Authority meeting held by teleconference

Date – 11 November 2020

Venue - Online

Agenda item	Time
1. Welcome, apologies and declarations of interest	1:00pm
2. Minutes of the Authority meeting held 16 September 2020	1:05pm
3. Performance report and strategic risk register	1:10pm
4. Covid-19 updates	1:30pm
5. PRISM update	2:00pm
6. Business planning 2021-22	2:05pm
7. Treatment add-ons progress report 2020	2:25pm
8. Compliance & enforcement policy pre-consultation	2:55pm
9. HFEA preparations for the end of the EU exit transition period	3:15pm
10. Any other business	3:35pm
11. Close	3:40pm

Minutes of Authority meeting 16 September 2020

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	11 November 2020		
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 16 September 2020 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 16 September 2020 held via teleconference

Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Anthony Rutherford Emma Cave Anne Lampe	Jonathan Herring Gudrun Moore Ruth Wilde Yacoub Khalaf Ermal Kirby Kate Brian
Apologies	None	
Observers	Steve Pugh Marina Pappa	(Department of Health and Social Care - DHSC)
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Dan Howard Joanne Triggs	Yvonne Akinmodun Rachel Cutting Helen Crutcher Catherine Drennan Debbie Okutubo

Members

There were 12 members at the meeting – eight lay members and four professional members.

1. Welcome, apologies and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members, the public and staff present online. She 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 deliberations to hear it afterwards.

1.2. There were no apologies for absence.

1.3. Declarations of interest were made by:

- Yacoub Khalaf (PR at a licensed clinic)
- Anthony Rutherford (clinician at a licensed clinic)
- Ruth Wilde (counsellor at licensed clinics)
- Kate Brian (working at Fertility Network UK).

2. Minutes of the meeting

2.1. Members agreed that the minutes of the meeting held on 17 August 2020 were a true record and be signed by the Chair.

3. Performance report

3.1. The Chair invited the Chief Executive (CE) to present the performance report for the period ending July 2020 to the Authority.

3.2. It was noted that there were two red indicators (debt collection and debtor days) and both were related to the impact of Covid-19 upon clinics and reduced income for the HFEA during this period.

3.3. The CE informed members that employee turnover was down and currently in target. He explained that this was welcome news and was probably due to a combination of the impact of Covid-19 which had meant that there were fewer roles being advertised and the fact that a number of staff were successfully working from home.

Strategy and Corporate Affairs

3.4. The Director of Strategy and Corporate Affairs gave an overview of her area. Members were advised that the treatment add-on pages on our website had been recently updated with more information and we were now in the process of carrying out user-testing from patients on these web pages. A paper on treatment add-ons would be brought to the November Authority meeting.

3.5. In relation to EU exit, Members were reminded that the end of the transition period is 31 December 2020. From that date, licensed clinics in Northern Ireland (NI) would remain subject to aspects of the EU regulatory rules and clinics and the rest of GB would not. We would be working to set up a 'regulator within a regulator' to effect these changes and would be returning to Authority in November with more information.

3.6. Members asked about EU exit and if there were any concerns about clinics getting supplies from abroad. The Director of Strategy and Corporate Affairs responded that clinics had confirmed that they were confident about supply issues and hoped that there would be minimal disruption.

3.7. In discussion, Members queried why embryo glue was no longer on the treatment add-ons list. The Director of Compliance and Information responded that embryo glue was still included as a treatment add-on but it was now called by its non-commercial name – hyaluronate enriched medium.

3.8. In response to another question, the Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC) confirmed that observers were welcome to attend their meetings.

Compliance and Information

3.9. The Director of Compliance and Information commented that at the last meeting permission was given by the Authority to restart inspections of licensed centres and that these had been scheduled from November 2020 to April 2021:

- centres to be inspected had been prioritised
- logistics were being worked out
- PPE packs were being sourced
- the Inspection team were being supported
- risk assessments were being carried out in the teams and policies revisited where necessary.

Finance and Resources

3.10. The Director of Finance and Resources provided an overview of the financial position. Reduced clinic activity because of the pandemic had meant there was a projected shortfall of up to 50% in our income. Following discussion with the Department of Health and Social Care (DHSC) we had reached an agreement where we would remain operational though a combination of additional Grant-in Aid and the use of our cash reserves.

3.11. Regarding the future fees work, the Director of Finance commented that it was not appropriate to consult on it at this time due to the impact of Covid-19 on the sector. We were in conversation with the DHSC and we would revisit this in 2021.

3.12. The Chair asked why we were forecasting a deficit rather than a balanced budget and another member asked how well could we predict our treatment (and therefore income) levels compared to where we were last year. The Director of Finance and Resources responded that we were reporting in line with government accounting rules and that we were managing the financial position actively to return a balanced budget by year end.

3.13. The CE confirmed that treatment levels would determine if we would need additional Grant-in-Aid to enable us to arrive at a balanced budget.

3.14. The Director of Finance and Resources advised members that the impact of Covid-19 on the wider construction sector meant that our planned office move to Stratford was unlikely to take place this calendar year.

3.15. It was noted that the earliest move date we were looking at was the first week in January 2021. In the meantime, to support staff who were struggling to work from home on a permanent basis we had reached agreement with the Care Quality Commission (CQC) in Victoria to use some of their office space from October to the end of this calendar year and staff had been made aware of this. This was to support the mental wellbeing of those staff who were finding it difficult to work from home, as well as those who have unsuitable space for indefinite home working. In response to a question it was noted that CQC had their current office space until March 2021.

3.16. The CE commented that we were also going to look at the bigger picture of what home-office balance meant post Covid-19 and we needed to reach an agreement as to what we should best use the office for.

3.17. Members commented that the Senior Management Team (SMT) and all staff were doing a very good job and offered their thanks.

3.18. Members asked for a status update on Opening the Register (OTR). The Director of Compliance and Information responded that there was a backlog due to the service pausing its operations during lockdown but there was an ongoing discussion with the team on how and when the service will be re-opened.

3.19. The Chair concluded by thanking all staff for managing our operations during the pandemic and reiterating that we would continue to respond to future events as best we could, for example if we have a second wave of Covid-19 and what the impact of that could be.

3.20. Members noted the performance report.

4. Covid-19 updates

4.1. The Director of Compliance and Information gave an overview. Covid-19 patient and media enquiries had reduced significantly so there was nothing specific to report from the Strategy and Corporate Affairs perspective.

4.2. We were working with the sector and reporting performance back to the DHSC and NHS England.

Comparing clinic activity with 2019, NHS funded cycles were at 64% of the activity level of 12 months ago whilst privately funded cycles were at 89%.

4.3. It was noted there were a number of reasons for the reduced activity including:

- pre-screening requirements for clinic visits was time consuming
- clinic appointments were taking longer
- getting COVID-19 tests was proving difficult
- children going back to school had meant that those clinic staff that had children of school age needed to take time off when children were sent home
- there are delays in reopening NHS gynae outpatient services and fewer GP appointments which was leading to reduced referral numbers.

4.4. The Chair requested that anecdotal evidence where clinics were not communicating clearly with their patients should be reported via the inspection teams.

4.5. Members commented that some patients were also finding it difficult to telephone clinics due to fewer clinic staff being available.

4.6. The Chair commented that the lack of diagnostic tests, fewer GP appointments and non-urgent appointments being cancelled, were causes for concern and asked if the DHSC representatives could take this up. The DHSC representative confirmed that they would, following further discussion with the HFEA executive.

4.7. Members noted the Covid-19 updates.

5. PRISM

5.1. The Chief Information Officer presented to the Authority. It was noted that the Audit and Governance Committee (AGC) was providing oversight on PRISM and the next meeting was on Friday 18 September 2020 to discuss progress.

5.2. In terms of progress to date the meeting noted:

- the new data standard
- PRISM system development including functional testing
- data quality improvements
- infrastructure and security, and
- third party system interfaces had all been completed.

5.3. In terms of the framework for sign off and launch, it was reported that we were on track to begin the launch process this autumn. The AGC had the delegated authority to oversee its launch.

5.4. The sign off date was crucial as there were other factors to consider including

- the office move, and
- the necessary migration of the current data submission system.

5.5. The Chair noted that PRISM would be released to the sector in approximately three weeks and that training would follow. The Chair commented that we would not go live with the PRISM system if it was not working as it should.

5.6. The AGC Chair thanked staff and clinics for the work done to date and reiterated that accuracy was the key thing for the AGC and that they were keeping a close eye on PRISM as it was approaching its final launch stage.

5.7. The Vice Chair of the AGC commented that the assurance they were going to be looking for at the next meeting was that the PRISM system was ready. Also, in the event that there was a second wave of Covid-19 that it could cope. The AGC would also be considering the impact of the office move and the need for contractors to stay through the launch period to ensure continuity of expertise in the face of any launch issues.

5.8. The CE commented that data quality was of the utmost importance. He noted that he was confident that we could start the launch process in a couple of weeks and that integrated testing would tell us about accuracy.

5.9. The Chair stated that we would update the Authority after the AGC meeting on Friday 18 September.

5.10. Members noted the status update on PRISM.

6. Equality and diversity

6.1. The Chair invited the Head of Human Resources to present this item. It was noted that HFEA compared favourably when measured against both the DHSC and the Civil Service in all areas (gender and BAME) other than disability, where we are consistent when measured against other bodies. The Board represented a similar pattern to staff with 25% of Authority members from a BAME background.

