the Authority shall be published in accordance with the

HFEA's policy on the publication of Authority and committee papers and shall be made available to the public in accordance with the HFEA's publication scheme and the Freedom of Information Act 2000.

4.7. Chair of meeting

4.7.1. At any meeting of the Authority, the Chair, if present, shall preside. If the Chair is absent from the meeting, the Deputy Chair shall preside. If the Chair and Deputy Chair are absent, such Authority member as the Authority members present shall choose, shall preside.

4.7.2. If the Chair of the HFEA is absent temporarily or is disqualified from participating on the grounds of a declared conflict of interest, the Deputy Chair, if present, shall preside. If the Chair and Deputy Chair are absent, or are disqualified from participating, such Authority member as the Authority members present shall choose, shall preside.

4.7.3. The decision of the Chair of the meeting on questions of order, procedure, relevancy, regularity and any other matters shall be final.

4.8. Quorum

4.8.1. No business shall be transacted at a meeting unless at least one third of the Authority members are in attendance at that meeting.

4.8.2. At the discretion of the Chair, Authority members may attend meetings of the Authority by telephone or video-conferencing.

4.8.3. In determining whether or not there is a quorum, the Chair shall take into account the provisions of section 4 (4) of Schedule 1 of the Act regarding the composition of the Authority. If the quorum comprises a majority of non-lay Authority members, the Chair of the HFEA may decide that a particular vote or decision cannot be taken. The decision of the Chair on such matters is final.

4.8.4. Any Authority member (including the Chair of the Authority) who has been disqualified from participating in the discussion on any matter and/or from voting on any question by reason of the declaration of a conflict of interest shall no longer count towards the quorum. If a quorum is then not available for the discussion and/or the decision on any matter, that matter may not be discussed further or voted upon at that meeting. Such a position shall be recorded in the minutes of the meeting.

4.9. Voting

4.9.1. The Authority shall usually seek to achieve consensus on issues requiring a decision by the Authority members.

4.9.2. Where the Chair determines that a vote is necessary, the nature of that vote shall be at the discretion of the Chair, and may be by oral expression or show of hands or by paper ballot if a majority of the Authority members present so request.

4.9.3. Only those Authority members (including the Chair of the Authority) actually in attendance at the time that a vote is to be taken shall be entitled to vote. Voting by proxy is not permitted.

4.9.4. Where a vote is held, the issue shall be decided by a majority of the votes of the Authority members who are in attendance at the meeting (including the Chair of the Authority) and who have not been disqualified from participating in the decision by reason of any declared conflict of interest.

4.9.5. In the event of the number of votes for and against a motion being equal, the Chair of the meeting shall have a second or casting vote.

4.10. Minutes

4.10.1. The proceedings of every meeting of the Authority shall be formally recorded. The recording shall be made available on the Authority's website as soon as is reasonably practicable.

4.10.2. The Chief Executive shall ensure that an employee is present at every meeting of the Authority to act as secretary to that meeting and to produce the minutes of the meeting.

4.10.3. The names of the Chair and Authority members present at the meeting shall be recorded in the minutes.

4.10.4. The minutes shall not usually record:

a) the names of individual Authority members who made specific comments, contributions or suggestions at a meeting, or

b) the vote (or abstention) of individual Authority members.

4.10.5. If an Authority member so requests, his/her vote or the fact that he/she abstained from participating in a discussion or voting on any matter, shall be recorded in the minutes.

4.10.6. The draft minutes of the proceedings of a meeting of the Authority shall be drawn up and submitted for agreement by the Authority members at the next meeting, and the person chairing that meeting shall sign the minutes with any agreed amendments which may be necessary.

4.11. Attendance by officers and auditors

4.11.1. The following persons shall be entitled to attend all meetings of the Authority and to bring any matter to the attention of the Authority members:

a) Chief Executive

b) Corporate Management Group

c) internal auditors, and

d) external auditors.

4.12. Attendance of non-Authority members

4.12.1. Observers from the Department of Health and employees of the Authority may attend ordinary meetings of the Authority.

4.12.2. At any meeting of the Authority, the Chair may require persons who are not Authority members (including members of the public, officers, other observers, and employees) to withdraw for any part of a meeting, if the Chair considers it desirable for the Authority members to meet in private or in the absence of some of those present.

4.12.3. The Chair of the HFEA may require any person whose presence the Chair considers to be disruptive to the proceedings to withdraw from the meeting.

4.12.4. The Chair of the HFEA may invite such persons as he or she considers desirable to attend a meeting of the Authority and to advise the Authority members on any matter on the agenda for that meeting.

5. Reservation of powers to the Authority

5.1. List of reserved matters

5.1.1. The following matters shall be reserved to the Authority and shall not be delegated:

a) appointment of the Chief Executive, with the approval of the Secretary of State

b) disciplinary action against the Chief Executive

c) approval and amendments of standing orders

d) establishing of committees and working groups

e) agreement of the terms of reference and reporting arrangements of committees and working groups

f) receiving reports from committees, working groups and individual members

g) the appointment of HFEA representatives on external bodies

h) approving the strategic aims of the HFEA

i) approving the HFEA's corporate strategy or any equivalent documentation required by the Department of Health

j) approving the HFEA's annual business plan

k) approving the annual budget

l) approving the annual report and accounts

m) (in consultation with the Department of Health and the Treasury) approving the structure and level of fees levied on licence holders and applicants for licences

n) monitoring of the HFEA's performance against the strategy, the annual business plan and the budget

o) determination of all policies relating to the performance of the HFEA's functions under Section 8 of the Act

p) consideration of all proposed updates to the Code of Practice and general directions, while retaining the power to delegate revisions where necessary, provided this is done in accordance with paragraph 6.6 of Standing Orders

q) ratification of any urgent decisions taken by the Chair in accordance with section 5.2 of these standing orders.

5.2. Emergency powers of Chair and Chief Executive

5.2.1. The powers which the Authority has reserved to itself in paragraph 5.1 may, in an emergency, be exercised by the Chair of the HFEA and the Chief Executive.

5.2.2. An emergency is any situation in which decisions or actions are required and such decisions or actions cannot be postponed until the next ordinary meeting of the Authority.

5.2.3. The Chair of the HFEA shall, before exercising emergency powers under this section, make best endeavours to obtain the views of Authority members on the required decision or action.

5.2.4. The Chair of the HFEA may, alternatively, form a sub-group of members to make decisions outside the cycle of meetings in the event of urgent or business critical issues arising.

5.2.5. The exercise of emergency powers by the Chair of the HFEA and the Chief Executive shall be reported to the next meeting of the Authority, and may be ratified by the Authority members.

6. Arrangements for the exercise of functions by delegation

6.1. Power to delegate

6.1.1. The matters below are delegated in accordance with section 9A of the Act.

6.2. Litigation

6.2.1. Decisions on litigation against or on behalf of the HFEA shall be delegated to the Chair of the HFEA.

6.2.2. Before making a decision on litigation, the Chair of the HFEA may consult with the Deputy Chair of the HFEA and the Chair of the Audit and Governance Committee, or where appropriate, with two other Authority members.

6.2.3. Subject to 6.2.4 below, the Chair of the HFEA shall ensure that Authority members are regularly updated on key decisions and stages reached, in respect of litigation affecting the HFEA.

6.2.4. Where the Chair of the HFEA considers that it would be inappropriate to update Authority members on litigation issues because there are associated matters that are yet to be determined by a committee of the HFEA, including licence applications, the Chair may defer updating Authority members until the associated matters are determined by the relevant committee.

6.3. Licensing functions

6.3.1. The HFEA shall establish the role of Licensing Officer. The HFEA delegates to the Licensing Officer (who shall be an HFEA employee, a member of the Executive Licensing Panel and be appointed by the Chief Executive):

a) the exercise of certain administrative licensing functions, as set out in annex B to these standing orders and amended from time to time by the Authority.

6.3.2. The HFEA shall establish and maintain an Executive Licensing Panel. The HFEA delegates to the Executive Licensing Panel:

a) the exercise of certain routine licensing functions (including those delegated to the Licensing Officer), as set out in annex B to these standing orders and amended from time to time by the HFEA, and

b) the power to issue directions under sections 24(5A) to (5E) and section 24(13) of the Act.

6.3.3. The Executive Licensing Panel shall be constituted and shall operate in accordance with the Executive Licensing Panel protocol set out in annex C to these standing orders.

6.3.4. In accordance with Section 9A(2) of the Act, the HFEA shall establish and maintain a Licence Committee which will include Authority members and such additional committee members as the HFEA considers necessary.

6.3.5. The HFEA delegates to the Licence Committee:

a) the exercise of its complex or controversial licensing functions (but also including those delegated to the ELP and Licensing Officer), as set out in annex B to these standing orders as amended from time to time by the HFEA, and

b) the power to issue directions under sections 24(5A) to (5E) and section 24(13) of the Act.

6.3.6. Save when considering representations under Section 19(4) of the Act, the Licence Committee shall be constituted and shall operate in accordance with the Licence Committee protocol set out in annex D to these standing orders.

6.3.7. When considering representations under Section 19(4) of the Act, the Licence Committee shall be constituted and shall operate in accordance with the Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009 (as amended).

6.4. Reconsideration of licensing decisions

6.4.1. In accordance with section 20A of the Act, the HFEA shall establish and maintain an Appeals Committee.

6.4.2. The HFEA delegates to the Appeals Committee the power to carry out its functions under section 20 of the Act.

6.4.3. The Appeals Committee shall be constituted and shall operate in accordance with the Human Fertilisation and Embryology (Appeals) Regulations 2009.

6.5. Disclosure of information for research purposes

6.5.1. The HFEA shall establish and maintain:

a) a Register Research Panel

b) a Register Research Review Panel, and

c) an Oversight Committee

to exercise the Authority's functions under the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010.

6.5.2. The Authority delegates to the Register Research Panel, the power to:

a) authorise access to Register data for the purposes of medical or non-medical research, and

b) deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.

6.5.3. The Authority delegates to the Register Research Review Panel, the power to:

a) uphold or overturn the decisions of the Register Research Panel

b) authorise access to Register data for the purposes of medical or non-medical research, and

c) deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.

6.5.4. The membership, functions, and arrangement for meetings of the Register Research Panel; Register Research Review Panel; and the Oversight Committee, shall be as set out in annex A to these standing orders.

6.6. Delegation of amendments to the Code of Practice, General Directions and other guidance

6.6.1. The HFEA may agree from time to time to the delegation of revisions to the Code of Practice and general directions.

6.6.2. The terms of reference of such delegations shall be approved by Authority members at meetings of the Authority, and the minutes of that meeting shall record the matters delegated by the HFEA.

6.7. Delegation to other committees, working groups and individual members

6.7.1. The HFEA may agree from time to time to the delegation of functions and powers to other committees, sub-committees, working groups, or individual members.

6.7.2. The constitution and terms of reference of these committees, sub-committees or working groups, and their specific delegated powers and those of any individual member shall be approved by Authority members at meetings of the Authority, and the minutes of such meetings shall record the matters delegated by the Authority.

6.8. Delegation to officers

6.8.1. Those functions of the Authority, which have not been reserved by the Authority or delegated to the Chair (in Section 5 of these standing orders); or delegated to a committee, working group, panel, or officer (in Section 6 of these standing orders), shall be exercised by the Chief Executive on behalf of the Authority.

6.8.2. The Chief Executive shall determine which functions he/she will perform personally and shall nominate officers or other employees, as appropriate, to undertake the remaining functions for which he/she will retain accountability to the Authority.

6.8.3. The Chief Executive shall report periodically to the Authority on the exercise of powers so delegated.

7. Committees, working groups and advisory groups

7.1. Power to establish committees and working groups

7.1.1. In accordance with section 9A(2) of the Act, the Authority shall establish and maintain the committees set out in annex A to these standing orders.

7.1.2. In accordance with paragraph 9 of schedule 1, the Authority may from time to time, establish working groups of Authority members and other members as deemed necessary by the Authority.

7.1.3. A proposal to establish a working group shall identify the purpose of the group, the likely budget and employee resources needed; the outputs required of the group, and the timeframe for which the group shall exist.

7.1.4. The Chief Executive shall ensure that a person is appointed to act as secretary to each Committee or working group and to take the minutes of each meeting.

7.2. Membership of committees and working groups

7.2.1. This paragraph does not apply to the Appeals Committee.

7.2.2. The Chair of the HFEA shall appoint the Chair of a Committee, committee members and the Chair and members of working groups established by the Authority.

7.2.3. The Chair of the HFEA shall only appoint persons who are not Authority members to a committee or working group where ~~the Appointments Committee~~ it has been agreed during the recruitment and interview process that such persons are suitable for appointment ~~to a committee~~.

7.2.4. The remuneration for persons who are not Authority members but who have been appointed as a committee or working group member shall be as agreed from time to time with the Department of Health.

7.2.5. The terms of office for members of committees or working groups shall be decided by that committee or working group's Chair, but shall not normally be for more than three years.

7.3. Conduct of meetings of committees and working groups

7.3.1. This paragraph does not apply to meetings of the Licence Committee, Executive Licensing Panel or Appeals Committee.

7.3.2. Subject to paragraph 7.3.3 and 7.3.4 below, and in accordance with paragraph 9 of schedule 1 to the Act, committees and working groups established by the Authority may regulate their own proceedings.

7.3.3. The Chair of the committee or working group shall at each meeting:

a) inquire whether any committee or working group member has any interests to declare, and if so, ensure that such interests are recorded

b) where potential conflicts are identified, ensure that the committee or working group refers to and follows the 'Guidance for Authority and committee members on handling conflicts of interest'

c) where appropriate, sign the minutes of any previous meetings with any agreed amendments that may be necessary; except in the case of the Remuneration ~~and Appointments~~ Committee~~s~~, whose minutes should be signed off by the Chair as soon as they have been agreed by members following the most recent meeting, and

d) ensure that the proceedings of the committee or working group comply with the terms of reference and delegated powers set out in Annex A to these standing orders or established by the Authority.

7.3.4. With the permission of the Chair of the committee or working group, committee members may participate in a meeting by the use of telephone- or video-conferencing facilities, or other appropriate means.

7.4. Distribution of agenda and papers

7.4.1. The committee secretary shall send the agenda and papers to all committee or working group members in good time before the meeting, and usually no less than five working days before the meeting.

7.4.2. Papers shall be distributed by such method as is determined by the committee Chair.

7.5. Minutes of meetings

7.5.1. Paragraph 4.10 of these standing orders shall apply with appropriate modifications.

7.6. Publication of papers

7.6.1. The minutes of the meetings of committees shall be published in accordance with the HFEA's policy on the publication of Authority and committee papers and shall be made available to the public in accordance with the HFEA's publication scheme and the Freedom of Information Act 2000.

7.7. Advisers and advisory groups

7.7.1. The Authority delegates to the Chief Executive and his/her Senior Management Team the power to appoint advisers or advisory groups to support committees or working groups, and to determine remuneration necessary (if any) for those appointees.

8. Sealing and execution of documents

8.1. Application of seal

8.1.1. The application of the Authority's seal shall be authenticated by the signature of the Chair or Deputy Chair of the Authority.

8.2. Signing of documents

8.2.1. The following Authority members and officers shall be authorised to sign deeds or other documents on behalf of the Authority:

a) Chair of the Authority

b) Deputy Chair of the Authority

c) Chief Executive, and

d) Members of the Corporate Management Group.

8.3. Signing of contracts

8.3.1. Officers and employees shall be authorised to sign contracts on behalf of the Authority in accordance with the authorised delegations for ordering goods and services set out in the financial procedures approved by the Authority.

Standing orders: Annex A

Standing committees and additional committees established by the Authority and their terms of reference

1. Standing committees of the Authority

1.1. The Authority shall maintain the following standing committees concerned with licensing:

a) Licence Committee, and

b) Appeals Committee.

1.2. The membership and procedures of the Licence Committee (other than when considering representations made under section 19(4) of the Human Fertilisation and Embryology Act 1990) are set out in the 'Protocol for the conduct of meetings of the Licence Committee' (Annex D to the Authority's standing orders).

1.3. The membership and procedures of the Licence Committee when considering representations made under section 19(4) of the Human Fertilisation and Embryology Act 1990 are set out in the Human Fertilisation and Embryology (procedure for revocation, variation or refusal of licences) regulations 2009 (as amended).

1.4. The membership and procedures of the Appeals Committee are set out in the Human Fertilisation and Embryology (appeals) regulations 2009.

1.5. The Authority shall maintain the following additional committees:

a) Audit and Governance Committee

b) Statutory Approvals Committee

c) Remuneration Committee

~~d) Appointments Committee~~

~~e)~~d) Scientific and Clinical Advances Advisory Committee, and

~~f)~~e) Oversight Committee.

1.6. A report of the activities of the non-licensing standing committees shall be presented to every ordinary meeting of the Authority (if they have met since the last Authority meeting), and presentation of such reports shall be a standing item on the agenda for all ordinary Authority meetings.

1.7. All the Authority's additional standing committees may:

a) receive expert advice where the committee Chair considers that such advice would assist the committee in its deliberations, and

b) sit with a legal adviser in attendance and may allow the legal adviser to remain with the committee during any private deliberations.

1.8. Where an issue is considered by a committee across several meetings, the validity of the proceedings of that committee shall not be affected by reason only that members of that committee,

a) who were in attendance at a former meeting were not in attendance at a later meeting of the committee, or

b) who were not in attendance at a former meeting of the committee are in attendance at a later meeting.

1.9. The validity of the proceedings of any of the committees shall not be affected by reason only of:

a) a defect in the appointment of any committee member, or

b) a vacancy in the membership of that committee.

2. The Audit and Governance Committee

Purpose of the committee

2.1. The purpose of the Audit and Governance Committee is to oversee corporate governance, risk, audit arrangements and financial matters.

Delegated powers and functions of the Audit and Governance Committee

2.2. The Authority delegates to the Audit and Governance Committee, the following powers:

a) approval of the internal audit programme, and

b) approval of the statement on internal control or equivalent annual governance statement included in the annual accounts.

2.3. The functions of the Audit and Governance Committee shall be to:

a) oversee the general corporate governance of the Authority (including supervision and review of the operational effectiveness of the Authority's internal control and risk management procedures)

b) ensure that the Authority complies with its statutory functions, and with the requirements of the regulators' code, requirements applicable to arm's length bodies, and the principles and best practice guidance issued by the Better Regulation Executive

c) meet regularly with the Authority's internal and external auditors to ensure that the Authority is complying with statutory requirements and best practice relating to internal control systems risk management, audit, and financial reporting requirements

d) review the annual financial statements before their submission to the Authority focusing particularly on changes in, and compliance with accounting policies and practices, and

e) review and manage the effectiveness of the Authority's whistle-blowing policy.

2.4. In particular, the Audit and Governance Committee shall:

a) review the adequacy of all risk and control related disclosure statements, together with any accompanying statement from the internal auditors, prior to endorsement by the Authority

b) review the adequacy of structures, processes and responsibilities for identifying and managing key risks facing the Authority

c) review the adequacy of internal audit policies to ensure compliance with the controls assurance standards and other relevant guidance

d) review the adequacy of policies and procedures for all work related to fraud and corruption as set out in the Secretary of State directions and as required by the National Health Service Counter Fraud Service

e) make recommendations to the Authority about the appointment (including renewal) and, where necessary, dismissal of the internal audit service and the audit fee payable

f) manage the relationship with the external auditor (the Comptroller and Auditor General), and ensure that any chargeable non-audit services provided do not compromise the auditors' independence or objectivity

g) review the planning, conduct and conclusions of the external audit process (including review of all reports and annual audit letters, together with the associated management responses)

h) receive reports from the tender panel established in accordance with the financial procedures approved by the Authority, and

i) receive reports about all consultancy contracts made by the Authority.

2.5. In pursuance of these functions, the Authority authorises the Audit and Governance Committee to:

a) require a review or investigation of any procedures and activities undertaken by the Authority that fall within its remit

b) obtain from any employee, such information as it considers relevant to the carrying out of its functions (all employees are directed to co-operate with any request made by the Audit and Governance Committee)

c) obtain such external legal or other professional advice as it considers necessary to enable it to fulfil its functions, and

d) provide such advice or recommendations to the Chair, the Authority members and the Authority's Chief Executive, as it considers necessary or appropriate.

Membership of the Audit and Governance Committee

2.6. The Audit and Governance Committee shall consist of up to six members including:

a) a Committee Chair (who shall be an Authority member)

b) a Deputy Committee Chair (who shall be an Authority member)

c) up to two other Authority members

d) two persons who shall not be Authority members and who have relevant legal, financial, public sector or other corporate governance expertise, if required.

