Human Fertilisation & Embryology Authority

Authority meeting held by teleconference

Date and time - Wednesday 24 March 2021, 3pm – 5pm

Venue - online

Agenda items	Time
1. Welcome, apologies and declarations of interest	3.00pm
2. Minutes of the meeting held 27 January 2021 **For decision**	3.05pm
3. Chairs report **For information**	3.10pm
4. Chief Executive's report **For information**	3.25pm
5. Performance report **For information**	3.30pm
6. Covid-19 update **For information**	3.40pm
7. Effective governance **For decision**	3.55pm
8. Business plan 2021-22 **For decision**	4.00pm
9. Treatment add-ons update **For information**	4.15pm
10. HFEA response to CMA/ASA guidance **For decision**	4.30pm
11. Compliance and Enforcement policy post consultation **For decision**	4.45pm
12. Any other business	4.55pm
13. Close	5.00pm

Minutes of Authority meeting 27 January 2021

Details:			
Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society		
Agenda item	2		
Meeting date	24 March 2021		
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 27 January 2021 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 27 January 2021 held via teleconference

Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Anne Lampe Jason Kasraie Catharine Seddon	Jonathan Herring Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby Kate Brian Tim Child
Apologies	Emma Cave	
Observers	Alison Marsden Marina Pappa (Department of Health and Social Care - DHSC)	
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Rachel Cutting Catherine Drennan	Paula Robinson Debbie Okutubo Nora Cooke-O'Dowd Dan Howard

Members

There were 13 members at the meeting – eight lay and five professional members.

1. Welcome and declarations of interest

1.1. The Chair opened the meeting by wishing everyone a happy new year and welcoming Authority members, observers and staff present online. She welcomed the new Authority members Jason Kasraie, Tim Child, Catharine Seddon and Alison Marsden and informed all present that Alison's appointment starts on 1 April 2021 but she would be observing the meeting today.

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:

- Yacoub Khalaf (clinician at a licensed clinic)
- Tim Child (PR at a licensed clinic)
- Ruth Wilde (counsellor at licensed clinics)
- Kate Brian (working at Fertility Network UK)
- 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 11 November 2020 were an accurate record of the meeting and could be signed by the Chair.

3. Chair's report

3.1. On 18 December, the Chair met online with Lord Bethell; the Chief Executive (CE) and the Director of Strategy and Corporate Affairs were also present. The discussion focused on our plans to celebrate the 30th anniversary of the HFEA in 2021.

3.2. The Chair commented that the HFEA was one of the longest serving public bodies in the health sector, supporting patients over the last 30 years. The impact of Covid-19 on clinics and patients could not be underestimated, and as a regulatory body we will continue to support clinics and see that our inspection regime and the way we ensure safety for patients is carried out in an effective and efficient way.

Decision

3.3. Members noted the Chair's report.

4. Chief Executive's report

4.1. The Chief Executive (CE) reported back on some of the engagements he had with the sector. He explained that due to the Covid-19 restrictions, the 2021 joint professional societies' fertility conference was held online and he was part of a wider panel discussion reflecting on the impact of Covid-19 on the sector.

4.2. The CE updated the Authority on the impact of Covid-19 on the organisation. Staff had been working at home since March 2020 and staff, systems and IT were all working well. The organisation continues to support staff who find it difficult to work from home. The CE commented that the added impact of this third lockdown was now having a negative effect on some staff who had coped well during the first lockdown.

4.3. It was noted that some staff were eligible for key worker status which has helped some who have children of school age. Covid-19 continues to impact on the welfare of staff and we continue to look at ways to support wellbeing.

4.4. The CE informed the Authority that with the agreement of the sector we will be delaying the launch of PRISM, our new information submission system for clinics, as it was felt that launching an IT system in the middle of a pandemic would not be beneficial to clinics who would have other priorities. It was noted that this item was on the agenda for this meeting and will be discussed further then.

4.5. The EU exit transition period ended on 31 December 2020. We issued all relevant changes to clinics including new general directions in advance of this date. We also passed on all communications from the Department of Health and Social Care (DHSC) to licensed clinics.

4.6. It is too early to determine the full impact of EU exit on clinics but we are monitoring the situation and we communicate regularly with the DHSC. There are some issues relating to VAT on imported sperm that have been brought to our attention and we have raised this with the DHSC who are liaising with the HMRC. As soon as we get any definitive answers we will pass them to clinics. We are at the beginning of this new process and will keep Authority members abreast of developments.

4.7. Lastly, the CE updated on the appointment of a new Chair. He commented that the process was run by the DHSC and members would be kept informed of the outcome. The CE stated that we do not expect to be without a Chair at any point in time and DHSC will put in place any interim arrangements if needed.

Decision

4.8. Members noted the CE's report.

5. Performance report

5.1. The CE introduced the performance report covering the period up to November 2020. It was noted that performance was generally good and that there were no red indicators. Despite the pressures from the impact of Covid-19 on staff, turnover was at manageable levels and the sickness absence rate was also very low. Some staff had contracted Covid-19 and all but one recovered fairly quickly.

Strategy and Corporate Affairs

5.2. The Director of Strategy and Corporate Affairs gave a brief overview on ongoing work in the directorate.

5.3. We are looking forward to marking the 30th anniversary of the HFEA and looking to the future of us as a regulator and the fertility sector. Lord Bethell had said in the meeting in December that he was supportive of us looking into possible legislative change in the years ahead.

5.4. The Competition and Markets Authority guidance in relation to the fertility sector is in the final days of their public consultation. They have consulted widely with professionals, patient groups and individuals and we look forward to the launch of their final guidance later in the year.

5.5. The Advertising Standards Authority (ASA) would also be issuing guidance to ensure clinics are aware of their obligations under the ASA Code.

5.6. Members will be aware that we publish an annual report, Fertility Trends, which is our annual statistical report on our register data. In March 2021, we will publish a supplementary report looking at our register data relating to black and minority ethnic patients.

5.7. We are working on some small updates to the Code of Practice to incorporate, for example, any legislative changes and further guidance, for example, on medicines management, where there have been high levels of non-compliance in recent years. The draft text for the Code of Practice would be brought back to the Authority later in the year.

5.8. We are making further progress on our work on treatment add-ons following the discussions at the Authority meeting in November 2020, for example on changing the website text in response to patient feedback and adding text on holistic therapies. There will be an update on this at the March Authority meeting.

5.9. The next Scientific and Clinical Advances Advisory Committee (SCAAC) meeting would take place in February.

Compliance and Information

5.10. The Director of Compliance and Information gave an overview of the work in her directorate. Starting with the compliance side, she reminded the Authority that inspections resumed in

November 2020 and that the methodology had been developed to minimise time on site. A risk-based desk-based assessment alongside virtual technology is now undertaken. This allows inspectors to have a virtual 'walk around', discuss issues with staff and minimise time on-site. If concerns remain after the assessment process, on-site visits are carried out. The feedback from inspectors and clinics was positive, although the document review process for inspectors is proving work intensive.

5.11. Both interim inspections and renewals have been scheduled to take place in the next few months using the new approach. In a few instances, licences of clinics with no concerns have been extended from 4 to 5 years to enable the workload to be spread out. The Director of Compliance and Information commented that we will continue to learn from this process and it will inform how inspections can be conducted after the pandemic.

5.12. Members were reminded that the Opening the Register (OTR) service reopened in October and there has been a substantial increase in requests received. Individuals who made a request have been emailed and advised of an increased waiting time due to the increase in requests. There is a recruitment in progress for a 12-month contract for an additional staff member to support the service. The demand will continue to be monitored.

5.13. Members asked about the increased number of people coming forward for information and if this was the start of a trend ahead of people preparing for 2023, which is 18 years after donor anonymity was removed. The Director of Compliance and Information responded that there was no evidence that it was a trend. It was believed that it was the backlog from when the service was closed at the start of the pandemic which meant that people were unable to ask for the information they required.

5.14. Members commented that the website cited an 8 to 10 month delay in processing applications for OTR and requested that this be looked at, including the possibility of re-deploying internal resources to reduce the waiting time. The Director replied that the waiting time will be reviewed once the new member of staff is in post and working through requests. It is anticipated that this will significantly reduce waiting times.

5.15. The Register team have completed the data verification process ahead of Choose a Fertility Clinic data (CaFC) being published in February. The data is now frozen and the team have resolved a significant number of data quality issues. There remain six clinics that are yet to sign off their data and we will continue to work with them.

Finance and Resources

5.16. The Director of Finance and Resources presented to the Authority. It was noted that in line with the performance data in the report, the HFEA was expecting a small shortfall against budget, but it now appeared to be smaller than anticipated.

5.17. The ongoing PRISM work had increased our expenditure, but savings had been realised from fewer activities including travelling to on-site inspections and face to face meeting costs.

5.18. For the office move, this is now complete and we are formally operating from the new office. However, staff are not yet able to attend the office due to the present lockdown.

5.19. The Chair thanked all staff for the hard work during this difficult period and asked, on the income side, how many treatments were anticipated in clinics.

5.20. The Director of Finance and Resources responded that it was too early to put a figure on this but that we monitored the situation carefully and the Director of Compliance and Information discussed treatment numbers regularly with the DHSC and NHS England including any concerns we have about referrals into the IVF pathway from primary and secondary care.

Other issues

5.21. The Chair invited professional members to reflect on the situation in relation to the pandemic.

5.22. Some members working in the sector commented that the present situation was not as bad as in March 2020 when the pandemic started but redeployment of targeted medical staff was still expected and happening already in some cases. Lessons learnt from 2020 were being implemented and patients were now more familiar with what to expect.

5.23. It was discussed that whilst the number of patients being treated has been near normal levels in many licenced centres, we are seeing an issue with a drop in referrals into the start of the IVF pathway due to delays in referrals from primary care, whether from GPs to specialist fertility clinics or from GPs to hospital trusts for general gynaelogical tests and procedures.

5.24. The availability of the vaccine for patient facing staff in private centres had been raised and we had worked to ensure they were included in the correct group of priority staff for vaccinations. Concerns had been raised from patients about the effect of the vaccine on fertility or in pregnancy. We had updated our FAQ on this following a change in advice from the JCVI and further statements from professional bodies.

5.25. It was also raised that the two-year extension to storage limits that had been introduced last year by the DHSC, was still causing concern for clinics and patients, who wanted the storage period to be longer.

5.26. Communication from clinics to patients had much improved during the pandemic, although there was still some variability. It was noted that NHS funding for those who had gone over the age limit due to Covid-19 was a concern for patients in light of the extended waiting times.

5.27. A member raised whether partners were being allowed to attend appointments at clinics with patients. This varies by clinic, depending on their wider policies about attendance for in clinic appointments. Clinics should be encouraged to offer support and counselling to patients at this difficult time.

5.28. The Director of Compliance and Information commented that part of the inspection process was to ask about the counselling that was made available to patients.

5.29. The CE stated that the importance of good communication with patients would continue to be highlighted to clinics.

In conclusion

5.30. The CE commented that most of these subjects were covered in the Covid-19 FAQs for patients and professionals that were on the HFEA website and updated frequently.

5.31. Members asked if there were any developments with the Government consultation on storage limits for Gametes and Embryos. The Director of Strategy and Corporate Affairs commented that the DHSC had consulted on this issue and were working through the responses. This was confirmed by the DHSC representative attending the meeting.

Decision

5.32. Members noted the performance report.

6. Covid-19 update

6.1. The Director of Compliance and Information presented to the Authority. Members were advised that following the start of the January lockdown, the CE issued a letter informing all centres through their persons responsible (PR) that treatments could continue in a safe manner for both patients and staff in accordance with our general direction 0014 (GD0014 v.2). The importance of minimising referrals into NHS emergency care was stressed in the statement.

6.2. It was noted that inspections would continue with a different methodology utilising a risk-based approach. As noted earlier, a thorough desk-based assessment of requested centre information is undertaken and virtual technology is used to explore concerns and discuss issues with staff members. Visits will be arranged on a risk-based approach if concerns remain. The rationale of not having onsite visits is being documented for all clinics.

6.3. The data to December 2020 on all cycles taking place in NHS and private centres in England was shared with the Authority. It was noted that cycle numbers were now similar to those seen in 2019.

6.4. Members were advised that nine centres had either suspended or reduced treatment services and this will continue to be monitored. It was acknowledged that we were aware of delays in referral pathways and have brought it to the attention of NHS England and the DHSC.

6.5. The Director of Strategy and Corporate Affairs informed the Authority that there were high levels of patient anxiety but patient feedback had indicated that they were appreciative of HFEA updates during this Covid-19 period, especially the recent announcement that a national closure of clinics was not expected.

6.6. The frequently asked questions (FAQs) section on the website will continue to be updated as soon as any professional or government guidance changes are issued.

6.7. Some patients who were also healthcare staff and in an early priority group to receive the vaccine had been in touch with concerns. It was noted that the UK advice is that those who are trying to become pregnant do not need to avoid pregnancy after vaccination.

6.8. It was noted that the British Fertility Society (BFS) and Association of Reproductive Scientists (ARCS) had updated their guidance on this.

6.9. In response to a question, the Director of Finance and Resources commented that it was too early to be certain about the implications for income.

Decision

6.10. Members noted the Covid-19 update.

7. PRISM update

7.1. The Chief Information Officer (CIO) presented the PRISM update to the Authority.

7.2. As the CE noted earlier, clinics had advised that they were likely to encounter challenges in being able to go live with PRISM during the lockdown. As staff are currently working from home this is causing difficulties and delays as the live data can only be tested within a licenced centre.

7.3. The audit and governance committee (AGC) met on 11 January and supported the position that we should not launch in January given the pressure in the sector. It was concluded that we should commence go live at the earliest by 31 March but ideally not beyond end of May 2021. However, the situation within clinics should be monitored so launch could proceed if the situation with regard to the pandemic improves and pressures decrease.

7.4. Members were informed of the programme elements that were being brought forward including the clinic engagements, bulk API testing, PRISM familiarisation, training for the Register and OTR teams. It was noted that they had originally been scheduled for after PRISM go live.

7.5. Handover had commenced to ensure that staff are able to provide a good level of support for PRISM as this is a key priority.

7.6. The AGC Chair commented that the programme was on track and that the team remained flexible about go live.

7.7. In response to a question, members were advised that all IT systems were now on cloud-based servers. Members asked about the affordability of the extra work that PRISM was incurring. Staff responded that we planned to meet additional programme costs through underspends in other areas.

7.8. Staff commented that the Covid-19 situation will continue to be monitored and launch options will remain flexible.

Decision

7.9. Members noted the PRISM progress to date.

8. The register research panel (RRP) annual report

8.1. The Head of Research and Intelligence addressed the Authority. Members were advised that we hold the largest Register of data on assisted reproduction treatments in the world.

8.2. We are also governed by legislation that enables us to provide information requested for research purposes. In 2020, two projects were approved and the team were in contact with 11 new researchers. A researcher engagement day was planned to take place in May 2020, but it had to be cancelled due to the Covid-19 pandemic and we will review how to carry out that engagement in alternative ways in 2021.

8.3. Members asked for clarification on the criteria on grounds for refusal of research projects. The Head of Research and Intelligence responded that this was clearly set out in the Regulations and it could be that the research question needed more work done and cited instances where the researchers had asked for data, but the panel felt that the data requested would not be adequate to answer the research question so the request had been turned down. In cases like that staff would work with the researchers to improve their proposal.

8.4. Members also asked if applications were encouraged from around the world. Staff responded that the Regulations were prescriptive on this issue but that anonymised data could be requested from anywhere in the world. However, identifiable data could only be requested by a UK based

research establishment. Where collaboration between a UK based and non-UK based institution or organisation had requested the data then a discussion would be held.

8.5. In response to a question it was noted that there is a maximum charge of £5000 per approved application.

8.6. Members commented that the availability of this data may not be known by researchers especially non-UK based researchers. In light of the HFEA's appetite to promote research, including international use of anonymised data, it should be advertised more broadly.

8.7. Members were informed that the anonymised data was already published on our website and was due to be updated in the Spring.

8.8. The Director of Strategy and Corporate Affairs commented that in terms of resources we had limited staff capacity. She also pointed out that the annual report lists only the formal requests that have come through and that on a daily basis, Register data was published through enquiries, freedom of information requests, and our reports.

8.9. Members suggested that in due course we should consider having a wider research panel to support the HFEA with screening and advising on decisions.

8.10. Members suggested that the make-up of the panel could include people with clinical and ethical expertise as one of our aims was to be a global leader in facilitating scientific research. A way to bring this to the awareness of the research community could be via the 30th anniversary communication tools.

8.11. The CE thanked Authority members for the endorsement and noted that some of these activities may need to take place in due course when this work has been further developed.

8.12. The Chair thanked staff, and members for their contribution.

9. Any other business

9.1. There was no other business.

Chair's signature

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

Signature

Chair: Sally Cheshire

Date: 24 March 2021

Performance report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	5
Meeting date:	24 March 2021
Author:	Helen Crutcher, 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:	To consider the performance presented and provide feedback ready for Authority
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 until January 2021.

1.2. Performance was reviewed by SMT at its 22 February meeting.

1.3. SMT noted and agreed the inclusion of a new indicator in the detailed SMT version of the report for internal incidents, following on from an earlier internal audit recommendation. This will be reported monthly at SMT, but only form part of the Authority report if it is Red. The target is that we close all incidents including follow up actions within 30 working days, to ensure that effective and timely action is taken. Our priority is to build a reporting culture, ensuring that we increase the numbers reported to maximise the learning and quality improvement undertaken.

2. Key trends

2.1. In January performance was generally good. Inspection and licensing continue to meet our performance metrics and staff sickness remains low. There was one red indicator.

Red indicators

2.2. The indicators classed as red are as follows:

- F3 – Prompt Payment

2.3. 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. Wider performance reporting review

3.1. We are currently in the middle of an internal audit of our performance indicators and internal performance measurement. This will include consideration of the metrics, their alignment to strategic aims, data production and the impact of the report on management action. The report of this audit will be considered by AGC following completion.

Annex 1 HFEA Performance scorecard and management commentary – January data

Breakdown of total Red, Amber, Green and Neutral Indicators

Figure 1 - Fewer red indicators this month

RAG	Area	Trend and key data
Green – within target	**People -** Employee turnover Target: between 5%-15%	11.9 % Turnover 0 leavers
Green – within target	**Regulatory efficiency -** Time for end-to-end inspection and licensing process Target: 100% in 70 working days or less	100% within target. Average of 12wds (items beginning with an inspection)
No target – more than 50% increase on Dec	**Engagement -** HFEA website sessions	103,804 sessions (68,330 in same month last year)

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

Type	Actual in YTD £'000s	Budget YTD £'000s	Variance Actual vs Budget £'000s	Forecast for 2020/21 £'000s	Budget for 2020/21 £'000s	Variance Budget vs Forecast £'000s
Income	**5,080**	**5,880**	**(800)**	**6,983**	**7,211**	**(228)**
Expenditure	**(5,376)**	**(5,944)**	**568**	**6,969**	**7,211**	**242**
Total Surplus/(Deficit)	**(296)**	**(64)**	**(232)**	**14**	**0**	**14**

Commentary on financial performance to end January

The Year to date position is a deficit of £232k against budget. Income has been higher than historic averages in the second and third quarter, slightly offsetting the impacts of limited activity in the first quarter. Our expenditure remains below budget, with YTD underspend of £569k, which is due to reduced activity in site inspection, meetings, events, and members travel as well as the impact of delayed launch of the PRISM system.
We are forecasting a surplus against budget of £14k which includes the net non-cash funding element (£221k) provided by DHSC to cover depreciation and amortisation charge, which we cannot use for other operational purposes. Forecast expenditure also includes a contingency for legal cost of £175k which is unlikely to be utilised. Given the impact of the pandemic on HFEA income DHSC have provided access to additional GIA of up to £2.4m of which £1.3m will be drawn down in March.