6.2. The Head of Human Resources thanked Ermal Kirby and Anita Bharucha for their input into the report.

6.3. Members were advised that the DHSC had suggested that all its ALBs should consider signing up to the Race at Work Charter. HFEA was in a position to meet the five criteria for this Charter, which were:

- appoint an Executive Sponsor for race
- capture ethnicity data and publicise progress
- commit at Board level to zero tolerance of harassment and bullying
- make clear that supporting equality in the workplace remained the responsibility of all leaders and managers and
- take action that supported ethnic minority career progression.

6.4. In terms of next steps, it was noted that there were planned in-depth studies of the different types of family formations following fertility treatment and on access to, and outcomes of that treatment. In addition, there would be a similar in-depth study on patients from a BAME background carried out in 2021.

6.5. Members commented that it was a great paper and supported the race at work charter. Also, whilst they were in support of having a champion at board level for equality and diversity, HFEA would be better served if equality and diversity was not an add-on but the norm.

6.6. Regarding unconscious bias training, members suggested that the training should be extended to board members.

6.7. Members further commented that with 80% of staff being female, work should be considered to attract more male staff.

6.8. The Authority approved the proposal to sign up for the Race at Work Charter and to have a small Board team championing EDI.

7. Marking 30 years of the HFEA – planning for 2021

7.1. The Director of Strategy and Corporate Affairs introduced this report. Members were reminded that the HFEA will mark its 30th anniversary in 2021. The HFE Act was also now 30 years old.

7.2. Activities to mark the anniversary were being planned for 2021, although the ongoing Covid-19 pandemic may change what we are able to do.

7.3. The activities and events would be used as opportunities to:

- celebrate the UK's achievements in having an effective regulatory regime
- look to the future of regulation of fertility treatment and research, and
- build a public conversation about future treatment and regulation.

7.4. The annual Persons Responsible (PR) event which takes place in November would be an opportunity for the Chair to talk to PRs about some of the issues and challenges outlined.

7.5. It would also be an opportunity to discuss the impact of the Covid-19 pandemic and to outline the work that the Competition and Markets Authority had done on consumer protection law and the fertility sector.

7.6. Looking to the future, it was suggested that the following areas of the Act should be considered:

- regulatory powers
- patient safety
- scientific changes and
- societal changes.

7.7. The DHSC representative suggested that once the plans and activities had been firmed up, HFEA should write to Lord Bethell giving him an update and inviting him to chair one of the anniversary events.

7.8. The Authority approved the development of plans to mark the 30th anniversary of the HFEA.

8. Business planning

8.1. The Risk and Business Planning Manager presented the six-month business plan for 2020/21 and the outline for the intended content for the new 2021/22 business plan to the Authority.

8.2. Members were reminded that both business plans would require the DHSC approval prior to publication.

8.3. The list of activities for the strategic work for the six-month business plan for 2020/21 was explained to the Authority.

8.4. Members suggested that as part of the narrative on suspended inspections for six-month period that the phrase 'in keeping with government policy' should be included.

8.5. Members suggested that staff should take into consideration all the relevant legal and judicial rulings when dealing with consent in the Act.

8.6. The CE responded that in time we might need to move to a simpler consent regime but that was a discussion for the future.

8.7. The Authority approved:

- the six-month business plan for the second half of 2020/21
- the outline plan for 2021/22, for it to be drafted in full and
- noted the activities that would be scheduled in more detail later, for the final two years of the strategy delivery.

9. Any other business

9.1. The Chair reminded everyone that the next Authority meeting was scheduled for 11 November 2020.

9.2. The Chair thanked everyone who prepared a paper, staff and observers.

Chair's signature

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

Signature

Chair: Sally Cheshire

Date: 11 November 2020

Performance report

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:	3
Meeting date:	11 November 2020
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:	Authority is asked to note and comment on the latest performance report.
Resource implications:	In budget
Implementation date:	Ongoing

Communication(s):	The Senior Management Team (SMT) reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper. The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are discussed in the subsequent SMT meeting. The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper).
Organisational risk:	Medium

1. Latest review

1.1. The attached report is for performance up until September 2020

1.2. Performance was last reviewed by SMT at its 26 October meeting.

2. Key trends

2.1. In September performance was generally good. There were 3 red indicators.

Red indicators

2.2. The indicators classed as red are as follows:

- F1 - Debt collection
- F3 - Prompt payment
- R1 - Register errors

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. Opening the Register performance monitoring

3.1. Authority is asked to note that the Opening the Register service reopened to new applicants on 20 October. Because the service has been closed for six months, we have already seen a significant increase in applications, due to pent-up demand.

3.2. SMT has taken the decision that given this increased pressure, for the next few months we will be unable to perform against our target of 95% of applications fully processed within 30 working days. It is still our intention to respond to applicants as quickly as possible, with effective support and accurate data, however the additional demand will make our earlier target impossible to meet for a period.

3.3. We will keep this situation under review and discuss with the Authority when this changes. The Compliance management team are reviewing the data on this recent influx to estimate the likely duration of this ongoing impact and will ensure that we continue to clearly communicate with both applicants and the wider sector.

Annex 1 HFEA Performance scorecard and management commentary – September data

Breakdown of total Red, Amber, Green and Neutral Indicators

Figure 1 – Same number of Red indicators as last month

RAG	Area	Trend and key data
Green – within target range	**People -** Employee turnover Target: between 5%-15%	12% Turnover 2 leavers
Neutral, none completed this month	**Regulatory efficiency -** Time for end-to-end inspection and licensing process Target: 100% in 70 working days or less	N/A as no such items due.
No target – increase since last month	**Engagement -** HFEA website sessions	61,766 sessions (56,801 in same month last year)

Summary financial position – September data (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	**2,518**	**3,646**	**(1,128)**	**7,242**	**7,211**	**31**
Expenditure	**3,210**	**3,521**	**311**	**7,030**	**7,211**	**181**
Total Surplus/(Deficit)	**(692)**	**125**	**(817)**	**212**	**0**	**212**

Commentary on financial performance to end September 2020

The Year to date position shows a deficit against budget of £817k due to the continued impact the COVID19 pandemic over the first 6 months of the financial year. Our expenditure is also below budget with an underspend of £311k, which is due to reduced activity levels in the early part of the year due to COVID-19 and the profiling of expenditure in the first part of the year. Our assumptions on profiling expected activity levels to increase from September. The DHSC are content with our financial position and have increased Grant in Aid to ensure that we deliver to budget.

We are forecasting an underspend that represents the non-cash funding element provided by DHSC to cover depreciation and amortisation charges as we cannot use it for other operational purposes.

Management commentary

In September, performance was generally good. We had 3 red indicators. The performance picture in September is largely one of continuity, as we continued to return to a more normal pre-Covid workload. For the first time in recent memory there was no relevant Compliance activity to report as no PGD, HLA and mitochondrial donation applications were due for completion, and no relevant licences (renewals, interims, covid-19 related one-year extensions) issued (minutes signed off) in September for the end to end inspection/licensing activity indicator. This is quite unusual, but likely due to expected clustering of activity; we anticipate a return to reporting more normal activity from October.

Over the coming weeks and months, we will be beginning a conversation about our future performance monitoring for the PRISM system, to ensure that we have meaningful measures in place to monitor performance once the system launches.

Red indicators:

Finance

- **F1 - Debt collection –** 66% compared to target of 85% of debts or more collected in the month being within 40 working days from billing. This indicator has been affected by Covid-19 impacting the sector but has been improving in recent weeks; we expect the collection rate to continue to improve over the coming weeks.
- **F3 - Prompt payment –** 74% compared with target of 85% or more of invoices paid within 10 working days. This was mainly due to a single substantial invoice (32K) settled at 12 working days.

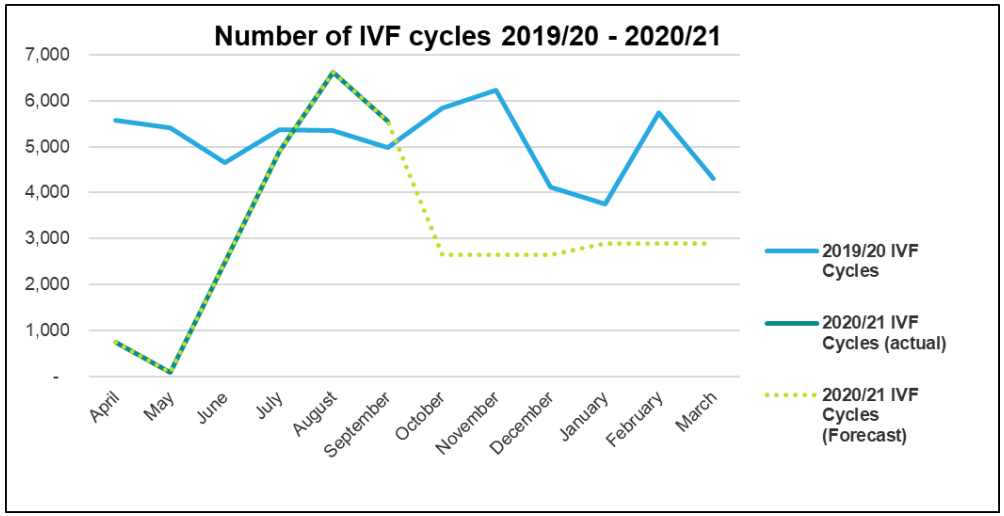
Finance KPI performance is improving month on month and debtor days are now well below our target of 30.