2.7. The Chair of the HFEA shall appoint the members of the Audit and Governance Committee.

2.8. Members of the Audit and Governance Committee shall usually be appointed for a term of three years.

Meetings of the Audit and Governance Committee

2.9. The quorum for a meeting of the Audit and Governance Committee shall be three, providing that two are Authority members, including the Committee Chair or Deputy Committee Chair.

2.10. The Audit and Governance Committee shall usually meet no fewer than four times a year.

Attendance at meetings of the Audit and Governance Committee

2.11. In addition to members of Audit and Governance Committee, the following persons shall usually attend its meetings:

a) the Chief Executive (or his delegated representative)

b) the Director of Finance and Resources

c) the Head of Planning and Governance

d) the Committee Secretary

e) a representative from the Department of Health

f) a representative from the Authority's internal auditors, and

g) a representative from the Authority's external auditors.

2.12. The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the committee and/or to provide advice to inform the deliberations of the committee.

2.13. The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Audit and Governance Committee to withdraw from the meeting to enable the committee to deliberate in private.

3. The Statutory Approvals Committee

Purpose of the committee

3.1. The purpose of the Statutory Approvals Committee is to keep under review and to authorise the use of embryo testing; to authorise the use of mitochondrial donation treatment; to issue special directions for the import/export of gametes; and to authorise the use of novel processes in licensed activities.

Delegated powers and functions of the Statutory Approvals Committee

3.2. The Authority delegates to the Statutory Approvals Committee the following powers:

a) the authorisation of the use of embryo testing for conditions not previously authorised by the Authority (under schedule 2, paragraph 1ZA(1)(a), (b) and (c) of the Act)

b) the authorisation of the use of embryo testing to establish whether the tissue of any resulting child would be compatible with that of a sibling that suffers from a serious medical condition (under schedule 2, paragraph 1ZA(1)(d)

c) the authorisation of the use of embryo testing to establish whether an embryo is one of those whose creation was brought about by using the gametes of a particular person (under schedule 2, paragraph 1ZA(1)(e)

d) the authorisation of the use of maternal spindle transfer (MST) and/or pronuclear transfer (PNT) for a named patient (under The Human Fertilisation and Embryology (mitochondrial donation) regulations 2015)

e) the issuing of special directions for the import/export of gametes or embryos (under section 24(4AA) of the Act), and

f) the authorisation of the use of novel processes in licensed activities.

3.3. The functions of the Statutory Approvals Committee shall include:

a) keeping under review the genetic conditions authorised by the Authority for embryo testing.

Membership of the Statutory Approvals Committee

3.4. The Statutory Approvals Committee shall operate from a pool of up to 10 members, with no more than five members attending each meeting. The membership shall include:

a) a Committee Chair (who shall be a lay Authority member).

b) a Deputy Committee Chair (who shall be a lay Authority member);

c) up to ~~five~~ eight other Authority members.

3.5. The Chair of the HFEA shall appoint the members of the Statutory Approvals Committee.

3.6. Members of the Statutory Approvals Committee shall usually be appointed for a term of three years.

Meetings of the Statutory Approvals Committee

3.7. The quorum for a meeting of the Statutory Approvals Committee shall be three including the Committee Chair or Deputy Committee Chair and two other members.

3.8. The Statutory Approvals Committee shall usually meet 12 times per year. At the discretion of the Chair, the committee may meet additionally at short notice (and, if necessary, by telephone- or video-conference) if the Chair considers there is an item (or items) which cannot be delayed until the next meeting.

3.9. No member of the Statutory Approvals Committee present at a meeting shall abstain from voting.

3.10. Decisions of the Statutory Approvals Committee to authorise embryo testing, mitochondrial donation treatment or novel processes, or to issue special directions, require a simple majority (and in the event of a tie, the Committee Chair shall have a casting vote).

Attendance at meetings of the Statutory Approvals Committee

3.11. In addition to members of the Statutory Approvals Committee, the following persons shall usually attend its meetings:

a) a legal adviser

b) a specialist adviser

c) the ~~Senior Governance~~ Licensing Manager or the Head of Planning and Governance

d) the Committee Secretary.

3.12. The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the Statutory Approvals Committee and/or to provide advice to inform the deliberations of the Statutory Approvals Committee.

3.13. The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the committee to withdraw from the meeting to enable the committee to deliberate in private.

4. The Remuneration Committee

Purpose of the committee

4.1. To consider matters relating to remuneration and human resources.

Delegated powers and functions of the Remuneration Committee

4.2. The Authority delegates to the Remuneration Committee the power to approve annual employee pay levels.

4.3. The functions of the Remuneration Committee shall be to:

a) develop the Authority's pay policy and strategy

b) monitor overall levels of remuneration

c) review, moderate and approve the remuneration of the Chief Executive and directors, and

d) consider human resource issues referred to it by the Chief Executive or Chair of the Authority.

Membership of the Remuneration Committee

4.4. The Remuneration Committee shall consist of three members, which shall include:

a) a Committee Chair (who shall be the Chair of the Authority)

b) a Deputy Committee Chair (who shall be the Deputy Chair of the Authority), and

c) the Chair of the Audit and Governance Committee.

4.5. In the event that the Deputy Chair of the Authority and the Chair of the Audit and Governance Committee are the same person, the Chair of the Authority shall appoint another Authority member to the third place on the Committee.

Meetings of the Remuneration Committee

~~4.5.~~4.6. The quorum for a meeting of the Remuneration Committee shall be two.

~~4.6.~~4.7. The Remuneration Committee shall usually meet at least once a year.

Attendance at meetings of the Remuneration Committee

~~4.7.~~4.8. The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the Remuneration Committee and/or to provide expert advice to inform the deliberations of the committee.

~~4.8.~~4.9. The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Remuneration Committee to withdraw from the meeting to enable the committee to deliberate in private.

5. The Appointments Committee

Purpose of the committee

5.1. To oversee the appointments of external members contributing to the work of the committees and working groups.

Functions of the Appointments Committee

5.2. The Authority delegates to the Appointments Committee, the following functions:

a) Advising the Chair of the HFEA on the appointment of all non-Authority members to the committees and working groups

b) Monitoring the balance of expertise, experience and backgrounds of committee members in accordance with the purpose and requirements of each committee or working group, and

c) Oversight of the Authority's mechanisms for identifying and appointing non-Authority members to the committees and working groups.

Membership of the Appointments Committee

5.3. The Appointments Committee shall consist of three members, which shall include:

a) a Committee Chair (who shall be the Chair of the Authority)

b) a Deputy Committee Chair (who shall be the Deputy Chair of the Authority), and

c) the Chair of the Audit and Governance Committee.

Meetings of the Appointments Committee

5.4. The quorum for a meeting of the Appointments Committee shall be two.

5.5. The Appointments Committee shall usually meet at least once a year.

Attendance at meetings of the Appointments Committee

5.6. The Committee Chair may invite such other persons (including employees) as the he/she considers appropriate, to attend the meetings of the Appointments Committee and/or to provide expert advice to inform the deliberations of the committee.

5.7. The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Appointments Committee to withdraw from the meeting to enable the committee to deliberate in private.

~~6.~~5. The Scientific and Clinical Advances Advisory Committee

Purpose of the committee

~~6.1.~~5.1. The purpose of the Scientific and Clinical Advances Advisory Committee is to advise the Authority on scientific and clinical developments (including research) in assisted conception, embryo research and related areas.

Functions of the Scientific and Clinical Advances Advisory Committee

~~6.2.~~5.2. The functions of the Scientific and Clinical Advances Advisory Committee shall be to:

a) make recommendations to the Authority on the safety and efficacy of scientific and clinical developments (including research) in assisted conception, embryo research and related areas

b) make recommendations to the Authority on patient information relating to those scientific and clinical developments

c) advise the Authority on significant implications for licensing and regulation arising out of such developments, and

d) where required, work with the Authority members to consider the social, ethical and legal implications arising out of such developments.

Membership of the Scientific and Clinical Advances Advisory Committee

~~6.3.~~5.3. The Scientific and Clinical Advances Advisory Committee shall consist of at least three Authority members, which shall include:

a) a Committee Chair (who shall be an Authority member)

b) a Deputy Committee Chair (who shall be an Authority member), and

c) up to three other Authority members.

~~6.4.~~5.4. In addition, up to eleven other persons, who shall not be Authority members, shall be appointed as expert advisers to the committee. Such persons shall not be entitled to vote.

~~6.5.~~5.5. At least one of the Authority members of the Scientific and Clinical Advances Advisory Committee shall have clinical or scientific expertise.

~~6.6.~~5.6. The Chair of the HFEA shall appoint the members of the Scientific and Clinical Advances Advisory Committee.

5.7. Members of the Scientific and Clinical Advances Advisory Committee shall usually be appointed for a term of three years. Expert advisers may be appointed for a maximum of two terms, with a period of one, two or three years.

Meetings of the Scientific and Clinical Advances Advisory Committee

~~6.7.~~5.8. The quorum for a meeting of the Scientific and Clinical Advances Advisory Committee shall be three including the Committee Chair or Deputy Committee Chair of the committee.

~~6.8.~~5.9. The Scientific and Clinical Advances Advisory Committee shall usually meet three times each year.

Attendance at meetings of the Scientific and Clinical Advances Advisory Committee

~~6.9.~~5.10. The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the Scientific and Clinical Advances Advisory Committee and/or to provide expert advice to inform the deliberations of the committee.

~~6.10.~~5.11. The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Scientific and Clinical Advances Advisory Committee to withdraw from the meeting to enable the committee to deliberate in private.

7.6. Oversight Committee

Purpose of the Oversight Committee

7.1.6.1. The purpose of the Oversight Committee is to fulfil the functions set out in the Human Fertilisation and Embryology (disclosure of information for research purposes) regulations 2010 ('the 2010 regulations').

Functions of the Oversight Committee

7.2.6.2. The functions of the Oversight Committee shall be to:

a) monitor the grant of authorisations to access Authority Register data made under the Human Fertilisation and Embryology (disclosure of information for research purposes) regulations 2010

b) monitor the processing of patient-, partner- and child-identifying Register data by research establishments

c) consider annual reports submitted by research establishments

d) consider such other matters relating to the 2010 regulations as the committee determines

e) oversee the functions of the Register Research Panel and the Register Research Review Panel

f) make recommendations to the Register Research Panel and the Register Research Review Panel about improvements to processes and the operation of the panels

g) approve any memorandum of understanding (MoU) or any contractual arrangements between the Authority and other public bodies with an interest in the safeguarding of personal information in the United Kingdom where these relate to the disclosure of Authority Register data for research purposes, and

h) approve variations of and amendments to such MoUs, contracts and agreements.

Membership of the Oversight Committee

7.3.6.3. The Authority is the Oversight Committee and, when performing the statutory functions of the Oversight Committee as set out in regulation 21 of the Human Fertilisation and Embryology (disclosure of information for research purposes) regulations 2010, the relevant sections of the standing orders will apply.

Meetings of the Oversight Committee

7.4.6.4. The quorum for a meeting of the Oversight Committee shall be four.

7.5.6.5. The Oversight Committee shall consider an overview report submitted by the Register Research Panel at least once a year.

Attendance at meetings of the Oversight Committee

~~7.6.~~6.6. The Chair of the HFEA may invite such other persons (including non-Authority members and representatives from the Department of Health) as he/she considers appropriate, to attend the meetings of the Oversight Committee and/or to provide expert advice to inform the deliberations of the committee.

~~7.7.~~6.7. The Chair of the HFEA may determine when and whether it is necessary or desirable for any non-members of the Oversight Committee to withdraw from the meeting to enable the committee to deliberate in private.

8.7. Executive Panels concerned with Disclosure of Information for Research Purposes

Register Research Panel

Purpose of the Register Research Panel

8.1.7.1. The purpose of the Register Research Panel is to consider applications made under the Human Fertilisation and Embryology (disclosure of information for research purposes) regulations 2010 ('the 2010 regulations'), and requests for additional fields on the anonymised register ("safeguarded" data).

Delegated powers and functions of the Register Research Panel

8.2.7.2. The Authority delegates to the Register Research Panel, the power to:

a) authorise access to Register data for the purposes of medical or non-medical research, and

b) deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.

8.3.7.3. The functions of the Register Research Panel shall be to:

a) consider requests for the provision of data for research purposes, including safeguarded and identifiable data

b) comply with the requirements of the 2010 regulations

c) review annual reports submitted by research establishments

d) publish lay summaries of research projects involving the use of Authority Register data

e) submit a report to the Authority's Oversight Committee about the work of the Register Research Panel not less than once a year

f) refer appeals against the decisions of the Register Research Panel to the Register Research Review Panel, and

g) liaise and collaborate with any appropriate bodies in the UK with an interest in the safeguarding of personal data and the oversight of research studies involving the linkage of complex datasets.

Membership of the Register Research Panel

8.4.7.4. The Register Research Panel shall consist of a Chair and Deputy Chair (or Deputy Chairs) and a pool of suitable employees, appointed by the Chief Executive from amongst the employees of the Authority. In the absence of the Chair of the Panel, a Deputy Chair or other person nominated by the Chair of the Panel may act as Chair of the Panel.

Meetings of the Register Research Panel

~~8.5.~~7.5. The quorum for a meeting of the Register Research Panel shall be five, and there shall be due consideration to the balance of membership to ensure a fair and robust appraisal of any research applications and decisions. All decisions and minutes must be signed off by the Chair.

~~8.6.~~7.6. Meetings of the Register Research Panel will be scheduled as required and in accordance with any memorandum of understanding between the Authority and bodies responsible for national information governance.

~~8.7.~~7.7. Meetings of the Register Research Panel will be private.

Attendance at meetings of the Register Research Panel

~~8.8.~~7.8. In addition to the Chair and members of the Register Research Panel, such other employees as the Chair considers necessary may attend the meetings of the Register Research Panel.

~~8.9.~~7.9. The Chair of the Register Research Panel may invite such other persons (including non-Authority members and representatives from the Department of Health and Social Care) as the Chair considers appropriate, to attend the meetings of that panel and/or to provide expert advice to inform the deliberations of the panel.

Register Research Review Panel

Purpose of the Register Research Review Panel

~~8.10.~~7.10. To consider appeals against the decisions of the Register Research Panel in accordance with Regulation 12 of the 2010 Regulations.

Delegated powers and function of the Register Research Review Panel

~~8.11.~~7.11. The Authority delegates to the Register Research Review Panel, the power to:

a) uphold or overturn the decisions of the Register Research Panel

b) authorise access to Register data for the purposes of medical or non-medical research, and

c) deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.

Membership of the Register Research Review Panel

~~8.12.~~7.12. The Register Research Review Panel shall consist of:

a) the Chief Executive, who will act as the Chair of the Register Research Review Panel, and

b) the Senior Information Risk Owner (SIRO) of the Authority.

Meetings of the Register Research Review Panel

~~8.13.~~7.13. Meetings of the Register Research Review Panel shall be scheduled as required following receipt of an appeal against the decisions of the Register Research Panel.

Attendance at meetings of the Register Research Review Panel

~~8.14.~~7.14. In addition to the Chair and members of the Register Research Review Panel, such other employees as the Chair considers necessary may attend the meetings of the Register Research Review Panel.

~~8.15.~~7.15. The Chair of the Register Research Review Panel may invite such other persons (including non-Authority members and representatives from the Department of Health) as the Chair considers appropriate, to attend the meetings of that panel and/or to provide expert advice to inform the deliberations of the panel.

Standing orders: Annex B

Instrument of delegation in respect of Authority licensing functions

1. Licensing functions delegated to a Licensing Officer

Consideration of the following variations of licences on application (under Section 18A(2) of the Act): • change of licence holder, and • change of a centre's name or address.
Consideration of applications for voluntary revocation of licences under Section 18(1) of the Act
The issuing, revocation, renewal and variation of Certificates of Authorisation of importing tissue establishments in accordance with EU requirements on the import of eggs, sperm and embryos.

2. Licensing functions delegated to the Executive Licensing Panel

All powers delegated to a Licensing Officer in table 1, above, plus:
Consideration of applications for initial licences for treatment, storage and provision of non-medical fertility services, and exercise of the Authority's power to grant such licences under section 16 of the Act.
Consideration of applications for the renewal of licences for treatment, storage and provision of non-medical fertility services, and exercise of the Authority's power to grant such licences under section 16 of the Act.
Consideration of renewal applications for research licences, which the Licence Committee has not reserved to itself for consideration or which do not raise complex or controversial issues, and exercise of the Authority's power to grant such licences under section 16 of the Act.
Consideration of interim inspections reports (treatment and/or storage, and research).
The following variations of licences on application:- • change of Person Responsible (under section 18A(1) of the Act) • changes to licensed activities (under section 18A(2) of the Act), and • change of a centre's premises (under section 18A(2) of the Act).
Authorisation to undertake HLA tissue typing for genetic conditions previously authorised by the Authority.
Consideration of reports of random unannounced inspections.
Consideration of reports of targeted inspections.
Consideration of executive proposals to place non-standard conditions on licences and exercise of the Authority's power to issue notices under section 19 of the Act.

Exercise of the Authority's power to issue directions under sections 24(5A) to (5E) and 24(13) of the Act.

3. Licensing functions delegated to Licence Committee in relation to research licences

All powers related to research licences delegated to a Licensing Officer in table 1 and Executive Licensing Panel in table 2, above, plus:
Consideration of applications for initial research licences and exercise of the Authority's power to grant such licences under section 16 of the Act.
Consideration of renewal applications for research licences and exercise of the Authority's power to grant such licences under section 16 of the Act.
Consideration of Grade A incidents and, where appropriate, Grade B incidents.
Consideration of executive proposals to revoke/suspend licences and exercise of the Authority's powers to revoke/suspend licences in accordance with sections 18(1) and (2) and 19(c) of the Act.
Consideration of representations under section 19(4) of the Act.
Exercise of the Authority's powers to vary a licence in accordance with section 18A of the Act.
Exercise of the Authority's power to issue notices under section 19 of the Act.

4. Licensing decisions delegated to Licence Committee relating to treatment and/or storage licences

All powers delegated to a Licensing Officer in table 1 and Executive Licensing Panel in table 2, above, plus:
Consideration of applications for initial licences for treatment, storage and provision of non-medical fertility services, and exercise of the Authority's power to grant such licences under section 16 of the Act.
Consideration of Grade A incidents and, where appropriate, Grade B incidents.
Consideration of executive proposals to revoke/suspend licences and exercise of the Authority's powers to revoke/suspend licences in accordance with sections 18(1) and (2) and 19(c) of the Act.
Consideration of representations under section 19(4) of the Act.
Exercise of the Authority's powers to vary a licence in accordance with section 18A of the Act.

Standing orders: Annex C

Protocol for the conduct of meetings of the Authority's Executive Licensing Panel

This Protocol is made by the Authority in accordance with its powers under paragraph 9 of Schedule 1 to the Human Fertilisation and Embryology Act 1990 (as amended) ('the Act') to regulate its own proceedings; its duty as a public body to comply with the Human Rights Act 1998; its common law duties and powers to ensure fairness in its procedures; and its duties under paragraph 8.4 of the statutory code of practice for regulators to enforce in a transparent manner, and to be transparent in the way in which it applies and determines penalties.

This protocol aims to ensure fairness and consistency in the proceedings before the Authority's Executive Licensing Panel ('the panel') and should be followed save where fairness requires otherwise.

The panel shall retain the power and duty to take such action, (provided always that any action is consistent with the requirements of the Act) as they consider appropriate and necessary to ensure fairness in a particular matter.

This protocol was approved by the Authority on 9 September 2009.

1. Composition and function of the panel

1.1. The Authority shall maintain an Executive Licensing Panel.

1.2. The function of the panel is to:

- perform the Authority's licensing functions under the Act in accordance with the delegated powers specified in the Authority's standing orders, and
- promote compliance with the requirements of the Act and the Code of Practice issued by the Authority.

1.3. In making its decisions, the panel shall have regard to relevant policies and guidance approved by the Authority.

1.4. The panel shall consider matters on the papers at a meeting in accordance with the provisions of this Protocol.

1.5. The panel shall consist of a Chair and Deputy Chair (or Deputy Chairs) and a pool of employees, appointed by the Chief Executive from amongst the employees of the Authority. In the absence of the Chair of the Panel, a Deputy Chair or other person nominated by the Chair of the Panel may act as Chair of the Panel.

1.6. The panel shall sit with three members at each meeting.

1.7. No member of the panel present at a meeting shall abstain from voting.

1.8. Decisions of a panel shall be taken by simple majority and the Chair of the Panel shall not have a casting vote.

1.9. Members of the panel shall attend regular training and update sessions on human rights and regulatory law, and matters relating to the provision of fertility treatment.