Management commentary

In January performance is generally good. We had one red indicator.

We continue to see very good performance across all areas of the organisation, despite ongoing Covid-19 impacts. This is particularly apparent in our consistently good licensing performance and low sickness rate.

The current national lockdown had a particular impact on our communications data in January, with noticeable increases in volumes of visits to our website, and Covid-19 information once again returning to our most visited pages. This echoes earlier increased interest during previous lockdowns. Despite the lockdown, we have continued to implement our revised inspection methodology and risk-based Covid-19 approach, following the restart of inspections in November. Onsite inspections have been limited and most inspections that have occurred have been done either by desk-based assessment or virtual inspection. This continues to ensure that we have effective oversight of compliance in the sector and manage both risk to patients and to our staff. Although we have found that the workload for such inspections can be somewhat greater than standard inspections, the compliance management team are carefully managing associated risks to ensure this is sustainable.

We have seen continued very high levels of Opening the Register applications and have recruited additional resource to ensure that we can address the backlog of these. Risk and performance are regularly discussed, and we have been clear in our communications with applicants.

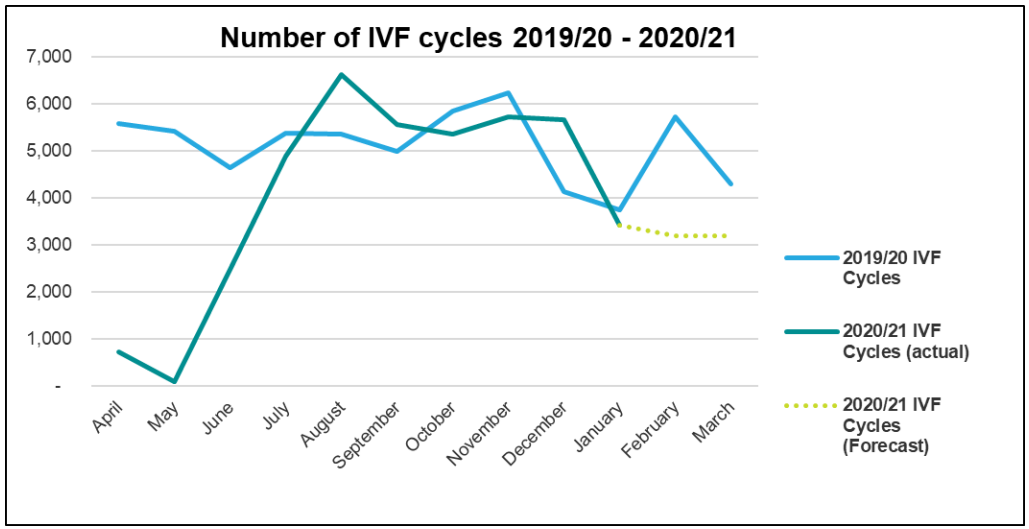
Red indicators:

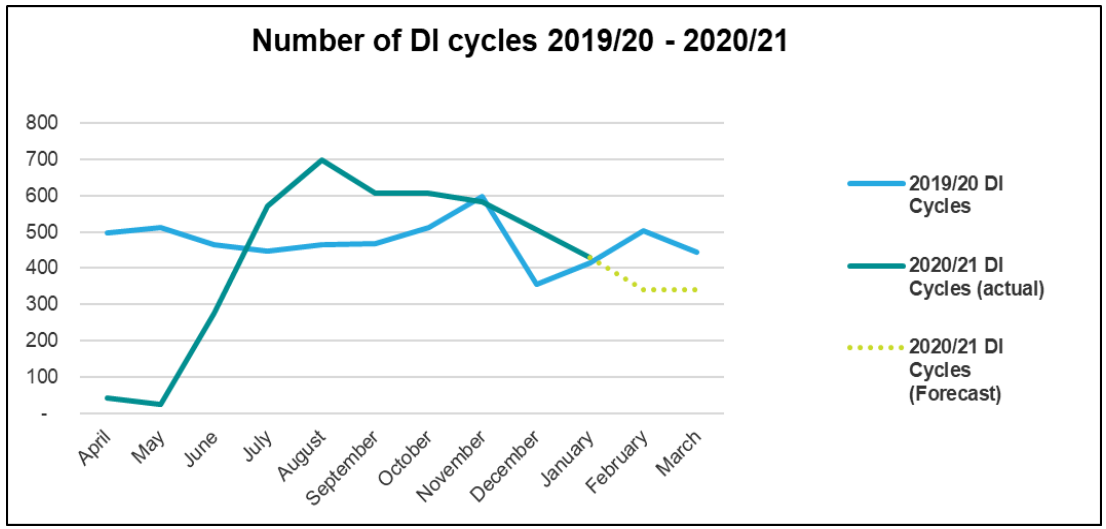
Finance

- **F3 Prompt Payment.** Our target is to pay 85% or invoices within 10 working days. In January we achieved 73% which we class as red.

The main reason that we missed the target in January was one significant invoice (£20k).

Annex 2 Financial management information





IVF Cycles	YTD		YE Position	
	Volume	£	Volume	£
2019/20 IVF Cycles	51,352	4,108,160	61,386	4,910,880
2020/21 IVF Cycles (actual)	40,549	3,243,920	46,929	3,754,320
Variance	10,803	864,240	14,457	1,156,560

DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2019/20 DI Cycles	4,729	177,338	5,676	212,850
2020/21 DI Cycles	4,342	162,825	5,025	188,419
Variance	387	14,513	652	24,431

The graphs illustrate IVF treatment cycle activity over the current and previous financial year. Activity for 2020/21 is 10,800 cycles (21%) lower than the same period (ten months ended 31 January) in the 2019/20 financial year. Activity in the second and third quarters have been broadly in line with historic activity, however, we have seen a drop in January of 40% of IVF cycles. Our final quarter forecast is for slightly lower activity, a prudent assumption given the uncertainty about clinic activity in the current climate.

DI treatments are lower (8%) than the same period last year. Activity over the second and third quarters is higher than historic activity which has led to a smaller drop in overall activity than we have seen in IVF cycles. In addition, we have seen DI volumes drop by 15% from December. Again, our forecast for the final quarter of this year is a prudent estimate of likely activity.

Management accounts – January 2021

	Year to Date				Full Year		
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %	Forecast £'000	Budget £'000	Variance £'000
Income							
Grant-in-aid	1,108	929	(180)	(19)	2,238	1,238	1,000
Non-cash (Ring-fenced RDEL)	425	425	8	2	100	510	(410)
Grant-in-aid - PCSPS contribution	75	83	0	0	510	100	410
Licence Fees	3,345	4,327	982	23	3,989	5,209	(1,219)
Interest received	1	8	7	88	1	10	(9)
Seconded and other income	127	108	(18)	-17	144	144	-
Total Income	5,080	5,880	799	14	**6,983**	**7,211**	**(228)**
Revenue Costs							
Salaries (excluding Authority)	3,941	3,912	(30)	1	4,726	4,629	(97)
Staff Travel & Subsistence	3	114	111		13	161	148
Other Staff Costs	72	88	15	(18)	90	121	31
Authority & Other Committees costs	161	231	70	(30)	215	284	69
Facilities Costs incl non-cash	557	769	212	(28)	705	928	224
IT Costs	407	427	20	(5)	604	517	(88)
Legal / Professional Fees	174	285	111	(39)	382	388	6
Other Costs	52	118	66	(56)	165	183	18
Other Project Costs	9	-	(9)		70	-	(70)
Total Revenue Costs	**5,376**	**5,944**	**568**	**(10)**	**6,969**	**7,211**	**243**
TOTAL Surplus / (Deficit)	**(296)**	**(64)**	**(232)**		**14**	**(0)**	**14**
Adjusted for non-cash income/costs	**(486)**	**(64)**	**(422)**		**203**	**(0)**	**203**

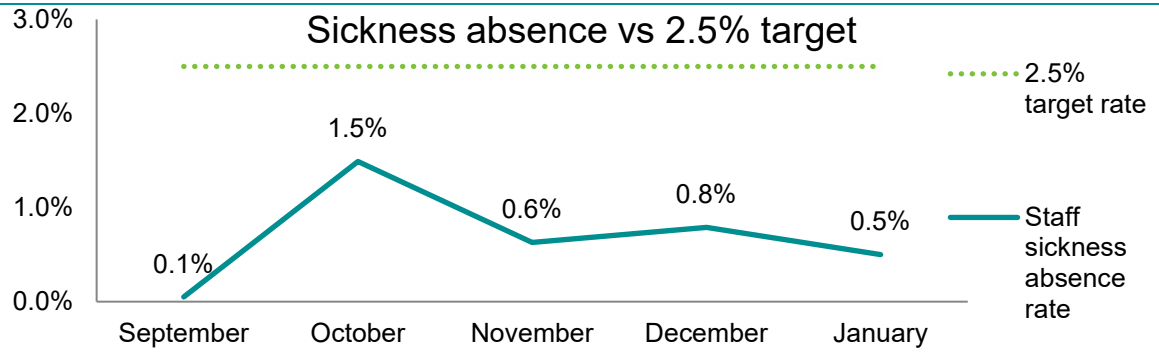
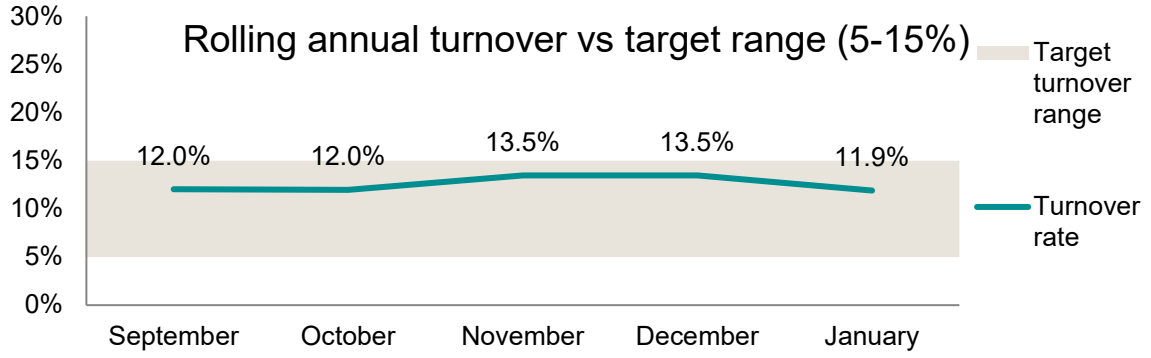
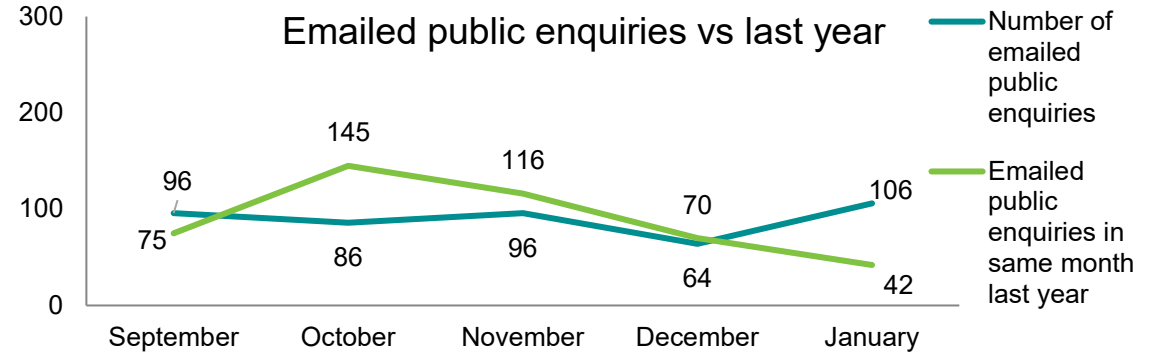
Management commentary

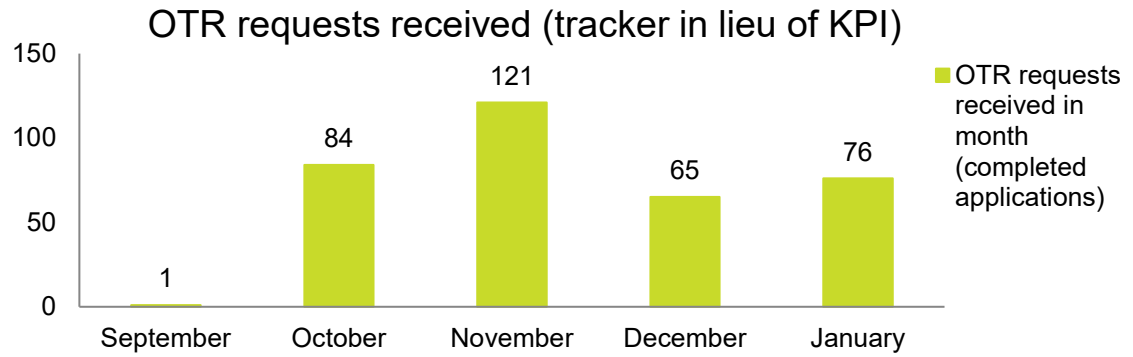
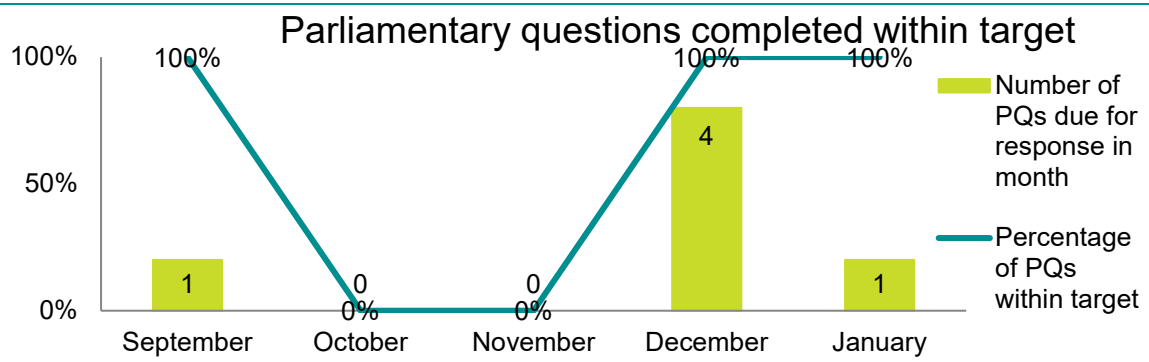
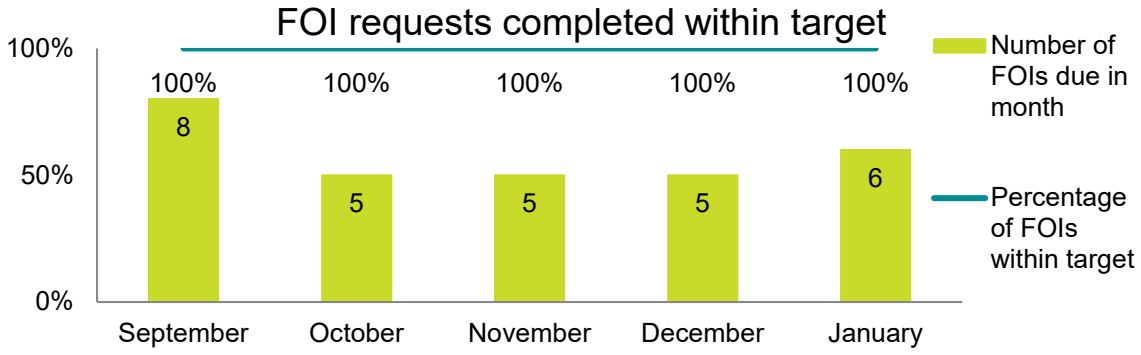
Income.
For the ten months ended 31 January, our total income is below budget by £0.8m. Our Grant in aid is above budget by £180k. This is because we have drawn down all our normal GIA plus funds for EU Transition. Our treatment fee income is below budget by £0.98m, affected by the pandemic that caused a slow-down of activities. We have seen a slight dip in January's IVF volumes by 38%, with DI volumes dropping by 16% from December.

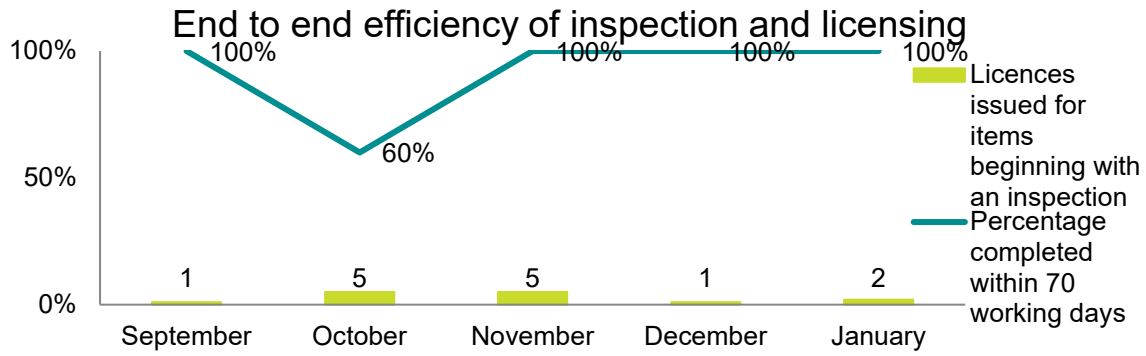
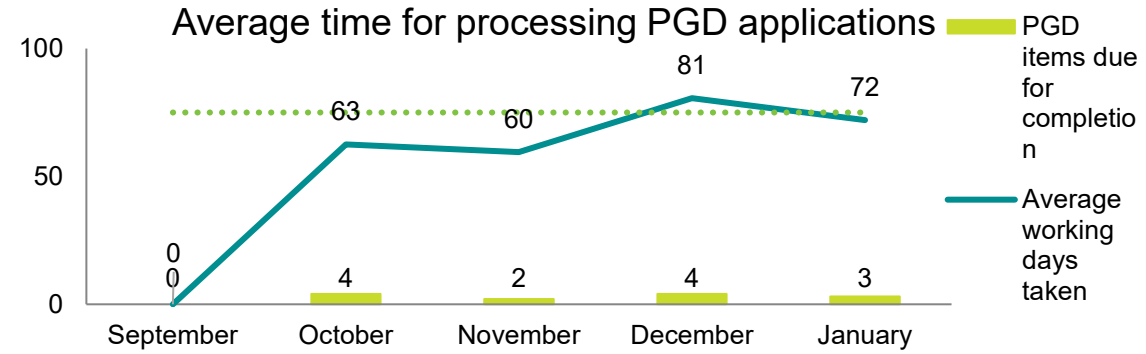
Expenditure by exception. Year to date we are underspent by £526k.
Salary costs - are under budget by £30k (up by £8k from December), impacted by recruitment to vacant posts and associated on-costs.
Staff Travel and Subsistence - underspending by £111k due to low inspection activity.
Authority & Other Committee costs - underspend of £70k represented by underspends within Members fees, travel, and venue costs due to remote working.
Facilities costs - underspent by £188k and include our non-cash costs of depreciation/amortisation (£235k). The underspend here is due to the timing of the capitalisation of PRISM. These costs are covered by Ring-fenced RDEL received from the DHSC. The balance is represented by small under and overspends in rent (£20k), meeting costs (£8k), offset by the unbudgeted costs associated with COVID-19 (£7k) not budgeted for.
Legal/Professional Fees - under budget by £111k represented by underspend in Legal Fees of £49k and underspend of £62k in audit fees and contingency.
Other costs - are underspent by £66k with significant variances within Inspection Advisors fees (£11k) below budget, underspends within LCP, DCR and discretionary training costs totaling £26k. There are overspends within Donor Information costs of £8k. We are underspending by £17k within Stakeholder events due to lack of an annual conference and within HFEA Publications £7k. These are offset by small overspends within other operating costs such as conference attendance and discretionary training.
Other Project cots - this line represents the costs incurred for EU Transition which is funded by Grant in aid of £70k. Actual expenditure to date is £9k.It is expected that we will significantly underspend against this funding.