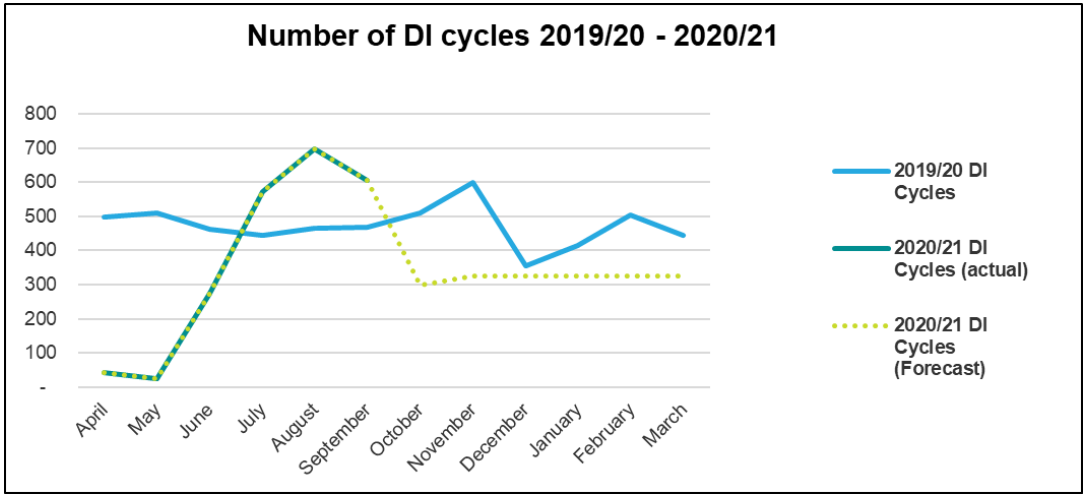
Information

- **R1 – Register errors –** September saw a 6% increase in errors, compared to our target of a 5% or greater reduction in register data errors. This increase is considered to be a fluctuation within the expected levels of variation, although our aim is to reduce the errors, and so this is still considered red. This comes after a very positive performance in August, when we had a 7% reduction in errors.

In September, the OTR service was still paused following our suspension of the service earlier in the year when fertility clinics were closed. Since then, the OTR team has processed the earlier backlog of applications. During this time there have been other issues that have affected the service and caused further delay, including staffing changes to the Donor Information team and our internal systems. Both these issues have now been resolved and the Opening the Register and Donor Sibling Link services reopened on 20 October 2020. At the time of writing, at the end of October, we have already seen a significant influx of applications due to the service being closed for six months. This will mean that it will take us longer than usual to process the applications and SMT has taken the decision to temporarily cease judging our performance against our standard KPI of 95% of applications processed within 30 working days. We will still report number of applications, and we are in the process of estimating expected volumes for the coming months and how long it may take us to process these new applications. We are ensuring that we continue to communicate clearly to the sector and applicants. We are working hard to deal with all applications as quickly as we can while providing accurate information and a supportive service and have provided some additional temporary administrative resource to the OTR team to support this. Reporting will be regularised once more as soon as we are able.

Annex 2 Financial management information





IVF Cycles	YTD		YE Position	
	Volume	£	Volume	£
2019/20 IVF Cycles	31,383	2,510,640	61,386	4,910,880
2020/21 IVF Cycles (actual)	20,381	1,630,480	37,031	2,962,480
Variance	11,002	880,160	24,355	1,948,400

DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2019/20 DI Cycles	2,850	106,875	5,676	212,850
2020/21 DI Cycles	2,217	83,138	4,142	155,325
Variance	633	23,738	1,534	57,525

The graphs illustrate the significant reduction in IVF treatment cycles (35%) in the period ended 30 September 2020 compared to 2019/20. We are currently forecasting a c50% reduction in activity across the year, but this is based on continuous increased activity over the remainder of the financial year.

DI treatments do not follow IVF activity patterns exactly, we continue to experience a reduction in volumes compared to 2019/20 (22%). We are again forecasting a c50% reduction but will continue to monitor throughout the year.

HFEA Income & Expenditure Sep-20

	Year to Date				Full Year		
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %	Forecast £'000	Budget £'000	Variance £'000
Income							
Grant-in-aid	525	619	94	15	3,338	1,238	2,100
Non-cash (Ring-fenced RDEL)	255	255	0	0	510	510	-
Grant-in-aid - PCSPS contribution	50	50	0	0	100	100	-
Licence Fees	1,615	2,644	1,029	39	3,140	5,209	(2,069)
Interest received	1	5	4	82	10	10	-
Seconded and other income	71	72	1	1	144	144	-
Total Income	2,518	3,646	1,128	31	**7,242**	**7,211**	**31**
Revenue Costs							
Salaries (excluding Authority)	2,338	2,477	139	(6)	4,723	4,629	(94)
Staff Travel & Subsistence	1	23	22		48	161	113
Other Staff Costs	40	54	14	(25)	99	121	22
Authority & Other Committees costs	94	105	11	(10)	223	284	61
Facilities Costs incl non-cash	335	457	122	(27)	804	928	124
IT Costs	269	250	(18)	7	533	517	(16)
Legal / Professional Fees	113	122	9	(7)	406	388	(18)
Other Costs	21	34	13	(39)	194	183	(9)
Total Revenue Costs	**3,210**	**3,521**	**311**	**(9)**	**7,030**	**7,211**	**181**
TOTAL Surplus / (Deficit)	**(693)**	**124**	**(817)**		**212**	**(0)**	**213**
Adjusted for non-cash income/costs	**(807)**	**124**	**(931)**		**(9)**	**(0)**	**(9)**

Management commentary

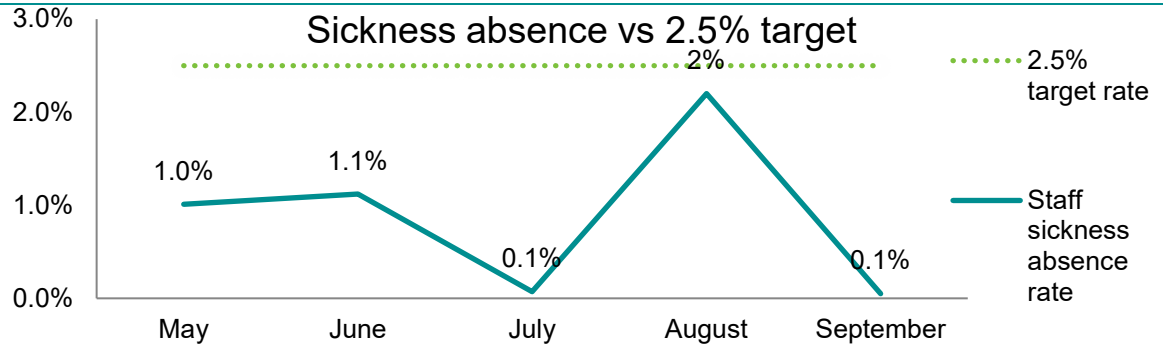
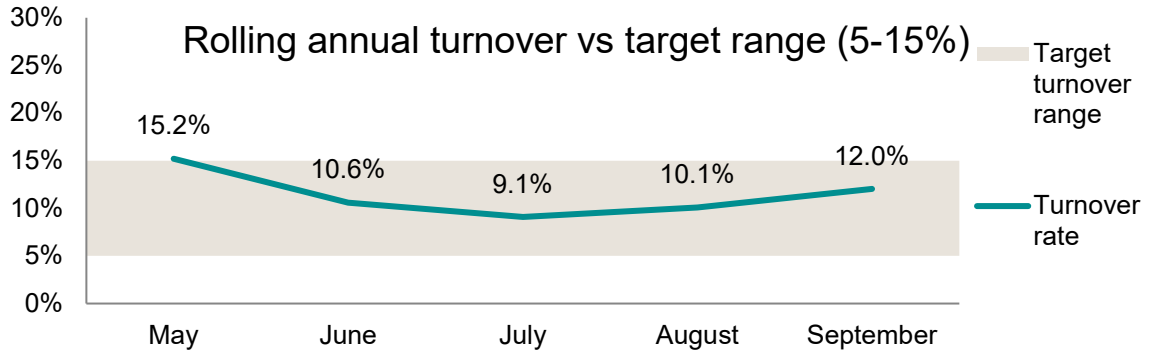
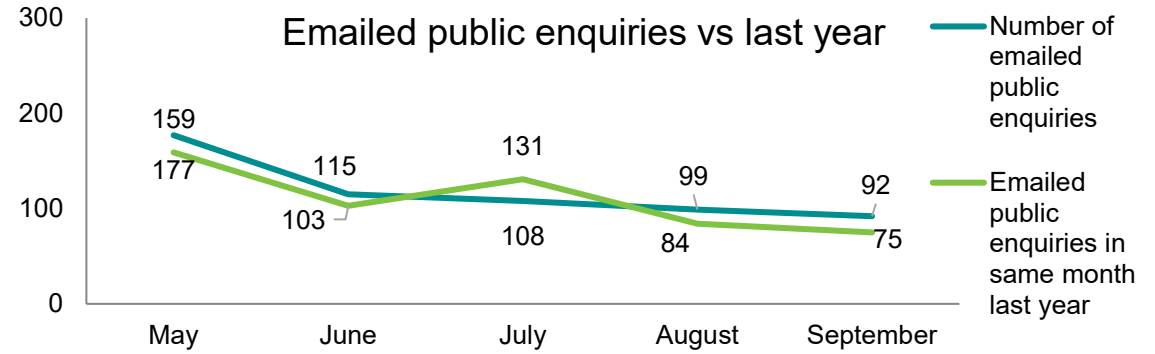
Income.
For the six months ended 30 September 2020, we are under budget by £1.13m which is due to the reduction in our treatment fee income of (39%). Volumes of both IVF and DI have decreased from August by 16% and 13% respectively. A close eye will be maintained to see if this is the beginning of a downward trend.