2. Advisers to committees

2.1. Where the Chair of the Panel considers it appropriate, the panel may seek written advice from a legal, clinical or specialist adviser before making its decision.

2.2. The Chair of the Panel shall ensure that the applicant, the proposed or actual person responsible, licence holder or person whose licence is under consideration is afforded a reasonable opportunity to comment on any written advice received by the panel before the panel makes its decision.

2.3. Where the Chair of the Panel considers it appropriate, the panel may sit with a legal adviser in attendance. Any advice provided in the course of a meeting shall be recorded in the minutes.

2.4. Where the panel does not accept the advice tendered by an adviser, the Chair of the panel should ensure that:

a) a written record is kept of the advice tendered, and the reasons why the panel refused to accept that advice, and

b) the written record is sent to the person concerned, together with the decision of the panel, and the reasons for its decision.

3. Secretary to the panel

3.1. A secretary shall be present at every meeting of the panel.

3.2. The function of the secretary shall be to make all administrative arrangements necessary for the proceedings of the panel to be effective, and to keep a record of:

a) the panel's decision and of the reasons for such decision

b) any advice tendered by a legal, clinical or specialist adviser, and

c) any declarations of interest (or potential conflicts of interest) made by a member of the panel during the proceedings.

3.3. The secretary shall not participate in the decision making of the panel (and is not entitled to vote).

4. Determination of agenda items

4.1. In determining the agenda for the panel, the relevant officers shall have regard to the instrument of delegation set out in Annex B to the Authority's standing orders.

4.2. Where the relevant officers are unsure whether a matter should be placed on the agenda of the panel or on the agenda of the Licence Committee, the presumption should be that the matter should be placed on the agenda of the panel. Where necessary, the Chair of the panel should be consulted.

5. Conduct of meeting

5.1. The panel shall consider matters on the papers.

5.2. Subject to paragraph 5.3, only the Chair and members of the panel, the secretary, and any other required support staff from the Planning and Governance team may be present at a meeting of the panel.

5.3. Employees of the Authority who have been appointed to the panel, or an external lawyer or auditor charged by the Authority with audit and evaluation of the effectiveness of the panel may attend a meeting of the panel as observers, or as part of their induction training. However, such observers shall not take any part in the discussion or deliberation of the panel, and are not entitled to vote.

6. Documents before the panel

6.1. At each meeting, the panel shall have access to:

a) this protocol

b) relevant edition(s) of the HFEA Code of Practice

c) the Human Fertilisation and Embryology Act 1990 (as amended)

d) the Human Fertilisation and Embryology (research purposes) regulations 2001 (where relevant)

e) General directions 0008 (where relevant), and any other relevant directions issued by the Authority

f) any relevant decision trees and explanatory notes approved by the Authority

g) 'Guidance for Authority and committee members on handling conflicts of interest'

h) 'Guidance on licensing' (where relevant)

i) the licence application (where relevant) and any relevant documentation in support of the application from the applicant and/or proposed person responsible for the centre to be licensed

j) the recommendation of the Authority's inspector dealing with the matter and any relevant supporting documentation (usually including three years' worth of a centre's licensing history, as appropriate, and in the case of applications for a research licence, any relevant academic literature and advice from the Authority's Scientific and Clinical Advances Advisory Committee)

k) the compliance and enforcement policy.

6.2. The panel shall not usually receive the recommendation of the Authority's inspector dealing with the matter or any relevant supporting documentation from that inspector, unless the applicant or person concerned (as appropriate) has been provided with a reasonable opportunity to comment on this material beforehand.

7. Panel papers

7.1. The secretary shall usually send the papers for a meeting of the panel to the Chair and members of the panel scheduled to attend the meeting, seven days in advance of the meeting.

7.2. Upon receipt of the papers, members of the panel must identify any potential conflicts of interest as soon as possible.

7.3. Where an actual or potential conflict is identified, members must inform the Chair of the panel and the secretary as soon as possible, and the procedure set out in the 'Guidance for Authority and committee members on handling conflicts of interest' shall be followed in deciding whether or not a conflict exists.

7.4. No member of the panel shall consider a matter if that member has an actual or potential conflict of interest in relation to that matter.

7.5. Members of the panel shall read the papers thoroughly in advance of the meeting and shall refrain from discussing matters to be considered by the panel with anyone except the other members of the panel, at the panel meeting.

7.6. Members of the panel shall only discuss panel business and the papers to be considered by the panel when the panel is in session.

8. Procedure to be followed at the meeting

8.1. Before any papers are considered by the panel, the Chair of the panel should:

a) check that the panel is quorate, and

b) ask for declarations of interest from each member.

8.2. Any interests declared should be noted and recorded by the secretary.

8.3. Where a potential or actual conflict is identified, the panel should follow the procedure set out in the 'Guidance for Authority and committee members on handling conflicts of interest'.

8.4. Each item on the agenda should be considered separately.

8.5. Where the panel is considering an application to grant or renew a licence, the Chair should direct the members of the panel to consider the requirements of section 16 of the Act.

8.6. In makings its decision, the panel may be aided by the relevant decision tree. Each stage of the decision tree should be considered separately, and in order.

8.7. Before the panel makes its decision, the Chair may adjourn to:

a) seek the advice of a legal, clinical or specialist adviser, and

b) require further information from the applicant or person responsible for the centre to be licensed (as appropriate), or from the Authority's inspector dealing with the matter.

8.8. In accordance with section 16(4) of the Act, where the panel considers that the information provided with an application is insufficient to enable it to determine that application, it need not consider the application until the applicant has provided it with such further information as the panel may require.

9. Decision to be taken by the panel

Applications to grant a licence (for the purposes of the panel, this covers renewal applications only)

9.1. On each application before it, the panel must decide:

a) whether the requirements of section 16 of the Act have been satisfied, and if so, whether to make a proposed decision to grant (renew) the licence

b) if the proposed decision is for the licence is to be granted (renewed), whether it is on the same or different terms, including whether any additional conditions should be attached to the licence in addition to the standard licence conditions, and

c) if the proposed decision is for the licence is to be granted (renewed), for what period that new licence is to be granted.

9.2. In determining the period of any licence to be granted (renewed), the panel should consider the indicative applications guidance.

Particular requirements for applications authorising embryo testing

9.3. Before the panel can grant an application authorising the testing of embryos, it must consider the requirements of paragraph 1ZA of schedule 2 to the Act.

9.4. Where the application seeks authorisation for the testing of an embryo in circumstances in which there is a particular risk that an embryo may have a gene, chromosome or mitochondrion abnormality, the panel must consider the requirement of paragraph 1ZA(2) of schedule 2 to the Act. In particular, the panel must be satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

10. Procedure for adding non-standard conditions and for refusal, variation or revocation of licence

10.1. If the panel is minded to refuse an application to grant, revoke or vary a licence, or minded to grant a licence subject to non-standard conditions, it must follow the procedure in section 19(1) of the Act.

10.2. If the panel is minded to revoke a licence on application, it must follow the procedure in section 19A(2) of the Act.

10.3. If the panel is minded to vary or revoke a licence otherwise than on application, it must refer the issue to the Licence Committee for consideration. The panel must record in the minutes of its deliberation the reasons why it was minded to vary or revoke the licence.

11. Reasons for the panel's decision

11.1. The panel shall give reasons for each decision that it makes, including any decisions to refer matters to the Licence Committee. These reasons must be recorded in the minutes.

11.2. The reasons shall set out:

a) any relevant findings of fact made by the panel

b) any matters taken into account by the panel (including any advice received from a legal, clinical, scientific or specialist adviser), and

c) why the panel reached its decision.

11.3. Additionally, in the case of applications to authorise embryo testing for gene, chromosome or mitochondrion abnormalities, the reasons must set why the panel is satisfied that there is a

significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition, and why the disability/illness/condition is considered to be serious.

11.4. The reasons should tell the person concerned in broad terms why the decision was reached, and may in some circumstances require an explanation of why a particular argument was rejected.

11.5. Where additional conditions have been proposed the reasons should indicate why the panel considers this course of action to be a proportionate response to any concerns identified from the papers before it.

11.6. The reasons should refer to the indicative applications guidance and indicative sanctions guidance where relevant.

12. Postponements and adjournments of meetings

12.1. The Chair may, of his or her own motion, or upon the application of a party to the proceedings, postpone any meeting of which notice has been given before such meeting begins.

12.2. The Chair may, of his or her own motion, adjourn the proceedings at any stage.

12.3. In considering whether or not to grant a request for postponement, or to adjourn, the Chair of the Panel should, amongst other matters, have regard to:

a) the public interest in the expeditious disposal of the proceedings

b) fairness to the parties, and

c) the conduct of the person seeking the postponement or adjournment.

12.4. Where the proceedings have been postponed or adjourned, the secretary should, as soon as practicable, notify the parties of the date and time of the postponed or resumed meeting.

13. Burden and standard of proof

13.1. The Authority's inspector dealing with the matter should bear the burden of establishing that a licence should be revoked, varied (otherwise than on an application) or that a licence should be suspended.

13.2. The person to whom the notice under section 19(1) is given should bear the burden of establishing that a licence should not be refused or additional conditions should not be imposed.

13.3. Where facts are in dispute, the panel should consider whether they have been established in accordance with the civil standard of proof.

13.4. Where the panel considers that a finding on disputed facts can only be made after oral evidence is heard, it shall refuse the application and issue a notice of proposal under section 19; invite the person to whom the notice is addressed to make oral representations to the Licence Committee and refer the matter for a hearing to be held in accordance with the Human Fertilisation and Embryology Act (procedure for revocation, variation or refusal of a licence) regulations 2009 (as amended).

14. Evidence at meetings

14.1. The panel may receive any written or real evidence whether or not such evidence would be admissible in a civil court of law in England and Wales, provided that it is satisfied that such evidence is relevant to the issues on which it has to make a decision, and that it is fair to admit such evidence.

14.2. The panel shall have regard to the Code of Practice in the circumstances set out in section 25(6) of the Act.

15. Directions

15.1. The Authority has delegated to the panel the power to issue directions under sections 24(5A) to (5E) and 24(13) of the Act.

15.2. When:

a) postponing or adjourning the consideration of a matter

b) making a proposed decision to refuse, vary, suspend or revoke a licence, or

c) considering evidence of an adverse incident or non-compliance with the Act, Code of Practice, licence conditions or directions issued by the Authority,

the panel should consider whether or not to issue directions under section 24 of the Act.

16. Evaluation and report to the Authority

16.1. The Chair of the panel shall hold regular periodic meetings for the purpose of reviewing decisions made by the panel to ensure consistency in the panel's decision making processes.

16.2. The Chair shall report to each Authority meeting on the activities of the panel.

Standing orders: Annex D
Protocol for the conduct of meetings of the Licence Committee

This Protocol is made by the Authority in accordance with its powers under paragraph 9 of Schedule 1 to the Human Fertilisation and Embryology Act 1990 (as amended) ('the Act')to regulate its own proceedings; its duty as a public body to comply with the Human Rights Act 1998 ; its common law duties and powers to ensure fairness in its procedures; and its duties under paragraph 8.4 of the statutory code of practice for regulators to enforce in a transparent manner, and to be transparent in the way in which it applies and determines penalties.

This protocol aims to ensure fairness and consistency in the proceedings before the Authority's Licence Committee and should be followed save where fairness requires otherwise.

The Licence Committee shall retain the power and duty to take such action, (provided always that any action is consistent with the requirements of the Act) as they consider appropriate and necessary to ensure fairness in a particular matter.

This protocol was approved by the Authority on 9 September 2009 and adopted by the chairs of the Authority's Licence and Research Licence Committees on the same date.

1. Composition and function of the Committee

1.1. The Authority shall maintain a Licence Committee.

1.2. The function of the Licence Committee is to:

a) perform the Authority's licensing functions under the Act in accordance with the delegated powers specified in the Authority's standing orders, and

b) promote compliance with the requirements of the Act and the Code of Practice issued by the Authority.

1.3. In making its decisions, the Licence Committee shall have regard to policies approved by the Authority, and where relevant, to the indicative applications guidance and indicative sanctions guidance.

1.4. Save where a Licence Committee is considering representations in accordance with section 19 of the Act, it shall consider matters on the papers at a meeting in accordance with the provisions of this protocol.

1.5. Where a Licence Committee is considering representations made under section 19(4) of the Act, it shall follow the procedure set out in the Human Fertilisation and Embryology (procedure for revocation, variation or refusal of licences) regulations 2009 (as amended).

1.6. The Licence Committee shall consist of no more than six members including a Chair and Deputy Chair, appointed by the Chair of the Authority. In the absence of the Committee Chair, the Deputy Chair or other person nominated by the Chair of the HFEA may act as Committee Chair.

1.7. The quorum for a meeting of the Licence Committee shall be three.

1.8. No member of a Licence Committee present at a meeting shall abstain from voting.

1.9. Decisions of a Licence Committee shall be taken by simple majority (and the Chair of a Licence Committee shall not have a casting vote).

1.10. Where there is a tied vote:

a) in the case of an application for a licence, that application shall not be granted

b) in the case of a proposal to impose non-standard conditions on a licence, or to vary, suspend or revoke a licence, that proposal shall not succeed, and

c) in any other case, the motion under consideration by the Licence Committee shall not be passed.

1.11. Members of the Licence Committee shall attend regular training and update sessions on human rights and regulatory law, and matters relating to the provision of fertility treatment.

2. Advisers to the Committee

2.1. A legal adviser shall be present at every meeting of the Licence Committee.

2.2. Where the Chair of the Licence Committee considers it appropriate, a clinical, scientific or specialist adviser may be present at a meeting or hearing of that Committee.

2.3. The function of an adviser to a Committee shall be to:

a) advise that committee on any areas within the adviser's expertise, and

b) intervene to advise that committee on an issue where it appears that without an intervention there is the possibility of an error being made.

2.4. With the consent of the Chair of the Licence Committee, an adviser who is present at a meeting of that committee may be present during the private deliberations of the committee, but the adviser shall not participate in the decision making of that committee (and is not entitled to vote).

2.5. The Chair of the Licence Committee shall ensure that a written record is kept of any advice tendered to the committee by an adviser.

2.6. The Chair of the Licence Committee shall also ensure that a written record is kept of any interventions made by an adviser during the private deliberations of that committee.

2.7. The Chair of the Licence Committee shall ensure that a copy of any advice tendered by an adviser to that committee is sent to the parties to the proceedings.

2.8. Where any advice tendered by an adviser to the Licence Committee is not accepted by that committee:

a) the committee Chair shall ensure that a written record is kept of the advice tendered, and the reasons why the committee refused to accept that advice; and

b) a copy of the record of the advice tendered and the reasons why the committee refused to accept that advice should be sent to the parties to the proceedings.

3. Executive support to the committee

3.1. A secretary shall be present at every meeting of the committee.

3.2. The function of the secretary shall be to make all administrative arrangements necessary for the proceedings of the Licence Committee to be effective, and to keep a record of:

a) the committee's decision and the reasons for such decision

b) any advice tendered by a legal, clinical, scientific or specialist adviser (and any interventions made by them when they are present during the private deliberations of the committee), and

c) any declarations of interest (or potential conflicts of interest) made by a member of the committee during the proceedings.

3.3. The secretary shall not participate in the decision making of the committee (and is not entitled to vote).

3.4. At the conclusion of every meeting of the Licence Committee, the Head of Planning and Governance shall collate any feedback from the Chair and members of the committee on matters that the Chair considers should be brought to the attention of the Authority's Director of Compliance and Information.

4. Determination of agenda items

4.1. In determining the agenda for a committee, the relevant officers shall have regard to the instrument of delegation set out in Annex B to the Authority's standing orders.

4.2. Where the relevant officers are unsure whether a matter should be placed on the agenda of a committee or on the agenda of the Executive Licensing Panel, the presumption should be that the matter should be placed on the agenda of the panel. Where necessary, the committee Chair should be consulted.

5. Conduct of meeting

5.1. The Licence Committee shall consider matters on the papers.

5.2. Subject to paragraph 5.3 only the Chair and members of the committee, the secretary, any other required support staff from the Planning and Governance team and advisers to that committee may be present at the meeting of the committee.

5.3. Members of the Licence Committee, or employees who have been appointed to the Executive Licensing Panel, members of the inspectorate requiring induction or training, or those with other relevant roles, may attend a meeting of the committee as observers, ~~or~~ as part of their induction or training. However, such observers shall not take any part in the discussion or deliberation of the committee, and are not entitled to vote.

6. Documents before the committee

6.1. At each meeting, the Licence Committee shall have access to:

a) this protocol

b) relevant edition(s) of the HFEA Code of Practice

c) the Human Fertilisation and Embryology Act 1990 (as amended)

d) the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 (where relevant)

e) direction 0008 (where relevant), and any other relevant Directions issued by the Authority

f) any relevant decision trees and explanatory notes approved by the Authority

g) guidance for Authority and committee members on handling conflicts of interest

h) 'guidance on licensing' (where relevant)

i) the licence application (where relevant) and any relevant documentation in support of the application from the applicant and/or proposed person responsible for the centre to be licensed

j) the recommendation of the Authority's inspector dealing with the matter and any relevant supporting documentation (usually including three years' worth of a centre's licensing history as appropriate, and in the case of applications for a research licence, any relevant academic literature and advice from the Authority's Scientific and Clinical Advances Advisory Committee)

k) the compliance and enforcement policy.

6.2. The Licence Committee shall not usually receive the recommendation of the Authority's inspector dealing with the matter or any relevant supporting documentation from that inspector, unless the applicant or person concerned (as appropriate) has been provided with a reasonable opportunity to comment on this material beforehand.

7. Committee papers

7.1. The secretary shall usually send the papers for a meeting of the Licence Committee to the Chair and members of that committee seven days in advance of the meeting.

7.2. Upon receipt of the papers, members of the committee must identify any potential conflicts of interest as soon as possible.

7.3. Where an actual or potential conflict is identified, members must inform the committee Chair and the secretary as soon as possible, and the procedure set out in the 'Guidance for Authority and committee members on handling conflicts of interest' shall be followed in deciding whether or not a conflict exists.

7.4. No member of the Licence Committee shall consider a matter if that member has an actual or potential conflict of interest in relation to that matter.

7.5. Members of the committee shall read the papers thoroughly in advance of the meeting and shall refrain from discussing matters to be considered by the committee with anyone except the other members of the committee, at the committee meeting.

7.6. Members of the committee shall only discuss committee business and the papers to be considered by the committee when the committee is in session.

8. Procedure to be followed at the meeting

8.1. Before any papers are considered by the Licence Committee, the Committee Chair should:

a) check that the committee is quorate, and

b) ask for declarations of interest from each member.

8.2. Any interests declared should be noted and recorded by the secretary.

8.3. Where a potential or actual conflict is identified, the Committee Chair should follow the procedure set out in the 'Guidance for Authority and committee members on handling conflicts of interest'.

8.4. Each item on the agenda should be considered separately.

8.5. Where the committee is considering an application to grant or renew a licence, the Chair should direct the members of the committee to consider the requirements of section 16 of the Act.

8.6. In makings its decision, the committee may be aided by the relevant decision tree. Each stage of the decision tree should be considered separately, and in order.

8.7. Before the committee makes its decision, the Chair may adjourn to:

a) seek the advice of a legal, clinical or specialist adviser, and

b) require further information from the applicant or person responsible for the centre to be licensed (as appropriate), or from the Authority's Inspector dealing with the matter.

8.8. In accordance with section 16(4) of the Act, where the committee considers that the information provided with an application is insufficient to enable it to determine that application, it need not consider the application until the applicant has provided it with such further information as the committee may require.

9. Decision to be taken by the committee

Applications to grant a licence (including renewals)

9.1. On each application before it, the committee must decide:

a) whether the requirements of section 16 of the Act have been satisfied, and if so, whether to make a proposed decision to grant (renew) the licence

b) if the proposed decision is for the licence to be granted (renewed), whether it is on the same or different terms, including whether any additional conditions should be attached to the licence in addition to the standard licence conditions, and

c) if the proposed decision is for the licence to be granted (renewed), for what period that new licence is to be granted.

9.2. In determining the period of any licence to be granted (renewed), the committee should consider the indicative applications guidance.

Particular requirements for applications authorising embryo testing

9.3. Before the Licence Committee can grant (or renew) an application authorising the testing of embryos, it must consider the requirements of paragraph 1ZA of schedule 2 to the Act.

9.4. Where the application seeks authorisation for the testing of an embryo in circumstances in which there is a particular risk that an embryo may have a gene, chromosome or mitochondrion abnormality, the Licence Committee must consider the requirement of paragraph 1ZA(2) of schedule 2 to the Act. In particular, the Licence Committee must be satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

Particular requirements for applications for research licences

9.5. Before the committee can grant (renew) an application for a research licence, it must consider the requirements of paragraphs 3(5) and 3A (1) of schedule 2 to the Act.