Forecast.
We are currently forecasting an underspend in expenditure against budget of £243k, this is largely due to underspends within our non-cash costs of £224k which we cannot benefit from.
We have provided for accommodation costs expected in Q4 but are still awaiting final figures.
Our forecast income stands at £7m vs budget of £7.2m, this is due to assumptions made around the amount of grant in aid that we will need to draw down in March.

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 absence remains very low.	Green
HR2 - Turnover **Target**: between 5 and 15% turnover for the rolling year.		68- Headcount 68 - Establishment (posts)	Green
Supplementary data - Public enquiries No target.			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 KPI not used from November 2020 data, TBD when to reinstate this.**		No new applications received until 20 October so partial month listed. We're not currently reporting against a target this is now a tracker – as agreed at Authority October 2020.	Neutral
RI1 – PQs responded to within deadline set (Based on deadlines agreed with DHSC) **Target:** 100% within deadlines set.			Green
RI2 - FOIs responded to within deadline **Target:** 100% within statutory deadlines.			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 –.12 Most days taken: 12 working days Least days taken: 12 working days	Green
C4 – 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.		Most days taken:78 working days Least days taken: 65 working days	Green

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:	7
Meeting date:	24 March 2021
Author:	Debbie Okutubo, Governance Manager
Annex:	Annex 1: HFEA Standing Orders with proposed revisions

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 changes to Standing Orders, effective from 1 April (vote required).
Resource implications:	In budget
Implementation date:	1 April 2021
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 clinics, patients and the wider public and to maintain trust in us as a regulator.

1.2. This paper 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
- A review 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 November 2020 and February 2021 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. 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	Once a year a meeting of ALB Audit Chairs is convened by the DHSC and we draw to their attention anything we need to escalate. New AGC members are invited to meet with key people. There is an induction process. Discussion of the substance at meetings helps to grow familiarity over time. There is a good match between the strategic risk register and the items discussed at AGC meetings. Good communicate is in place with the Authority Chair and Board (and vice versa – for example sending Board papers to non-Authority members on the Committee.)	The AGC Chair has regular bi-laterals with the key attendees. Meetings with the external auditor can be arranged if and when the need arises. Board turnover is high over the next year and committee membership will need to be well managed. Knowledge management and legacy will be important to maintain.

Committees	Positives	Areas to note or for improvement
Licence Committee	The balance of members is good with everyone bringing different expertise. It remains important for the committee to include a member who understands research. Members are able to have full and open discussions on items, even at times when they have different views on an issue. There is a good team dynamic, and it works well as a group.	The committee has previously written to the Chief Executive with comments on the star rating system on CaFC, for future review. Consider future legislative changes we could recommend to DHSC that would be helpful in licensing decisions.
Executive Licensing Panel	The committee engages effectively with the right issues. ELP is well attended and the group is always a sufficient size for different views to emerge and for panels usually to consist of a mix of staff from across different departments. Conversations are open and uninhibited. Everything always runs smoothly. The Chair sums up each item we are reviewing and pulls out key points, which is useful. The administration is handled really well - papers go out in good time, minutes are good and put together quickly and accurately.	The committee should continue to have extra time built into its meeting length, since in the event that an item needs longer, it is good to know there is sufficient time to have the discussion in full and to hear all views.
Statutory Approvals Committee	EU exit and Covid-19 restrictions have brought some temporary changes in guidelines and the work has therefore been more challenging but stimulating. The committee has coped very well. It is felt that the committee engage very well and the scope of the work remains very relevant. It is the right mix and skill with the added voice of an independent expert to inform discussions. SAC papers include recommendations from the	The Committee would like to look further at the issue of whether we could streamline straightforward PGD discussions. Where members are attending in rotation, this could lead to lack of continuity where similar symptoms/conditions are considered. Some members mentioned they had problems with their HFEA emails. The committee suggested the Executive contact the Genetics Alliance (GA) to thank it for its contributions and to discuss potential improvements to the current system.

Committees	Positives	Areas to note or for improvement
	Executive and always have clinic representatives on the committee. Everyone discusses issues with candour. Time is managed effectively with dissents allowed. Minutes are accurate and the reasons for decisions are clear. Reports are well written especially considering the complexity of the nature of them.	
Scientific and Clinical Advances Advisory Committee	Addition of new members from a variety of backgrounds has increased diversity of the committee, resulting in better quality discussions. There is a good balance of Authority and external members. Members with key expertise are highly valued.	A refresh of the membership should be considered, but high levels of change should be avoided. Preference would be for longer meeting time to allow for fuller discussions. Minutes have improved in the last year, but it would be good to have a timescale to receive them so that members know approximately when to expect them for review.
Register Research Panel	Appropriate papers are presented. There is an appropriate mix on the committee which allows different perspectives to be given. Having members of the Compliance team on the RRP works very well.	Terms of reference in Standing Orders to be reviewed to ensure that the panel remains relevant. Each project brings unique challenges, but where possible the approach should be standardised. A decision tree is in development. A staff recommendation could be included with applications.
Remuneration, Appointments and Oversight committees	*Formal reviews not undertaken due to infrequency of meetings.*	

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

3. Review of Standing Orders

3.1. Alongside the review of committees effectiveness we are proposing some changes to Standing Orders.

3.2. In the course of the past year, some opportunities for improvement have come to light. Some changes to terms of reference are also being proposed, partly to increase our flexibility in a high board turn-over year.

3.3. The Authority is asked to review and approve the proposed changes to Standing Orders, as set out below. If approved, the new Standing Orders would come into effect on 1 April 2021.

4. Reserved matters list

4.1. The list of reserved matters for the Authority (at 5.1.1 in Standing Orders), i.e. matters which cannot be delegated, includes the approval of updates to the Code of Practice and general directions. However, paragraph 6 of Standing Orders also allows the HFEA to delegate revisions of the Code and general directions 'from time to time', so long as the terms for such delegations are approved at an Authority meeting. This contradicts the notion that the Code and general directions are reserved to the Authority itself.

4.2. The existing wording of 5.1.1 also refers to the 'annual' update of the Code. It is no longer the case that updates always occur annually.

4.3. It is therefore proposed that in Annex 1, section 5.1 (p) we remove the word 'annual' and replace 'approval of' with 'consider all proposed updates to'. This retains the Authority's primary role in seeing and (usually) approving changes to the Code and general directions, and guarantees that all such proposals for change would need to be placed before the Authority, while still leaving the option of subsequent delegation open, should it be required.

> (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.

5. Delegated powers to the Chair

5.1. The complexities of the Covid-19 pandemic, and the measures we needed to take with the sector, saw us having more frequent, shorter meetings online in the past year. At times, things were moving very quickly, and it would have been useful to have the capacity to make some decisions in a more agile way.

5.2. It is therefore proposed that the delegated powers for the Chair be increased to allow the Chair to form a sub-group of members if this is needed, eg, to address urgent matters. The proposal is to add the following additional point (in Standing Orders section 5.2):

> 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.

6. Audit and Governance Committee (AGC)

6.1. During the current and next calendar year, there will be significant turn-over in board membership, and hence committee membership. To assist in managing this well, ensuring a good skill mix, and

balancing continuity with learning, it is proposed that we should increase the AGC membership from a maximum of five to six members.

6.2. The committee's terms of reference are set out in Annex A, section 2 of Standing Orders.

6.3. The changes proposed would alter paragraph 2.6 as follows:

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.

7. Scientific and Clinical Advances Advisory Committee (SCAAC)

7.1. Staff have conducted an annual review of SCAAC's membership and propose the changes shown below, to allow greater flexibility. The terms of reference currently specify five Authority members (Annex A, paragraph 6.3).

The Scientific and Clinical Advances Advisory Committee shall consist of at least three Authority members, including:

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.

8. Register Research Panel (RRP)

8.1. The terms of reference of the RRP are set out in Annex A, section 8. Changes are being proposed to ensure that the membership of the panel is fit for purpose and has sufficient flexibility, and that there are no unnecessary constraints, for example if staff roles or job titles change. The proposal is to re-word paragraph 8.4, to replace the detailed membership list with a more descriptive account. It is also proposed that the quorum for meetings (paragraph 8.5) should be increased from three to five.

8.4 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.

8.5 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.

9. ELP delegations

9.1. There is a minor anomaly in the wording of ELP's delegated powers to vary licences, under Annex B section 2 of Standing Orders.

9.2. The existing text gives ELP the power to vary licences 'either on application or otherwise' under sections 18A(1) and 18A(2) of the Act. However, the only variations the Authority can make without application are those set out in section 18A(3) of the Act. In practice, it is unlikely that the ELP would be asked to vary a licence without application, since such items would usually be viewed as a Licence Committee matter – often involving some complexity. It is also the case that variations without application are extremely rare.

9.3. ELP's delegated functions also include those that are delegated to the Licensing Officer, under section 1 of Annex B. These are changes of licence holder, changes of a centre's name or address, and applications for voluntary revocation. Again, all of these variations are on application, under sections 18A(1) and 18A(2) of the Act.

9.4. To correct the anomaly, it is proposed that the words 'or otherwise' simply be removed (see Annex B section 2, sixth point in the table). The wording of this delegation would therefore become:

> 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).

10. Recommendation

10.1. The Authority is 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 2021.

10.2. The Standing Orders will be updated and republished to reflect the changes agreed by the Authority.

Human Fertilisation & Embryology Authority

Standing orders

From 31 January 2019

- Showing proposed amendments to come into effect on 1 April 2021

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.

Version with proposed changes put to Authority on 24 March 2021.

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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 31 January 2019
With proposed amendments to come into effect on 1 April 2021

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

i) taking decisions on litigation

j) ensuring a log of whistle blowing incidents is maintained

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

l) representing the HFEA to the public, and

m) 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) ~~approval~~ consideration of ~~the annual~~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 has agreed 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 Committees, 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) Scientific and Clinical Advances Advisory Committee, and

f) 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 ~~five~~ 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.

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, which shall include 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 members, with no more than six 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 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 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.

Meetings of the Remuneration Committee

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

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

Attendance at meetings of the Remuneration Committee

4.7. 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. 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. The Scientific and Clinical Advances Advisory Committee

Purpose of the committee

6.1. 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. 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. The Scientific and Clinical Advances Advisory Committee shall consist of ~~five~~ 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. 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. At least one of the Authority members of the Scientific and Clinical Advances Advisory Committee shall have clinical or scientific expertise.

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

6.7. 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 period of one, two or three years.

Meetings of the Scientific and Clinical Advances Advisory Committee

6.8. 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.

6.9. 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

6.10. 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.

6.11. 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. Oversight Committee

Purpose of the Oversight Committee

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

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

Register Research Panel

Purpose of the Register Research Panel

8.1. 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. 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. 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. 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.

~~a) an HFEA Director, who will act as the Chair of the Register Research Panel~~

~~b) the Authority's Caldicott Guardian~~

~~c) the Head of Research and Intelligence~~

~~d) the Chief Information Officer~~

~~e) the Register Information Manager~~

~~f) the Data Analyst~~

~~g) a Policy team member~~

~~h) the Research Manager responsible for Register Research, who will act as secretary~~

Meetings of the Register Research Panel

8.5. The quorum for a meeting of the Register Research Panel shall be ~~three~~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. 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. Meetings of the Register Research Panel will be private.

Attendance at meetings of the Register Research Panel

8.8. 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. 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. 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. 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. 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. 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. 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. 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 ~~either~~ on application ~~or otherwise~~:- • 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, may attend a meeting of the committee as observers, or as part of their induction 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.

Business planning 2021-22

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy: 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:	8
Meeting date:	24 March 2021
Author:	Helen Crutcher, Risk and Business Planning Manager Paula Robinson, Head of Planning and Governance
Annexes	Annex A: Near final draft of 2021-2022 business plan

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to approve the draft business plan for 2021-2022 and note the remaining sections will be completed, following year end, in advance of publication.
Resource implications:	In budget
Implementation date:	1 April 2021 – 31 March 2022
Communication(s):	HFEA website
Organisational risk:	Low

1. Delivery context as we approach 2021–2022

1.1. We approach the next business year from one which can only be described as extraordinary. In 2020-2021 we had to fundamentally rethink our operations in response to Covid-19, first closing, then safely reopening the sector. We found ourselves redrafting our plans, and in some cases entire operational processes, at pace, marshalling a tremendous effort from all our staff in very uncertain times. The Authority took difficult decisions well, and the fertility sector reopened quickly and was praised by Ministers at the time. For the first six-months of the year, we operated without a formal business plan, instead focussing on managing risk, responding to changes affecting the sector and continuing to work on key organisational priorities like treatment add-ons and publishing data.

1.2. Despite these considerable challenges and while operating as an entirely remote working organisation, we handled changes arising from EU exit and our office relocation and still made significant progress against key strategic aims. On add-ons, we engaged with stakeholders and improved the information available to patients. For the first time, we published a report focusing on family formations. We collaborated with the Competition and Markets Authority to support their project on self-funded IVF and consumer law guidance. And we began important conversations about the future of the fertility sector, coinciding with our 30th anniversary this year. The looking back section on pages 7-9 of the business plan at Annex A, sets out these considerable challenges and summarise our substantial achievements.

1.3. We end the business year with a solid foundation from which to deliver the Authority's ambitious vision of regulating for excellence, shaping the future of fertility care and treatment. It is on this firm foundation that we have drafted the next, and first full-year, business plan.

2. Strategic delivery during the first full year

2.1. Our business plans are designed to help us deliver our overall strategy, year by year. This business plan, attached at Annex A, represents the first full year of strategic delivery of our 2020-2024 strategy, which launched in October 2020.

2.2. At the November Authority meeting, members approved the draft activities section of the business plan, to be developed further. But you also gave us a strong steer to ensure there were sufficient resources to implement such an ambitious plan, bearing in mind the small size of the organisation. We need to ensure that we do not overload staff, and that we are able to deliver on our published intentions. This is particularly important following the significant, and ongoing, disruption and altered ways of working caused by the Covid-19 pandemic.

2.3. Since November we have had a number of detailed planning conversations, both within teams and amongst our Corporate Management Group, and the attached plan is the result of these. We believe that the plan is achievable. However, a key ongoing consideration is the timing and capacity for ongoing IT development work following PRISM launch. We anticipate that support for PRISM after launch will take up much of our development capacity for a period, and so we are actively discussing prioritisation and interdependencies with other teams, to ensure that we are clear about the sequencing of key work after this point.

2.4. As noted above, we continued to make some good strategic progress in the last year, despite necessarily postponing some actions to prioritise important new work arising from the pandemic.

Consequently, this next business plan is also about fully resuming our strategic focus, with items such as engagement with researchers, establishing a data review board and preparing for changes affecting our Opening the Register service.

3. Finalising the business plan

Year-end content

3.1. Some content can only be added after year end. This includes performance data, HR benchmarking information, and various other facts and figures that provide a complete picture of the previous business year. We will add this data in April, before submitting the finalised document for Department of Health and Social Care (DHSC) approval.

Sign-off and publication

3.2. We are in discussion with the department about sign-off arrangements for this year.

3.3. The budget for 2021/22 has been provisionally agreed by SMT, subject to final confirmation of funding from the Department. Our forecast for licence fee income is to return broadly to pre-pandemic levels; activity over the last 8 months supports this assumption but we will monitor monthly activity closely and provide sufficient flexibility in our expenditure plans to respond to the emerging picture.

4. Recommendation

4.1. The Authority is asked to approve the business plan for 2021-2022, and to note that year-end information will be added in April.

4.2. We will publish the business plan and the associated budget once this has been agreed with the Department, at which point the business plan will be published on our website.

4.3. If further planning conversations, especially about IT interdependencies after the launch of PRISM, result in any significant changes to the business plan, we will circulate a revised version to members.

Human Fertilisation & Embryology Authority

Business plan

April 2021 – March 2022

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Our role and strategic aims

Who we are

The HFEA is the regulator of fertility treatment and human embryo research in the UK. Our role includes setting standards for clinics, licensing them, and providing a range of information for the public, particularly people seeking treatment, donor-conceived people and donors.

Our vision for 2020-2024 is:

Regulating for excellence: shaping the future of fertility care and treatment

We continue to put everyone who uses fertility services at the heart of everything we do - patients, partners, donors, donor-conceived people and surrogates. We want them all to receive excellent care, support and information.

Their experiences differ, based on their individual circumstances. Our strategic focus will be on providing the best, most effective care for everyone, recognising the diverse family structures in which treatment and donation take place. We want to ensure people can access the right information at the right time. As science and society advance, we will shape and respond to future changes, helping ensure that the translation from innovative treatment to everyday care is ethical and responsible.

As the regulator of fertility services and research involving human embryos, we aim to be effective and efficient, providing consistent oversight and advice to clinic staff and researchers.

What can we do to achieve excellent care, support and information?

Our strategy for 2020-2024 focuses on three areas in order to meet these needs:

The best care

- Effective and ethical care that is scientifically robust, accompanied by excellent support, and provided by well-led clinics.
- A transparent evidence base so that patients can make informed choices, and more research and innovation to improve the evidence base.
- Improved recognition by clinics of partners' importance in the care process.

The right information

- Accurate and useful information that is provided at the right time.
- Improved information at the earliest (pre-treatment) stage, with new information flows to support primary care professionals and patients.
- Access to relevant and impartial information for all – particularly about the evidence base, add-ons and treatment options.

Shaping the future

- Proactively embracing new developments in the changing fields of modern family creation, genetics, and artificial intelligence.
- Engaging with and facilitating debates on changes in science, law and society, integrating new developments into our work.
- Preparing for future legislative and operational changes, to ensure we remain a modern, effective and responsive regulator.

The Department of Health and Social Care's priority outcomes for 2021-2022 are:

- Improve healthcare outcomes by providing high-quality and sustainable care at the right time in the right place
- Improve healthcare outcomes through a supported workforce fit for the future
- Improve and protect the public's health, including from Covid-19, while reducing health inequalities
- Improve social care outcomes through an affordable, high quality and sustainable adult social care system

Given our specific remit, not all areas of these outcomes relate to the HFEA, however, we see our strong focus on The Best Care as directly supporting the Department's first aim. Our focus on the future will help us to ensure that we are also organisationally ready for any operational changes that are required, to make this a reality.

In 2020-2021, much of our focus was on responding to changes arising due to CovidCovid-19, and consequently we rescheduled some of our planned strategic work and only published a six-month business plan for the second half of the year. This business plan sets out how we will work towards our vision in 2021-2022, the first full year of our strategy.

Our legislation and functions

Our regulatory role and functions are set by two pieces of legislation:

- the Human Fertilisation and Embryology Act 1990 (as amended) – generally referred to as 'the 1990 Act', and
- the Human Fertilisation and Embryology Act 2008 ('the 2008 act').