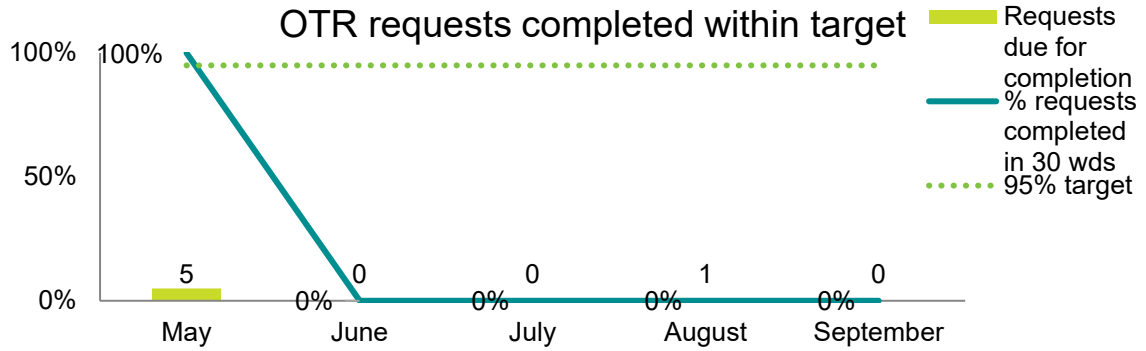
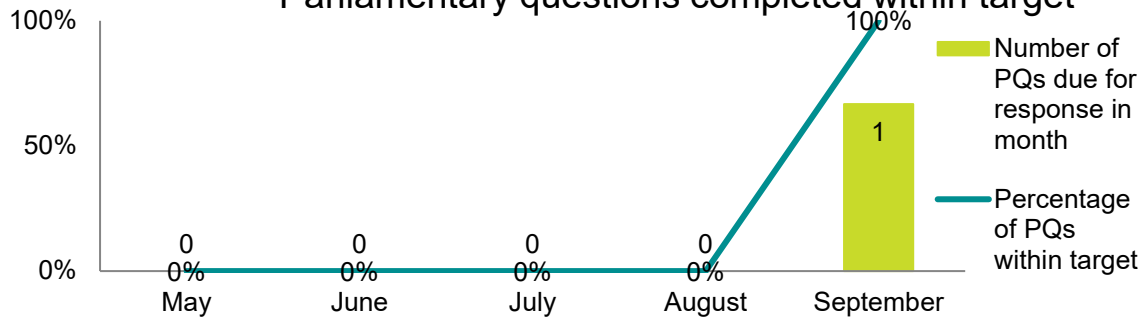
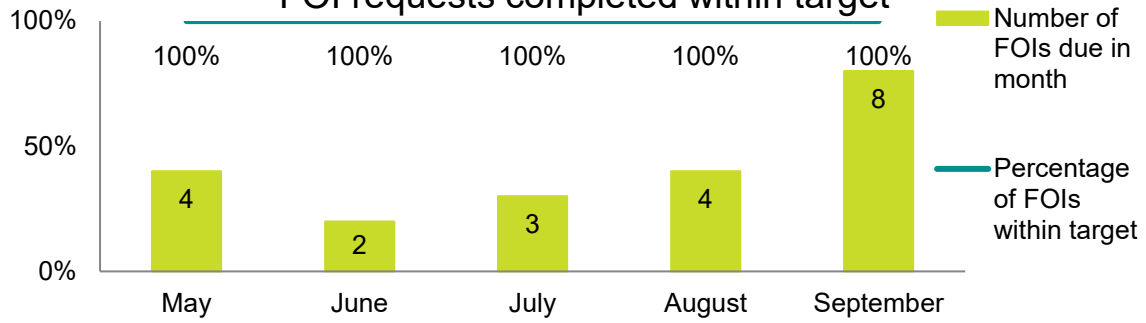
Expenditure by exception. Year to date we are underspent by £311k up £167k from August.

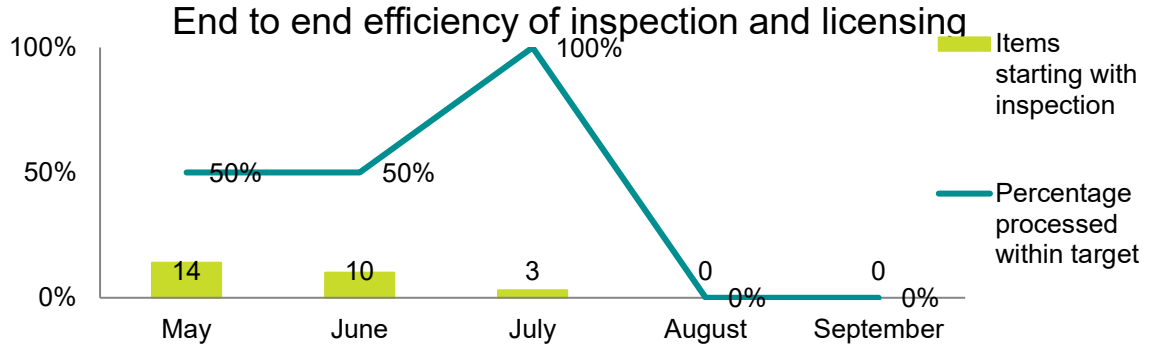
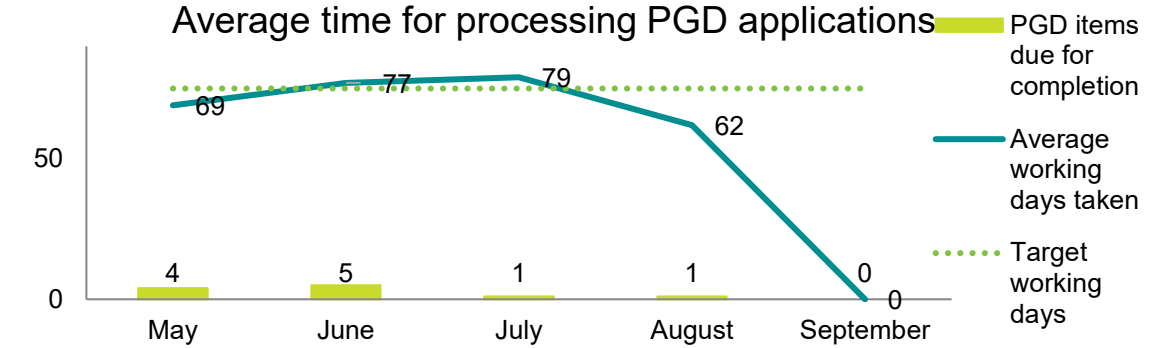
Salary costs - currently running under budget by £139k which is due to vacancies carried and associated on-costs
Staff Travel and Subsistence - underspending by £22k due to no inspection visits.
Other staff costs - are under budget by £14k with training costs underspent by £6k and £8k in recruitment. The balance represented by small over and underspends within staff welfare, payroll processing and other office costs.
Authority & Other Committee costs underspend of £11k due to profile of budget. Year to date costs include £11k for Appeals and cancellation cost for meetings (£3k), offset by underspends within Members' fees, training and on-costs.
Facilities costs - include our non-cash costs of depreciation/amortisation (£141k). The underspend here is due to the timing of the capitalisation of IfQ and PRISM. These costs are covered by Ring-fenced RDEL received from the DHSC. Also costs associated with COVID-19 (£4k) not budgeted for.
IT costs - show an overspend of £18k, due to costs associated with Alscient (support contract) accruals.
Legal/Professional Fees - under budget by £9k represented by overspend in Legal Fees of £24k (mainly within Representations and Hearings costs) and underspend of £33k in audit fees. However, both are affected by profile of the budget in the first half of the year.
Forecast.
We are currently forecasting an underspend in expenditure against budget of £181k, this is largely due to underspends within our non-cash coasts of £222k which we cannot benefit from.

At this point in the year, we have made some assumptions around future plans whilst we organise a more detailed review by directorate. It is likely that further savings will be found which will affect any surplus or deficit against budget.