9.6. In particular, the committee must be satisfied that any proposed use of embryos or human admixed embryos is (and in the case of applications for renewal) or remains necessary for the purposes of the research.

9.7. In addition, the committee must consider whether the activities to be authorised by the licence are or remain necessary or desirable:

a) for the listed purposes set out in paragraph 3A (2) or in regulations

b) for the purpose of providing knowledge that may be capable of being applied for the purpose of

c) increasing knowledge about serious disease or other serious medical conditions, or

d) developing treatments for serious disease or other serious medical conditions.

10. Procedure for adding non-standard conditions and for refusal, variation or revocation of licence

10.1. If the committee is minded to refuse an application to grant, revoke or vary a licence, or minded to grant a licence subject to non-standard conditions, it must follow the procedure in section 19(1) of the Act.

10.2. If the committee is minded to vary or revoke a licence, it must follow the procedure in section 19(2) of the Act.

10.3. If the committee is minded to vary a licence otherwise than in accordance with the application, it must follow the procedure in section 19(3) of the Act.

10.4. In all cases where the committee has refused, varied or revoked a licence otherwise than on application, it must issue a notice under section 19A (4) and (5) of the Act.

10.5. In addition to issuing the notice, the committee must give the person to whom the notice is addressed, an opportunity to make representations before making its decision. Representations may be oral and written.

10.6. Representations shall not be considered by the committee that issues the notice. Where a notice has been issued by the Licence Committee, any representations shall be considered by a Licence Committee normally comprised of members who are not Authority members.

10.7. Where the person to whom the notice has been given indicates that he wishes to make representations, the committee hearing those representations shall consider the matter in accordance with the provisions of the Human Fertilisation and Embryology Authority (procedure for revocation, variation or refusal of a licence) regulations 2009 (as amended).

10.8. Where after the expiry of the period of 28 days from the date on which the notice was served, the person to whom the notice was given has not responded, or has confirmed that he does not wish to make representations, the committee shall resume its consideration of the matter and shall proceed to make its decision.

11. Reasons for the committee's decision

11.1. The committee shall give reasons for each decision that it makes. These reasons must be recorded in the minutes.

11.2. The reasons shall set out:

a) any relevant findings of fact made by the committee

b) any matters taken into account by the committee (including any advice received from a legal, clinical, scientific or specialist adviser), and

c) why the committee reached its decision.

11.3. Additionally, in the case of applications to authorise embryo testing for gene, chromosome or mitochondrion abnormalities, the reasons must set why the committee is satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition, and why the disability/illness/condition is considered to be serious.

11.4. Additionally, in the case of applications to grant (renew) licences for research, the reasons must set out why the committee is satisfied that any proposed use of embryos or human admixed embryos is or remains necessary for the purposes of the research, and why the committee considers that the activities to be authorised by the licence are or remain necessary or desirable:

a) for the listed purposes set out in paragraph 3A (2) or in regulations; or

b) for the purpose of providing knowledge that may be capable of being applied for the purpose of:

i. increasing knowledge about serious disease or other serious medical conditions, or

ii. developing treatments for serious disease or other serious medical conditions.

11.5. The reasons should tell the person concerned in broad terms why the decision was reached, and may in some circumstances require an explanation of why a particular argument was rejected.

11.6. Where additional conditions have been proposed the reasons should indicate why the committee considers this course of action to be a proportionate response to any concerns identified from the papers before it.

11.7. The reasons should refer to the indicative applications guidance and indicative sanctions guidance where relevant.

12. Postponements and adjournments of meetings

12.1. The Chair may, of his or her own motion, or upon the application of a party to the proceedings, postpone any meeting of which notice has been given before such meeting begins.

12.2. The Chair may, of his or her own motion, adjourn the proceedings at any stage.

12.3. In considering whether or not to grant a request for postponement, or to adjourn, the Committee Chair should, amongst other matters, have regard to:

a) the public interest in the expeditious disposal of the proceedings

b) fairness to the parties, and

c) the conduct of the person seeking the postponement or adjournment.

12.4. Where the proceedings have been postponed or adjourned, the secretary should, as soon as practicable, notify the parties of the date and time of the postponed or resumed meeting.

13. Burden and standard of proof

13.1. The Authority's inspector dealing with the matter should bear the burden of establishing that a licence should be revoked, varied (otherwise than on application) or that a licence should be suspended.

13.2. The person to whom the notice under section 19(1) is given should bear the burden of establishing that a licence should not be refused or additional conditions should not be imposed.

13.3. Where facts are in dispute, the Licence Committee should consider whether they have been established in accordance with the civil standard of proof.

13.4. Where the committee considers that a finding on disputed facts can only be made after oral evidence is heard, it shall refuse the application and issue a notice of proposal under Section 19; invite the person to whom the notice is addressed to make oral representations and hold a hearing in accordance with the Human Fertilisation and Embryology Act (procedure for revocation, variation or refusal of a licence) regulations 2009 (as amended).

14. Evidence at meetings

14.1. The committee may receive any written or real evidence whether or not such evidence would be admissible in a civil court of law in England and Wales, provided that it is satisfied that such evidence is relevant to the issues on which it has to make a decision, and that it is fair to admit such evidence.

14.2. The committee shall have regard to the Code of Practice issued by the Authority in the circumstances set out in section 25(6) of the Act.

15. Directions

15.1. The Authority has delegated to the Licence Committee the power to issue directions under sections 24(5A) to (5E) and 24(13) of the Act.

15.2. When:

a) postponing or adjourning the consideration of a matter

b) making a proposed decision to refuse, vary, suspend or revoke a licence, or

c) considering evidence of an adverse incident or non-compliance with the Act, Code of Practice, licence conditions or directions issued by the Authority,

the Chair should consider whether or not to issue directions under section 24 of the Act.

16. Evaluation and report to the Authority

16.1. The Chair and Deputy Chair of the Licence Committee shall hold regular periodic meetings for the purpose of reviewing decisions taken by the Committee to ensure consistency in the decision-making processes of the Committee, and to hear updates from the Chair of the

Executive Licensing panel on the activities of the panel. The Chair may also reflect on any general licensing trends or issues arising from such review and propose such action to the Executive or Authority as they consider appropriate.

16.2. The Chair of the Licence Committee shall report to each Authority meeting on the activities of the Committee.

Standing orders: Annex E

Code of Conduct for Authority members and the seven principles underpinning public life

1. Code of Conduct for Authority members

All Authority members **undertake** to:-

- have regard to the functions and duties of the Authority set out in sections 8 and 8ZA of the Human Fertilisation and Embryology Act 1990 (as amended) ('the Act') and which are annexed to this code, when undertaking the business of the Authority or a committee
- comply with the standing orders and relevant protocols and policies approved by the Authority when undertaking the business of the Authority or a committee
- follow and support by example the principles published by the committee on standards in public life (the Nolan principles) which are annexed to this code
- follow and support by example best practice on equality and diversity issues and promote compliance by others
- in the conduct of Authority business, treat people equally and fairly and not discriminate unlawfully against anyone on the basis of any protected characteristics including their race or racial group, sex (including gender reassignment), sexual orientation, religion or belief marriage or civil partnership, pregnancy and maternity, age or disability
- in carrying out their public functions, have due regard to the need to eliminate any conduct prohibited under equality legislation including the Equality Act 2010, and to promote equality of opportunity and foster good relations between people with protected characteristics and others
- comply with the statement of general principles published by the Authority in accordance with Section 8(ca) (ii) of the Human Fertilisation and Embryology Act 1990 (as amended) which are annexed to this code
- ensure that actions taken in a personal capacity do not bring the Authority into disrepute
- in their interactions with each other and with employees, model the 'ways of working' agreed by the Authority
  - taking responsibility
  - challenging well
  - taking interest in others' ideas
  - demonstrating enthusiasm.
- be alert to the possibility of any conflicts of interest, and to declare any potential conflicts as soon as practicable
- in the event of a potential conflict of interest, consult and follow the Authority's 'Guidance for Authority and committee members on handling conflicts of interest'
- ensure that entries relating to them in the register of interests maintained by the Authority are accurate, complete and up-to-date

- declare any hospitality received which may be relevant to their work as an Authority member in the register of interests maintained by the Authority for that purpose
- only discuss Authority and committee papers at formal meetings of the Authority or committee to which the papers relate
- keep the deliberations of the Authority or committee meetings which are not open to the public confidential, and not to disclose such deliberations to any external party (save in accordance with the Authority's publication policy or where required to by a court, or by law)
- ensure that any telephone or videoconferencing facilities used to attend Authority or committee meetings are appropriate and ensure confidentiality
- use any information acquired solely by virtue of their membership of the Authority or a committee only for the purpose of Authority or committee proceedings, and not to use such information for personal gain
- comply with the provisions of section 33A of the Human Fertilisation and Embryology Act 1990 (as amended) and to uphold strictly the confidentiality of any patient identifying information that may be revealed to them as members of the Authority or of a committee
- make no public comment on behalf of the Authority without first obtaining approval from the Chair of the Authority
- when providing media interviews or commenting in public, make it clear that they are speaking in a private capacity or as an Authority member
- make every effort to attend all meetings, hearings and training sessions at which their presence is required
- once diaries have been checked and meetings scheduled, only cancel their attendance under exceptional and wholly unavoidable circumstances
- take all reasonable steps to give advance warning of absence to the Chair of the HFEA or committee of which they are a member in the event that they are unable to attend a scheduled meeting or hearing
- prepare for any meeting or hearing by reading any papers sent to them beforehand, and
- undertake periodic training provided or organised by the Authority.

2. The seven principles underpinning public life

The principles of public life apply to anyone who works as a public office-holder. This includes all those who are elected or appointed to public office, nationally and locally, and all people appointed to work in the civil service, local government, the police, courts and probation services, NDPBs, and in the health, education, social and care services. All public office-holders are both servants of the public and stewards of public resources. The principles also have application to all those in other sectors delivering public services.

Selflessness

Holders of public office should act solely in terms of the public interest.

Integrity

Holders of public office must avoid placing themselves under any obligation to people or organisations that might try inappropriately to influence them in their work. They should not act or take decisions in order to gain financial or other material benefits for themselves, their family, or their friends. They must declare and resolve any interests and relationships.

Objectivity

Holders of public office must act and take decisions impartially, fairly and on merit, using the best evidence and without discrimination or bias.

Accountability

Holders of public office are accountable to the public for their decisions and actions and must submit themselves to the scrutiny necessary to ensure this.

Openness

Holders of public office should act and take decisions in an open and transparent manner. Information should not be withheld from the public unless there are clear and lawful reasons for so doing.

Honesty

Holders of public office should be truthful.

Leadership

Holders of public office should exhibit these principles in their own behaviour. They should actively promote and robustly support the principles and be willing to challenge poor behaviour wherever it occurs.

Performance report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	6
Meeting date:	23 March 2022
Author:	Shabbir Qureshi, Risk and Business Planning Manager
Annexes	Annex 1: Performance scorecard Annex 2: Financial management information Annex 3: High level KPIs

Output from this paper

For information or decision?	For information
Recommendation:	The Authority is asked to note and comment on the latest performance report.
Resource implications:	In budget
Implementation date:	Ongoing
Communication(s):	The Senior Management Team (SMT) reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper. The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are discussed in the subsequent SMT meeting. The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper).
Organisational risk:	Medium

1. Latest review

1.1. The attached report is for performance up to and including January 2022.

1.2. Performance was reviewed by SMT in February 2022.

2. Key trends

2.1. Performance was generally good in January.

Red indicators in January (3)

- HR2: Turnover
- C1: Efficiency of the end-to-end inspection and licensing process
- F1: Debt collection

2.2. The annexes to this paper provide a scorecard giving a performance overview, high-level financial information and the monthly management accounts and more detailed information on KPIs.

3. Follow up from previous Authority performance discussion

3.1. We have recruited a new Head of IT (retirement), a new Head of Intelligence (relocating) and are in the recruitment process for a new Head of Communications (left role in January).

3.2. Guidance on public sector pay rises for 2022 is still awaited.

3.3. We have launched a new ‘Working from Home’ policy and will be offering permanent work from home contracts to all staff. Staff also have the option of a new more flexible office-based contract. Both of these contracts are planned to be in place from the start of the new financial year.

4. IT and Register performance reporting

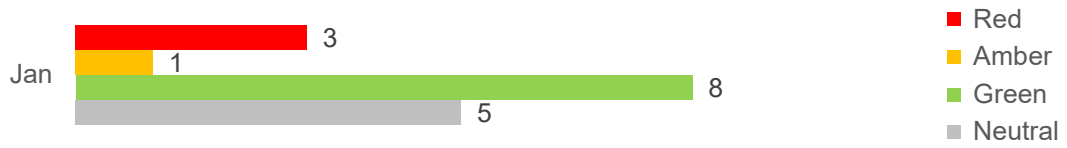
4.1. All clinics that used the old EDI system are now submitting data via PRISM. The first clinics using a third-party system are now also starting to come online; we are expecting 85-90% of clinics to be online by the end of March. We have a plan in place for each one of the remaining clinics with some due at the end of April.

4.2. Performance is good. Although it is not possible to directly compare current performance with old figures, we see an error rate of below 1% currently for clinics using PRISM directly (37 clinics) with many clinics having zero errors. This compares with an average of 6 - 8% for clinics submitting through a third-party system. The register team are working to get this level down to the level of those making direct entry to PRISM.

4.3. We are continuing to actively engage with clinics to support them in the transfer to PRISM.

Annex 1 HFEA Performance scorecard and management commentary – October to December data

Breakdown of total Red, Amber, Green and Neutral Indicators



RAG	Area	Trend and key data
Red – not at target	**People -** Employee turnover Target: between 5%-15%	18.7% Turnover 2 leavers
Red – not at target	**Regulatory efficiency -** Time for end-to-end inspection and licensing process Target: 100% in 70 working days or less	63% within target. Average of 69 wds (items beginning with an inspection)
Red – not at target	**Debt collection –** Percentage of debts collected Target: 85% in 40 working days or less	71% within target.
No target	**Engagement -** HFEA website sessions	85,116sessions (103804 in same month last year)

Summary financial position – December 2021 (Figures in thousands – £'000s)

Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s	Forecast for 2021/ 2022 £'000s	Budget for 2021/ 2022 £'000s	Variance Budget vs Forecast £'000s
Income	**6,121**	**5,755**	**366**	**7,487**	**7,049**	**438**
Expenditure	**(5,314)**	**(5,847)**	**533**	**(7,075)**	**(7,044)**	**(31)**
Total Surplus/ (Deficit)	**807**	**(92)**	**899**	**412**	**5**	**407**

Commentary on financial performance to 31 January 2022

Year to date we have a surplus against budget of £899k. This is largely due to licence fee income increase year to date (£367k) and underspends as detailed in the commentary.

Our forecast position as at 31 March 2022 is currently showing a surplus against budget of £407k which includes surpluses against our non-cash items. We are forecasting a gross surplus overall of £412k, removing non-cash items reduces this to £140k. We will monitor this closely in the last two months, as it is possible that we may incur additional legal or PRISM-related contractor costs that will impact our overall position.

Management commentary

During January, staff turnover has remained high. We had two leavers in January and no new starters. Comparatively high turnover will continue into the next quarter as we have two department heads due to leave, one through retirement and another relocating. Sickness has remained green for the past two months.

The end-to-end inspection and licensing process has remained in red in January and throughout the previous quarter with several inspections above the 70 working day target. A review of this KPI is in progress, and we will be dividing the existing 70-day KPI between the compliance and licencing teams to better identify where the shortfalls in performance are occurring and put in place appropriate measures to support improvement. We are keen to ensure the KPI remains appropriately challenging but is also achievable.

With the OTR backlog, we now have enough data to produce trend reports and have better defined the backlog as requests which have not been worked on yet. The quantity of OTR's being returned has increased in February and we expect this trend to continue.

Our web manager has also started implementing new reports and heat maps using Google Analytics to better represent website activity and track social media impact. Again, we expect to have the new reports in place shortly.

We are undertaking a full review of our performance management KPIs and are aiming to have a new suite of KPIs and performance measures in place for the new financial year with the first data available in May for April performance.

Red indicators in January:

HR:

- **HR2: Turnover:** turnover is slightly higher this month, we have two leavers and no new starters.

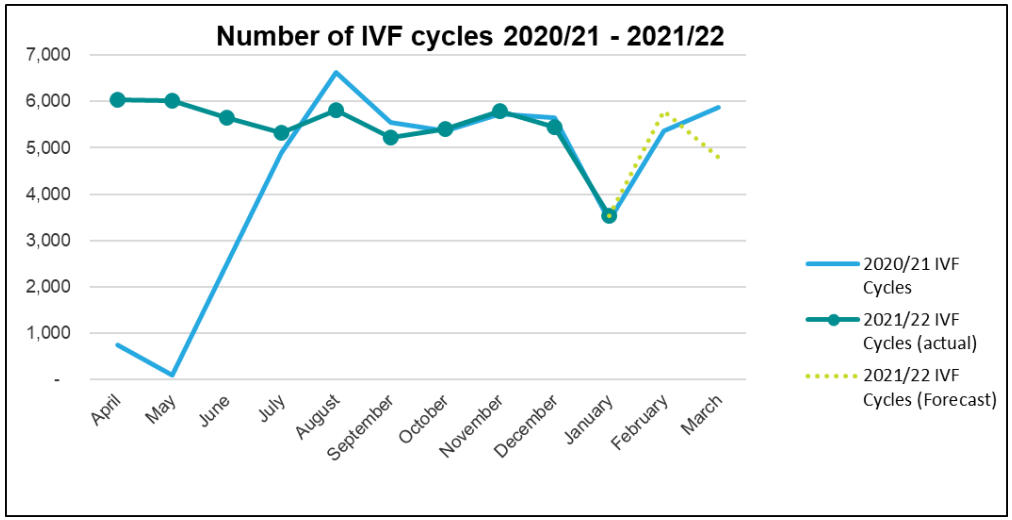
Compliance & licensing:

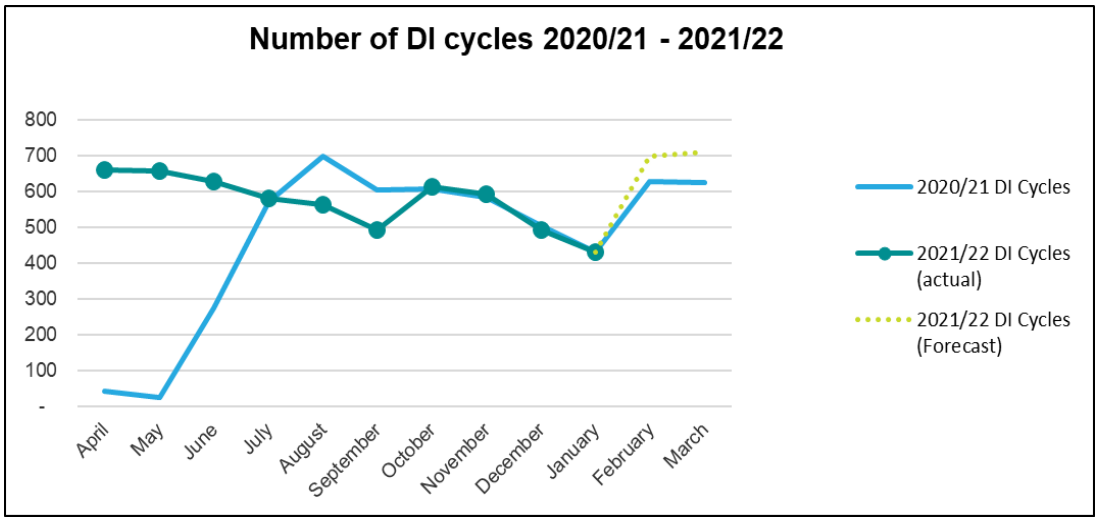
- **C1: Efficiency of the end-to-end inspection and licensing process:** this indicator is under review. The 70-day reporting cycle will be split up between licencing and compliance to better identify where performance shortfalls are occurring. For the four inspections that were over the KPI (70 working days), one was delayed due to the Christmas break, one due to inspector workload re-prioritisation and two others were part of the same group so were conducted using a group approach, however, due to the Christmas break, both were delayed further.

Finance:

- **F1: Debt collection – Percentage of debts collected:** Collection rate affected by estimation of billing leading to delays in settlement. This should improve as PRISM goes live in more clinics and data quality improves.