Under this legislation, our main statutory functions are to:

- license and inspect clinics carrying out in vitro fertilisation and donor insemination treatment
- license and inspect centres undertaking human embryo research
- license and inspect the storage of gametes (eggs and sperm) and embryos
- publish a Code of Practice, giving guidance to clinics and research establishments about the proper conduct of licensed activities
- keep a Register of information about donors, treatments and children born as a result of those treatments
- keep a register of licences granted
- keep a register of certain serious adverse events or reactions
- investigate serious adverse events and serious adverse reactions and take appropriate control measures.

In addition to these specific statutory functions, the legislation also gives us more general functions, including:

- promoting compliance with the requirements of the 1990 act (as amended), the 2008 act and the Code of Practice
- maintaining a statement of the general principles that we should follow when conducting our functions and by others when carrying out licensed activities
- observing the principles of best regulatory practice, including transparency, accountability, consistency, and targeting regulatory action where it is needed
- carrying out our functions effectively, efficiently and economically
- publicising our role and providing relevant advice and information to donor-conceived people, donors, clinics, research establishments and patients
- reviewing information about:
  - human embryos and developments in research involving human embryos
  - the provision of treatment services and activities governed by the 1990 act (as amended).
- advising the Secretary of State for Health on developments in the above fields, upon request.

The UK's future relationships with the EU and the rest of the world

Following the UK's exit from the EU, the Human Fertilisation and Embryology Authority has continued to work closely with the Department of Health and Social Care (DHSC) and its arm's-length bodies to understand the opportunities available to the UK and our health and care system. This includes supporting the cross-organisational work on the UK's future relationships with the EU and the rest of the world. We will work with the Department to contribute to delivering the future relationship with the European Union and implementing the Northern Ireland Protocol.

We have responded to a drive by Government (across healthcare and other industries) to maximise the potential for exporting our expertise, raising standards overseas and revenue for the UK. As such we have provided a service to various international partners, for example by providing assistance in establishing a regulatory regime in countries without one, though due to Covid-19 this has been limited in 2020-2021. In 2021-2022, we will continue to consider the opportunities available to us to build relationships internationally, including running an international horizon scanning meeting with our global partners.

We will continue to update our business continuity plans in line with the UK's future relationships with the EU and the rest of the world and continue to contribute to the post-transition planning and coordination work undertaken by the DHSC.

What we did in 2019-2020 and 2020-2021

Overview

2019-2020 was the final year of our 2017-2020 strategy and the past year represented the first year of our new 2020-2024 strategy. When launching our last business plan, we were still responding to Covid-19 and so chose to instead review the last two years of delivery together now.

In 2019-2020, as well as delivering our usual range of statutory functions, such as regulating and licensing clinics, we completed some key work towards our vision of high-quality care for everyone affected by assisted reproduction and created a new strategy for 2020-2024, with input from our stakeholders. As 2020-2021 began, we responded to the Covid-19 pandemic, which meant that much of the year was spent ensuring that we and the sector were able to recover safely. For the first six-months of the year, we operated without a business plan, instead focussing on managing risk and responding to changes affecting the sector. However, across the year we did make some progress towards our strategic delivery, setting the foundation for future successes. Our new strategy for 2020-2024 was launched in October 2020.

The below describes key work we undertook in 2019-2020 and 2020-2021 against our strategic aims for each year.

Delivery of the 2019-2020 business plan

Safe, ethical, effective treatment

We completed our full programme of clinic inspection, audit and licensing activities, embedding and inspecting against leadership and support principles, until the restrictions from Covid-19 were imposed in mid-March 2020.

During the year up to mid-March, we also undertook several unplanned investigations in response to a range of events. Our inspection activity is summarised in our annual State of the Sector report which we published in October 2019 for 2018-2019 data and again in November 2020 for 2019-2020 data. A new quarterly incident report to the sector was introduced to aid learning in clinics.

We published an update to the 9th edition of our Code of Practice in December 2019, which focuses particularly on clinic leadership and patient support. We held our second PR event for clinic leaders in the Autumn of 2019 to set out our expectations. The new Code also included changes in relation to surrogacy, screening and professional guidelines. We separately released guidance on electronic consent and this will be reflected in a future edition of the Code.

The multiple birth rate has continued to fall and stands at 8% for 2018 data – this is below our 10% target and as the biggest single health risk to mothers and babies represents a real public health success. The multiple birth rate from IVF stood at 24% in 2008 when we first launched our campaign.

We implemented recommendations from a review of our licensing function, including making process improvements and an improved quality assurance system, to enhance the quality of licensing products and the resulting decision-making.

Consistent outcomes and support

We provided advice and information to patients about accessing treatment and donation via our website. We also worked with professional stakeholders (such as the British Fertility Society (BFS)) to put patients in touch with better information and services when they first realise they may have a fertility issue. We undertook various patient and public engagements, attending several fertility shows and events to provide clear, unbiased information.

Through our inspection activities, we maintained our focus on quality and safety, focusing in particular on shortcomings in the taking and recording of consents, learning from incidents, medicines management, data submission, multiple birth rates, and the information clinics publish on their own websites. We also began to work with commercial groups of clinics to improve quality, consistency and compliance on a group-wide basis, as relevant.

We continued to work with NHS England on a piece of work led by them on price benchmarking, with the aim of assisting NHS commissioners in securing fair prices and effective fertility services for patients.

We continued to implement a project on the emotional experience of care before, during and after treatment, working with professional stakeholders to bring about improvement. This led to changes to the Code of Practice.

With the aim of improving the chances of successful treatment, we have published more information in our data reports and focused on success rates through inspection reports and risk tool alerts.

We introduced new processes and certifications to fully comply with European Union (EU) requirements relating to the import and coding of donor eggs and sperm.

Improving standards through intelligence

We delivered a number of aspects of our Intelligence strategy which was approved by the Authority in January 2018 and sets out how we will analyse, publish and use our data to improve the quality of the information we produce and, ultimately, to provide a sharper focus in our regulatory work.

We maintained our role as the UK's competent authority for assisted reproductive technologies in the EU, participating in one meeting. We cooperated with the department to prepare for the UK's exit from the EU and began a project to consider the organisational and sector implications of this. This continued into 2020-2021.

We continued to deliver our programme of improvement work on the Register infrastructure and maintained the Register of treatments and outcomes throughout the year, working with clinics to ensure accurate reporting of data. We also continued to publish the information we hold, and to respond to a range of enquiries from patients, clinics and central Government.

Delivery of the 2020-2021 business plan

Our Covid-19 response

As mentioned above, the first six-months of the 2020-2021 business year were primarily about responding to Covid-19.

The Authority decided on 23 March 2020 that all licensed fertility clinics should close from 15 April. HFEA General Direction 0014 was issued setting out clinic requirements. Consideration of how clinics could reopen began in April and a revised GD0014 (v.2) was issued on 7 May. Clinics were able to apply to reopen from 11 May. Any clinic wishing to apply to reopen was required to complete an HFEA Covid-19 Treatment Commencement Self-assessment questionnaire which measures the robustness of their Treatment Commencement Strategy and assess their compliance with professional body guidance. A key element of the HFEA response throughout the pandemic has been the provision of clear, responsive guidance and information to both patients and clinics.

The fertility sector reopened quickly and was praised by Ministers at the time. The requirements of GD0014 (v.2) have proved to be adaptable and robust, allowing most clinics to continue to safely offer treatment, even during subsequent waves of the pandemic and various measures, including further local and national lockdowns.

HFEA inspections were paused when clinics were closed and only resumed in November. In the interim, a new inspection methodology was developed, which includes desk-based assessments, a risk-based approach and the use of virtual technology to assess clinic compliance in order to minimise on-site visits.

Throughout our Covid-19 response and since, we continued to undertake our core delivery and key regulatory functions including, licencing clinics, processing applications, launching data reports and engaging with stakeholders and communicating guidance. Following the launch of our strategy in October 2020, we prioritised progress in a few key strategic areas in the final six-months of the year:

The best care

We started a key strategic project on add-ons, following on from earlier work with the sector, with the aim to improve the provision of treatment add-ons and to encourage responsible supply of these by clinics.

We reviewed our Compliance and Enforcement policy, including a consultation with stakeholders, with the aim that this provides a consistent ongoing basis for making regulatory decisions about clinics.

The right information

A significant area of focus was around the patient information about add-on traffic lights. We completed a survey of patients and worked with partners from across the sector review and improve the information available, with the aim that all patients have the information needed to make informed decisions

In September 2020, we published a family formations report, which focused on IVF and DI statistics for heterosexual, female same-sex and single patients in the UK, identifying the changes that have taken place in the treatments used by different groups over the last ten years. And in March 2021 we published a report on ethnic diversity in fertility treatment, covering data from the same period.

We worked alongside the Competition and Markets Authority to support their project on self-funded IVF and consumer law guidance.

We undertook an update of the data on the Choose a Fertility Clinic (CaFC) pages on our website, to ensure that patients have access to up to date success rates information about clinics, to inform their choices.

We continued to develop our PRISM system, for clinics to submit data to the Register.

Shaping the future

We planned a series of blogs and events to mark the 30th anniversary of the HFEA, both to celebrate what has been achieved and also to begin a public conversation on the future, including developments in fertility treatment, wider scientific advancements and possible legislative change to support our role.

We handled a significant number of Opening the Register requests, following an earlier pause to the service, and began to look at the operational arrangements for this work, to ensure that we are set up to deliver effectively into the future.

We continued to monitor areas of likely future developments, such as Artificial Intelligence (AI), which is a key consideration for our Scientific and clinical Advances Advisory Committee (SCAAC).

Towards the end of the year we welcomed several new members to the Authority and some of our other Committees and we began preparing to welcome a new Chair in 2021-2022.

Measuring our performance

To be populated April 2021, including:

Facts and figures

Required HR benchmarking information

Key performance indicators

Activities for 2021-2022

This business plan represents the first full year of our 2020-2024 strategy which launched in October 2020. This focuses on the best care, right information and shaping the future.

2021-2022 follows on from a year that was profoundly affected by the coronavirus pandemic, for patients, the sector and our staff. Having begun certain pieces of work in 2020-2021, this year will allow us to take our strategic activities further and to begin new strategic work. This is also our anniversary year, marking thirty years since the HFEA was established. As such, we will take the opportunity to look forward to the future of fertility treatment and regulation.

The activities set out over the next few pages will help us to deliver our strategic objectives in 2021-2022.

The best care

Our first aim is for effective and ethical care for everyone. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Table 1 - Strategic objective 1. Treatment that is effective, ethical and scientifically robust. Table outlining planned activities for April 2021 to March 2022

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
Review of the compliance regime to ensure this remains robust and able to effectively assess care against target outcomes.	Review and development of: • inspection priorities • plans for quality improvements • our use of intelligence gained from inspections • inspection reports Roll out of • revised compliance and enforcement policy • the revised PREP test. Readiness for next steps to ensure the HFEA's compliance regime is more aligned to strategic priorities.	Throughout the year with further work falling into subsequent years.
Maintenance and adjustment as needed of our regulatory approach, and ongoing monitoring of Covid-19 risks and impacts on fertility sector and the HFEA. Clear actions and communication as the situation develops.	Clear ongoing recovery plan and assistance for clinics in response to the latest Covid-19 situations and government guidance. Risk-based approach to inspection activity. Clinics effectively respond to Covid-19 related risks. We effectively adapt and respond to any changes in Covid-19 circumstances, such as any local lockdowns and new government guidance, and also assist the sector to do so.	Throughout the year

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
Full programme of clinic regulation, encompassing all of our inspection, audit and licensing activities. This includes a revised approach to respond to Covid-19.	All clinics and research establishments in the sector are: • appropriately inspected and monitored against the requirements of the act and published performance indicators, and • issued with licences for up to five years. Assurance of consistent standards and safety for the public and other stakeholders. Positive overall impact on quality of care, outcomes, safety, support, and information clinics publish (eg, on their websites) and provide to us. Patients know that all clinics are safe and appropriately licensed. Reduction in the number of critical, major and other non-compliances.	Throughout the year
Collaborative and partnership working with other ALBs and health regulators UK wide, such as the Care Quality Comission (CQC), NHS England, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom Accreditation Service (UKAS), Health Research Authority (HRA), General Medical Council (GMC) and the devolved nations.	Ability to capitalise on previously established relationships, eg, to address issues that require joint working in an efficient and coordinated way, or to establish the best approach if any new areas of regulatory overlap should arise Continued savings and avoidance of unnecessary administrative or regulatory burden, by avoiding duplication of effort or uncoordinated approaches between regulators. Participation in cross-organisational working such as the regulatory advice service for regenerative medicine, as relevent. Learning from each other and acquiring best practice.	Throughout the year
Continuation of a project to improve the provision of treatment add-ons and to encourage responsible supply of these by clinics. Including further development and publicising of	Responsible supply of add-ons by clinicians/clinics based on good evidence Add-ons offered: • with full information so patients can make informed decisions • only to specific groups where there is evidence of effectiveness and safety.	Summer 2021 with further work to be planned for subsequent years.

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
patient information and traffic lights.	General agreement within the fertility sector around the direction of travel toward best practice around add-ons. Patients and clinics understand the risks associated with add-ons. SCAAC annual review of add-on treatments so that patients and clinics have accessible information on sound scientific evidence	
Scoping of a project to build on earlier success rates work.	We use our data to understand variations between clinics and collaboratively define best practices. We are prepared to deliver further targeted work in this area in 2022-2023.	Throughout the year
Engagement with researchers across the field of fertility research, particularly those using – or with potential uses for – HFEA Register data and those involved or interested in commencing research with human embryos.	Improved relations and communication with the fertility research community. Researchers have access to relevant and valuable data in our Register, to inform high quality research. We implement the 2017 review of the application process for researchers to use HFEA data, or human embryos. Promote quality research and collaboration using HFEA Register data and/or human embryos. More research and innovation to improve outcomes. We continue to be active members of the UK health data research alliance to encourage widespread and responsible access to data	Throughout the year
Scoping a review of guidance and implementation of the 10-family limit to consider what more can be done to provide clarity on this.	We monitor compliance with the guidance and understand any issues with this, to inform possible future work.	By March 2022
Effective handling of and communication about: • clinical incidents and adverse events, including publication of 2020-2021 'State of the Sector'	Continued strong focus on learning in dialogue with the sector. Sector provided with useful information about learning points from incidents and adverse events. Reduction in the number of clinic incidents, owing to learning from own and others' mistakes. Learning gained, to inform future inspections.	Throughout the year, with the state of the sector report

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
report and quarterly compliance reports • complaints about clinics	Patients' experiences used to make improvements and prevent recurrence. Better understanding of factors contributing to particular types of adverse events.	published in Autumn 2021
Ensuring governance tools underpinning licensing and other decisions are in place and effective.	Ensure that licensing decisions and other approvals are well governed. Efficient and effective decision-making is maintained. Decisions are evidenced, transparent and consistent. Committee governance arrangements and effectiveness reviewed annually.	Throughout the year
Processing applications for the licensing of preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) and mitochondrial donation.	Applications handled effectively, efficiently and transparently and processed according to performance indicator timelines. Decisions on whether to authorise such treatments made, and communicated, in a proper and timely manner for the direct benefit of patients waiting for treatment. Mitochondrial donation and PGD approvals taken in an accountable and transparent way.	Throughout the year
Ongoing review of guidance for clinics to ensure this remains fit for purpose, including: • delivery of an update to the Code of Practice • Issuing other clinic-facing communications, such as Clinic Focus, on issues that require further clarification to the sector.	Guidance for clinics is up to date and reflects latest scientific developments, legal advice and policy decisions. A clear Code of Practice and other guidance for clinics.	Throughout the year. Revised Code of Practice to be published in Autumn 2021.
Servicing the legal information needs of the HFEA including:	HFEA licensing decisions are sound and based on comprehensive legal advice. HFEA policy decisions and approaches are compatible with the regulatory framework.	Throughout the year

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
• provision of legal advice to inform other HFEA work • management of team of external legal advisers to support effective licensing processes. • supporting the review of the Compliance regime and Code of Practice		
Review of information provided on HFEA website about: • routine treatments for instance 'standard' IVF and associated costs • testing of new information using the patient engagement group.	We use our communications channels to make sure patients receive the right information at the right time. Information is reviewed on a cyclical basis to ensure that it is fit for purpose and new information added when needed.	Throughout the year
Implementing the changes that result from the end of the EU exit transition period, to ensure that the HFEA is able to function smoothly within new operating circumstances and licensed clinics can continue to provide high quality and safe treatment.	Identify and mitigate post-transition risks and issues, such as the continued supply of medicines, equipment and gas to licensed clinics. Implement changes to General Directions, licences, import and export forms and processes and any consequential organisational changes to ensure effective regulation across the UK.	Throughout the year New licences activated 1 July 2021.

Table 2 - Strategic objective 2. Improved recognition of partners' importance (of the same or opposite sex) in the care process. Table outlining planned activities for April 2021 to March 2022

Objective 2 Improved recognition of partners' importance (of the same or opposite sex) in the care process - methods and channels	**Benefits and outcomes**	**Timescale**
Nothing planned against this objective in the first full year, work to follow in years two and three.	None this year.	Not applicable

The right information

Our second aim is to ensure that people can access the right information at the right time. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Table 3 - Strategic objective 3. Improved access to information at the earliest (pre-treatment) stage. Table outlining planned activities for April 2021 to March 2022

Objective 3 Improved access to information at the earliest (pre-treatment) stage - methods and channels	Benefits and outcomes	Timescale
Using social media and other channels, including the media, we will communicate relevant information to the wider general public and those who are not having fertility treatment.	We communicate via a range of channels and methods so people can access the right information at the right time for them. We will utilise our content strategy to position our information effectively. We will raise our profile and provide the general public, not just current fertility patients, with useful information.	Throughout the year

Table 4 - Strategic objective 4. High quality information to support decision-making during and after treatment or donation. Table outlining planned activities for April 2021 to March 2022.

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	Benefits and outcomes	Timescale
Ongoing work to review our compliance with accessibility requirements and make changes as necessary.	Stakeholders' accessibility needs are considered so that they are able to access our information. HFEA services are available to everyone that needs them. We ensure that HFEA appropriately complies with government accessibility requirements and legal obligations. We maintain a clear accessibility statement for our website and Clinic Portal.	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Clinic Portal and website updates to ensure ongoing stability and functionality for all users.	Our systems support continued information provision and improvements. Implementation of website improvements identified by users. The Clinic Portal remains useful and easy to use for clinic staff and meets their updated requirements.	Throughout the year
Continuation of scoping work to consider how clinic data will be published in future.	We identify actions to ensure that patients have access to regularly updated data on clinic performance to inform their treatment decisions.	Throughout the year
Improved Register data analysis tools to improve reporting and analysis	Realisation of a post-PRISM reporting database. Increased ability to analyse data and report from the Register.	Throughout the year
Follow on work from the Competition and Markets Authority (CMA) project on self-funded IVF and consumer law guidance. Including working with the Advertising Standards Authority (ASA).	We support the CMA to communicate and embed their guidance so that clinics understand their obligations under consumer law in relation to self-funded treatment. Consider any changes to our guidance and other activities in response to the CMA and ASA guidance.	April-Oct 2021
Data review board established	Clear methodology and process established for considering any future additions to the Register	First meeting Autumn 2021
Complete a review of our compliance against the NHS Digital Data Security and Protection Toolkit and submit a response to this.	We measure our performance against the National Data Guardian's ten data security standards. We assure ourselves that we are practising good data security and personal information is handled correctly.	Final Submission for 2020-2021 in June 2021. Review annually ongoing.