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 in September is very low - 8 days in total.	Green
HR2 - Turnover **Target**: between 5 and 15% turnover for the rolling year.		67- 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.		See commentary above – SMT decision taken in October that from October data onward we will cease reporting against this KPI for a period.	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.		No relevant items. One voluntary revocation issued. Average working days taken – N/A Most days taken: N/A working days Least days taken: N/A working days	Neutral
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.		No PGD items were due for completion in September. Most days taken: N/A Least days taken: N/A	Neutral

Strategic risk register

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:	3
Meeting date:	11 November 2020
Author:	Helen Crutcher, Risk and Business Planning Manager
Annexes	Annex 1 – strategic risk register 2020-2024

Output from this paper

For information or decision?	For information and comment.
Recommendation:	The Authority is asked to note and comment on the latest edition of the strategic risk register.
Resource implications:	In budget.
Implementation date:	Ongoing.
Communication(s):	The risk register is reviewed monthly by the Senior Management Team (SMT) and presented at every Audit and Governance Committee (AGC) meeting. AGC last reviewed the risk register at its meeting on 6 October and will review it again at its meeting on 8 December.
Organisational risk:	Medium.

1. Latest reviews

1.1. The strategic risk register is a live document and is reviewed on a monthly basis by SMT, with input from Heads as needed. SMT last reviewed all risks, controls and scores in the register at its meeting on 21 October.

1.2. The risk register was last discussed at AGC on 6 October. No changes were made to the risk scores at that time.

1.3. SMT and AGC's comments are summarised in the commentary for each risk and at the end of the register, which is attached at Annex 1.

1.4. Two of the ten risks are above tolerance.

2. Recommendations

2.1. The Authority is asked to note and comment on the latest edition of the strategic risk register

Latest review date – 21/10/2020

Strategic risk register 2020-2024

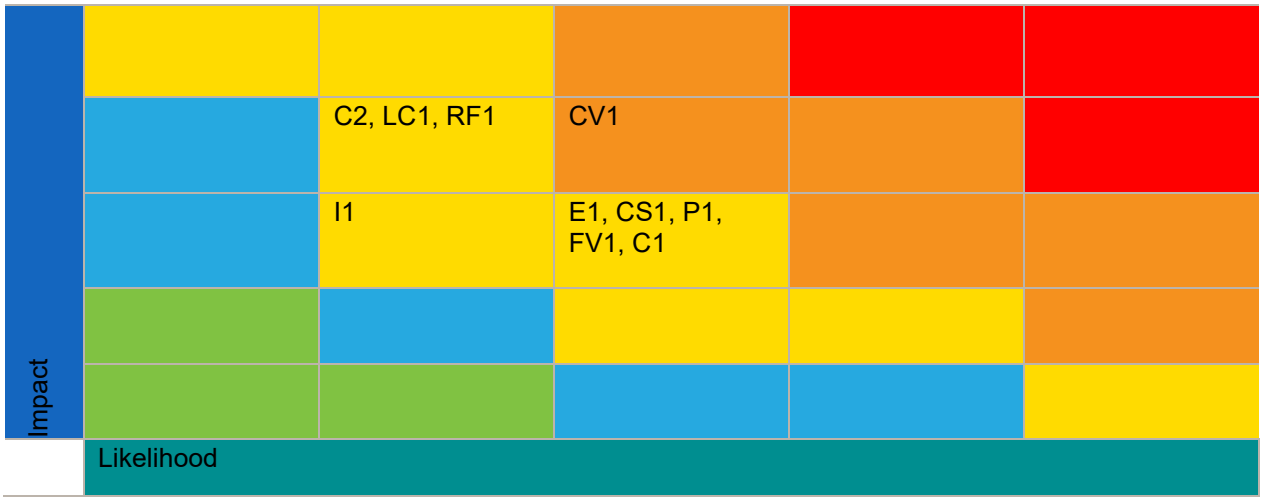
Risk summary: high to low residual risks

Risk ID	Strategy link	Residual risk	Status	Trend*
CV1 - Coronavirus	Whole strategy	**12 – High**	At tolerance	⇔⇔⇔⇔
E1: Relocation of HFEA offices in 2020	Generic risk – whole strategy	**9 – Medium**	Above tolerance	⇔⇔⇔⇔
FV1: Financial viability	Generic risk – whole strategy	**9 – Medium**	At tolerance	⇔⇩⇔⇔
P1 – Positioning and influencing	Shaping the future (and whole strategy)	**9 - Medium**	At tolerance	⇔⇔⇔⇔
CS1: Cyber security	Generic risk – whole strategy	**9 – Medium**	At tolerance	⇔⇔⇔⇔
C1: Capability	Generic risk – whole strategy	**9 – Medium**	Below tolerance	⇔⇔⇔⇔
C2: Board capability	Generic risk – whole strategy	**8 – Medium**	Above tolerance	⇔⇩⇔⇔
RF1 – Regulatory framework	The best care (and whole strategy)	**8 - Medium**	At tolerance	⇔⇔⇔⇔
LC1: Legal challenge	Generic risk – whole strategy	**8 – Medium**	Below tolerance	⇔⇔⇔⇔
I1 – Information provision	The right information	**6 - Medium**	Below tolerance	⇔⇔⇔⇔

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

Recent review points: SMT 20 July 2020 ⇨ SMT 7 September 2020⇨ AGC 6 October 2020⇨SMT 21 October

Summary risk profile – residual risks plotted against each other:



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

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

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

Commentary
As a regulator, we are by nature removed from the care and developments being offered in clinics and we must rely on our regulatory framework to provide sufficient powers to assure the public that treatment and research is safe and ethical. The result of not having an effective regulatory framework could be significant, the worst case of this risk would be us being without appropriate powers or ability to intervene, and patients being at risk, or not having access to treatment options that should be available to them in a safe and effective way.

Causes / sources	Controls	Timescale / owner of control(s)
We don't have powers in some of the areas where there are or will be changes affecting the fertility sector (for instance artificial intelligence).	We are strengthening or seeking to build connections with relevant partners who do have powers in such areas (for instance, the CMA in relation to pricing of treatments). We take external legal advice as relevant where developments are outside of our direct remit (eg, on an incidence of AI technology being used in the fertility sector) and utilise this to establish our legal/regulatory position. We are analysing where there are gaps in our regulatory powers so that we may be able to make a case for further powers if these are necessary, whenever these are next reviewed.	In progress - Clare Ettinghausen Ongoing - Catherine Drennan In progress - Laura Riley, Joanne Anton, Catherine Drennan
We may have ineffective tools, systems, or regulatory interventions available which are	Regular review processes for all regulatory tools such as:	

Causes / sources	Controls	Timescale / owner of control(s)
too rigid and cannot be adapted to changes.	• Code of Practice. • Compliance and enforcement policy (Draft revised policy to come to Authority in November with consultation to follow) • Licensing SOPs and decision trees To enable us to revise these and prevent them from becoming ineffective or outdated.	In place, next update 2021 – Laura Riley, Joanne Anton Currently under review as at October (delivery extended due to Covid-19) – Catherine Drennan, Rachel Cutting In place and review ongoing – Paula Robinson
Change may be too fast for us to adequately respond to if we do not understand the nature of the changes arising. Resulting in us being under-prepared or taking an insufficiently nuanced approach.	We cannot control the rate of change, but we can make sure we are aware of likely changes and make our response as timely as possible by: • Annual horizon scanning at SCAAC • maintaining links with key stakeholders including other professional organisations and the licensed centres panel to get a sense of changes they are experiencing or have early sight of. We necessarily have to wait for some changes to be clearer in order to take an effective regulatory position. However, we may choose to take a staged approach when changes are emerging, issuing quick responses such as a Chair's letter, Alert or change to General Directions to address immediate regulatory needs, before strengthening our position with further guidance or regulatory updates.	In place – Laura Riley, Joanne Anton In place - Peter Thompson
We may focus on 'pet projects' or ephemeral interests, being influenced by personal preferences or biases.	Strategic aims have been clearly articulated; all projects must be aligned to these aims to ensure that our work is focused on delivering these objectives. We ensure this by consideration at Corporate Management Group.	Ongoing – Peter Thompson
We have limited capacity, which may reduce our ability to respond quickly to new work, since we may need to review and stop doing something else.	Monthly opportunity for reprioritising at CMG when new work arises and weekly SMT meetings for more pressing decisions. Any reprioritisation of significant Strategy work would be discussed with the Authority.	In place – Peter Thompson
We may have a lack of staffing expertise or capability in the areas developments occur in.	As developments occur, Heads consider what the gaps are in our expertise and whether there is training available to our staff.	Ongoing - Relevant Head/Director