Annex 2 Financial management information





IVF Cycles	YTD		YE Position	
	Volume	£	Volume	£
2020/21 IVF Cycles	40,549	3,243,920	51,795	4,143,600
2021/22 IVF Cycles (actual)	54,255	4,340,373	64,855	5,188,373
Variance	13,706	1,096,453	13,060	1,044,773

DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2020/21 DI Cycles	4,342	162,825	5,598	209,925
2021/22 DI Cycles	5,711	214,163	7,121	267,038
Variance	1,369	51,338	1,523	57,113

As demonstrated by the tables above, we are currently exceeding the 2020/21 volumes for both IVF and DI cycles. For the last 4 months we have been billing clinics based upon their submissions in the same period in 2020 financial year. There is a risk that our estimated bills are higher than actual submission, however this will not be known until early April when a reconciliation is conducted.

Currently, we are forecasting a 25% increase in IVF income and a 24% increase in DI cycles compared to 2020/21.

HFEA Income & Expenditure Jan-22

	Year to Date				Full Year		
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %	Forecast £'000	Budget £'000	Variance £'000
Income							
Grant-in-aid	923	825	(98)	(0)	1,256	1,098	158
Non-cash (Ring-fenced RDEL)	430	430	-	-	516	516	-
Grant-in-aid - PCSPS contribution	83	83	-	-	100	100	-
Licence Fees	4,597	4,306	(291)	-7%	5,504	5,188	316
Interest received	0	2	2	2	1	2	(1)
Seconded and other income	88	109	21	19	110	145	(35)
Total Income	6,121	5,755	(366)	**(6)**	**7,487**	**7,049**	**438**
Revenue Costs							
Salaries (excluding Authority)	3,820	3,733	(87)	(2)	4,726	4,447	(279)
Staff Travel & Subsistence	52	54	2	4	64	73	9
Other Staff Costs	55	86	31	36	99	111	12
Authority & Other Committees costs	181	198	17	9	268	234	(35)
Facilities Costs incl non-cash	417	766	349	46	673	954	281
IT Costs	348	534	186	35	560	642	82
Legal / Professional Fees	228	281	53	19	336	339	3
Other Costs	134	195	61	31	246	244	(2)
Other Project Costs	79	-	(79)	-	102	-	(102)
Total Revenue Costs	**5,314**	**5,847**	**533**	**9**	**7,075**	**7,044**	**(31)**
TOTAL Surplus / (Deficit)	**807**	**(92)**	**899**		**412**	**5**	**407**
Adjusted for non-cash income/costs	**565**	**(119)**	**683**		**140**	**4**	**136**

Management commentary

Income.
Overall our income exceeds budget by 6% or £367k. The main reason for this is that our Licence Fee income - particularly IVF fees continue to be above budget and are also exceeding 2020/21 volumes. The positive variance against our grant in aid is due to profiling.

Expenditure by exception.
Year to date we are under budget by £533k.
Salary costs - excluding contract staff are under budget by £210k, an increase of £2k from December. This is offset by the overspend in contract staff of £297k. Contract staff costs are mainly related to PRISM.

Other Staff Costs - are £31k under budget. There are significant underspends within Staff training and Payroll and Pension processing (£28k and £10k respectively), offset by an overspend in staff welfare of £14k. Staff Welfare costs include unbudgeted costs for mediation, staff survey and job evaluations not budgeted for totalling £7.5k

Authority & Other Committee costs - £17k under budget which relates mainly to overspends within Members Travel and Subsistence (£23k) and Members Training (£23k). These are offset by overspend within Venue costs (£23k) and smaller overspends within Advisors fees (£7k) and Appeals costs (£2k).

Facilities costs - underspent by £349K, (an increase of £60k from December) of which £124k relates to our accommodation costs for 2 Redman Place which we are awaiting final figures from DHSC. In addition we have an underspend (£214k) within our non-cash costs, the majority of which relates an asset that has come to the end of its useful life. The balance is made up of small underspends within Office Administration costs.

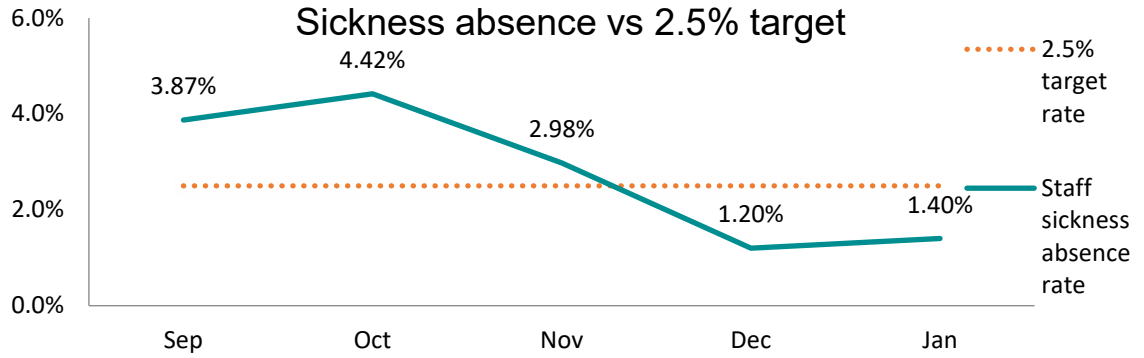
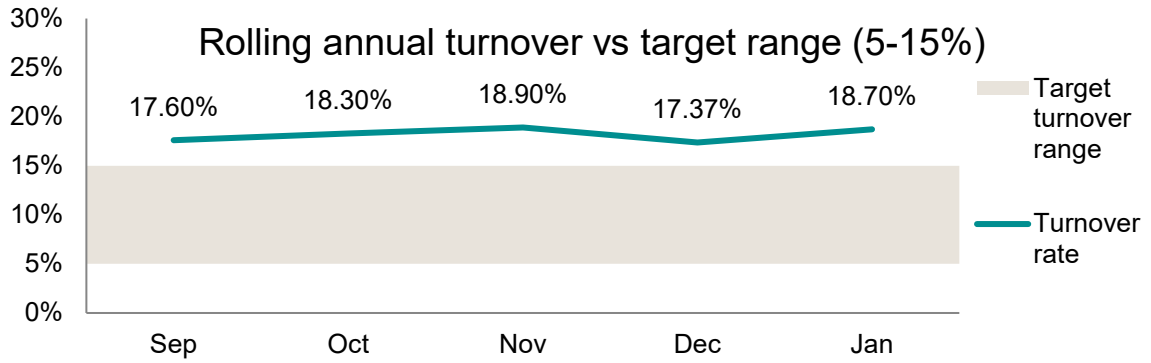
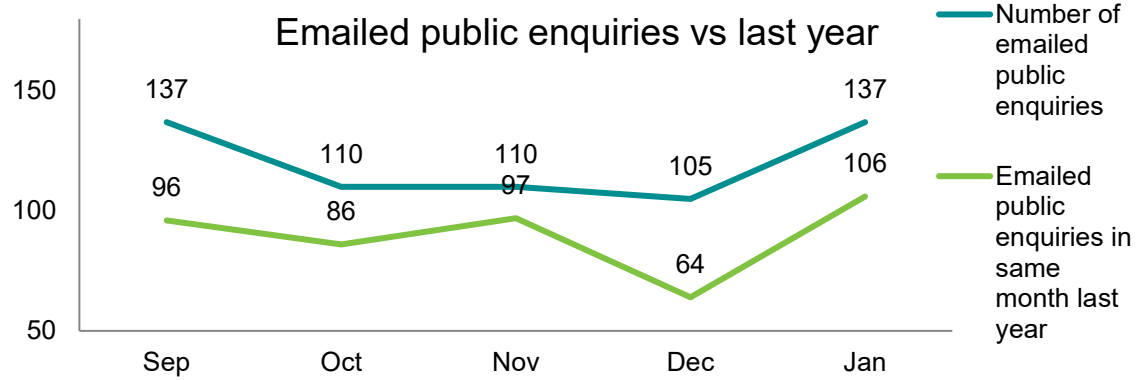
IT Costs - underspent by £186k. The main underspends are within our Support costs £115k, IT Subscriptions of £71k and Low value fixed assets of £10k.. The reduction in both support and subscriptions costs is due to reduced usage of Alscient (Support contract) and within the contract renegotiated for Microsoft Office subscriptions. Offsetting the above is an overspend within our Telephone costs of £12k.The balance is made up of small under and overspends within Photocopying, IT Low value software, Internet and Consumables.

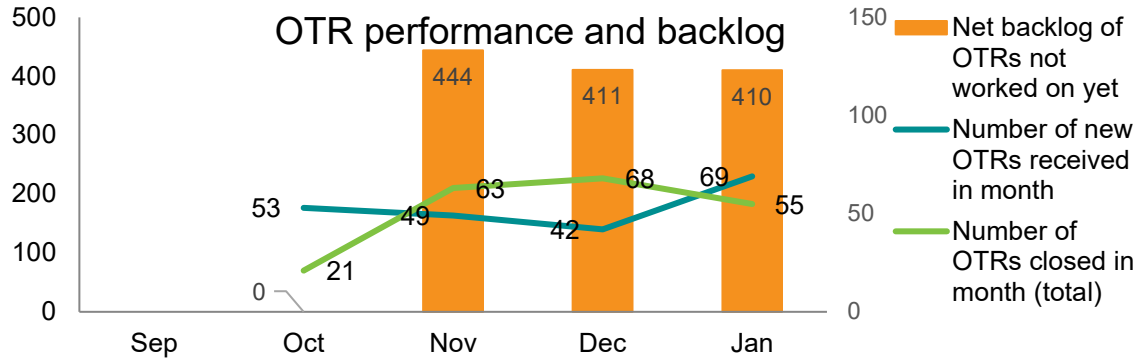
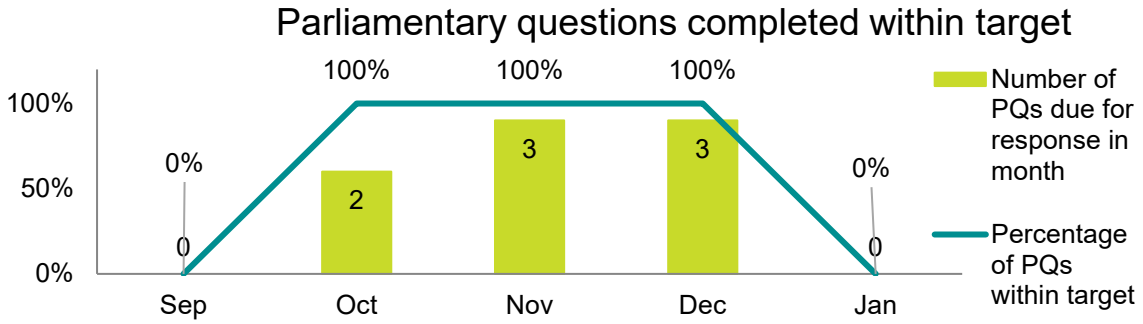
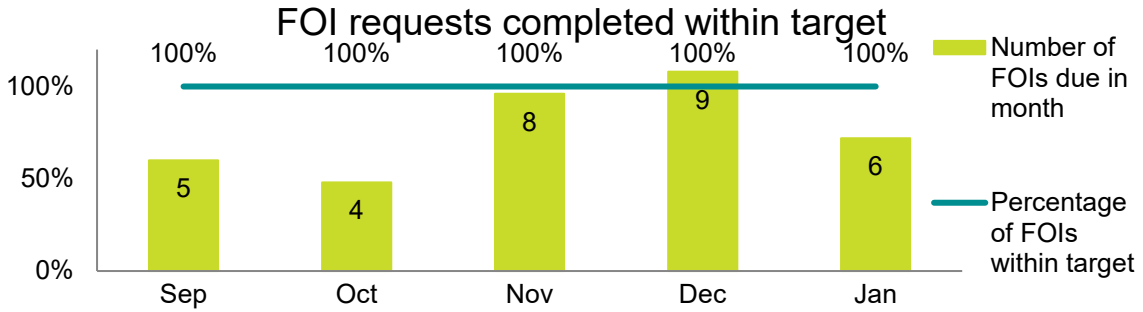
Legal/Professional fee - are under budget by £53k. This is represented by an underspend within the legal budget of £62k which includes a contingency of £30k. Offsetting the above are overspends within our Internal and External Audit fees of £9k.

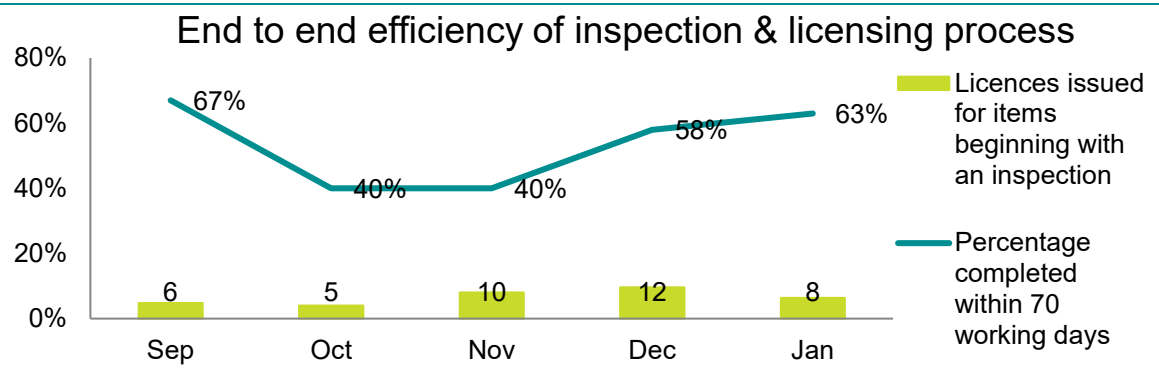
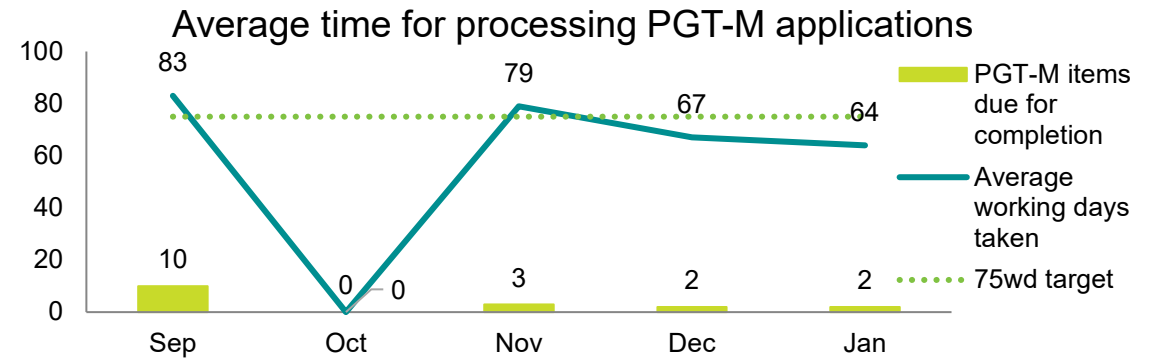
Other costs/Project Costs - are underspent by £61k and overspend of £79k respectively. The most significant variances are within Compliance Other (£14k), Stakeholder Events (£38k), Discretionary training (£6k). There are smaller underspends sub £5k across areas such as Inspection Advisor Fees, T&S and Communications costs. There is an overspend against Donor Information costs of £12k. These cost relate to the Donor Conceived Register and includes costs relating to prior year.

Forecast.
All things remaining equal, we are forecasting a surplus net of non-cash income and costs of £123k which is a surplus against budget of £119k. The net non-cash costs currently stand at £241k due to the delay the implementation of PRISM.

Annex 3 – Key performance indicators – Authority summary

Key performance indicator name and description	Graph showing performance trend for last 5 months	Commentary (if any)	RAG rating
HR1 – Sickness **Target**: less than or equal to 2.5%. Target is based upon ONS 2018 data (2.7% for the public sector)		Sickness remains low despite one person on long term sick and one person who was hospitalised.	Green
HR2 – Turnover **Target**: between 5 and 15% turnover for the rolling year.		70 – Headcount 68 – Establishment (posts) Turnover is slightly higher this month, we have two leavers and no new joiners.	Red
Supplementary data - Public enquiries No target.		Wide range of emailed enquiries, and 17 enquiries calls.	No target

Key performance indicator name and description	Graph showing performance trend for last 5 months	Commentary (if any)	RAG rating
R1 – Percentage of Opening the Register requests completed within 30 working day target. (excludes counselling time) **Target:** changed from 100% in 20wd to 95% in 30wd from April 2020. **Note: target not currently active.**		The 69 applications received in month was higher than the last 8 months. We did not close quite as many as previous months. The no. of OTRs closed will increase in following months when the Snr Donor Information Officer starts to send out OTRs.	Neutral
RI1 – PQs responded to within deadline set (Based on deadlines agreed with DHSC) **Target:** 100% within deadlines set.		None.	Green
RI2 - FOIs responded to within deadline **Target:** 100% within statutory deadlines.		There were also 7 generic enquiries received in January.	Green

Key performance indicator name and description	Graph showing performance trend for last 5 months	Commentary (if any)	RAG rating
C1 - Efficiency of end-to-end inspection and licensing process. **Target:** 100% within 70 working days (wds). % processed in 70 working days, for items where minutes were sent in month. Measured from inspection date to date minutes sent.		Average working days taken – 69. Most days taken: 115 working days Least days taken: 31 working days.	Red
C3 – Average PGD processing **Target:** average processing time of 75 working days. Average number of working days taken for those due in month. Note: Target changed from 66 to 75 in April 2020.		Average working days taken – 64 Most working days taken: 71 Least working days taken: 57	Green

2022/23 Budget proposal

Details about this paper

Area(s) of strategy this paper relates to:	
Meeting:	Authority
Agenda item:	7
Meeting date:	23 March 2022
Author:	Richard Sydee, Director of Resources
Annexes	N/a

Output from this paper

For information or decision?	For decision
Recommendation:	To update Authority members on the implementation of the recommended licence fee increase from 1 April 2022 and the final operating budget for the HFEA for the 2022/23 financial year
Resource implications:	N/a
Implementation date:	N/a
Communication(s):	The fee increase has been published and communicated to the sector on 1 March 2022.
Organisational risk:	High

1. Introduction

1.1. Following papers to the November and January Authority this paper provides an update on progress with the proposed licence fee increase or 2022/23 and presents the final operating budget for the HFEA for the 2022/23 financial year, as approved by the Executive.

2. Licence Fee increase

2.1. At the November meeting the Authority agreed to proposals to increase the clinic licence fee per IVF cycle from £80 to £85, the increase to take effect from 1 April 2022.

2.2. As advised at that time any increase in our licence fees would require approval by both Her Majesty's Treasury (HMT) and the Department for Health and Social Care (DHSC).

2.3. Confirmation of HMT approval was received on 18 January 2022, with confirmation of approval by DHSC following on 24 January 2022.

2.4. Following this approval, a Chairs letter (CH 22/01) was published on 1 March 2022 informing all licensed establishments of the changes to our licence fees and the date and process for implementation.

3. HFEA operating budget 2022/23

3.1. Following the final approval of the licence fee increase a final budget has been prepared that accounts for the increase in licence fee income and includes the agreed areas of additional expenditure for the 2022/23 business year.

3.2. The agreed increase to the licence fee, the first in 6 years, will allow the HFEA to increase its headcount and invest further in information technology in support of our use of data. Areas that will see increased investment include

- Opening the Register team (OTR) – will fund a permanent increase in the team to 4 FTE, to meet both the increase in current demand and in preparation for further increases in demand from 2023, when we begin to receive the first requests for Donor information from those conceived using donor gametes after the removal of donor anonymity in 2005.
- Policy, Data & Intelligence – funding additional post within our data and policy teams to meet the increased demands internally and externally for our data and to support the introduction and development of legislative change.
- Compliance – temporary increase to the team will now be made permanent, increasing the capacity and resilience of our inspection and compliance function.
- Information technology – increase the size and capability of our in-house development team, to support and develop our new register and data submission system (PRISM).
- In addition to the developer support above there will be further funds available to support much needed upgrades to, or migration from, legacy technology tools and systems via third party and external providers.

3.4. The expenditure budget contains a number of assumptions around inflationary and demand pressures as well as providing for some difficult to predict areas of spend. The Authority should note:

- The Wages and Salaries budget is based on a full establishment of 76 FTE and allows for a modest increase to staff salaries in this business year, Cabinet Office have confirmed there will be no extension to the pay freeze in 2021, although no announcement has been made regarding the scope and ceiling of any increase to public sector pay in 2022.
- Other staff costs include Inspection travel costs, as well as staff wellbeing and training budgets, we anticipate a significant increase in this area compared to 2021/22 as more assessments will take place on clinic premises rather than remotely.