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Make use of patient feedback and our patient engagement group to ensure that information is fit for purpose.	We gain an insight into the patient experience in clinics and encourage good practice based on feedback. Patient feedback loop in place to ensure a regular flow of fresh feedback which can be incorporated into our stakeholder interactions and regulatory approach. We gain valuable insight into the experiences of those going through fertility and donor treatments, to inform our other work and the information that we publish.	Throughout the year
Maintain up to date and accurate information and advice on our public-facing website.	Patients see HFEA information as 'go to' impartial advice. People understand the possibilities and the difficulties of treatment and can weigh up the options open to them. People can easily find relevant information and signposting on our website to inform their next steps.	Throughout the year
Responding to media reports.	Balance and accuracy provided for issues the media is covering. Using the data and other information we hold to inform media coverage on a wider range of issues.	Throughout the year
Maintaining effective Opening the Register (OTR) and counselling services.	Opening the Register requests continue to be met in a sensitive manner and within agreed time limits. Counselling support is offered for all Opening the Register (OTR) applicants (those seeking non-identifying information) and for donor-conceived applicants receiving donor-identifying information. OTR applicants feel more supported and prepared to deal with the information they receive from us.	Throughout the year
Performance management of Donor Conceived Register (DCR) services including counselling provision.	The provision of the DCR is properly performance managed against agreed KPIs, to ensure that it remains fit for purpose. Intermediary training and systems in place for dealing with identity release to donors and donor conceived people. Intermediary services are in place for when donors and donor-conceived people meet.	Throughout the year
We provide timely and appropriate responses to freedom of information (FOI),	We comply with FOI, PQ and DPA requirements. Requesters have access to accurate information in a timely fashion.	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	Benefits and outcomes	Timescale
parliamentary question (PQ), and subject access requests.	We actively publish information on our business activities on our website, following best practice, to be transparent in our working whilst maintaining compliance with the FOI Act.	
To publish good quality statistical and other reports, including the Fertility Trends report.	We provide the public, patients, clinic staff and others with up-to-date, high quality information about treatment outcomes, trends and the performance of clinics. We provide important information to those affected by donor conception, including patients seeking treatment. We make use of our data to help us to enhance the quality of care that patients and donors receive in clinics through our regulatory work.	Throughout the year
Effective handling of enquiries, complaints about the HFEA and whistleblowing.	These are handled efficiently and appropriately. Learning gained and actions identified where necessary to secure improvements.	Throughout the year
Maintaining the Register of Treatments and Outcomes and working with clinics to ensure they are accurately reporting their data.	Register data and forms continue to be processed and quality assured through liaison with clinics on errors and omissions and through validation and verification of Register entries. High quality data available to develop patient information and respond to information requests.	Throughout the year
Information provision for researchers requesting access to Register data, including ongoing review of the processes that support this.	Running the Register Research Panel to oversee applications for data release and ensure approved data is released effectively and securely to researchers. Information for researchers is provided within specified timeframes. Register information is used to best effect, to increase understanding and facilitate good research and ultimately benefit patients. More researchers can access and use our Register data. Increased standardisation and clarity of processes and efficient use of time and resource. Anonymised Register dataset available for researchers.	Throughout the year

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Ongoing compliance with government information requirements.	We respond to government requirements and new initiatives in a manner consistent with our legal status, and proportionately within our small resource envelope, carefully recognising our duties. Annual report published including required information.	Throughout the year
Effective records management and information governance.	Appropriate information governance policies and processes are in place, and regularly reviewed, ensuring roles and responsibilities and correct processes are clearly set out for staff. Good records management practice is embedded and maintained, including records retention and appropriate behaviours, to ensure access to information is maintained at all times. Information governance arrangements comply with latest requirements. Records management and information governance risks are managed effectively.	Throughout the year
Responding to external consultations, calls for evidence and reviews including from the Department of Health and Social Care, other departments, regulators and wider public sector.	HFEA is part of discussions that may affect us, relevant legislation or the wider fertility sector.	Throughout the year
Induction of new Authority and other committee members.	HFEA governance and decision-making capabilities maintained. Effective induction to ensure new members are up to speed and able to carry out effective decision-making. Key knowledge is retained where possible, during a period of high member turnover.	Throughout the year
Launch of PRISM and the new Register. Early life support for the PRISM data submission system and ongoing engagement with and feedback from clinics.	PRISM fully bedded in with clinics and data being submitted into new register. Updates completed by third party system suppliers to their systems, and their updated systems deployed with data being submitted into the new register. Reduced transactional costs for clinics and increased user satisfaction. Minimal system downtime. 'Right first time' data quality and reduction in effort by clinics submitting the data.	By October 2021, and ongoing use as BAU(PRISM

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	Benefits and outcomes	Timescale
		launch will be in June 2021)
Launch, early life support and further development work on a new Register Information Team Application (RITA), to enable us to query the new register and run reports.	Targeted support to improve data quality across the sector. Reports being provided and the ability to query the new register to internal HFEA teams' requirements to enable Register team and OTR team to provide an acceptable level of service. Ability for OTR team to provide statutory service and search across the new register. Ability for register team to provide support to clinics and provide cross-sector reporting. Ability for register team to improve their data quality focus, addressing patterns or trends of data quality issues across sector or within specific areas.	By June 2021, and ongoing use as BAU

Shaping the future

Our final aim is to embrace and engage with changes in the law, science and society. We have two strategic objectives relating to this aim and the activities planned to deliver these are set out in the tables below.

Table 5 - Strategic objective 5. Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI). Table outlining planned activities for April 2021 to March 2022.

Objective 5 Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI) - methods and channels	**Benefits and outcomes**	**Timescale**
Scoping piece on clarifying guidance to clinics about what to do when donors wish to make restrictions on their donation that could potentially disadvantage protected characteristic groups.	We take legal advice as required and are clear about legal and policy implications. We facilitate a discussion with the Authority about possible next steps.	Late 2021
Activity to monitor the use of AI and data-driven new technologies in fertility clinics and the wider sector.	We understand any developments and are responsive to these. We ensure that our regulatory regime is fit for purpose. We monitor AI and data-driven new technologies that are in or potentially approaching clinical use via SCAAC horizon scanning (AI is a priority topic, meaning there are scheduled reviews and discussions on the issue). We monitor patient-facing AI and data-driven new technologies by gathering together short regular reports detailing issues raised to inform policy working and share as relevant.	Throughout the year

Table 6 - Strategic objective 6. Preparing for future legislative and operational changes. Table outlining planned activities for April 2021 to March 2022.

Objective 6 Preparing for future legislative and operational changes - methods and channels	Benefits and outcomes	Timescale
Delivering activities to mark the 30th anniversary of the HFEA.	We mark this historic milestone, and take a forward view as to the future of the fertility sector and our regulatory role. We will engage a wide audience to consider the next 30 years of fertlity treatment and facilitate expert discussion on key issues such as anonymity, responsible innovation and modern regulatory powers.	Throughout 2021
Respond to any requests for consultation on possible legislative changes as these occur and consider how these will impact the HFEA.	Early consideration of possible impacts of any changes on the sector and the HFEA. To ensure the HFEA and the sector are prepared for future changes in the fertility field. We inform any work by DHSC on fertility sector regulation.	As these occur
Scoping and implementation of any legislative changes that occur, for example on storage limits.	Any legislative changes are successfully implemented as required.	September 2021 onwards dependent upon external timeframes
Conducting our annual horizon scanning exercise to ensure we identify relevant new scientific developments.	The Horizon Scanning Panel meets once per year. The Scientific and Clinical Advances Advisory Committee meets to discuss issues identified through horizon scanning three times per year. Policy developments and website material are informed by expert input and an understanding of scientific issues and future developments. Future work planning is facilitated by early identification of upcoming issues.	June 2021 Throughout year
Delivery of a project to scope future 'Opening the Register' (OTR) demand and logistics.	Scope and deliver a project to operationally prepare for a growth in demand as donor-conceived people are eligible to make OTR requests from 2021 and 2023, ensuring that the OTR team can handle increasing demand.	Early 2021-2022

Objective 6 Preparing for future legislative and operational changes - methods and channels	Benefits and outcomes	Timescale
Snagging following HFEA Office relocation to Stratford.	Any residual issues are resolved following the move to Stratford to ensure the smooth functioning of the new office. HFEA have the space and facilities needed to operate effectively within the new office and for staff working remotely. We consider ways of working changes resulting from the move and Covid-19 operational changes.	Early 2021-2022
Continuing to ensure that our working arrangements are suitable for maintaining appropriate Covid-19 safe working conditions.	We maintain appropriate ways of working, including relevant policies. Our office-based staff are able to return to working in an office environment when it is safe to do so. Our People Strategy has highlighted key actions that will be put in place to help support staff welfare and wellbeing during and beyond Covid-19. We will put initiatives in place to support positive mental health such as awareness sessions carried out by our mental health first aiders and greater promotion of our employee assistance and counselling programs.	Throughout the year
Ensuring that we retain and recruit the staff we need in order to operate a good quality service and implement our People Strategy for 2020-2024.	We are able to maintain the staff capacity and capability to deliver our strategy and our core statutory duties. People strategy in place, setting out our vision for ensuring we strike the right balance of staff skills, capacity and capability to deliver our strategy and our core statutory duties. Continuing to develop our staff to ensure they have the skills they need through training and other means. We take into account equality and diversity in the design and implementation of our policies, to ensure that these are fair and appropriate for all staff. Skills mapping to enable better oversight of organisational skills mix and deployment of resource. Staff feel valued and motivated to deliver our strategic aims, by taking action on the results of our staff survey. We reflect our values and behaviours in all our work to ensure that quality and service improvement is part of our ongoing way or working.	Throughout the year

Objective 6 Preparing for future legislative and operational changes - methods and channels	**Benefits and outcomes**	**Timescale**
To be confirmed: Undertake a fee review informed by our income forecasting model.	We ensure that we meet the financial needs for regulation.	By March 2022

Financial picture

To be populated following agreement of budget with the Department of Health and Social Care.

Our finances and high-level budget

Income

Expenditure

Other required information

Introduction

A sound delivery framework and a well-maintained organisational infrastructure are prerequisites for the successful delivery of any strategy or business plan. It is also important that we remain compliant with Government rules that apply across the whole family of arm's length bodies (ALBs).

Our governance structure includes corporate governance tools, a people strategy and HR policies, and a business continuity plan. These enable us to manage our work effectively and meet external and internal requirements such as information requests, compliance with the Equality Act 2010, the production and laying in Parliament of our annual report, and the management of organisational risks and performance.

The information below is provided to explain those aspects of our organisation that are structural, or which help us to meet particular Department of Health and Social Care or cross-Government requirements.

Better regulation and innovation

The objective of the business impact target (BIT) is to reduce unnecessary regulatory burdens on business and ensure that regulatory decisions are made in the light of high quality, robust evidence about the likely impact on business.

We will satisfy the statutory requirements that are relevant to us in a proportionate manner that assists our continued implementation of effective regulation across the whole of the IVF sector, and our strategy objective of the best care.

Organisational structure and establishment

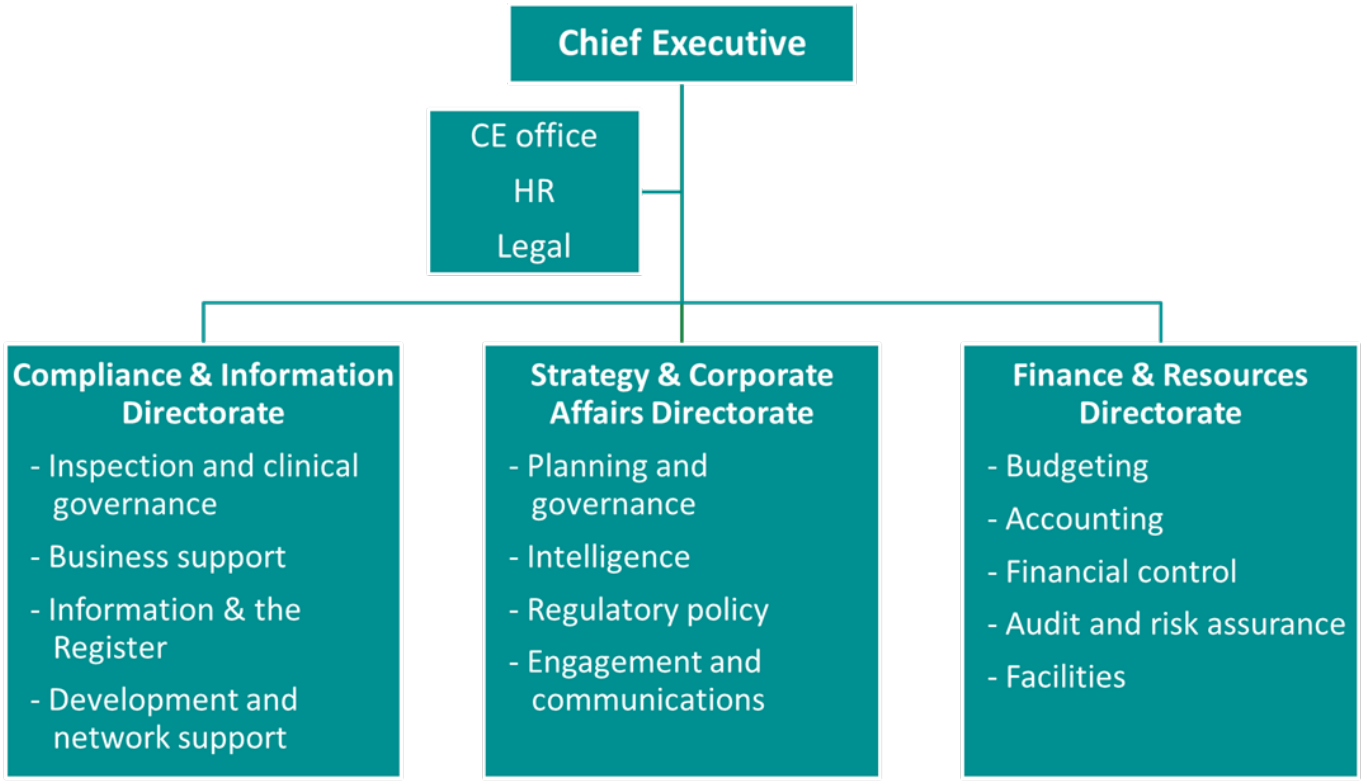
Our staff complement is now 68 (compared to 86 in 2010-2011). We have put in place shared services arrangements with other bodies where feasible. For example, we share part of our finance and resources team staffing with the Human Tissue Authority, and our facilities management service is shared with the four other Health ALBs with whom we occupy the same premises. We are seeking ways in which to work alongside these ALBs on talent management, to provide cost-effective leadership development programmes and other development opportunities.

We need to ensure we retain the capability and capacity to deliver our overall strategy for 2020-2024.

We have a people strategy, referenced earlier in this business plan, which sets out how we will ensure we attract and retain the capacity and skills we need in order to deliver our strategy. Our learning and development activities continue to equip our staff with the skills they need. Services are procured in accordance with continuing Government requirements to ensure value for money.

All staff pay is determined in line with HM Treasury annual guidance. We adhere to the formal pay remit when it is announced.

Our current organisational structure is illustrated below.



Financial management systems

We continue to maintain sound financial governance and business planning processes. We manage our processes efficiently and continue to develop and deepen our various collaborative relationships and shared services with other bodies, which provide increased value as well as some economies of scale.

Internal audit

We continue to be part of the Department of Health and Social Care group assurance framework and to work with the co-sourcing provider on delivering the annual internal audit plan for each year. The programme of internal audits has been streamlined to meet our needs and to make best use of the group audit arrangement, which helps to improve the overall levels of assurance for the group.

Assurance framework

A framework agreement with the Department of Health and Social Care sets out the critical elements of the relationship between us and the department and other ALBs where relevant. As an ALB, we will continue to operate our assurance and risk management independently and report this to the Authority. We recognise that, on rare occasions, our risks or assurance may have a significant impact or interdependency with the Department of Health and Social Care or other ALBs and understand the correct dialogue and escalation mechanisms for communicating the issues and relevant mitigations.

Equality Act 2010

We remain compliant with the requirements of the Equality Act 2010. There is an equality champion within our Senior Management Team. We will collectively continue to ensure, throughout the year, that we fulfil our obligations under the Equality Act.

Whistleblowing policy

We value staff who raise concerns over potential wrongdoing and are committed to ensuring that our staff have access to, and a clear understanding of, public interest disclosure (whistleblowing). Our policy is reviewed each year to ensure that the details are up to date and reflect latest legislation and guidance. Should any individual raise a concern through this route, we are committed to ensuring that their

confidentiality is appropriately protected and that they will not suffer any detriment as a result of whistleblowing.

Transparency requirements

We will continue to comply with the various data requests and requirements for the publication of data, arising from the wider government transparency agenda. We regularly publish all required spending data openly, in the required file format.

All of our Authority meetings are held in public (except in exceptional circumstances, such as during the early period of Covid-19) and the papers and audio recordings are published on our website. Committee papers and a wealth of other information are also routinely published on our website.

Information technology (IT) and data security

We maintain an information asset register identifying our key IT systems and their owners. Our IT systems ensure we comply with the data management requirements of legislation, including the HFE Act 1990 (as amended) and help us to manage the significant databases we hold.

Our databases are currently held on highly secure servers within the within the Microsoft cloud. Security measures are in place to ensure that 'section 33A patient-identifying data' is appropriately protected. While we occupy premises shared with another ALB, this necessarily entails sharing a communications room on-site to house a small number of servers. Security measures are in place to ensure that 'section 33A patient-identifying data' is appropriately protected.

We remain fully compliant with Cabinet Office rules regarding data security and with our own legislative requirements regarding confidentiality of information under the HFE Act 1990 (as amended).

Our IT strategy includes secure arrangements for our cloud and onsite servers, while adhering to all applicable central Government requirements. We have a cloud-based Office 365 arrangement for our desktop systems, which is more cost-effective and increases our resilience in the event of any business continuity issues with our physical premises.

The robust information security arrangements we have in place, in line with the information governance toolkit, include a security policy for staff, secure and confidential storage of, and limited access to, Register information and stringent data encryption standards for systems and IT hardware. We will be completing the Data Security Protection Toolkit for the first time in 2021, which will further increase the security controls we have in place. A programme of information security and cyber security training is conducted, and this is regularly reviewed.

We have a clear desk policy in place within our office along with confidential material disposal arrangements.

Business continuity

We review our business continuity plan regularly to ensure it remains fit for purpose. The plan is regularly updated and periodically tested. Our key IT functions are cloud-based, and as was seen during the Covid-19 pandemic, staff are able to work from home for extended periods, if necessary, in the event of a business continuity event.

Estates strategy

We have no estate. Our office strategy is to co-locate with other public bodies. To that end, we moved office in 2020. Our site, 2 Redman Place in Stratford, brings together multiple health ALBs under one roof, with some key services shared.

We will work with other ALBs at 2 Redman Place on health and safety and general facilities services, which will be provided centrally.

Sustainable development

We recycle paper, card, glass, plastic cups, containers and bottles, metal cans and toner cartridges.

Our multi-function devices (for secure printing, scanning and photocopying), are pre-set to print on both sides of the paper. Our IT equipment is re-used and working lives extended where possible and is switched off when not in use. Surplus equipment is either sold or donated. A proportion of our staff are able to work from home, allowing reduced travel impacts.