Causes / sources	Controls	Timescale / owner of control(s)
	If a specific skills gap was identified in relation to a new development, we could consider whether it is appropriate or possible to bring in resource from outside, for instance by employing someone temporarily or sharing skills with other organisations.	with Yvonne Akinmodun
If RITA (the register information team app – used to review submissions to the Register) is not completed in a timely way, we may not effectively use data and ensure our regulatory actions are based on the best and most current information. Note: as at October 2020 we are actively discussing risk management, as we continue to plan RITA delivery.	Launch date of PRISM delayed due to Covid-19. RITA will be built sequentially after PRISM. Development has been split into phase 1 (essential) and phase 2 (nice-to-have). While RITA development has not started, it is expected that essential phase 1 RITA development (relating to functionality to support the OTR and Register teams) will be complete before the team need to support a fully launched PRISM. If RITA is not completed in a timely way, the Register and OTR team will still be able to use manual workarounds to get access to the information they need to support clinics and / or to provide information to support our regulatory work. although these workarounds will result in a substantial delay to responding to an OTR or providing clinic support. If additional development work is required to complete RITA phase 1 development in a timely way, we will consider options for providing the necessary resource. However, this control may impact on our ability to support or develop other internal applications.	Plans in place – Dan Howard Ongoing – Dan Under review as plans develop - Dan
We may not have all the right data from the sector (from inspections or the Register) to make informed interventions, for instance on add-ons.	As part of planning and delivering the add-ons project we will look at the evidence available and consider whether we can access other information if we do not have this already. Revising our approach on inspection where relevant, to ensure that the right information is available (for instance, launching an add-ons audit tool). Process to be established for reviewing data on the Register and adding fields when required.	In place - Laura Riley Audit tool launched in clinics from Autumn 2020 - Rachel Cutting Within 2020/2021 business year - Dan Howard
We may face barriers to adding fields to the Register, preventing us from collecting the right data to reflect changes in the sector. This might reduce the evidence available to inform regulatory interventions and maintain	Process to be established for reviewing data on the Register and adding fields when required.	Within 2020/2021 business year - Dan Howard

Causes / sources	Controls	Timescale / owner of control(s)
patient safety as the sector changes.		
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC - If there was a review of our regulatory powers, there would be a strong interdependency with the Department of Health and Social Care.	Early engagement with the Department to ensure that they are aware of HFEA position in relation to any future review of the legislation. Provided a considered response to the Department's storage consent consultation to give the HFEA position.	Ongoing - Peter Thompson

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

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	3	12 - high	**2**	**3**	**6 - Medium**
Tolerance threshold:					**8 - Medium**
Status: Below tolerance					

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

Commentary
Information provision is a key part of our statutory duties and is fundamental to us being able to regulate effectively. We provide information to the public, patients, partners, donors, the donor conceived, their families and clinics alike. If we are not seen as relevant then we risk our information not being used, which in turn may affect the quality of care, outcomes and options available to those involved in treatment. As at October 2020, the Opening the Register service has reopened after being paused since clinics shut down due to Covid-19. Due to this pause, we anticipate an influx of applications which will mean we are unable to meet our usual KPI for completing responses for a period. We will be managing this carefully to ensure that applicants receive accurate data and effective support as quickly as we are able, with a focus on continuing to provide a quality, effective service. Ongoing communication with applicants and centres has been clear, to ensure they understand, and we manage expectations.

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

Causes / sources	Controls	Status / timescale / owner
We aren't in the places that people look for information meaning they do not find us. In some cases, this is because we have decided not to be, for instance on some social media platforms.	We are developing relationships with key influencers to ensure that we have an indirect presence on social media or forums.	In place and ongoing - Jo Triggs
We do not have effective relationships with key strategic stakeholders.	Ensure a strategic stakeholder engagement plan is agreed and revisited frequently. Stakeholder engagement plans considered as part of project planning to ensure this is effective.	Early work done but development needed, future control – Clare Ettinghausen Ongoing – Paula Robinson
We have more competition to get information out to people. For instance, other companies have set up their own clinic comparison sites, or clinics post their own data.	Monitoring of clinic websites at the renewal inspection point to ensure that the data there is accurate and in line with guidance. A review of all centre websites undertaken during summer 2020. Ensure we maximise the information on our website and the unique features of our clinic inspection information and patient ratings. Clinics are encouraged to ask patients to use the HFEA patient rating system. We have optimised Choose a Fertility Clinic so that it is one of the top sites that patients will find when searching online.	In place and all clinic websites reviewed during summer 2020 - Rachel Cutting, Sharon Fensome Rimmer In place and ongoing - Jo Triggs
There are gaps in key strategic information flows on our website, for instance after treatment, resulting in missed opportunities to share information.	Digital Communications Board with membership from across the organisation in place to discuss information available and identify any gaps and what to do to fill these.	In place and ongoing - Jo Triggs
We may not signpost effectively elsewhere resulting in us trying to reinvent the wheel and stepping on other organisation's toes rather than targeting our resources.	We have an ongoing partnership with NHS.UK to get information to patients early in their fertility journey and signpost them to HFEA guidance and information. Links to other specialist organisations in place as relevant on the website (ie, Fertility Network UK, BICA, BFS, Endometriosis UK etc).	In place and ongoing - Jo Triggs
We may provide too much information, leading to information overload and lack of clarity about what information we provide and how.	Regular review cycle for website ensures that the information provided is relevant.	In place and ongoing - Jo Triggs

Causes / sources	Controls	Status / timescale / owner
We may provide inaccurate information to the media or public enquiries. Though we have well established and effective working practices and controls, we must continue to be aware of and mitigate this risk.	Regular communication between relevant teams. Information provided in enquiries is checked within teams and by legal or at a more senior level if needed. Briefings when key reports etc are issued to ensure others know the key issues, statistics etc.	In place and ongoing - Jo Triggs, Joanne Anton In place and ongoing – Nora Cooke O'Dowd
Given the advent of increased DNA testing, we no longer hold all the keys on donor data (via our Opening the Register (OTR) service). Donors and donor conceived offspring may not have the information they need to deal with this.	Maintain links with donor organisations to mutually signpost information and increase the chance that this will be available to those in this situation. Developed links with DNA testing organisations to ensure that they provide information to those using direct to consumer tests about the possible implications.	In place and ongoing - Jo Triggs In place and ongoing - Laura Riley
Our OTR workload will increase and change in 2021/2023 (when children born after anonymity was lifted turn 16 and 18) and we may lack the capability to deal sensitivity with donor issues.	Plans to undertake service redesign work to review resourcing and other requirements for OTR to ensure these are fit for purpose.	Future control – to be undertaken in Q3/4 2020/2021 - Dan Howard
The OTR service may be negatively impacted by an influx of applications following reopening after being paused, with demand outstripping our ability to respond.	Our focus is on accuracy and effective support for applicants; therefore we have temporarily ceased reporting against our usual KPI, during the period of dealing with this pent-up demand. We are continuing to clearly communicate with applicants and the sector to manage expectations. We have provided some temporary additional administrative resource to support he OTR team to process applications.	From October 2020 – Dan Howard
Ineffective media management may mean we don't correct incorrect information available elsewhere or signpost our own.	Media monitoring service in place that is checked daily to identify items where a decision should be taken about need to correct information or not. We review the contract for our media monitoring service annually to ensure that it is fit for purpose. We would choose an alternate provider if this was not working effectively. Relationship with the media ensures that we are asked for comment and that we have internal processes in place to provide the comment in an effective way.	In place and ongoing - Jo Triggs In place - Jo Triggs Jo Triggs – Last reviewed January 2020
Risk that key regulatory information will be missed if Clinic focus, Clinic Portal or emails are not being read.	There is a statutory duty for PRs to stay abreast of updates. We duplicate essential communications by also sending via email to the centres' PR and LH (for instance, all Covid-19 correspondence).	In place – Rachel Cutting

Causes / sources	Controls	Status / timescale / owner
	We ensure that the Code and other regulatory tools are up to date, so that clinics find the right guidance when they need it regardless of additional communicated updates. We are implementing a formal annual catch-up between clinics and an inspector.	In place – Laura Riley, Joanne Anton Being scheduled as at November – Rachel Cutting
We don't provide tangible insights for patients in inspection reports to inform their decision making.	Review of inspection reports is underway to identify future improvements to inspection reports. We do provide patient and inspector ratings on CaFC to provide some additional insight into clinics.	Underway, likely to complete mid-2021 – Rachel cutting In place – Rachel Cutting
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None.		

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

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16	**3**	**3**	**9 - Medium**
Tolerance threshold:					**9 - Medium**
Status: At tolerance					

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

Commentary
This risk is about us being in a position to influence effectively to achieve our strategic aims. If we do not ensure we are, we may not be involved in key debates and developments, others will not present the HFEA perspective, meaning we may be voiceless, or our strategic impact may be limited. Although we have not yet publicly launched our new strategy, the decisions taken over the next months prior to its launch will have an impact on these strategic risk areas, so we are already beginning to think about these risks and controls in order to manage them effectively.