- IT Costs and development includes expenditure to fund the use of external providers and developers to enhance and upgrade systems, only expenditure relating to the development of a case management system for OTR requests has been committed at this time.
- Our legal budget provides for both normal operational expenditure, in support of committees, and a provision for emerging issues relating to policy, legislation or challenges to our regulatory position.

3.5. A more detailed breakdown of the income and expenditure budget can be seen below:

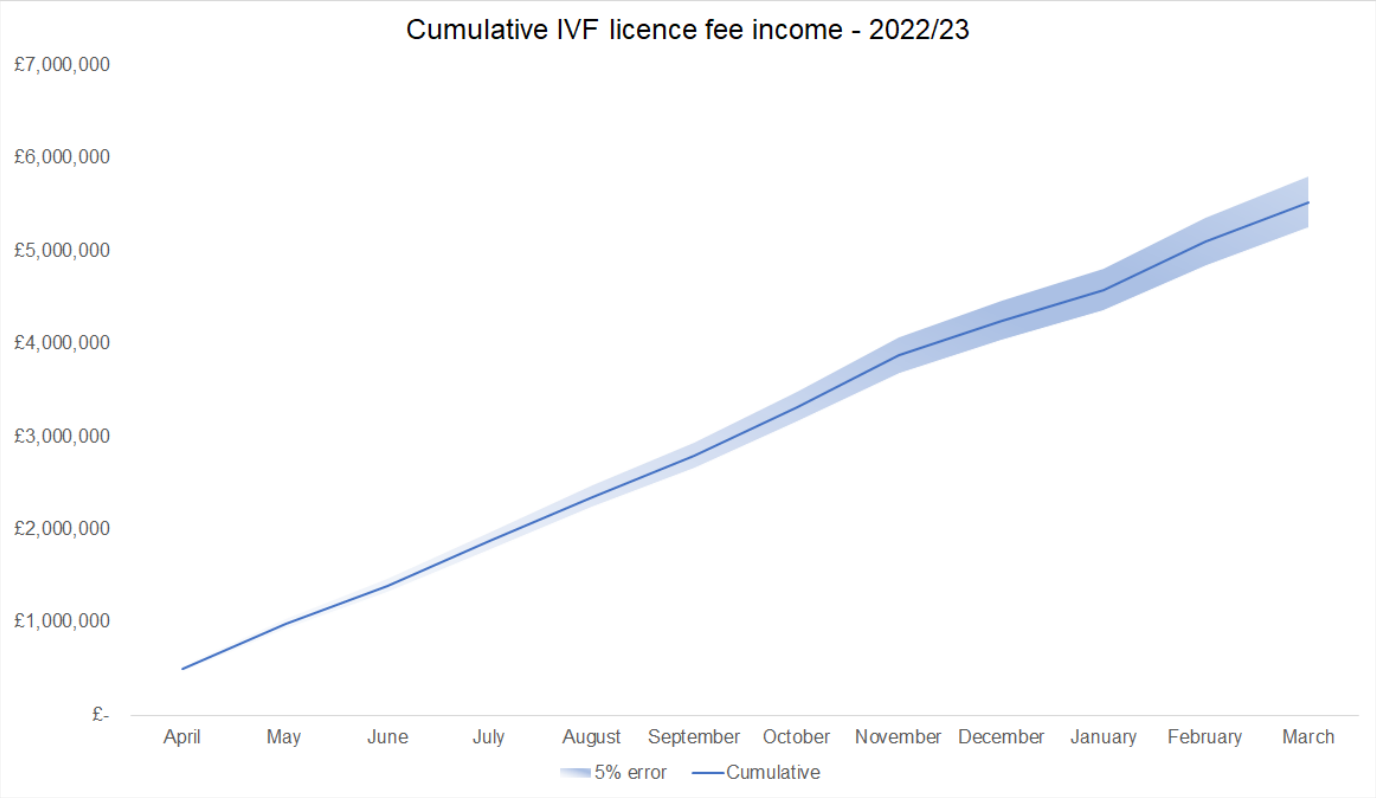
HFEA Operating budget 2022/23

Budgeted Income	**£**	
Licence Fees - Activity	5,802,613	
Licence Fees - Renewal	16,125	
Licence Fees - Storage	900	
Licence Fees - Research	7,125	
EUTD Fees	11,500	
Interest Received	1,300	
Miscellaneouse Income	145,193	
DHSC Funding		
Grant in Aid	938,000	
Ring-fenced RDEL	265,058	
Pension funding	100,000	
		7,287,814

Budgeted expenditure		
Wages and salaries	4,661,850	
Other Staff costs	296,900	
Authority & Committee costs	230,749	
IT Costs & Development	894,354	
Legal Costs	215,000	
Other costs	305,729	
Accommodation	418,174	
Depreciation & Ammortisation	265,058	
		7,287,814

3.6. Our licence fee income position has been based on an assumed 65,000 new IVF cycles that meet the criteria for the payment of a clinic licence fee. Data relating to the 2020/21 and 2021/22 business years varies significantly to historic activity data in both volume and distribution, as such our budget is based on activity from the 2019/20 business year.

3.7. A 1% variance against this estimate would result in a change to our income forecast of £55,000, the graph on the following page provides an illustration of a 5% error range against our income budget.



3.8. As our income position is predicated on sector activity, we retain internal leavers to limit expenditure should activity fall below our baseline. Responding to activity levels that might generate additional income proves more challenging, activity can vary dramatically month on month, and we would look to have at least a quarters data before considering additional activity – although we do have a pipeline of activity that could be accelerated, it is not always possible to complete these projects In the same financial year.

3.9. We will look to improve our ability to react to the emerging income position and will discuss 2021/22 financial performance with the Audit and Governance Committee at its June meeting.

4. For discussion

4.1. Members are asked to:

- Note the approval and announcement of the HFEA licence fee increase for 2022/23
- Note and approve the HFEA operating budget proposed by the Executive for 2022/23
- Note the assumptions that underpin the 2022/23 budget, and that further work will be undertaken with AGC to review the HFEA's financial performance for 2021/22 at its meeting in June 2022.

Next steps in relation to HFEA response to Covid-19

Details about this paper

Area(s) of strategy this paper relates to:	The best care
Meeting:	Authority
Agenda item:	8
Meeting date:	23 March 2022
Authors:	Rachel Cutting, Director Compliance and Information
Annexes	Annex A – GD 0014 v2 Annex B - Updated BFS/ARCS guidance on Fertility treatment during the Covid-19 pandemic

Output from this paper

For information or decision?	For decision
Recommendation:	That the Authority notes the current situation with respect to the changes to Covid-19 restrictions in England, Wales, Scotland and Northern Ireland and updates to professional body guidance. In light of the situation, the Authority is asked to decide when, or if, GD0014vs 2 should be revoked.
Resource implications:	N/a
Implementation date:	Dependent on Authority decision
Communication(s):	See section 4
Organisational risk:	Medium

1. Introduction

1.1. In March 2020 the Authority suspended all licensed fertility treatment in the UK, in response to the Covid-19 pandemic and government restrictions. Treatment was halted by means of General Direction 0014 v1. In April 2020 the Authority agreed a pathway setting out how fertility treatment could be offered safely during the pandemic, provided clinics were compliant with guidance from the UK and devolved governments, professional bodies and the HFEA.

1.2. The framework governing the resumption of treatment during the ongoing Covid-19 pandemic was set out in the revised General Direction 0014 v2 which issued on 11 May 2020 and remains in place today.

1.3. Government restrictions, though at a different pace across the four nations have now started to ease. On 27th January 2022 England lifted all legal restrictions. Face masks, however, remain a requirement in healthcare settings such as GP surgeries, hospitals and care homes. This requirement therefore remains for HFEA licenced centres.

1.4. Differing levels of legal restrictions remain in Scotland, Wales, and Northern Ireland. Face coverings in shops and public transport remains a legal requirement in Scotland. This requirement will be reviewed at the beginning of April. The law regarding face coverings, self-isolation and regulated premises having to conduct risk assessments in Wales is due to expire on 28th March. Only if the situation is stable will remaining restrictions be lifted. The legal requirement for face coverings has been downgraded to guidance in Northern Ireland but there are no changes to the rules on isolation (although this rule is not enshrined in legislation).

1.5. General Direction 0014 was viewed as a necessary measure to ensure that treatment could resume safely. However, as government restrictions are lifted, it is right that we consider whether General Direction 0014 v2 should remain in place.

1.6. Authority is asked to consider whether it is proportionate that General Direction 0014v2 should remain for so long as government restrictions remain in force, be retained indefinitely or whether it should be revoked and archived now or at some defined point in the future.

1.7. The structure of this paper is as follows: section 2 provides an overview of General Direction 0014v2; an update on current professional guidance (section 3); the decision (section 4); and a communications plan (section 5).

2. GD 0014 v2

2.1. As noted above, the Authority decided in April 2020 that the process for allowing a licensed centre to resume treatment should be set out in a revised GD0014. GD 0014 v2 was published on 11 May 2020.

2.2. Given the differing impact of the pandemic on licensed centres across the UK, centres were not required to resume treatment at the same time. Rather it was for each centre to decide whether they were in a position to seek approval from the HFEA to resume treatment. To recommence treatments the key document licensed centres had to produce

was their 'Treatment Commencement Strategy' which recorded the measures the centre put in place to comply with specified guidance on safe and effective treatment during the Covid-19 emergency. The document detailed the risk assessments undertaken, the mitigating measures in place and the practical and logistical measures taken to deliver safe treatment.

2.3. Centres submitted a Covid-19 Treatment Commencement SAQ to their inspector for approval before any treatment could commence.

2.4. GD0014 v2 is at Annex A. For the most part it sets out the conditions the centre is required to have in place *before* treatment resumed. Apart from paragraph 6(d), it does not impose any ongoing obligations on clinics. Paragraph 6(d) requires clinics to record "all new or revised standard operating procedures or protocols whilst maintaining compliance with the Government's current requirements relating to freedom of movement and social distancing." The aim of this paragraph was to ensure that centres were able to continue to deliver services safely as Government requirements changed.

2.5. It is important to note that whilst compliance with General Directions is mandatory, the scope is limited by the powers set out in the Act to requiring clinics to record or provide information to the Authority. We could not, for example, use our powers to make general directions to mandate that centres must follow professional guidance. However, in thinking about how best to ensure that services remain appropriate it is important to consider the professional body guidance, and this is outlined in section 3.

2.6. GD 0014vs2 could stay in place indefinitely as it does not require any further activity, save for any changes that may be required to reflect any new or revised Government requirements.

2.7. Given that there are still restrictions in place in Scotland, Wales, and Northern Ireland, it may be more sensible to retain GD 0014vs2 for the present time.

3. Updated professional guidance

3.1. The BFS/ARCS issued updated guidance on 28 February 2022.

3.2. The guidance covers infection control measures, information regarding the vaccination against covid-19 and the actions to take in the event of a positive test during treatment.

3.3. Infection control measures recommended in the guidance include the requirement for facemasks to be worn within fertility clinics and the need to balance the protection of patient and staff safety with the needs of patients undergoing treatment (for example, the need for partners to be present at crucial times in the patient journey such as embryo transfer and pregnancy scans).

3.4. With regard to vaccination the guidance strongly encourages patients planning or undergoing fertility treatment to get vaccinated or to complete the course if started.

3.5. The BFS/ARCS recommend that patients who test positive for the coronavirus during treatment should have their treatment delayed to minimise the risk of infection to other patients and staff and to mitigate any potential adverse effects of the infection on treatment cycle outcome. The duration of delay of treatment following infection should take into account the severity of the infection, the nature of the planned treatment and

relevant local/national guidelines. UK multidisciplinary guidance advises that elective surgery should be delayed for at least 7 weeks following a positive Covid-19 test. Where procedures do not require anaesthesia or deep sedation, a shorter delay may be reasonable in mild or asymptomatic cases, once they are past the infectious period.

4. Decision

4.1. As noted above, General Direction 0014 v2 was introduced to ensure the safe resumption of treatment. However, since it does not impose ongoing obligations save for the one requirement highlighted above, the Authority could decide to leave it place indefinitely especially as the progress of the pandemic is not necessarily certain.

4.2. That said, it is good regulatory practice to remove unnecessary rules and were the pandemic to develop a serious further wave that required new restrictions we could always reintroduce the measure in the same form or amended to suit the new circumstances.

4.3. We can either:

- Retain GD 0014v2 indefinitely
- Retain GD 0014v2 until all four nations have lifted legal restrictions or at some other point in the future
- Revoke GD 0014v2 now in the expectation that this is the clear direction of travel.

5. Communications

If General Direction 0014v2 is revoked the date of revocation will be communicated to the sector.

5.1. Any Chief Executive's letter will stress that whilst legal restrictions may have been lifted it is expected professional body guidance will be adhered to.

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:	Authority
Agenda item:	9
Meeting date:	23 March 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:	The Authority 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):	-
Organisational risk:	Medium

1. Latest reviews

1.1. The Audit and Governance Committee received the Strategic Risk Register at its meeting on 15 March. We will report verbally on any feedback from the AGC discussion at the Authority meeting.

1.2. Following earlier feedback from AGC, the senior management team conducted an in-depth review in February 2022, resulting in a number of changes.

1.3. All risk and tolerance scores have been reviewed, and the text of all risks has been brought up to date so that they reflect the latest position. The main changes (prior to the AGC meeting) are:

- I1 (information provision) has been updated slightly, pending further work on our communications strategy. In the longer term, this risk will need to be reframed, to focus more on the risks to us achieving the desired impact and reach with our information. Given that further work is still needed, the risk remains slightly above tolerance. We will update this risk further before the June AGC meeting.
- FV1 (financial viability) has been comprehensively updated in light of the Q3 position and following the approval of HMT for our fees increase this year.
- C2 (leadership capability) has been revised to update the position on Board appointments. The risk score has been lowered. We have also raised the tolerance threshold a little, since on reflection (and consistent with wider comments about tolerances at the December AGC meeting) it was felt that a tolerance of 4 was unrealistically low for this risk. This risk is therefore now at tolerance.
- CS1 (cyber security) has been updated significantly following a planned review. The update reflects recent steps taken to improve our resilience to cyber attacks and data loss.
- CV1 (business continuity and covid) – the text has been updated to reflect the current position. It was proposed to AGC that this risk be retired in June, at which point any remaining elements could instead be fed into the ongoing capability risk.

1.4. Comments from the previous four reviews by AGC and SMT are addressed in the commentary for each risk and summarised at the end of the risk register, which is attached at Annex 1. The annex also includes a graphical overview of residual risk scores plotted against risk tolerances.

1.5. One of the ten risks (I1) is currently above tolerance.

2. Plan for risk management review

2.1. The departure of the previous Risk and Business Planning Manager delayed the intended review of our risk management policy and associated processes in late 2021. Therefore AGC requested that a new plan for this work be brought to their March meeting.

The plan will include a review of the risk register itself, a review of the risk policy, and consideration of risk appetite and risk tolerances. In addition, an internal audit of our risk system is now in progress, which will also inform the plan once the report is available. The following plan was presented to AGC at its recent meeting:

2.2. Plan for the coming months:

March	Support the internal audit of our risk systems and begin to consider recommendations once the report is ready.
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.
May	Commence review of operational risk management practices and identification and mitigation of weaknesses, in line with recommendations arising from the current audit, and our own observations about current team practices. Redrafting of policy to begin. 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.
October	Revised draft of risk policy and risk register completed and presented to AGC for consideration. Discussion on risk appetite and tolerance levels.
November	Agreement of risk appetite with Authority alongside their periodic review of the risk register.
December	Finalisation and launch of the revised risk policy and feedback to AGC on the Authority's discussion on risk appetite.

2.3. AGC's previous and latest comments on the plan will be taken into consideration during the review, as well as additional input that will be received shortly from our internal auditors. For instance, we will consider how we might make the risk register, and our consideration of controls, more dynamic, and review our approach to setting individual risk tolerances. We will consider how we can develop the new 'deep dives' approach to incorporate risk assurance mapping into AGC items on a range of topics, and a more thorough assessment of the effectiveness of mitigations. We will develop a way of incorporating periodic horizon scanning into our risk conversations, to anticipate upcoming areas of risk.

2.4. It has been some time since the Authority last discussed our organisational risk appetite. We will schedule a discussion with members about this later in our review process, towards the end of the calendar year. This will be timely given the significant changes in the composition of the Board.

3. Recommendation

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

3.2. The Authority is also asked to note the recommendation to last week's AGC that the Coronavirus risk, CV1, be discontinued from June 2022 onwards, with any residual elements that still present an ongoing risk being integrated into the capability risk (C1) or other risks as appropriate. We will feed back to members on this, and other matters discussed at AGC, when we present this item.

Latest review date – 21/02/2022

Annex 1

Strategic risk register 2020-2024

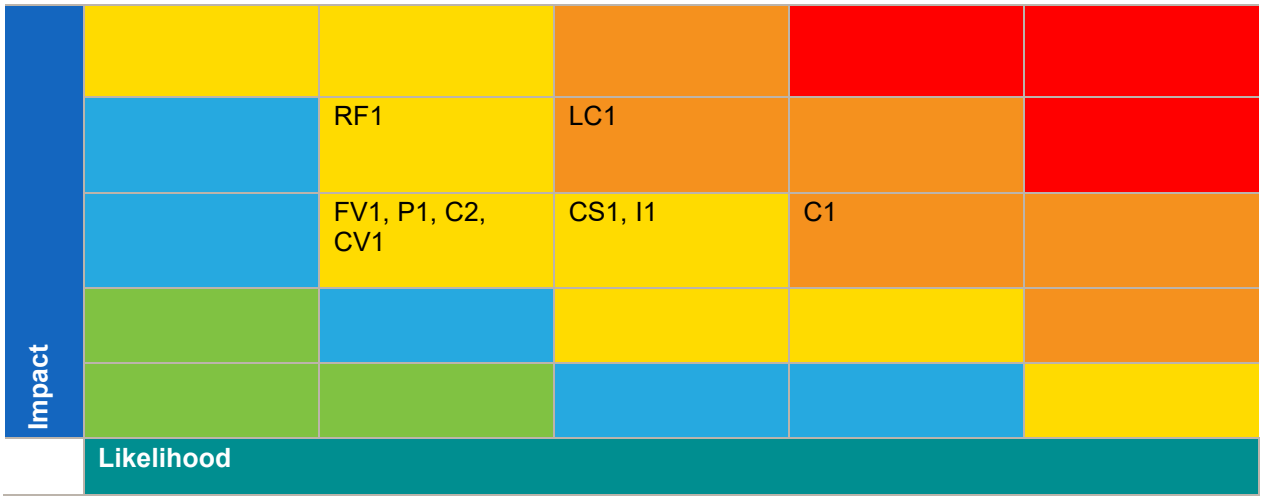
Risk summary: high to low residual risks

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	⇔⇔⇔⇔
CV1: Coronavirus	Whole strategy	9 – Medium	**6 – Medium**	Below tolerance	⇔⇔⇔⇔

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

Recent review points: SMT 1 November ⇨ AGC 9 December ⇨ SMT 10 January ⇨ SMT 21 February

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. Post Covid restrictions lifting, the hybrid methodology will continue to be used for renewal inspections and will be integrated into interim inspections for those starting to be 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. We will initiate the first stage of a multi-year project in 2022-2023.	Ad hoc ongoing - Catherine Drennan Pre-business case project planning in progress - Joanne Anton, Catherine Drennan
Developments occur which our regulatory tools, systems and interventions have not been designed to address and they are unable to adapt to.	Regular review processes for all regulatory tools such as: • Code of Practice. • Compliance and enforcement policy • Licensing SOPs and decision trees Regular reviews enable us to revise these and prevent them from becoming ineffective or outdated. Regular liaison with DHSC and other health regulators to raise issues.	In place - Joanne Anton Revised version of the policy launched 1 June 2021– Catherine Drennan, Rachel Cutting In place and ongoing – Paula Robinson In place - Peter Thompson
The revised inspection approach (including a period of fully remote and hybrid inspections due to Covid-19, introduced November 2020) requires greater resources from the inspection team. This affects ongoing delivery. Note: risk cause arises from control under CV1.	Reviewing the new way of working and inspection approach as this continues to be embedded. Moving towards a steady state balance between desk-based elements and on-site inspections. Compliance management in discussion with the wider Inspection team to ensure that scrutiny is at the correct level and inspections are ‘right sized’ in accordance with revised methodology. Review of documentation required for DBA undertaken in July 2021 to ensure this is proportionate. Clear communication to the inspection team about appropriate level of scrutiny. Continued extensions to some licences where appropriate (ie, low risk clinics with good compliance) to manage the pressure on inspection delivery workload.	Plan in place, agreed by Authority September 2021 – Sharon Fensome Rimmer, Rachel Cutting