We do not procure energy or other items with significant environmental impacts.

Procurement

We comply with all relevant Department of Health and Social Care and Cabinet Office efficiency controls. These cover advertising, marketing and communications, IT, digital, professional services and learning and development. Business case approval from the department is required in most cases.

We are aware of the green agenda in relation to procurement. However, we rarely set our own contract terms or purchase directly and are dependent on Crown Commercial Service (CCS) and other framework holders for integrating sustainability features in their contract letting.

Nearly all of our procurement is done through CCS. So, as far as we are able, we aim to meet the Department of Health and Social Care target for public sector procurement of 33% of procurement spend going to small and medium sized enterprises (SME) but we are dependent (as with sustainability) on CCS ensuring that SME suppliers are present on the relevant frameworks in the first place. Where we have a choice of supplier, our criteria do include both sustainability and SME usage.

We are too small to have a procurement pipeline. Any necessary procurement will be conducted using CCS frameworks and with close CCS oversight. We provide the Department of Health and Social Care with quarterly reporting on procurement.

There is no significant non-pay spend that is not via CCS or Department of Health and Social Care frameworks or contracts.

2 Redman Place

London

E20 1JQ

T 020 7291 8200

E enquiriesteam@hfea.gov.uk

www.hfea.gov.uk

Treatment add-ons progress report March 2021

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time
Meeting	Authority
Agenda item	9
Meeting date	24 March 2021
Author	Dina Halai, Scientific Policy Manager
Annexes	Annex A: Screenshots of some of the key updates made on patient information on add-ons

Output from this paper

For information or decision?	For information
Recommendation	To note progress made in relation to treatment add-ons
Resource implications:	Within budget
Implementation date:	With immediate effect
Communication(s):	Code of Practice updates, clinic focus articles and website updates and wider media and patient-focused activities where necessary
Organisational risk:	Medium

1. Introduction

1.1. Addressing treatment add-ons is a key feature of our organisational strategy for 2020-24. This paper gives an update on progress since the Authority last discussed add-ons in November 2020. At that meeting the Authority agreed the following actions:

1.1.1. Clarify what a 'routine IVF treatment' cycle involved for most patients.

1.1.2. Clarify which add-ons could be green for some types of patients (while perhaps being amber or red for other patients).

1.1.3. Clarify which treatment add-ons have limited evidence and therefore would fall into the amber or red categories.

1.1.4. The information we publish on our website should make it clear for patients that it is their own choice to opt for a treatment add-on which is over and above the routine IVF cycle, and that they should bear in mind that it would cost extra, and there may be no robust evidence base to suggest that it would have any benefit.

1.1.5. Members agreed that information on holistic/alternative therapies should be featured on our website as a separate item to the treatment add-ons list and that it need not be traffic light rated. This information should make it clear that holistic/alternative therapies are in addition to IVF cycles and could be expensive.

1.2. We have completed almost all the actions agreed by the Authority in November. The detailed activities are set out in sections 2-5 below.

1.3. Taken together, this work means that patients have access to clearer information on our website, enabling them to better understand the evidence and risks and potential benefits for each add-on. Significantly, information on each add-on is now framed within a reminder that for most patients, routine IVF is an effective treatment. We have also made important progress towards strengthening patients' position when discussing add-ons with their clinic, through a checklist of key questions to ask.

1.4. Our work on add-ons continues and the remainder of the paper sets out some of the planned future activity to September 2021 (section 6) and beyond (section 7).

2. Update on patient information on add-ons

2.1. We have recently carried out a second substantial update to the information for patients on treatment add-ons on the HFEA website (the last big update was in August 2020). The updates were based on feedback sought from the Authority, the Scientific and Clinical Advances Advisory Committee (SCAAC), the Treatment Add-ons Working Group (TAG) and a recent patient survey with 122 self-selecting respondents. Screenshots of some of the updates can be found at Annex A.

2.2. **Routine IVF is effective:** A key message of the new update is to clearly state that for most patients, having a routine cycle of proven fertility treatment will be effective without using any treatment add-ons. We want patients to consider, especially if they are self-funding treatment, whether it might be more effective and/or affordable to pay for multiple routine, proven treatment cycles, rather than spending large sums of money on a single treatment cycle with treatment add-

ons that aren't proven to be effective at increasing the likelihood of having a baby. This is a significant shift in how we present information on each add-on.

2.3. **Add-ons may be offered for reasons other than improving chances of having a baby:** The traffic light RAG-rated list includes evidence-based information on the use of treatment add-ons for the general population of patients seeking fertility treatment. However, add-ons may be offered to an individual for reasons other than to improve their chances of having a baby. For some fertility patients, there may be a justifiable medical reason for using the add-on as part of their fertility treatment.

2.4. **Clarity about the evidence base used:** Traffic light ratings are allocated by SCAAC based on evaluation of the evidence base in the form of high quality randomised controlled trials (RCTs), and advice from an independent expert in systematic reviews and evidence assessment.

2.5. **Effectiveness is now the key measure:** Traffic light RAG-ratings now only indicate the effectiveness of a treatment add-on, at improving the chances of having a live birth for the general population seeking fertility treatment. Traffic light ratings will no longer indicate the safety of a treatment add-on. If there are specific safety concerns about a treatment add-on these are still included in the information on the webpage for that treatment add-on, under the dedicated section 'Is this treatment add-on safe?'.

2.6. **Green rated add-ons:** Add-ons which would qualify for a green rating according to our definition do exist in routine use in fertility treatment. Patient information on these treatments can be found elsewhere on the HFEA website, for example the use of intracytoplasmic sperm injection (ICSI), if the cause of infertility is sperm-related, would qualify as green rated because more than one high quality RCT supports its use for this reason.

2.7. **Immunological tests and treatments:** Our information on the use of immunological tests and treatments for fertility has also been updated, with advice from external experts, to make it clearer, more detailed and informative.

2.8. Clinics were informed of the update via the February 2021 edition of Clinic Focus and we will continue to promote it to the sector. Communications activities through the HFEA's social media platforms also took place to promote our updated information on add-ons to our stakeholders. We will continue to promote this work through over the coming months in conjunction with other add-ons activity to ensure a wide reach of our information. This will be monitored via the website and social media analytics at the monthly digital communications board to provide an indication of how the updates are performing.

2.9. Going forward, the add-ons webpages will continue to be reviewed annually along with the SCAAC's annual review of evidence to provide up to date traffic light RAG-ratings, to ensure that these continue to be useful for patients.

3. Patient checklist on add-ons developed with Fertility Network

3.1. Many patients report feeling confused about add-ons, and overwhelmed when they are offered these during their clinic appointments. Facing a trusted professional, it can be difficult to know what questions to ask. It was therefore agreed at the last Treatment Add-ons Working Group

(TAG)[1] meeting in November 2020 that the HFEA would work with Fertility Network (FNUK) to develop a list of questions that patient could ask their clinicians when discussing add-ons.

3.2. With FNUK we have developed a checklist for patients that includes:

3.2.1. Key points to consider before accepting an add-on

3.2.2. A list of key questions to ask the clinic about add-ons

3.2.3. A separate list of more detailed questions to ask the clinic about treatment add-ons, including questions about the evidence base, suitability for each patient and cost

3.2.4. A list of questions for the patient to ask themselves, ie to make sure the patient feels informed and sure about whether they wish to have an add-on or not and considering if they are happy with the associated costs etc

3.3. FNUK sought patient feedback on the draft with many positive comments being received about the usefulness of having a specific list of questions to support a patient's conversation with their clinician, which anecdotally some patients have reported some concerns about doing.

3.4. The checklist is currently being finalised and will go live on the HFEA website in April 2021. It will be added to our existing information on how to prepare for a clinic appointment and what to expect at a fertility clinic.

3.5. A communications plan has been devised to publicise the checklist. The key patient questions will be designed as infographics in various formats for use on Instagram (post grid), Instagram Stories, Facebook, Twitter and LinkedIn. These will be shared with key influencers and FNUK to promote on their social media channels, while they will also be published across the HFEA's digital channels. An article about the patient checklist will be included in the April 2021 edition of Clinic Focus. In addition, we will develop a patient guest blog(s) from patients (sourced through FNUK) and a possible webinar in association.

4. Professional guidelines on add-ons

4.1. Some professionals also report a degree of confusion about the evidence base and available guidance for various add-ons to support their conversations with patients. The TAG therefore also agreed that it would be useful if all professional guidelines or guidance relevant to treatment add-ons could be found in a single place. Links to guidance could be hosted on the HFEA Clinic Portal. This would support clinicians in having conversations with patients and explaining the reasons as to why they don't think an add-on is appropriate for that patient and would enable gaps and duplications to be clearly seen, helping the TAG members to consider together how these might be best addressed..

4.2. We are reviewing the guidance with the intention that it will go live on our Clinic Portal in April 2021. The sector will be informed of the update via the April 2021 edition of Clinic Focus. We will

[1]The membership of the TAG is made up of the 11 professional and patient bodies that are signatories of the consensus statement - Association of Biomedical Andrologists (ABA), Association of Clinical Embryologists (ACE), British Andrology Society, British Fertility Society (BFS), British Infertility Counselling Association (BICA), European Society of Human Reproduction and Embryology (ESHRE), Fertility Network UK (FNUK), Human Fertilisation and Embryology Authority (HFEA), Royal College of Nursing (RCN), Royal College of Obstetricians and Gynaecologists (RCOG) and Senior Infertility Nurses Group (SING)

also ask TAG members to publicise it further via their channels including social media to reach as many professionals as possible.

5. Information on complementary and alternative therapies

5.1. In recent years the range of holistic, complementary and alternative therapies that are marketed to fertility patients, whether in clinics and elsewhere, has increased. In response, the Authority agreed in November 2020 that information on holistic/alternative therapies should be featured on our website as a separate item to the treatment add-ons list and that it would not be traffic light rated as part of SCAAC's annual review of evidence at this stage.

5.2. We have drafted some introductory information on the uses of complementary and alternative therapies to improve general health and wellbeing during fertility treatment. It will highlight that if a patient is offered such treatments with the aim of improving their chances of having a baby, then it is important to question whether there is good evidence to support that claim. We will also say that complementary therapies can be expensive so patients should shop around between providers and consider free or low-cost and simple lifestyle changes that they can make to improve their physical and mental health, linking to various sources of information on the NHS website.

5.3. Specific information on the use of acupuncture and nutritional advice has been drafted, as these were the most commonly offered complementary therapies by licensed clinics in the UK, as established by our survey of licensed clinic websites.

5.4. This new information is currently being peer-reviewed by external experts. The information will also be reviewed by patients to ensure it is useful and appropriate.

5.5. It will go live on the HFEA website in April 2021. Again, this will be publicised as part of the wider communications plan, including infographics for use on social media, social media posts on all platforms and an article in the April 2021 edition of Clinic Focus.

6. Additional work planned (until September 2021)

6.1. In August 2020 the HFEA introduced a new audit tool for use by clinics and HFEA inspectors to review a clinic's patient information about add-ons and the practices by which add-ons are delivered to patients, as measured against the specifications of the consensus statement. Clinics were required to return their completed audit tool and action plan to address any non-compliances to their inspector. An analysis of the completed audit tools will commence in the coming months to investigate the common non compliances with the consensus statement. This will assist the development of targeted patient information and guidance for clinics in the future. Crucially, the audit will allow inspectors to address non-compliances and any items of significant concern on inspection. The TAG will next meet on 25 May 2021 to continue discussions on how we can work together to tackle issues relating to treatment add-ons.

6.2. We will continue discussions with the GMC to help inform and refine our work on add-ons. Where this reveals common purpose with existing GMC guidance, we hope that the GMC will highlight these in any future guidance.

6.3. Continue to promote our add-ons information over the coming months using different hooks to do so. We will continue to produce social media content for this that we will post on our channels.

6.4. Maintain and develop the new add-ons page on Clinic Portal to be published in summer 2021, to create a professional-facing hub for our work around add-ons. This work will begin with the list of professional guidance,

7. Looking ahead

7.1. The HFEA's add-ons evidence review scheme was the first of its kind in the world since it began in 2017 and makes an important contribution to informing patients and the sector. It was joined in October 2020 by a Cochrane Special Collection review looking at some of the same add-on treatments and which also includes some patient-facing content. This Cochrane Special Collection review will be updated regularly. It may be that in future, other regulators or patient organisations, including outside the UK, may also produce their own regularly-updated and evidence-based ratings systems, potentially also involving some of the same treatment add-ons that the HFEA assesses, as the use of add-ons develops globally.

7.2. Going forward, we will monitor new sources of reviewed evidence for regularly updating patient-facing evidence-based information on add-ons, to ensure that HFEA resources continue to respond to UK patients' needs in the context of other available published sources of evidence-based patient-facing information about treatment add-ons. We will also monitor the potential for any collaborative opportunities for the future, in order to make the clearest high-quality information offer to patients and the best use of HFEA resources.

7.3. We will also consider findings from the UK/Australian VALUE study of qualitative patient and professional views around add-ons decision-making and information-giving. This research has recently begun and is likely to refer to the HFEA's treatment add-ons webpages.

7.4. Lastly, we will continue our annual snapshot clinic website review around treatment add-ons offered and their advertised costs. This helps us to gather a regular view of the changing picture of charged-for add-ons offered in UK clinics.

8. Recommendations

8.1. The Authority is asked to note the progress made in relation to add-ons.

Annex A: Screenshots of some of the key updates made on patient information on add-ons

- Reminding patients that for most patients, having a routine cycle of proven fertility treatment will be effective without using any treatment add-ons on the main page:

> It is important to keep in mind that for most patients, **having routine cycles of proven fertility treatment are effective without using any treatment add-ons.** If you are paying directly for your own treatment, you may want to think about whether it might be more effective and/or affordable to pay for multiple routine proven treatment cycles, rather than spending large sums of money on a single treatment cycle with treatment add-ons that haven't been proven to be effective at increasing the likelihood of you having a baby.

At the top of each individual add-ons page:

> ## Artificial egg activation calcium ionophore
>
> Treatment add-on with limited evidence.
> **For most patients, having a routine cycle of proven fertility treatment is effective without using any treatment add-ons.**

- Highlighting that, for some fertility patients, there may be a justifiable medical reason for using the add-on as part of their fertility treatment:

> ## When is it appropriate to use an add-on?
>
> Treatment add-ons listed on this page are allocated their rating based on whether there is enough evidence from RCTs that they improve the chance of a live birth for most fertility patients. Our traffic-light rated list of add-ons consists of three colours that indicate whether the evidence, in the form of high-quality RCTs, shows that a treatment add-on is effective at improving the chances of having a baby for someone undergoing fertility treatment. This provides useful information to patients and allows them to question the use of add-ons.
>
> Add-ons may be offered for reasons other than to improve the chances of having a baby. In some circumstances there may be a justifiable medical reason for using the add-on as part of fertility treatment. Some treatment add-ons show benefits in certain groups of patients for outcomes other than improving your chances of having a baby. For example, there may be evidence that a treatment add-on could reduce the chance of having a miscarriage or reduce the risk of ovarian hyperstimulation syndrome (OHSS). Therefore, it may be that a red or amber rated add-on could be used appropriately for specific clinical cases after careful discussion with a clinician.
>
> The add-ons such as PICSI and PGT-A while remaining red for overall or routine use in fertility patients, could be considered appropriate to use in certain circumstances as there is either some or emerging evidence that there may be a benefit for some patients specifically. For example, PICSI could be used to reduce the chance of miscarriage or PGT-A may improve the chance of pregnancy for women over 35.
>
> The evidence that supports the use of add-ons in specific cases might not be as high quality as that used to decide the traffic light ratings. Often the findings have been reported in a subgroup analysis of RCT's and not studied independently. The studies may also be of poorer quality, for example because they include low numbers of patients or have bias.
>
> If an add-on is offered, a patient should question why it is being offered and ask if it may be of benefit for them specifically. Your clinic will be able to discuss with you whether a treatment add-on would be appropriate given your personal circumstances.

- Traffic light RAG-ratings now only indicate the effectiveness of a treatment add-on, at improving the chances of having a live birth for the general population seeking fertility treatment. Traffic light ratings will no longer indicate the safety of a treatment add-on:

How do I know if a treatment add-on is safe?

Our traffic light ratings only indicate the effectiveness of a treatment add-on at improving your chances of having a baby. Specific safety concerns about a treatment add-on are included in the information on the webpage for that treatment add-on, under the dedicated section **'Is this treatment add-on safe?'**. This will set out the evidence we have used.

If you have any questions about the safety and risks of an add-on, your clinic will be able to discuss whether a treatment add-on would be safe for you to use considering your specific medical history and circumstances.

Before January 2021, our traffic light ratings indicated both the effectiveness and safety of each treatment add-on. After considering survey feedback from patients and recommendations made at the **Scientific and Clinical Advances Advisory Committee (SCAAC)**, we felt it would be clearer to use the traffic light rating to indicate effectiveness only.

There are a few reasons for this:

- The safety of undergoing medical treatments can be specific to a person's medical history; traffic light ratings may not be relevant or helpful in considering that person's risks.
- Safety could include the risks for the person undergoing fertility treatment, the eggs, sperm or embryo and the child born as a result of fertility treatment so cannot easily be communicated under one rating.
- The evidence base used to decide the traffic light ratings, RCTs, may not set out to report on safety or risk factors if they were designed to report on the effectiveness of a treatment add-on.

- Updated information on what a green rating means:

Green - A green rated add-on 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. These treatment add-ons may be routinely used in fertility treatments and information on these can be found elsewhere on our website, for example the use of **intracytoplasmic sperm injection (ICSI)** if the cause of infertility is sperm related. Therefore, green rated add-ons will not be included in this review list.

HFEA response to CMA /ASA

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:	24 March 2021
Author:	Clare Ettinghausen, Director of Strategy and Corporate Affairs
Annexes	Annex 1: Further information Annex 2: Extract from the HFEA Code of Practice

Output from this paper

For information or decision?	For decision
Recommendation:	To agree the next steps of HFEA response to this work
Resource implications:	Staffing resources at this stage
Implementation date:	Over the next three months
Communication(s):	To be determined, depending on decisions
Organisational risk:	Medium

1. Background

1.1. The Competition and Markets Authority (CMA) and, separately, the Advertising Standards Authority (ASA) approached the HFEA during late spring/summer 2019 to discuss various aspects of their work and the interplay with the areas we regulate.

1.2. The focus for the CMA was on looking at how fertility patients were given information about fees and contracts under existing consumer law obligations. The focus for the ASA was on the way fertility clinics advertise claims to success rates and display information on their websites in line with the advertising codes of practice.

1.3. After initial separate conversations with both regulators, three-way discussions took place and it was agreed that the work the CMA and ASA would carry out would be aligned so that it was published at the same time, cross referenced to each other and supported by us.

1.4. The CMA identified a number of potential breaches of consumer law in the provision of IVF services. It should be noted that consumer law already applies to fertility clinics, but the CMA questioned how well it was being interpreted and how well any existing broad guidance on the law was being interpreted by clinics. The CMA has a key strategic priority to help 'vulnerable consumers' which this work fits into. The ASA, who have dealt with complaints in the past relating to fertility clinics, also identified potential breaches of the advertising code.

1.5. The CMA formally launched this work in early 2020 and, although their planned timetable was impacted by the Covid 19 pandemic, it is now drawing to a conclusion, together with that of the ASA.

1.6. The work these regulators has undertaken, raises some important issues for the HFEA which are outlined below as next steps for consideration at this stage in section 3.