Causes / sources	Controls	Status/timescale / owner
We may not engage widely enough or have the contacts and reach we need to undertake key work, meaning aspects of the strategy are too big to complete within our resources.	Ensure a stakeholder engagement plan is agreed and revisited frequently. Stakeholder identification undertaken for all projects to ensure that these are clear from the outset of planning, and that we can plan communications, involvement and if necessary, consultations, appropriately.	Early work done but to be reviewed in preparation for a new Chair– Clare Ettinghausen In place - Paula Robinson
We may be unable to persuade partner organisations to utilise their powers/influence/resources to achieve shared aims.	Early engagement with such organisations, to build on shared interests and reduce the likelihood of this becoming an issue. For instance, the treatment add-ons working group.	In place - Clare Ettinghausen

Causes / sources	Controls	Status/timescale / owner
The sector may disagree with HFEA about key strategic terms and principles, such as 'ethical care' creating negative publicity for us and reputational damage.	We will clearly communicate our intentions, to ensure that these are not misunderstood or misinterpreted and engage with our established stakeholder groups.	In place - Clare Ettinghausen
The sector may take a different view on the evidence HFEA provides in relation to Add-ons and so we may be ignored.	The working group for the add-ons project will focus on building on earlier consensus and pull together key stakeholders to reduce the likelihood of guidance and evidence being dismissed. SCAAC sharing evidence it receives and having an open dialogue with the sector on add-ons.	Ongoing - Laura Riley
In relation to changes, HFEA and sector interests may be in conflict, damaging our reputation. This may particularly be the case in relation to Covid-19 and the use and removal of General Directions 0014 (GD0014).	Decisions taken within the legal framework of the Act and supported by appropriate evidence, which would ensure these are clear and defensible. Framework for decision making around removing GD0014 drawn up following Authority discussion.	In place - Peter Thompson In place – Rachel Cutting
We may not engage with early adopters or initiators of new treatments/innovations or changes in the sector.	Regular engagement with SCAAC enables developments to be flagged for follow up by compliance/policy teams. Routine discussion on innovation and developments at Policy/Compliance meetings to ensure we consider developments in a timely way. Inspectors feed back on new technologies, for instance when attending ESHRE, so that the wider organisation can consider the impact of these. We are investigating holding an annual meeting with key innovators (in industry).	In place - Laura Riley/Joanne Anton In place - Laura Riley/Joanne Anton In place and ongoing – Sharon Fensome-Rimmer Future control, delayed due to Covid-19 but to be reviewed in Q4 - Rachel Cutting
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: The Department may not consider future HFEA regulatory interests or requirements when planning for any future consideration of relevant legislation which could compromise the future regulatory regime.	Early engagement with the Department to ensure that they are aware of HFEA position in relation to any future review of the legislation. Provided a considered response to the Department's storage consent consultation to give the HFEA position.	Ongoing - Peter Thompson Completed - Joanne Anton

Causes / sources	Controls	Status/timescale / owner
Government: Any consideration of the future legislative landscape may become politicised.	There are no preventative controls for this, however, clear and balanced messaging between us, the department and ministers may reduce the impact. Develop improved relationships with MPs and Peers to ensure our views and expertise are taken into account.	Ongoing - Peter Thompson
Government: Consideration of changes to the regulatory framework may be affected by political turbulence (for instance changes of Minister).	There are no preventative controls for this, however, we will ensure that we are prepared to effectively brief any future incumbents to reduce turbulence. We would also do any horizon scanning as the political landscape changed if needed.	Ongoing - Peter Thompson

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

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16–High	**3**	**3**	**9– Medium**
Tolerance threshold:					**9 - Medium**
Status: At tolerance					

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

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

Causes / sources	Controls	Timescale / owner
There is uncertainty about the annual recovery of treatment fee income – this may not cover our annual spending. This is no longer a risk for 2019/2020 but is a live issue for 2020/2021 as we have reduced income for as long as GD0014 (version 2) is in place. Although clinics have reopened it will take	Heads see quarterly finance figures and would consider what work to deprioritise or reduce should income fall below projected expenditure. We would discuss with the Authority if key strategic work needed to be delayed or changed. We have a model for forecasting treatment fee income, and this reduces the risk of significant variance, by utilising historic data and future population projections. We will refresh this model	CMG monthly and Authority when required – Peter Thompson Quarterly, ongoing, with AGC model review at least

Causes / sources	Controls	Timescale / owner
some time for activity to return to 'normal' levels.	quarterly internally and review at least annually with AGC. We are undertaking a fee review project in 2021/2022 to ensure that the income model is fit for purpose and reflects the changing nature of sector activity. We are discussing with the Department of Health and Social Care how this issue will be managed from 2020/2021.	annually - Richard Sydee Planning underway – Peter Thompson and Richard Sydee
Our monthly income can vary significantly as: • it is linked directly to level of treatment activity in licensed establishments • we rely on our data submission system to notify us of billable cycles. As at October 2020 we have reduced income due to the deployment of GD0014 in response to Covid-19 and the subsequent reopening of the sector.	Our reserves policy takes account of monthly fluctuations in treatment activity and we have sufficient cash reserves to function normally for a period of two months if there was a steep drop-off in activity. The reserves policy was reviewed by AGC in June 2019. If clinics were not able to submit data and could not be invoiced for more than three months, we would invoice them on historic treatment volumes and reconcile this against actual volumes once the submission issue was resolved and data could be submitted. **Note**: we have decided not to employ this control in the light of the significant impact of Covid-19 on the sector (clinics are not working at historic levels). We will look to review this risk and controls on a quarterly basis depending on the level of activity underway across the sector.	Given the Covid-19 related drop in income, we have actively employed this control – Richard Sydee Control under quarterly review as sector reopens – Richard Sydee
Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend.	Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with Directorates flag any shortfall or further funding requirements. All project business cases are approved through CMG, so any financial consequences of approving work are discussed.	Quarterly meetings (on-going) – Morounke Akingbola Ongoing – Richard Sydee
Additional funds have been required for the completion of the data migration work and this will constrain HFEA finances and may affect other planned and ad hoc work. This may not be sufficient to complete the work if it is delayed due to Covid-19.	The most cost-effective approach was taken to procure external support to reduce costs and the resulting impact. Ongoing monitoring and reporting against control totals to ensure we do not overspend. Funding was received from the Department to complete the PRISM programme. Additional funding has been allocated from underspends elsewhere in order to cover budget needed to complete the project following impact of Covid-19 while minimising the impact on the wider organisation.	In place – Richard Sydee Ongoing, – Richard Sydee October 2020 – Richard Sydee

Causes / sources	Controls	Timescale / owner
Inadequate decision-making leads to incorrect financial forecasting and insufficient budget.	Within the finance team there are a series of formalised checks and reviews, including root and branch analyses of financial models and calculations. The organisation plans effectively to ensure enough time and senior resource for assessing core budget assumptions and subsequent decision making.	In place and ongoing - Richard Sydee Quarterly meetings (on-going) – Morounke Akingbola
Project scope creep leads to increases in costs beyond the levels that have been approved.	Finance staff member present at Programme Board. Periodic review of actual and budgeted spend by Digital Projects Board (formerly IfQ) and monthly budget meetings with finance. Any exceptions to tolerances are discussed at Programme Board and escalated to CMG at monthly meetings, or sooner, via SMT, if the impact is significant or time critical.	Ongoing – Richard Sydee or Morounke Akingbola Monthly (on-going) – Samuel Akinwonmi
Failure to comply with Treasury and DHSC spending controls and finance policies and guidance may lead to serious reputational risk and a loss of financial autonomy or goodwill for securing future funding.	The oversight and understanding of the finance team ensures that we do not inadvertently break any rules. The team's professional development is ongoing, and this includes engaging and networking with the wider government finance community. All HFEA finance policies and guidance are compliant with wider government rules. Policies are reviewed annually, or before this if required. Internal oversight of expenditure and approvals provides further assurance (see above mitigations).	Continuous - Richard Sydee Annually and as required – Morounke Akingbola
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: Covid-19 impacts on HFEA income.	The final contingency for all our financial risks is to seek additional cash and/or funding from the DHSC and we are in active discussion with the Department about this issue.	Ongoing - Richard Sydee
DHSC: Legal costs materially exceed annual budget because of unforeseen litigation.	Use of reserves, up to appropriate contingency level available at this point in the financial year. The final contingency for all our financial risks would be to seek additional cash and/or funding from the Department.	Monthly – Morounke Akingbola
DHSC: GIA funding could be reduced due to changes in Government/policy.	A good relationship with DHSC Sponsors, who are well informed about our work and our funding model. Annual budget has been agreed with DHSC Finance team. GIA funding has been provisionally agreed through to 2021.	Quarterly accountability meetings (on-going) – Richard Sydee December/January annually,

Causes / sources	Controls	Timescale / owner
		– Richard Sydee

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

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
5	4	20 – Very high	**3**	**3**	**9- Medium**
Tolerance threshold:					**12 - High**
Status: **Below tolerance.**					

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

Commentary
This risk and the controls are focused on organisational capability, rather than capacity, though there are obviously some linkages between capability and capacity. For 2019/2020 Turnover was 12.2% (in 2018/19 this was 26.8%). This reduction in turnover suggests that we are currently in a more stable situation and this will naturally strengthen our capabilities as staff develop more experience in their roles. We have also often been able to recruit internally which has assisted in reducing turnover as staff have been able to develop their careers within the HFEA. We have taken steps to improve retention, focussing on things that we can control like learning and development. AGC receive 6-monthly updates on capability risk to consider our ongoing strategies for the handling of these, to allow them to track progress. Looking further ahead, we need to find ways to tackle the issue of development opportunities, to prevent this risk increasing. An idea we are keen to explore is whether we can build informal links or networks with other public sector or health bodies, to develop clearer career paths between organisations. Unfortunately, this work has not progressed further due to Covid-19, although conversations about such development opportunities continue on an individual level. We have two Authority member vacancies which create Board capability gaps, these risks are captured in the separate C2 risk, below. Although we reduced our assessment of this risk score in May 2020, we are aware that ongoing impacts of Covid-19 may affect capability in future months, and we are considering approaches to manage this as the situation develops.