Causes / sources	Controls	Timescale / owner of control(s)
Some changes can be very fast meaning our understanding of the implications is limited, affecting our ability to adequately prepare, respond and take a nuanced approach	We cannot control the rate of change, but we can make sure we are aware of likely changes and make our response as timely as possible by: • Annual horizon scanning at SCAAC • maintaining links with key stakeholders including other professional organisations and the licensed centres panel to get a sense of changes they are experiencing or have early sight of. We necessarily must wait for some changes to be clearer to take an effective regulatory position. However, we may choose to take a staged approach when changes are emerging, issuing quick responses such as a Chair's letter, Alert or change to General Directions to address immediate regulatory needs, before strengthening our position with further guidance or regulatory updates.	In place – Joanne Anton In place - Peter Thompson
We have limited capacity, which may reduce our ability to respond quickly to new work, since we may need to review and stop doing something else.	Monthly opportunity for reprioritising at CMG when new work arises and weekly SMT meetings for more pressing decisions. Any reprioritisation of significant Strategy work would be discussed with the Authority.	In place – Peter Thompson
Developments occur in areas where we have a lack of staffing expertise or capability.	As developments occur, Heads consider what the gaps are in our expertise 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	As part of planning and delivering the add-ons project we have looked at the evidence available	In place – Joanne Anton

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

Causes / sources	Controls	Status / timescale / owner
with demand outstripping our ability to respond. Note, this is being managed as a live issue as of September 2021.	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.	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 underway to identify future improvements to inspection reports. This will be delivered alongside other transparency work. Consideration of further changes to the information we publish in discussions on 'regulation and transparency' at Authority meetings. We do provide patient and inspector ratings on CaFC to provide some additional insight into clinics. Further work on transparency and regulation was planned for 2022 but may need to be delayed.	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 In place but will need to

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

Causes / sources	Controls	Status/timescale / owner
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.	Taking an alternative approach to covering the Chief Technology Officer role in the interim. We also reviewed our approach to longer-term recruitment. Looking for alternative ways to allocate skills and resources for hard-to-fill roles to cover gaps.	In place Rachel Cutting Ongoing – hiring managers, Yvonne Akinmodun
Poor morale leading to staff leaving, opening up capability gaps.	Communication between managers and staff at regular team and one-to-one meetings allows any morale issues to be identified early and provides an opportunity to determine actions to be taken. The staff intranet enables regular internal communications. Ongoing CMG discussions about wider staff engagement (including surveys) to enable	In place, ongoing – Peter Thompson In place – Clare Ettinghausen In place - staff survey October

Causes / sources	Mitigations	Status/Timescale / owner
	management responses where there are areas of concern.	2021 with wellbeing pulse survey September 2021 and quarterly thereafter– Yvonne Akinmodun
	Policies and benefits are in place that support staff to balance work and life (stress management resources, mental health first aiders, PerkBox) promoting staff to feel positive about the wider package offered by the HFEA. This may boost good morale.	In place - 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.	In place – Paula Robinson
	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.	In place – Paula Robinson
	Oversight of projects by both the monthly Project Assurance Group and CMG.	In place – Paula Robinson
	Project guidance to support early identification of interdependencies and products in projects, to allow for effective planning of resources.	In place– Paula Robinson
	Planning and prioritising data submission project delivery, within our limited resources.	In place until project ends – Rachel Cutting (pending CTO recruitment)
	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.	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.	Early progress, ongoing – Yvonne Akinmodun
	Future control – use of Redman Place intranet to enable cross-organisational communications.	Planned but not yet in place

Causes / sources	Mitigations	Status/Timescale / owner
		– Richard Sydee
Stratford is a less desirable location for some current staff due to: • increased commuting costs • increased commuting times • preference of staff to continue to work in central London for other reasons, leading to lower morale and lower levels of staff retention (resulting in knowledge loss and capacity and capability gaps) as staff choose to leave because of the office location.	We have an agreed excess fares policy to compensate those who will be paying more following the move to Stratford (those in post before December 2019). Efforts taken to understand the impact on individual staff and discuss their concerns with them via staff survey, 1:1s with managers and all staff meetings to inform controls. These have informed the policies developed. Conversely, there will be improvements to the commuting times and costs of some staff, which may improve morale for them and balance the overall effect. Reduction in number of days in the office following Covid-19 is likely to have reduced the risk of loss of staff.	In place – Yvonne Akinmodun, Richard Sydee Done - Yvonne Akinmodun,
There is a risk that staff views on the positives and negatives of homeworking due to Covid-19 are not considered, meaning we miss opportunities for 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.	Clarity provided to staff that the current arrangement of working in the office one day per week will continue unless Government advice changes. CMG to balance staff desire for certainty about post-Covid-19 arrangements with need for flexibility of response during a period of ongoing change. CMG is discussing policies, to provide assurance, for instance about maximum office attendance requirements.	Discussions in progress Ongoing with specific culture discussion in September – Peter Thompson
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
Government/DHSC	Funding in place for additional resource to manage EU Exit workload in 2021-2022.	Communications ongoing – Clare

Causes / sources	Mitigations	Status/Timescale / owner
The UK leaving the EU has ongoing consequences for the HFEA which we must manage.	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. NB unless any further funding is secured for future years then this work will need to be absorbed within existing activity.	Ettinghausen/ Andy Leonard
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**
4	4	16 - High	**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 now been recruited to replace the three members whose terms have already finished, and four members whose terms will finish at the end of March and the end of April 2022. Three members' terms of office were extended by three months, which was helpful in managing committee quoracy in the interim. New members have relatively long onboarding times at the HFEA owing to the need for specialist training for the licensing committees, and the need to then accumulate experience and knowledge. However, the seven new 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	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
sitting on licensing committees, which may experience an initial 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	

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 – Peter Thompson In place - Yvonne Akinmodun with relevant Manager for specific role In place – Relevant Director alongside managers As required – Director and staff as relevant As required – Peter Thompson, Julia Chain 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	Clear communication with the Department about the management of this risk and mitigations that sit outside of HFEA control.	Ongoing - Peter Thompson

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

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

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

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

Commentary
Cyber-attacks and threats are inherently 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 will be introduced by the end of March 2022.	In place – Steve Morris In place - Peter Thompson Last undertaken January 2020. New course for Authority

Causes / sources	Controls	Timescale / owner
		members to be implemented Autumn 2021. – Steve Morris
Insufficient executive oversight of cyber security risks, resulting in them not being managed effectively	Cyber security training in place to ensure that all staff are appropriately aware of cyber risks and responsibilities. Further training including lunch and learn sessions planned for Q1 2022. Regular review of cyber / network security policies to ensure they are appropriate and in line with other guidance. Policies currently under review, for completion by end of 2021-2022.. Regular review of business continuity plan to ensure that this is fit for purpose for appropriate handling cyber security incidents to minimise their impact.	Undertaken by staff October/ November 2020 – Steve Morris Update agreed at CMG in June 2020– Steve Morris In place and ongoing process – Steve Morris
Changes to the digital estate open up potential attack surfaces or new vulnerabilities. Our relationship with clinics is more digital, and patient identifying information or clinic data could therefore be exposed to attack.	Penetration testing of newly developed systems (PRISM, the Register) assure us that development has appropriately considered cyber security. We undertake penetration testing regularly but a full network penetration test will cover access control, encryption, computer port control, pseudonymisation and physical control Clear information security guidance to HFEA staff about how identifying information should be shared, especially by the Register team, to reduce the chance of this being vulnerable.	Testing is undertaken regularly, – next cycle of testing for completion by March 2022– Steve Morris 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 – Steve Morris
We cannot mitigate effectively for emerging or developing cyber security threats if we are not aware of these.	We maintain external linkages with other organisations (such as ALB CIO network and NHS Digital Cyber Associates Network) to learn from others in relation to cyber risk. We receive regular security alerts and action the high priority ones when they arrive.	Ongoing– Steve Morris
Technical or system weaknesses could lead to loss of, or inability to access,	We undertake regular penetration testing to identify weaknesses so that we can address these.	Ongoing, next round of testing to

Causes / sources	Controls	Timescale / owner
sensitive data, including the Register.	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.	complete by March 2022– Steve Morris In place – Steve Morris Ongoing (Upgrade to Pulse RAS system completed during summer 2021) – Steve Morris
Physical devices used by staff are lost, stolen or otherwise fall into malicious hands, increasing chance of a cyber-attack.	Hardware is encrypted, which would prevent access to data if devices were misplaced. Staff reminded during IT induction about the need to fully shut down devices while outside of secure locations (such as travelling) to implement encryption. 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) – Steve Morris Conditional access should be complete by 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 – Steve Morris
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.

In May, we were served with a Judicial Review claim. We filed our summary grounds of resistance and both the claim, and our summary grounds were considered by a judge, who refused permission to proceed with the Judicial Review claim. The Civil Procedure rules make provision for the claimant to renew their application by way of an oral hearing. At a hearing on 12 October the claim for Judicial Review was rejected. We now understand that the claimant has applied for permission in the Appeal Court.

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

Causes / sources	Mitigations	Timescale / owner
Legal challenges related to clinical implementation of regulation in terms of individual cases (ie, consent-related cases). Ongoing legal parenthood and storage consent failings in clinics and related cases are specific examples. The case-by-case nature of the Courts' approach to matters means resource demands are unpredictable when these arise. Note: we are in dialogue with the Department on the proposed changes to the statutory storage period and the impact that it will have on consent for gametes and embryos currently in storage.	We undertake good record keeping, to allow us to identify and access old versions of guidance, and other key documentation, which may be relevant to cases or enquiries and enable us to see how we have historically interpreted the law. Through constructive and proactive engagement with third parties, the in-house legal function serves to anticipate issues of this sort and prevent challenges. This strengthens our ability to find solutions that do not require legal action. Legal panel in place, as above, enabling us to outsource some elements of the work. Scenario planning is undertaken with input from legal advisors at the start of any legal challenge. This allows the HFEA to anticipate a range of different potential outcomes and plan resources accordingly. We took advice from a leading barrister on the possible options for handling storage consent cases to ensure we take the best approach when cases arise. We also get ongoing ad hoc advice as matters arise. Significant amendments have been made to guidance in the Code of Practice dealing with consent to storage and this will be published in October 2021. This guidance will go further to supporting clinics to be clearer about the legal requirements. Storage consent has been covered in the revision of the PR entry Programme (PREP).	Ongoing – Catherine Drennan In place – Catherine Drennan In place – Peter Thompson Done in 2018/19 and we continue to apply this advice and take further ad hoc advice as required – Catherine Drennan Revised guidance– Catherine Drennan PREP in place – Catherine Drennan/ Joanne Anton
Committee decisions or our decision-making processes being contested. ie, Licensing appeals and/or Judicial Reviews. Challenge of compliance and licensing decisions is a core part of the regulatory framework, and we expect these challenges even if decisions are entirely well founded and supported. Controls therefore include measures to ensure	Compliance and Enforcement policy and related procedures to ensure that the Compliance team acts consistently according to agreed processes. Well-evidenced recommendations in inspection reports mean that licensing decisions are adequately supported and defensible. The Compliance team monitors the number and complexity of management reviews and stay in close communication with the Head of Legal to	In place new version launched June 2021– Rachel Cutting, Catherine Drennan In place – Sharon Fensome-Rimmer

Causes / sources	Mitigations	Timescale / owner
consistency and avoid process failings, so we are in the best position for when we are challenged, therefore reducing the impact of such challenges.	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: • Provision of previous committee papers and minutes to the advisor for the following meeting • Annual workshop • Regular email updates to panel to keep them abreast of any changes. Consistent and well taken decisions at licence committees supported by effective tools for committees and licensing team (licensing pack, Standard operating procedures, decision trees etc) which are regularly reviewed.	In place – Peter Thompson Since Spring 2018 and ongoing – Catherine Drennan In place – Paula Robinson
Any of the key legal risks escalating into high-profile legal challenges resulting in significant resource diversion and reputational consequences for the HFEA which risk undermining the robustness of the regulatory regime.	Close working between legal and communications teams to ensure that the constraints of the law and any HFEA decisions are effectively explained to the press and the public. The default HFEA position is to conduct litigation in a way which is not confrontational, personal, or aggressive. We have sought to build constructive relationships with legal representatives who practice in the sector and the tone of engagement with them means that challenge is more likely to be focused on matters of law than on the HFEA. Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise workload should this become necessary.	In place – Catherine Drennan, Clare Ettinghausen In place – Peter Thompson, Catherine Drennan In place – Peter Thompson
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: If HFEA face unexpected high legal costs or damages which it could not fund. This is an interdependent risk as the Department must ensure the ability to maintain the regulatory regime.	If this risk was to become an issue, then discussion with the Department of Health and Social Care would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also an interdependent risk because DHSC would be involved in resolving it.	In place – Peter Thompson

Causes / sources	Mitigations	Timescale / owner
DHSC: We rely upon the Department for any legislative changes in response to legal risks or impacts.	Our regular communications channels with the Department would ensure we were aware of any planned change at the earliest stage. We highlight when science and medicine are changing so that they can consider whether to make changes to the regulatory framework. Joint working arrangements would then be put in place as needed, depending on the scale of the change. If necessary, this would include agreeing any associated implementation budget. Departmental/ministerial sign-off for key documents such as the Code of Practice in place.	In place – Peter Thompson
DHSC: The Department may be a co-defendant for handling legal risk when cases arise.	We work closely with colleagues at the Department to ensure that the approach of all parties is clear and is coordinated wherever possible. We also pre-emptively engage on emerging legal issues before these become formal legal matters.	In place – Peter Thompson

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

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

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

Commentary
Risk management of these risk causes has been our organisational priority since the beginning of the pandemic. All staff were working from home (and returned to the office at least one day per week, from October 2021, followed by a return to working from home in December 2021 and January 2022). We remain able to operate on either basis. A strategy to manage inspections is in place. Communications to the sector and patients have been in place throughout and are ongoing as and when needed. We would revisit and revise our plans as circumstances change, as is possible in the autumn and winter. Our revised inspection processes are effective and include comprehensive risk assessment and controls; we are assured that we can effectively maintain this regulatory function. Licensing has continued effectively remotely. SMT considered the risk score in March 2021 and decided that the effective inspection methodology reduced the impact of this risk, as the controls ensured we can continue to undertake this statutory function, bringing the score down. The implementation of the methodology has caused a secondary risk, while it beds in, but that is being managed and is captured under RF1. While the implementation has now bedded in well, any increase in infection rates later in the year is likely to impact the inspection team so we will monitor the effects on our delivery approach and review this if required. Preparations for the Covid public inquiry are under way, with relevant documents being catalogued. The extent of the HFEA's involvement in the inquiry is not yet known. **It is proposed that this risk be discontinued in June, and any residual elements (such as those relating to capacity) integrated into other risks as appropriate.**

Causes / sources	**Controls**	**Status/Timescale / owner**
Risk of providing incorrect, inconsistent, or non-responsive advice to clinics or patients as guidance and circumstances change (ie, not updating our information in a timely manner) and this leading to criticism and	Business continuity group (including SMT, Communications, HR, and IT) meeting frequently to discuss changes or circumstances and planning timely responses to these.	In place, ongoing – Richard Sydee In place - SMT and

Causes / sources	Controls	Status/Timescale / owner
undermining our authoritative position as regulator.	Out of hours media monitoring being undertaken, to ensure that we respond to anything occurring at weekends or evenings in a timely manner. Close communication with key sector professional organisations to ensure we are ready to react to any developments led by them (such as guidance updates). Proactive handling of clinic enquiries and close communication with them. Careful monitoring of the need to update information and proactive handling of updates. Public enquiries about Coronavirus are being triaged, with tailored responses in place. Enquirers are being directed to information on our website, to ensure that there is a single source of truth, and this is up to date. Enquiries team have additional support from Managers and Directors. We have reviewed our approach regularly to ensure that this is fit for purpose. Close monitoring of media (including social) to identify and respond to any perceived criticism to ensure our position is clear. Regular review of communications activities to ensure they are relevant and effective.	Communic-ations team In place and ongoing – Clare Ettinghausen In place and ongoing – Sharon Fensome-Rimmer, Rachel Cutting Clare Ettinghausen – in place In place and under regular review – Joanne Anton In place – Clare Ettinghausen
Risk of being challenged publicly (eg during the Covid public inquiry) or legally about the HFEA response, resulting in reputational damage or legal challenge. (This risk also therefore relates directly to LC1 above)	As above – ensuring approach is appropriate. As above – continuing to liaise with professional bodies. We may choose to put out a press release in case of public challenge. Legal advice was sought to ensure that HFEA actions were in line with legislative powers. Further advice available for future decisions. Ability to further engage legal advisors from our established panel if we are challenged. Framework for decision making around removing GD0014 in place and Directions kept under periodic review.	In place – Richard Sydee Ongoing - Rachel Cutting If required - Clare Ettinghausen Done – Peter Thompson If required – Peter Thompson, Catherine Drennan In place – Rachel Cutting and

Causes / sources	Controls	Status/Timescale / owner
	Preparations for the Covid inquiry are under way to ensure we are ready to respond as needed.	Catherine Drennan In progress – Clare Ettinghausen
Gaps in HFEA staffing due to sickness, caring responsibilities etc	Possible capability gaps have been reviewed by teams to ensure that these are identified and managed. Other mitigations as described under the C1 risk.	In place – Yvonne Akinmodun
Risk of disproportionate impact of coronavirus on staff from black and ethnic minority backgrounds. Note: we do not have evidence of this being an issue within the HFEA.	Decision taken to delay routine return to the office subject to government guidance, reducing work-related risk. We are engaging with other similar organisations to consider possible approaches to managing this risk. We have considered the impact as part of planning for the return to inspections and office working, including individual risk assessments for inspection staff, performed before each inspection.	In progress – Yvonne Akinmodun In place – Sharon Fensome-Rimmer
Clinics stop activity during the epidemic and so we are unable to inspect them within the necessary statutory timeframes.	Extending of licences (noted above) should remove this risk by ensuring that the licence status of clinics is maintained.	In place - Paula Robinson
Precipitous decrease in funding due to large reductions in treatment undertaken because of Coronavirus. Note: this risk may be both short and longer-term if clinics close as a result.	As per FV1 risk - We have sufficient cash reserves to function normally for a period of several months if there was a steep drop-off in activity. The final contingency would be to seek additional cash and/or funding from the Department.	In place – Richard Sydee Ongoing discussions if needed as ongoing impact becomes clearer – Richard Sydee
Negative effects on staff wellbeing (both health and safety and mental health) caused by extended working from home (WFH), may mean that they are unable to work effectively, reducing overall staff capacity.	Provided equipment for staff who must WFH without suitable arrangements in place. Ability of staff unable to work from home to work in Covid-19 secure office. Mental Health resources provided to staff, such as employee assistance programme and links to other organisations' resources. Mental Health First Aiders in place to increase awareness of need to care for mental health. Available to discuss mental health concerns confidentially with staff. Regular check-ins in place between staff and managers at all levels, to support staff, monitor	In place – Richard Sydee In place – Yvonne Akinmodun In place – Yvonne Akinmodun In place and ongoing –

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

Reviews and revisions

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 – 9 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.

SMT review – 1 November 2021:

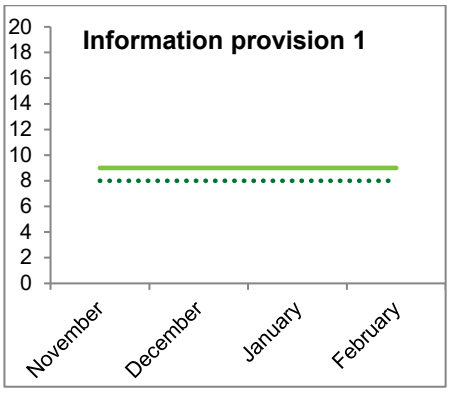
SMT reviewed all risks, controls and scores and made the following points in discussion:

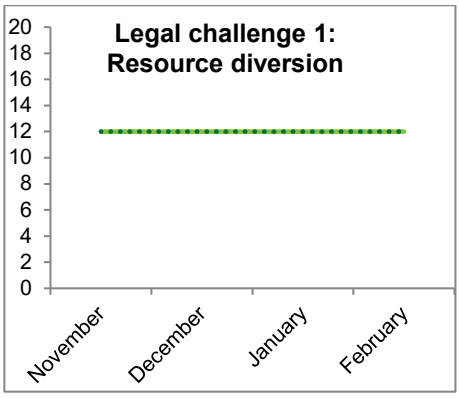
- RF1 - Risk sources relating to general capacity and capability challenges should be reflected in risk C1, since they were not linked to the regulatory framework itself.
- I1 – The residual risk likelihood score was increased slightly, in recognition of points raised at AGC. The next CMG meeting would need to discuss managing the gap in CAFC reporting (until Autumn 2022). Discussions about this are ongoing. New performance measures are being developed to enable reporting to the Authority on the OTR backlog.
- C1 – SMT reflected on discussions at AGC, and agreed that the points about upcoming risks and new areas of work should be reflected in this risk. Our 'business as usual' work continues to expand, and this is a risk without additional resources to meet the new requirements.
- C2 – There was no news at the time of this review about the possibility of extending members' terms of office (three extensions were subsequently agreed). The November Authority meeting would be the last for some members, so we did need to know the outcome. Extensions would help us to manage licensing quoracy in the new year. 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.
- CS1 – SMT agreed this risk should be reviewed following recent discussions at CMG about cybersecurity, especially in relation to the use of personal devices and members' personal email accounts.
- OM1 – SMT considered that this risk had changed. Some elements were dealt with, and others related relating mainly to capacity and capability issues. It was therefore agreed that this risk would be merged into C1, removing those elements that were now out of date.
- LC1 – this risk has potentially reduced somewhat, since the recent JR proceedings had been rejected by a court. However, there may yet be an appeal, and so the residual risk score has not been reduced at this time.
- CV1 – SMT considered whether this risk was still pertinent at this stage in the pandemic, but agreed that it was. Infection rates were currently high again, and factors around vaccinations could still potentially affect clinic on-site visits. The inherent risk score was lowered. We will continue to monitor this risk.