2. CMA/ASA activity

Draft CMA guidance launched November 2020

2.1. The CMA launched their guidance for consultation at the HFEA PR event on 3rd November 2020. It was developed with input from HFEA Authority members and staff, consultations with key professionals, stakeholder, and patient groups, as well as research with patients through their consumer research.

2.2. Over the consultation period the CMA engaged with many clinic staff from across the sector, the professional bodies, patient groups, clinic groups, other regulators and individual clinicians and patients.

2.3. The final guidance, due for publication in late Spring is aimed at fertility clinics (although it explains that consumer law also applies to related services). A short guide for patients will also be published when the final guidance is published later in 2021.

2.4. A few months after the guidance is issued, the CMA will conduct a compliance review to assess adherence with their guidance. The CMA may consider enforcement action if it finds evidence during the review that indicates clinics are not complying with the law. The CMA (like other bodies that enforce general consumer law such as local authority Trading Standards Services) can take enforcement action and seek court orders to prevent breaches of consumer protection law. It can

also make use of its "enhanced consumer measures" powers, where there have been breaches of consumer law, and apply to court to obtain redress on behalf of patients. You can see here how the CMA have applied the law to care homes following a similar piece of work in the care home sector.

ASA to launch enforcement notice

2.5. The ASA will publish an enforcement notice at the same time as the CMA final guidance. The ASA notice will give guidance to clinics as to how they can market or communicate their services. It will be jointly branded with us and the CMA (TBC) and will be similar to one on Botox issued recently with the MHRA. The ASA publish where their codes have been broken here. The notice gives certain 'do's' and 'don'ts'.

2.6. The ASA issued FAQs at the time to help advertisers including how they might use certain phrases or key words.

3. Actions and considerations for the HFEA now

3.1. The discussions and work with the CMA and ASA raise several questions for the HFEA. Considerations of actions that need to be taken immediately are outlined below. Both regulators allow for a 'bedding in' period of somewhere between three to six months before any enforcement action is taken and, during this time, we will have further discussions about wider issues raised.

Issues to note

1.	Overall HFEA response	We have welcomed the involvement of both regulators in areas where we have poor or no regulatory powers. We will reiterate that support at the launch of the CMA / ASA guidance.
2.	Code of Practice – to add	We will make any changes to the Code to ensure we correctly reference the guidance issued by the CMA and ASA. The ASA Code is already mentioned at para 4.8 in relation to advertising success rates but there is no reference to consumer law. Section 4 of the Code, information to be provided prior to consent and the information about costed treatment plans, is likely to be the best place to add further detail into the Code. The CMA/ASA guidance will not be incorporated into our Code but should be clearly referred to. The Code will come back to Authority in July for decision.
3.	Develop MOUs and protocols	We need to develop detailed MOUs with both regulators as to what we will do with information received either via inspection or patient complaints. These MOUs should outline the distinct powers of each regulator. It will not be the HFEA's role to

		assess compliance with the CMA/ASA guidance, but we are the regulator most likely to view non-compliances through our inspection activity or patient complaints.
4.	Training for inspectors	Enforcement of the CMA / ASA guidance is for the bodies themselves. However, HFEA inspectors are by virtue of their roles, likely to see non-compliances with CMA and ASA rules. Both the CMA and ASA will provide training for inspectors, should it be agreed that they will play a role in monitoring compliance with consumer law and ASA codes, or referring concerns onto the CMA or ASA. Options include, for example, highlighting or referring concerns when inspectors have identified potential non-compliances with ASA/CMA guidance. To be agreed as part of discussions on MOUs and protocols.

Issues to discuss

1.	Code of Practice for us to consider	Our Code currently refers to the ASA in relation to success rates, but the CMA and ASA guidance will apply to all activities by clinics, not just success rates. We should consider how we reference both regulators in our Code, so it is broader than display of success rates.
2.	Non-compliance with our Code on publication of information on success rates and treatment add-ons	We know that there is degree of non-compliance with existing sections of the Code in this area. Should we draw greater attention to this on inspection and in reports to licensing committees?
3.	Look at leadership role for PRs	We expect PRs to understand their obligations in relation to not just our legislation but to other legislation (e.g. equalities or health and safety). Do we need to amend the PR role description or emphasise anything here about not misleading patients through any material/website/advertising information?

4. Issues for future discussion

4.1. The work of both regulators in the fertility sector has brought to attention several related issues that we will need to bring back for further discussion with the Authority in the months ahead. For example, both the CMA and the ASA publish non-compliances in a more prominent way than we do, and we may wish to consider our stance on this.

5. Recommendations

5.1. The Authority are asked to review the actions in section 3 above and approve the following actions:

- Overall HFEA response
- Code of Practice – to add
- Develop MOUs and protocols

5.2. The Authority are asked to review the issues above in relation to further work on:

- Code of Practice for us to consider
- Non-compliance with our Code on publication of information on success rates and treatment-add ons
- Look at leadership role for PRs

5.3. The Authority are asked to note that we will come back in due course for further discussions on related issues as noted in section 4 above.

Annex A: Further information

CMA consumer law pages on IVF https://www.gov.uk/cma-cases/self-funded-ivf-consumer-law-guidance

ASA links to codes, enforcement action and other examples of enforcement notices
https://www.asa.org.uk/codes-and-rulings.html

Annex B: HFEA Code of Practice

Extracts from guidance note 4

Information about success rates

4.8 In line with the Advertising Standards Authority's Code, the centre should ensure that the information provided on its website complies with the following guidance. This also applies to other relevant marketing communications of the centre and associated satellite and transport centres.

(a) The information should include the most recent data available from the past three years.
(b) Centres are encouraged to display live birth rate data per embryo transferred where relevant and this may be displayed alongside other success rate measures. The information should not highlight a high success rate that applies only to a small, selected group of patients.
(c) The data should show split by maternal age and, if appropriate, by treatment type.

(d) The information should provide raw numbers rather than just percentages.
(e) The website should provide the national rate and like-for-like comparisons (the same year, maternal age, treatment type, etc.).
(f) The centre's published success rate data should refer to the HFEA as the source of national information through its Choose a Fertility Clinic function.
(g) The information must state clearly that information on success rates is of limited value in comparing centres and choosing where to seek treatment. It should include a link to the HFEA's advice on choosing a clinic: www.hfea.gov.uk/choose-a-clinic/learn-about-choosing-a-clinic/
(h) If the information refers to comparative costs, it should indicate the likely total cost for a typical cycle, based on the actual costs for recent patients, not individual items in tariffs.

Information about the cost of treatment

4.9 Before treatment, storage or both are offered, the centre should also give the person seeking treatment or storage, and their partner (if applicable) a personalised costed treatment plan. The plan should detail the main elements of the treatment proposed (including investigations and tests), the cost of that treatment and any possible changes to the plan, including their cost implications. The centre should give patients the opportunity to discuss the plan before treatment begins.

Compliance and Enforcement Policy

Details about this paper

Area(s) of strategy this paper relates to:	The Best Care: That patients, partners and donors receive evidence-based high-quality care
Meeting:	Authority
Agenda item:	11
Meeting date:	24 March 2021
Authors:	Rachel Cutting, Director of Compliance and Information Catherine Drennan, Head of Legal
Annexes	Annex A – draft Compliance and Enforcement Policy Annex B – summary of consultation responses

Output from this paper

For information or decision?	For decision
Recommendation:	That members: - approve the final version of the Compliance and Enforcement Policy and the proposed timeline for implementation - agree to delegate sign-off of the revised Guidance on Licensing to the Chair and Deputy Chair of Licence Committee
Resource implications:	N/a
Implementation date:	June 2021
Communication(s):	The sector will be informed through direct communications and the webpage (Compliance and enforcement policy | HFEA) will be updated.
Organisational risk:	High

1. Introduction

1.1. The new draft Compliance and Enforcement policy was presented to the Authority in November 2020.

1.2. The Authority were supportive of the proposed policy and approved a focussed consultation with the sector.

1.3. The Authority is asked today to approve the final version of the new HFEA Compliance and Enforcement Policy (Annex A). The policy would come into effect on 1st June 2021. The Authority is also asked to agree to delegate sign-off of the revised Guidance on Licensing to the Chair and Deputy Chair of Licence Committee

2. Detail of the Policy

2.1. The new policy sets out the Authority's Regulatory Aims which underpin all our compliance and enforcement activities. This policy aims to provide a framework to guide inspectors and serves as a clear and transparent statement of the circumstances in which clinics can expect regulatory action to be taken. This policy would supersede all previous Compliance and Enforcement policies.

2.2. Inspection activities are a statutory requirement and the procedure set out in this policy will normally be followed by inspectors if areas of concern or non-compliance are identified in the course of scheduled and unscheduled clinic inspections, clinic visits outside of inspections, investigations into incidents (serious adverse events and serious adverse reactions), complaints, whistle-blowing disclosures or referrals from other regulators, professional bodies or government agencies or any other circumstances which may give rise to risks or concerns about a clinic's compliance.

2.3. The policy will only be engaged in circumstances that warrant regulatory action. The 'gateway' is a series of questions which, if answered in the affirmative, indicate that regulatory action is necessary. Having determined that regulatory action is necessary, the policy then sets out a risk-based step-by-step approach to determine what regulatory action to take. The regulatory actions are set out in the Regulatory Action Table and are defined in the policy. The level of action is determined by the risk score after having considered the 'broader context'.

2.4. The broader context recognises that clinics do not operate in a vacuum and that multiple factors may have a bearing in any given set of circumstances. Thus, the policy prompts consideration of any relevant aggravating or mitigating factors and, consistent with the importance accorded to the role of the Person Responsible (PR) by the statutory scheme, the role that the PR has played. This is the principal innovation in this policy and one that should result in greater consistency for clinics.

3. Consultation and further development

3.1. We consulted on the draft policy in January 2021. Twenty-three responses were received with a near equal mix received from the NHS and private sector. Responses were helpful and insightful and **showed broad support for the risk-based approach and the step by step procedure in the policy to achieve procedural fairness**. Comments from Authority members have also been

incorporated where applicable. A summary of the responses can be found at Annex B. The key issues raised and our actions in response are set out below.

3.2. Most respondents said they understood the definitions of **likelihood and impact**, but some feedback suggested there was scope for further clarification and so minor amendments have been made to achieve clarity.

3.3. It was encouraging that the majority agreed with the list of **aggravating and mitigating factors** and that the role of the PR is a relevant consideration. These sections have undergone some minor changes but have largely remained as originally drafted.

3.4. There was a common theme that ran through some of the comments which reflected, in our view, a lack of understanding about where this policy sits in the broader context of our compliance activities and perhaps a concern that clinics may face regulatory action without having had an opportunity to engage with inspectors first. To address this, changes have been made in various places which aim to **clarify when and how the policy will be used**, and to assure clinics that they are most unlikely to face regulatory action without first having had an opportunity, or several opportunities, to engage with inspectors about remedial steps and or action plans etc.

3.5. As has always been the case, this policy is based on proportionality, **regulatory action will be proportionate to the risk**. As such, clinics that are well run and largely compliant with only a few minor non-compliances are going to have a low-risk score and consequently the nature and scale of any recommendations made in that clinic's report will be proportionate to their risk i.e., level 1 regulatory action with a longer time allowed for the PR to implement any necessary remedial actions. On the other hand, for example, a clinic with several serious non-compliances and a dis-engaged PR who has shown no understanding, or even a reluctance to put remedial actions in place, is likely to face regulatory action of a more serious and burdensome nature, and the PR will be expected to put remedial steps in place in much shorter timescales given the high risk.

3.6. Whilst two thirds of respondents said that they felt the regulatory action set out in each column of the **Regulatory Action Table** (RAT) was reasonable and proportionate some comments suggested it could be clearer. In response we have changed the headings of the three categories to an escalating numerical scale which aligns with the risk score. Level 1 being the least burdensome and time critical, Level 2 being slightly more burdensome and time critical and Level 3 being the most serious or impactful and time critical action that could be recommended. Where a risk score is determined to be in the middle range of the RAT (i.e., between 10 and 16), it gives the inspector scope to recommend a combination of both Level 1 and Level 2 actions. But for instance, if the score is at the higher end of that range the inspector may for example recommend action is taken within tighter timescales or that instead of the clinic doing their own audit, they bring in an external specialist to do an audit.

3.7. As most respondents said that they considered the **licence lengths** set out in the RAT to be reasonable and proportionate to the risk we made no changes with regard to the licence length. However, for clarity we have removed some of the detail from the table and instead included it under the descriptions of the levels of regulatory action. As members who sit on Licence Committee will be aware, one of the tools that Licence Committee has reference to is the Guidance on Licensing first published in 2016. The draft new Compliance and Enforcement Policy incorporates elements from the Guidance on Licensing, however, to the extent that the two documents cover the same topics, the Guidance on Licensing will need to be reviewed to ensure it is aligned with the current approach assuming of course that the Compliance and Enforcement

Policy is approved. This will be done in time to ensure the new Guidance on Licensing is in place when the new Compliance and Enforcement Policy comes into effect. **Members are invited to delegate the sign-off of this to the Chair and Deputy Chair of the Licence Committee**.

4. Next Steps

4.1. **Members are asked to approve the final policy to come into effect on 1st June 2021**. This is slightly delayed from the planned date of 1st April and is to allow time for inspectors' training. Inspections recommenced in November 2020 with a modified methodology. The desk-based assessment process has increased workload for inspectors and with the policy having only been finalised in the last few weeks following the end of the consultation, postponing till June allows more time to ensure inspectors are fully conversant with the policy before formal implementation.

4.2. As noted above, it was evident from some of the consultation responses that there was some misunderstanding to how the policy would be applied in practice. Confusion seemed to be around when the policy would be used and whether the PR would be involved in determining the risk score. The webpage (Compliance and enforcement policy | HFEA) will be updated with a brief explanation to provide clarity and the sector will be informed of when the policy comes into force.

4.3. An internal review is planned for June 2022 to determine how well the policy has been embedded and whether it is working effectively. An implementation date of 1st June 2021 will also allow sufficient time for the sector to be informed of when the policy comes into force.

Annex A: Compliance and Enforcement Policy

Compliance and Enforcement Policy

Introduction

1. This policy sets out the Human Fertilisation and Embryology Authority's ('the Authority') Regulatory Aims which underpin all the Authority's compliance and enforcement activities. This policy will normally be used by inspectors and serves a clear and transparent statement of the circumstances in which clinics can expect regulatory action to be taken. This policy supersedes all previous Compliance and Enforcement policies.

2. In the exercise of this policy, the inspectors will act effectively, efficiently and economically and so far as is relevant, have regard to the Regulator's Code and principles of best regulatory practice, including that regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed.

3. This policy provides an overarching tool to guide decision making in relation to compliance and enforcement activities. The policy may require some subjective input and evaluation from inspectors and does not automatically generate decisions. The procedures set out in this document aim to ensure fairness and consistency in the Authority's compliance and enforcement activities and will normally be followed by inspectors when regulatory action is necessary to achieve one or more of the Authority's Regulatory Aims.

4. The policy sets out a range of regulatory actions that may be taken by an inspector, some of which may be taken without recourse to a licensing committee[1] i.e. during post-inspection monitoring or other informal engagement with clinics. The reports produced by inspectors following an inspection or clinic visit are usually considered by a licensing committee which has delegated authority to make a range of licensing decisions. The delegated powers are set out in the Authority's Standing Orders. This policy sets out the range of regulatory action that may be recommended by an inspector in a report submitted to the Authority's licensing committee.

[1] References in this policy to licensing committee(s) includes the Executive Licensing Panel, any licence committee or any committee that hears representations or appeals against licensing decisions.

Regulatory Aims

5. The Regulatory Aims underpinning the Authority's compliance and enforcement activities include:

5.1. Promoting compliance with the requirements imposed by or under the Human Fertilisation and Embryology Act 1990 ('the 1990 Act') and the Code of Practice.

5.2. Protecting those using or affected by the services offered at licensed clinics and ensuring the quality and safety of gametes and embryos.

5.3. Maintaining public confidence in the safe, effective, and ethical conduct of licensed activities.

When the procedure set out in this policy will be engaged

6. The Authority's inspection activities are a statutory requirement and the procedure set out in this policy will normally be followed by inspectors if issues of concern or non-compliance are identified in the course of scheduled and unscheduled clinic inspections, clinic visits outside of inspections, investigations into incidents (serious adverse events and serious adverse reactions), complaints, whistle-blowing disclosures or referrals from other regulators, professional bodies or government agencies or any other circumstances which may give rise to risks or concerns about a clinic's compliance. In other words, in any circumstances in which regulatory action in one form or another is or may be required, the procedure set out in this policy will normally be followed.

7. This policy will be used in conjunction with the Authority's standard operating procedures for compliance activities. Non-compliances and concerns will be investigated, and inspectors will seek evidence or assurance from the Person Responsible (PR) and clinic staff to establish the nature and seriousness of the issue. Immediate actions or mitigating steps taken in response to any finding(s) will be noted. Throughout this process, there will be open and transparent communication with the PR regarding any concerns or issues identified. The steps set out in this policy will be implemented once the facts have been established and available evidence has been evaluated. The risk score may be re-evaluated if new evidence emerges which materially changes the conclusions reached by inspectors.

8. In any of the circumstances referred to in paragraph 6 above, inspectors will consider whether regulatory action is necessary by asking the following four questions.

8.1. Is regulatory action necessary to protect those using or affected by the services offered at licensed clinics or to protect clinic staff?

8.2. Is regulatory action necessary to ensure the quality and safety of gametes or embryos?

8.3. Is regulatory action necessary to maintain public confidence in the regulatory scheme?

8.4. Is there evidence of non-compliance with statutory requirements, licence conditions, General or Special Directions or the Code of Practice, or do the facts available suggest there may have been or is likely to be non-compliance?

9. If one or more of the questions at paragraph 8 above is answered in the affirmative, regulatory action will be necessary and inspectors will then proceed with the further steps set out below.

A risk-based approach to regulatory action

10. The Authority adopts a risk-based approach to regulation. Risk is the chance that an event or incident could happen and could cause harm. However, risks do not arise in isolation and therefore, inspectors will consider the wider context within which a clinic operates, and may have regard to a range of factors that may be relevant when determining the risk, and what regulatory action is proportionate.

11. The more severe the impact or likely impact arising from any risk, the greater the imperative to act and the more serious the action taken is likely to be. An imminent risk of serious harm is likely to warrant immediate regulatory action. To ensure consistency of approach in every scenario in which regulatory action is indicated, inspectors will use the risk matrix (see Step 3 below) and the Regulatory Action Table ('RAT') (see Step 5 below). The position on the RAT will indicate the regulatory action required in the circumstances.

12. When following these steps, inspectors will consider all relevant information, evidence, and circumstances they are aware of at the time. Should circumstances change or additional information or evidence become available, it may be necessary for inspectors to go through these steps more than once. The procedure followed by the inspector will be documented on each occasion.

Risk Grading

13. The formula employed in the risk matrix below is likelihood x impact = risk score. Risks will vary depending on the context, but may include for example, the risks arising from the most serious non-compliance in an inspection report, the highest risk factor in any incident or the highest risk factor in any complaint. Risks may also include:

13.1. risk of harm to patients[2], gametes or embryos, or any child(ren) that may be born as a result of proposed treatment.

13.2. risk of harm to staff.

13.3. risk of non-compliances, incidents, or complaints or recurrence of these.

13.4. risk that the public may lose confidence in the regulatory scheme.

Harm may include physical, psychological, or emotional injury or trauma, or financial harm to patients or staff.

14. Risk refers to the highest risk factor(s) or the worst-case scenario(s). The risk score will be determined by reference to the likelihood or probability of the risk event occurring or recurring should action not be taken, and the impact or harm that may result should the risk materialize. In some cases, it is likely that inspectors will be considering a risk event that has already happened. In such circumstances, consideration will be given to the impact that has been experienced and the likelihood of recurrence of the risk event should action not be taken.

An imminent risk of serious harm is likely to warrant immediate action. In circumstances in which inspectors identify an imminent risk, inspectors will usually engage with the Chief Inspector and/or Director of Compliance before proceeding further.

STEP 1: Assessing likelihood

15. Likelihood is the possibility of a risk event occurring or recurring if no action is taken and is a qualitative assessment.

The possibility or likelihood of a risk event occurring can be:

Remote - will probably not happen or recur;

Unlikely - not expected to happen or recur but it may;

Possible - might happen or recur;

Likely - will happen or recur;

Certain - has happened or will undoubtedly happen or recur more than once or on a frequent basis.

Whether something has happened in the past may be a reasonable indicator of whether it will happen again in the future, particularly if mitigating actions or corrective measures have not been put in place.

16. The assessment of likelihood will be based on information and evidence available at the time the assessment is carried out. This assessment may need to be conducted more than once in the light of any new information that may be made available to the inspector and will be documented.

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[2] References in this policy to patient or patients include the person having treatment, their partner if they have one, as well as donors and their partners if they have one.

STEP 2: Assessing Impact

17. Impact refers to the consequences or harm that will be caused if a risk materializes; the actual or likely impact or harm that the risk factor will have on anyone who is or may be affected by it. The impact may be insignificant, minor, moderate, major or catastrophic (see definitions at 18 below) and harm may include physical, psychological or emotional injury or trauma, or financial harm to patients or staff.

18. Inspectors will consider how a risk factor has affected or may affect patients, the quality and safety of gametes or embryos, any child(ren) that may be born as a result of treatment or clinic staff.

An insignificant impact includes a near-miss or an event or incident that has no negative or adverse effect and does not cause harm or injury (e.g. completion of an incorrect or unnecessary consent form and no treatment has been provided);

A minor impact causes minor harm or damage requiring minimal support of any sort or other remedial action (e.g. informing the patient of the incorrect date for egg collection or frozen embryo transfer but where there are no clinical implications, failure to screen patients and partners within the specified timescales);

A moderate impact causes moderate harm or damage where recovery is expected or rectification can be made without significant intervention, it may also include any harm that has resulted in or may result in a moderate increase in treatment (e.g. surgery being required where it would otherwise not have been required, discrepancies in embryo storage periods stated in consent forms of each gamete provider);

A major impact causes serious harm or damage that can be rectified but only with significant intervention (e.g. missing or incorrectly complete consent to legal parenthood forms requiring a court order of legal parenthood to be made);

A catastrophic impact causes very serious harm or damage to patients, staff, gametes or embryos, or any child(ren) that may be born as a result of proposed treatment and/or centre staff, and may include death or destruction of gametes or embryos (e.g. failure of a cryo-storage dewar, failure to screen a donor at all).

Step 3 Determining the Risk Score

Risk Matrix

A five-point rating will be used when assessing the likelihood and impact of risks.

Likelihood of the risk materialising if no action is taken:

1. **Remote** - will probably not happen or recur;
2. **Unlikely** - not expected to happen or recur but it may;
3. **Possible** - might happen or recur;
4. **Likely** - will happen or recur;
5. **Certain -** has happened – or will undoubtedly happen or recur more than once or on a frequent basis.
   Whether something has happened in the past may be a reasonable indicator of whether it will happen again in the future if mitigating actions or corrective measures have not been put in place.

Impact that the risk has had or may have:

1. **Insignificant** - includes a near-miss or an event or incident that has no negative or adverse effect and does not cause harm or injury (e.g. completion of an incorrect or unnecessary consent form and no treatment has been provided);
2. **Minor** - causes minor harm or damage requiring minimal support of any sort or other remedial action (e.g. informing the patient of the incorrect date for egg collection or frozen embryo transfer but where there are no;
3. **Moderate** - causes moderate harm or damage where recovery is expected or rectification can be made without significant intervention, it may also include any harm that has resulted in or may result in a moderate increase in treatment e.g. surgery being required where it would otherwise not have been required (e.g. discrepancies in embryo storage periods stated in consent forms of each gamete provider);
4. **Major** - causes serious harm or damage that can be rectified but only with significant intervention (e.g. missing or incorrectly complete consent to legal parenthood forms requiring a court order of legal parenthood to be made);
5. **Catastrophic** - causes very serious harm or damage to patients, staff, gametes or embryos, or any child(ren) that may be born as a result of proposed treatment and/or centre staff, and may include death or destruction of gametes or embryos (e.g. failure of a cryo-storage dewar, failure to screen a donor at all).

Impact the risk has had or may have						
	Catastrophic	5	10	15	**20**	**25**
	Major	4	8	12	16	**20**
	Moderate	3	6	9	12	15
	Minor	2	4	6	8	10
	Insignificant	1	2	3	4	5
Risk Score = Impact x Likelihood		**Remote**	**Unlikely**	**Possible**	**Likely**	**Certain**
		Likelihood of risk materializing if action is not taken				

STEP 4 Consideration of the broader context

19. Having determined the initial risk score at Step 3 above, the inspector will then reflect on the broader context within which the clinic operates and within which the risk event arises. The broader context refers to any relevant mitigating and aggravating factors (see indicative list at paragraphs 22 and 23 below). Aggravating and mitigating factors may be both directly and indirectly related to the likelihood of the risk materializing and the impact that it may have. Any aggravating and mitigating factors considered will be documented.

20. By section 17 of the 1990 Act, the PR has overall statutory responsibility and must ensure amongst other things, that the clinic is fully compliant and operating to prescribed standards of quality and safety. Consistent with the importance of the role and the duties imposed on a PR by statute, the inspector, when considering the broader context and in determining a clinic's risk score, will consider the role the PR has played in the circumstances. When considering the role of the PR, the factors set out at paragraph 24 below, will be taken into account, as well as whether the PR has demonstrated effective leadership in line with guidance published in the Code of Practice and the PR Role Description[3], and any professional codes of conduct they may be bound by.

21. This step is an opportunity for the inspector to reassess and if necessary, adjust the risk score by reference to relevant aggravating and mitigating factors and the role the PR has played. The risk score may be adjusted up or down. Any adjustment to the risk score and the factors considered in making the adjustment will be documented. By reference to the RAT at Step 5 below, the risk score will be used to help determine what regulatory action is proportionate and where relevant, what length of licence to recommend.

Mitigating factors

22. These factors are not listed in any hierarchy and this is not an exhaustive list. Not all these factors will be applicable in every case and there may be other factors not listed here that may be relevant and may therefore be taken into consideration.

Patient focus and integrity

22.1. The PR has recognised the impact or potential impact on patients and has done the right thing in response (this may include making full disclosure to patients or donors,

[3] The Person Responsible key behaviours and role description is published online at this link https://www.hfea.gov.uk/media/2993/person-responsible-role-description-and-key-behaviours.pdf

offering an apology, offering appropriate support, financial remediation, or further treatment at no or low cost).

Compliance with and understanding of requirements

22.2. The PR understands the requirements or standards that they are expected to meet, has recognised where or in what way the clinic has fallen short, and has taken responsibility for the non-compliances or for enabling a situation or circumstances that resulted in the non-compliances.

22.3. The PR has taken appropriate remedial action to mitigate the risk of recurrence or has established an action plan and has done so proactively and within reasonable timescales. The PR has demonstrated insight i.e., the PR has reflected on the issue, recognised the shortcomings, and accepted that things should have been done differently to avoid the scenario arising.

Cooperation

22.4. The PR has fully co-operated with inspectors regarding the current issue and has the PR answered questions honestly and provided information freely. The PR has made full disclosure regarding the circumstances of any non-compliances and has encouraged their staff to be cooperative and open with inspectors. The PR provided information within the timescales agreed or specified.

Aggravating factors

23. These factors are not listed in any hierarchy and this is not an exhaustive list. Not all these factors will be applicable in every case and there may be other factors not listed here that may be relevant and may therefore be taken into consideration.

Patient focus and integrity

23.1. Failure to notify patients affected of an incident and or failure to offer appropriate support.

23.2. Failure to investigate or provide an adequate response to patient complaints, including failure to take account of the impact or potential impact of the clinic's actions on patients.

23.3. Any financial or other gain made by the clinic at the patients' expense or as a consequence of what has happened.

Compliance with and understanding of requirements

23.4. The PR does not understand the requirements or standards that they are expected to meet nor recognised where or in what way the clinic has fallen short. The PR has not taken responsibility for the non-compliances or for enabling a situation or circumstances that resulted in the non-compliance.

23.5. The number and seriousness of any non-compliances or issues identified; failure to take the initiative to address non-compliances or the consequences of non-compliances.

23.6. Whether or to what extent the non-compliance occurred deliberately or recklessly, including the extent to which the PR, Licence Holder or other senior staff knew, or ought to have known, of the non-compliance or the risk of the non-compliance occurring.

23.7. The number and seriousness of any incidents i.e. grade A, B or C with grade A being the most serious.

23.8. Failure to report incidents at all, or within the specified timescales.

23.9. Demonstrating a lack of interest or willingness to remedy non-compliances or take appropriate remedial action at all, or within appropriate timescales.

23.10. Failure or repeated and ongoing failure, or inability to identify the appropriate remedial steps that should be taken including failure to implement or embed agreed action plans.

23.11. Demonstrating a lack of insight by for example not recognising the seriousness and impact of non-compliances.

23.12. History of non-compliance or disregard for the system of regulation which may include repeated or ongoing breaches of the statutory framework and repeated or ongoing failure to comply with recommendations for remedial action at all, or within agreed or specified timescales.

Co-operation

23.13. Failure to engage or cooperate with inspectors including failure to let inspectors conduct an inspection of the licensed premises.

23.14. Failure to respond to inspectors' reasonable requests including requests made during an inspection, investigation, or other clinic visit.

23.15. Failure to adhere to the terms of a voluntary undertaking or to comply within the timescales set out in such an undertaking.

23.16. Failure to respond to correspondence or telephone calls from inspectors without good reason.

23.17. Dishonesty or deliberate attempts to mislead or misinform inspectors including providing incorrect or misleading information.

23.18. Failure to notify the Authority of any material change in circumstances.

23.19. Failure to perform a root cause analysis to identify underlying causes and implement appropriate solutions.

23.20. Abuse of trust or position.

The Person Responsible

24. Inspectors will consider the extent to which the PR has at the current time and historically:

24.1. fulfilled their duties under section 17 of the 1990 Act.

24.2. has completed the PR Entry Programme ('PREP'), or specified sections of the PREP within specified timescales and demonstrates that they fulfil the requirements of the 'Person Responsible Key Behaviours and Role Description'[4] as published by the Authority.

24.3. acted with integrity, insight and knowledge and understanding.

24.4. been cooperative, fully engaged and responsive in their dealings with inspectors and any affected patients.

24.5. has open and direct communication with senior staff and where the organisational structure necessitates, the PR has escalated relevant issues to senior management.

24.6. taken responsibility for what has happened.

24.7. has shown insight and taken the initiative to put remedial actions in place without prompting from inspectors.

24.8. has demonstrated that they will embed and sustain the required improvement or changes.

24.9. has been open, transparent, and honest in their dealings with inspectors and affected patients.

24.10. has been proactive in ensuring compliance and implementing corrective actions.

[4] The Person Responsible key behaviours and role description is published online at this link https://www.hfea.gov.uk/media/2993/person-responsible-role-description-and-key-behaviours.pdf

Step 5: Regulatory Action Table (RAT)

25. The RAT is a guide for inspectors. Consistent with the Authority's risk-based approach, the risk score calculated in Step 4 will, by reference to the RAT, guide inspectors in determining what regulatory action is proportionate. In the context of licensing matters, the RAT will guide inspectors in determining what length of licence to recommend. Regulatory action may include Level 1, Level 2 and/or Level 3 actions. These actions are defined in broad terms below in paragraphs 28, 29, and paragraph 30, with the action required, and the timescales within which clinics will be expected to take action escalating in impact from Level 1 to 3 across the table.

26. Inspectors will have regard to regulatory action taken or recommended in similar cases but may depart from previous cases depending on the particular facts, and the context of the case under consideration.

Risk score 1-4	**Risk score 5-9**	**Risk score 10-12**	**Risk 15-16**	**Risk 20 - 25**
Level 1 action(s) requiring response within reasonable timescales.	Level 1 action(s) requiring more intensive scrutiny or shorter response timescales (e.g., additional audits, seeking legal advice).	Level 1 and/or Level 2 action(s) requiring urgent and/or immediate interventions or actions.	Level 1 and/or 2 action(s) requiring immediate interventions or actions.	Level 3 action
4-year licence	3- or 4-year licence with or without additional conditions	2-year licence with or without additional conditions	1-year licence with or without additional conditions	Recommendation not to grant a licence, or revocation or immediate/ongoing suspension of licence

27. **Level 1** action may include one or more of the following.

27.1. Informing the PR of any non-compliances and identifying the remedial or improvement action that must be taken to achieve compliance and the timescales for doing so if further regulatory action is to be avoided. This communication may be verbal or written and can be in the form of a meeting but should be recorded.

27.2. Performance monitoring including requiring regular verbal or written updates or reports from the PR in relation to the implementation of any remedial or improvement plans with timeframes agreed to by the PR.

27.3. Promoting awareness of requirements and the need for appropriate remedial action including requiring the PR to complete the PREP or specified parts thereof.

27.4. Referring the case for consideration by a licensing committee with a recommendation to impose additional conditions.

28. **Level 2** action may include one or more of the following.

28.1. Calling an accountability meeting with the PR and any relevant clinic staff, relevant inspectors, the Chief Inspector or Director of Compliance (accountability meetings will usually be held at the HFEA offices however this is at the discretion of the Chief Inspector or Director of Compliance).

28.2. Agreeing a voluntary undertaking with the PR in which the PR implements certain prescribed actions or agrees to cease prescribed activities within a specified timescale (voluntary agreements will be formalised in writing by the inspector).

28.3. Commissioning an independent review or requiring the clinic to commission an independent review into a matter.

28.4. Additional announced or unannounced inspections (to be agreed in consultation with a Senior Inspector and/or the Chief Inspector and/or Director of Compliance).

28.5. Sending a warning letter to the PR informing him/her that enforcement action may be recommended if remedial actions are not taken, or improvements not made within a specified timescale.

28.6. Referring the case for consideration by a licensing committee with a recommendation that an additional announced or unannounced inspection should take place within a specified time.

28.7. Referring the case for consideration by a licensing committee with a recommendation that the licence should be varied, which may include variation by imposing additional conditions under section 18A (2) of the 1990 Act. The imposition of conditions may be appropriate where the risk or non-compliance is capable of being remedied and where a specific, measurable, achievable, relevant and time-bound condition can be formulated. This recommendation will only be made where there is evidence that the PR is likely to comply with any condition imposed.

28.8. Where professional codes of conduct may have been breached or where the requirements or standards of another regulatory body may have been breached, a recommendation that the individual or clinic is referred to the relevant professional body or regulator. The final decision on any referral will be taken by the Director of Compliance, usually in consultation with the Chief Executive.

28.9. Making a recommendation regarding the PR's failure to fulfil their duties under section 17 of the 1990 Act or that the PR has failed to fulfil their section 17 duties and is therefore not suitable to remain PR, or that a person is not suitable to be appointed as PR.

29. **Level 3** actions may include.

29.1. Referring the case for consideration by a licensing committee with a recommendation that:

29.1.1. an application for the grant, which includes renewal, of a licence should be refused under section 16 of the 1990 Act.

29.1.2. the licence be immediately suspended under section 19C(1) of the 1990 Act or, in any case where a licence has previously been suspended, a recommendation under section 19C(2), that the suspension should continue for a further period of time.

29.1.3. the licence should be revoked under section 18(2) of the 1990 Act.

29.2. In any case in which the RAT indicates Level 3 action, a management review will be held before further steps are taken. Level 3 action will only be recommended following a management review at which a Senior Inspector, the Chief Inspector and/or the Director of Compliance are in attendance and will usually only follow where engagement with the PR to address issues or mitigate risks has been unsuccessful.

29.3. A minute will be kept of any management review meeting where Level 3 action is agreed. In any case in which the management review concludes that regulatory action other than that indicated by the RAT is necessary, reasons for the decision will be recorded in the minutes.

29.4. The use of these powers will always be proportionate and will only be recommended where the relevant statutory tests can be met.

30. Licensing committee procedure where recommendations for action are made.

30.1. In cases in which a recommendation for action has been made and a licensing committee has accepted the recommendation or decides on an alternative to the recommendation, the procedures governing the relevant committee will be engaged and the PR can expect to receive notification of the decision or proposed decision from the relevant committee secretary.

30.2. The committee secretary will serve any statutory notices on the PR and inform them of any right to reconsideration or, where relevant, any right of appeal and the timescale within which these rights must be exercised.

Suspected Criminal Offences

31. Where inspectors have reasonable grounds for suspecting that an offence under the 1990 Act has been committed, the inspector will consult with the Director of Compliance before a decision is reached to recommend to the Chief Executive that the matter be referred to the police for investigation or to apply to a Justice of the Peace for a warrant to enter, search and seize materials from any premises where offences are suspected to have been committed.

32. The final decision to refer a matter to the police for investigation or apply for a warrant rests with the Chief Executive in consultation with the Chair of the Authority. The Chair may consult with the Deputy Chair and Chair of the Audit and Governance Committee about the recommendation. In the event of a disagreement between the Chief Executive, the Chair of the Authority, the Chair or Deputy Chair of the Audit and Governance Committee, the matter will be put to a vote. The Chair of the Authority will hold a casting vote.

The evidence relied on and the decision to refer the matter to the Chief Executive and the Chair will be documented by the inspector. Any decision reached by the Chief Executive and Chair and the members who are consulted will be recorded by the Chief Executive.

Version/revision control

Version	Changes	Updated by	Approved by	Release date	Review date

Annex B: Summary of Consultation responses

- The Compliance and enforcement policy consultation in January 21 received 23 responses:
    - 22% from Persons Responsible (PR) at private clinics
    - 17% from PRs at NHS clinics,
    - 35% from clinic staff at private clinics
    - 26 % from clinic staff at NHS clinics
- 92% of respondents agreed that the step by step procedure set out in the policy will help achieve procedural fairness.
- 63% of respondents agreed that it is fair and proportionate to consider the highest risk factor(s) or worst-case scenario(s)
- 92% agreed with the risk-based approach set out in the policy.
- 79% of respondents said they understood the definitions of likelihood and agreed that they are an appropriate way of assessing likelihood.
- 75% of respondents said that they understood the definitions of impact and agreed that they are an appropriate way of assessing impact.
- 79% of responded agreed that it is fair and reasonable for the initial risk score to be moderated up or down by reference to any aggravating or mitigating factors and the role of the PR.
- 79% of respondents agreed with the list of aggravating and mitigating factors.
- 83% agreed that the role of the PR is a relevant consideration in any circumstances and agreed with the range of factors to be considered in relation to the role of the PR.
- 67% of Respondents said that they felt the regulatory action set out in each column of the Regulatory Action Table (RAT) was reasonable and proportionate to the risk score.
- 71% of respondents said that they considered the licence lengths set out in the RAT to be reasonable and proportionate to the risk.