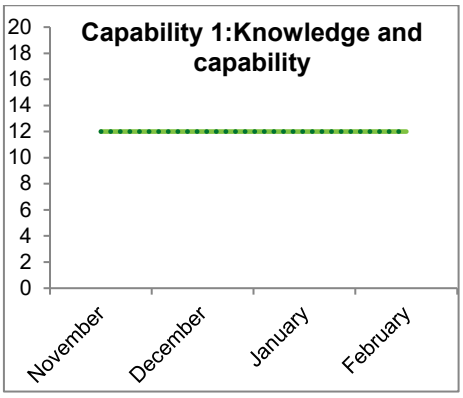
Risk trend graphs (February 2022)

Key:

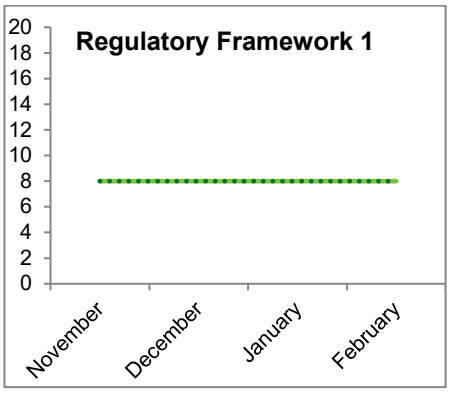
High and above tolerance risks

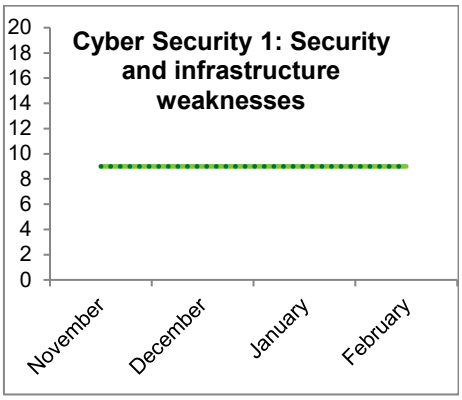


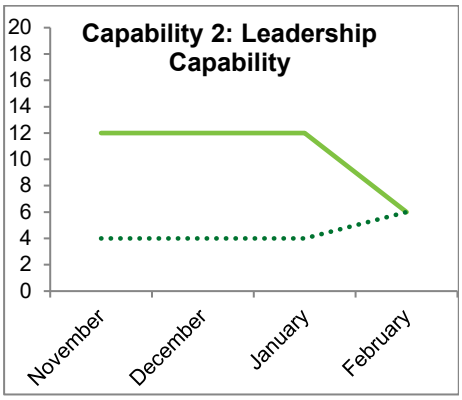


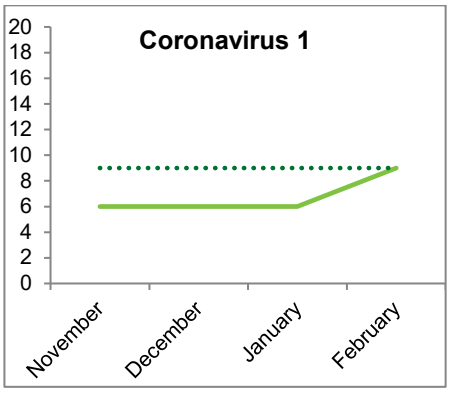


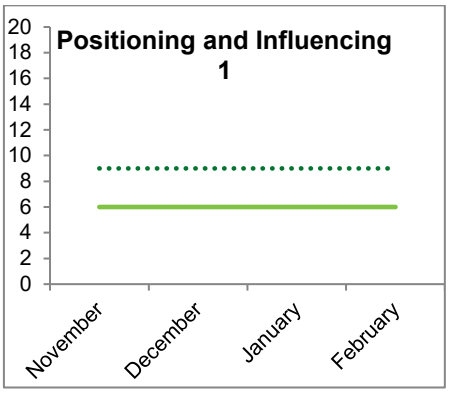
Lower and below tolerance risks

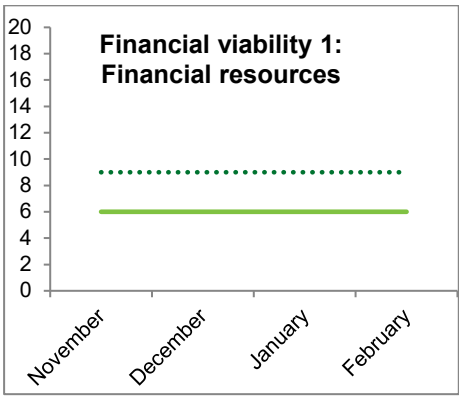












Criteria for inclusion of risks

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.

Add-ons rating system and survey options

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.
Meeting:	Authority
Agenda item:	10
Meeting date:	23 March 2022
Author:	Georgina Allen, Policy Manager Sonia Macleod, Scientific Policy Manager
Annexes	Annex A Options to be included in the public/clinic survey

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to consider and agree: - The proposed options for inclusion in the public/clinic survey - The proposed next steps
Resource implications:	Within existing resources.
Implementation date:	25 March 2022
Communication(s):	A full communications plan to publish and advertise the public/clinic survey to both clinics and patients/ the public.
Organisational risk:	Medium
Relating papers	September 2021 Authority Paper November 2021 Authority Paper

1. Introduction and Background

1.1. At the Authority meeting in September 2021 it was agreed that we would undertake work to further **evolve the public webpage presentation of the rating system for treatment add-ons aimed at making it as useful as possible for patients**. The meeting reiterated that patients should remain the primary audience for any future system. It was agreed that specifically we would:

- Carry out scoping work on the extent to which the current rating system could evolve and improve (e.g. do we stick with RAG or move to a different rating scale) and/or introduce multiple ratings per add-on (e.g. illustrating various outcomes for each add-on).
- Come back to a future Authority meeting to report the outcome of that scoping work and set out a proposed engagement strategy.
- Come back to an Authority meeting in 2022 with a recommendation on how best to evolve/change the rating system based on engagement findings.
- Aim for Authority members to approve changes to the rating system by July 2022 so that the required work can be undertaken to inform the October 2022 SCAAC meeting. This is the next meeting at which ratings are due to be allocated to our list of add-ons as part of their annual review.

1.2. In November 2021, we informed the Authority of the scoping work which had already been carried out and included:

- Identifying and meeting with research experts in data communication and health presentation to develop options for how the rating system could be evolved (outlined in the **November Authority paper** on treatment add-ons**)**
- Presenting the developed options to our Licenced Clinic Panel (LCP) and Patient Organisation Stakeholder Group (POSG) to gain insights from a clinic and patient organisation perspectives.

1.3. The Authority noted the progress made on the scoping work and agreed with further scoping work planned until February 2022 including:

- Presenting to and gaining the views from the Treatment Add-ons Working Group (TAG) summarised in section 2 below.
- Carrying out some in-depth one-to-one interviews with patients in early 2022 summarised in section 2 below. Findings from these interviews would be used to establish their:
    - Understanding of the current RAG rating system.
    - Understanding of the alternative options.
    - Top three preferences for evolving the current rating system.

- Based on feedback and views from researchers, stakeholders, patients and TAG, developing options for evolving the current RAG rating system for treatment add-ons which will be presented in a public/clinic engagement survey.
- It was agreed that the current RAG system would be one of the options presented in the engagement along with a maximum of two other options.

1.4. The scoping work has now been completed and we are ready to move onto the wider engagement work. This paper outlines

1.4..1. The findings from the most recent element of the scoping work up to February 2022 (in section 2);

1.4..2. The overall findings from all the scoping work conducted (in section 3);

1.4..3. Proposals for the public/clinic engagement phase and next steps (in section 4), including the proposed options for the survey (in Annex A).

2. Scoping Work up to February 2022

2.1. Since the November Authority meeting, we have discussed the add-ons ratings with TAG members and conducted detailed patient interviews.

The views from TAG

2.2. We presented the 10 options outlined in the November Authority paper to TAG.

2.3. The views from TAG were similar to those from LCP and POSG highlighted in the November Authority paper:

- To keep the current Red, Amber, Green rating system with some modifications to the wording.
- A variation of the current rating system, (e.g. to change the red rating to demonstrating 'evidence of potential negative effects' and adding another rating (e.g. grey) to demonstrate 'no evidence' (or e.g. a gradient of one colour).
- To include additional outcomes.

  Similarly to LCP, TAG suggested that we consider reviewing evidence in respect of additional patient groups (other than just 'most fertility patients') as well as additional outcomes in our continued scoping work.
  We listened to the views from LCP and TAG to include additional patient groups in our continued scoping work and also narrowed down visual presentation options (see paragraph 2.5) based on LCP, POSG and TAG views.

The views from patient interviews

2.4. We conducted five in-depth patient interviews. The aim of these interviews was to obtain a snapshot of how these patients responded to the proposed options.

2.5. Based on the feedback from earlier scoping work we narrowed down from ten to six options which we presented to patients. These were:

- Option 1 - A variation of the current Red, Amber Green (RAG) rating system
- Option 2 - The addition of a Grey rating. Red, Grey, Amber and Green (RGAG)
- Option 3 - A colour gradient rather than RAG or RGAG
- Option 4 - The use of symbols rather than the round circles 'traffic lights'
- Option 5 – The addition of ratings for outcomes other than live births
- Option 6 – The addition of ratings for specific sub-groups of patients.

2.6. The views from patients were generally similar to those from LCP, POSG and TAG but varied slightly. Their views were:

- To change the red rating to demonstrating 'evidence of potential negative effects' and adding another rating (e.g. grey) to demonstrate 'no evidence' (i.e. option 2) because it would provide more information to patients.
- Symbols (i.e. option 5) are useful as they provide more detail and nuance which the other rating systems presented (and the current rating system) cannot do.
- To include, where relevant and available, ratings for additional outcomes per add-on, rather than just live birth rates (i.e. option 5)
- To include ratings for additional patient groups per add-on rather than just for the majority of fertility patients (i.e. option 6).
- To include more information (e.g. about the evidence and scale of impact that an intervention has on live birth rates or other relevant outcomes) on the website through layered pages, which would allow those who wanted more information to click through to a page which contains greater detail.

3. Overall findings from Scoping work

3.1. Our scoping work suggests that patients and professionals generally like the simplicity of the presentation in the current Red, Amber, Green rating system. A variation of the current system has been a consistent choice across a range of stakeholders.

3.2. From this work we have identified several areas for where refinement of the current rating system could be considered. These were:

- **The lack of a green rating**. The green rating is defined on our website as an add-on that has more than one high quality RCT which shows that the procedure is effective at improving the chances of having a baby for most fertility patients. When the add-ons policy was first developed the Authority were of the view that since add-ons are

by definition additional treatments, rather than part of the standard IVF cycle, any procedure that has been shown in high quality RCTs to be effective at improving the chances of having a baby for most fertility patients (so would be classified as 'green') may form part of the standard IVF treatment. Accordingly, a green rated add-on is not included in our add-ons list. Given some of the views we have heard, the Authority may wish to revisit this decision, particularly in respect of potentially rating additional outcomes.

- It was highlighted to us by researchers that the phrasing **'no-evidence' could be interpreted in different ways**: 1) there has been no research conducted and so there is 'no evidence' either for its success or lack of success, OR 2) the research that has been conducted shows that it is not successful, therefore, there is 'no evidence' to suggest that it is successful.
- **Red and green in many contexts have implicit meanings of 'stop' and 'go'**, and their use in the current RAG system may not align the with implicit expectations of some users.
- **Patients tended to focus on the impact** of an intervention,
- **Professionals tended to focus on the strength of the evidence** used to generate a rating

3.3. The simplicity of the current RAG rating has been praised by patients and professionals alike, and when considering any evolution of the current rating system a balance must be struck between creating a system that is both clear and simple yet has sufficient detail to aid informed decision making.

3.4. Taking into account the factors highlighted above we have developed three options to propose and evaluate via a public survey (see **Annex A**).

3.5. **Option 1** As set out in the November Authority paper, the first of the three options is an evolution of the current RAG rating. This has been slightly modified from the existing RAG ratings so that the focus is more on the impact of the intervention, which was preferred by patients.

3.6. **Options 2 & 3** The next two options narrow the use the red-coloured rating to indicate a detrimental impact on live birth rates and/or a potential safety concern, which aligns with the implicit understanding most people have of 'red' meaning 'stop'. These options also have added rating categories; there are four categories in the second option and five categories in the third option. This allows for differentiation between lack of RCTs and a lack of evidence of impact and addresses the 'no evidence' issue.

3.7. **Symbols** When they are asked about option three, survey respondents will have an opportunity to indicate if they prefer the round circles of our current RAG system or the use of symbols.

3.8. **Additional outcomes** The survey will also ask about rating additional outcomes other than live births, for example miscarriage rates. If a decision is made to rate additional outcomes, we note that it would potentially be possible for an add-on to be rated green for specific outcomes (see 'the lack of a green rating' in 3.2 above).

3.9. **Choice of option** Our scoping work suggests that all three options are viable refinements of the current rating system. All will meet some of the preferences expressed. There is no absolute 'right' answer for all patients, because views differ; diverse preferences were expressed and these were not always mutually compatible. In the end the choice of rating system will need to be a judgement of the Authority, informed by the evidence we have gathered throughout this project, and including the patient and clinic survey stage that we will begin next.

4. Public/clinic engagement and next steps

4.1. The scoping work and patient interviews summarised above have enabled us to develop three options that we will include in the patient and clinic engagement survey (see **Annex A)**.

4.2. We have had to ensure that we account for the feasibility of any proposed changes to our rating system and the impact of such changes on all relevant stakeholders.

4.3. We plan to now conduct a public survey for both the public/patients and the sector/clinics to understand their views on each of the options in Annex A. This survey is intended to run for a month, with the option to extend if required.

4.4. Findings from the survey will be analysed and used to inform a proposal for evolving the presentational aspects of the add-ons rating system which we intend to bring to Authority for decision later this year. In conjunction we will bring an updated recommendation from SCAAC on the evidence base which should be used to create ratings for add-ons, which the Authority will also be asked to decide upon. Associated information on the potential resource implications for the HFEA of any changes recommended will be included to enable an informed conclusion to be reached.

4.5. Once we have a final recommendation from Authority on any updates to the current rating system, our final iterative task will be to create test webpages which will be put through user acceptance testing with patients and be refined accordingly as needed. The options in **Annex A** contain suggested wording and should not be read as final wording, because the text is likely to be refined in response to user acceptance testing.

5. Recommendations

5.1. The Authority is asked to agree:

- The proposed options for inclusion in the public/clinic engagement survey set out in Annex A
- The proposed next steps set out in section 4

Annex A – Options to include in the public/clinic survey

When deciding on which options to include in the survey we considered:

The views of researchers, stakeholders and patient groups

The suggestions from researchers, stakeholders and patients

The feasibility of each option

Based on this, in the survey we will present the below **three alternative rating system options** (the format may vary to ensure that the survey can be easily read online):

1. A variation of the current rating system

Green – On balance, the evidence from high quality RCTs **shows this add-on is effective** at improving the chances of having a baby for most fertility patients.

Amber – On balance, **it is not clear whether this add-on is effective** at improving the chances of having a baby for most fertility patients. This is because there are conflicting findings between different high quality RCTs – in some RCTs the add-on has been found to be effective, but in other RCTs it has not**.**

Red – **There is a lack of evidence that this add-on is effective** at improving the chances of having a baby for most fertility patients. This may be because

- no RCTs have been done, or
- if RCTs have been done, on balance, they have not shown that this add-on is effective

Points to note:-

a. It has been highlighted through our preliminary scoping work that people liked the simplicity of the RAG rating system.
b. The only change here is to the wording used. The emphasis has shifted from focusing on the strength of the evidence (which we found experts tend to do) to focusing on the impact of an intervention (which we found patients tended to do),

2. The addition of a grey rating (GRAG)

Green - On balance, the evidence from high quality RCTs **shows this add-on is effective** at improving the chances of having a baby for most fertility patients.

Amber – On balance, **it is not clear whether this add-on is effective** at improving the chances of having a baby for most fertility patients. This is because there are conflicting findings between different high quality RCTs – in some RCTs the add-on has been found to be effective, but in other RCTs it has not**.**

Grey - There is a lack of evidence that this add-on is effective at improving the chances of having a baby for most fertility patients. This may be because
1) no RCTs have been done, or
2) if RCTs have been done, on balance, they have not shown that this add-on is effective

Red - On balance, the evidence from high quality RCTs show that the add-on **may reduce the chances of having a baby** for most fertility patients **or there are potential safety concerns**

Points to note:-

a. There has been some suggestion that the red rating may be confusing as some may have a pre-existing interpretation of red to mean ‘danger’ or ‘stop’. This interpretation could conflict with the current meaning of red as ‘no evidence’.
b. Here we have changed the red rating to show where there is evidence that the add-on causes either a reduction in the chances of having a baby, or that there are potential safety concerns.
c. Here we have added an additional grey rating which would demonstrate ‘lack of evidence’.

3. A symbol rating system

Green ✓ On balance, the evidence from high quality RCTs **shows this add-on is effective** at improving the chances of having a baby for most fertility patients.

Yellow - On balance, the evidence from high quality RCTs show that the add-on **has no effect at improving the chances of having a baby** for most fertility patients

Grey – We cannot rate the effectiveness of this add-on at improving the chances of having a baby for most fertility patients as there have been so few or no RCTs done.

Amber ? On balance, **it is not clear whether this add-on is effective** at improving the chances of having a baby for most fertility patients. This is because there are conflicting findings between different high quality RCTs – in some RCTs the add-on has been found to be effective, but in other RCTs it has not**.**

Red - On balance, the evidence from high quality RCTs show that the add-on **may reduce the chances of having a baby** for most fertility patients **or there are potential safety concerns**

Points to note:-

a. The current rating system cannot provide nuance and some patients have said that more information would be useful.
b. One way to provide more nuance is by using symbols.

Further questions in the Survey

- The scoping work has indicated that patients in particular, would like information on other outcomes in addition to live birth rates
- One potential option for rating additional outcomes is to use a table, like the one below, as researcher have reported that tables are accessible and easy for most people to understand. Feedback will be sought on this option as part of the public/clinic survey.
- Another option is to put any rating of additional outcomes on the webpage for each specific add-on rather than on the main add-ons webpage, where the RAG-rated overview is currently presented.
- As part of the survey we will ask whether people would like **additional outcomes** to be rated and if so where they consider this additional rating should be displayed on the HFEA website.

Treatment add-on	Live birth rate	Other Outcomes			
		Reduces **miscarriage risk**	Reduces **time to clinical pregnancy**	Reduces the Ovarian Hyperstimulation syndrome **(OHSS) risk**	Reduces **multiple birth** risk
Add-on 1				N/A	N/A
Add-on 2			N/A		N/A
Add-on 3		N/A			

Points to note:-

a. It was suggested that we could either provide information on other outcomes (additional outcomes) or on how an add-on impacted on a particular sub-set of patients (additional patient groups). Additional outcomes was chosen for the survey, rather than providing information for additional patient groups because although there is limited data for both, we have more information about additional outcomes.
b. We note that there is the potential for additional outcomes to be rated green (or equivalent e.g. a green tick)
c. Some outcomes may not apply to certain add-ons, where this is the case, we will state ‘not applicable for this add-on’.