Causes / sources	Mitigations	Status/Timescale / owner
High turnover, sick leave etc., leading to temporary knowledge loss and capability gaps.	Organisational knowledge captured via documentation, handovers and induction notes, and manager engagement. We have developed corporate guidance for all staff for handovers. A checklist for handovers is circulated to managers when staff hand in their notice. This checklist will reduce the risk of variable handover provision.	In place – Yvonne Akinmodun Checklist in use – Yvonne Akinmodun
	Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention. CMG and managers prioritise work appropriately when workload peaks arise. Contingency: In the event of knowledge gaps we would consider alternative resources such as using agency staff if appropriate.	In place – Yvonne Akinmodun In place – Peter Thompson In place – Relevant Director alongside managers
Poor morale could lead to staff leaving, opening up capability gaps.	Communication between managers and staff at regular team and one-to-one meetings allows any morale issues to be identified early and provides an opportunity to determine actions to be taken. The staff intranet enables regular internal communications. Ongoing CMG discussions about wider staff engagement (including surveys) to enable management responses where there are areas of concern. Policies and benefits are in place that support staff to balance work and life (stress management resources, mental health first aiders, PerkBox) promoting staff to feel positive about the wider package offered by the HFEA. This may boost good morale.	In place, ongoing – Peter Thompson In place – Jo Triggs In place, staff survey undertaken June 2020 – Yvonne Akinmodun In place - Peter Thompson
Work unexpectedly arises or increases for which we do not have relevant capabilities.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG – standing item on planning and resources at monthly meetings. Team-level service delivery planning for the next business year, with active involvement of team members. CMG will continue to review planning and delivery. Requirement for this to be in place for each business year. Oversight of projects by both the monthly Programme Board and CMG meetings.	In place – Paula Robinson In place – Paula Robinson In place – Paula Robinson

Causes / sources	Mitigations	Status/Timescale / owner
	Review of project guidance to support early identification of interdependencies and products in projects, to allow for effective planning of resources. Planning and prioritising data submission project delivery, within our limited resources.	Ongoing review in progress 2020-2021– Paula Robinson In place until project ends – Dan Howard
The future office move, may not meet the needs of staff (for instance location), meaning staff decide to leave sooner than this, leading to a significant spike in turnover, resulting in capability gaps.	See separate E1 risk for full assessment of risk causes and controls.	Engagement with staff and other organisations underway and ongoing – Richard Sydee
Possible capability benefits of colocation with other organisations, arising out of the office move, such as the ability to create career pathways and closer working may not be realised.	Active engagement with other organisations early on. We are collaborating with other relevant regulators to see what more can be done to create career paths and achieve other benefits of working more closely, including a mentorship programme.	Ongoing – Richard Sydee Early progress, ongoing – Yvonne Akinmodun
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
Government/DHSC The UK leaving the EU may have unexpected operational consequences for the HFEA for which we do not have the relevant capabilities.	We continue to work closely with the Department to ensure that we are prepared and can provide detailed guidance to the sector at the earliest opportunity, to limit any impact on patients. We have provided ongoing updates to the sector. Since December 2018, we have run an EU exit project to ensure that we fully consider implications and are able to build enough knowledge and capability to handle the effects of the UK's exit from the EU. We have progressed this project through the transition period. We continue to engage with DHSC and clinics to prepare for the end of the transition period. Actions will depend on the progress of the UK/EU talks. Authority and AGC are also updated at their meetings, as appropriate.	Communications ongoing – Clare Ettinghausen/Andy Leonard
In-common risk Covid-19 (Coronavirus) may lead to high levels of staff absence leading to capability gaps or a need to redeploy staff.	Management discussion of situation as it emerges, to ensure a responsive approach to any developments. We have reviewed our business continuity plan to ensure it is fit for purpose.	Ongoing - Peter Thompson

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

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

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

Commentary
The HFEA board is unusual as members undertake quasi-judicial decision-making as part of their roles, sitting on licensing and other committees. This means that changes in Board capability and capacity may impact the legal functions of the Authority. We need to maintain sufficient members with sufficient experience to take what can be highly controversial decisions in a robust manner. As such our tolerance threshold for this risk is low. Out of a current Board membership of 14, we have two vacancies. In addition, one members' term ends on 11 November 2020, bringing the Board membership down to eleven. The Chair's term expires on 31 March 2021. Four other senior Authority members' terms also end on that date. If we are not able to recruit to all these positions, the membership would be reduced to six. This would pose a significant challenge to robust statutory decision-making and knowledge management. The extension of the Chair's term to March 2021 was helpful and recruitment to this post has now begun. The Department are in the latter stages of recruitment to four posts which we hope will be completed by the end of November 2020. The advert for the Chair issued in October, although the final timing of a new appointment is uncertain. We remain in contact with the Department on these matters. SMT reduced the risk score from 16 to 8 in September to reflect the progress made on recruitment, although the risk remains above tolerance. Contingency plans will be put in place from November 2020 for the decrease Authority membership and for the Chair if needed.

Causes / sources	**Mitigations**	**Status/timescale / owner**
As at November 2020, we will have three member vacancies. The reduction of available members that is possible by March 2021, including the Chair, would put at risk our ability to meet our statutory responsibilities to licence fertility clinics and research centres and	Membership of licensing committees has been actively managed to ensure that formal decision-making can continue unimpeded by the current board vacancies. However, there is no guarantee that this would be possible for future vacancies, especially if there were several at once and bearing in mind that a	In place, ongoing - Paula Robinson

Causes / sources	Mitigations	Status/times cale / owner
authorise treatment for serious inherited illnesses.	lay/professional balance must be maintained for some committees.	
The uncertainty about Chair reappointment may result in a gap in leadership and direction for the Authority. The Chair's term has been extended until March 2021, which gives more time to consider controls, though it only changes the proximity of this risk.	The Department is actively considering extending certain Board appointments to ensure a smooth transition.	Further controls to be considered - Peter Thompson
Any member recruitment may take some time and therefore give rise to further vacancies and capability gaps. The recruitment process is run by DHSC meaning we have limited power to influence this risk source. Historically, decisions on appointments have taken some time which may create additional challenges for planning (the annual report from the commission for public appointments suggests appointments take on average five months).	Recruitment is underway for four Board posts. This is being run by the Department of Health and Social Care (DHSC) and is expected to complete in the autumn.	In progress as at October, with plan to appoint Autumn 2020- Peter Thompson
Several current Board members are on their second terms in office, which expire within the same period (six Members of the Board by March 2021, in addition to the two pre-existing vacancies).	We are discussing options with the Department for managing the cycle of appointments, in order to reduce the impact of this.	In progress, ongoing - Peter Thompson
The induction time of new members (including bespoke legal training), particularly those sitting on licensing committees, may lead to a loss of collective knowledge and potentially an impact on the quality of decision-making. Evidence from current members suggests that it may take up to a year for members to feel fully confident.	The Governance team are reviewing recruitment information and member induction to ensure that this will be as smooth as possible once it starts.	In progress, ongoing - Paula Robinson

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

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

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

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

Commentary

Cyber-attacks and threats are inherently very likely. Our approach to handling these risks effectively includes ensuring we:

- have an accurate awareness of our exposure to cyber risk
- have the right capability and resource to handle it
- undertake independent review and testing
- are effectively prepared for a cyber security incident
- have external connections in place to learn from others.

We continue to assess and review the level of national cyber security risk and act as necessary to ensure our security controls are robust and are working effectively.

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

Causes / sources	Controls	Timescale / owner
Insufficient board oversight of cyber security risks, resulting in them not being managed effectively.	Routine cyber risk management delegated from Authority to Audit and Governance Committee which receives reports at each meeting on cyber-security and associated internal audit reports to assure the Authority that the internal approach is appropriate and ensure they are aware of the organisation's exposure to cyber risk. The Deputy Chair of the Authority and AGC is the cyber lead who is regularly appraised on actual	In place – Dan Howard In place - Peter Thompson

Causes / sources	Controls	Timescale / owner
	and perceived cyber risks. These would be discussed with the wider board if necessary. Annual cyber security training in place to ensure that Authority are appropriately aware of cyber risks and responsibilities.	Last undertaken January 2020 – Dan Howard
Insufficient executive oversight of cyber security risks, resulting in them not being managed effectively	Cyber security training in place to ensure that all staff are appropriately aware of cyber risks and responsibilities. Regular review of cyber / network security policies to ensure they are appropriate and in line with other guidance. We undertake independent review and test our cyber controls, to assure us that these are appropriate. Regular review of business continuity plan to ensure that this is fit for purpose for appropriate handling cyber security incidents to minimise their impact.	Undertaken by staff October/November 2020 – Dan Howard Update agreed at CMG in June 2020– Dan Howard In place, review last undertaken March 2019 – Dan Howard In place, reviewed as part of Covid-19 response – Dan Howard
Changes to the digital estate open up potential attack surfaces or new vulnerabilities. Our relationship with clinics is more digital, and patient identifying information or clinic data could therefore be exposed to attack.	Penetration testing of newly developed systems (PRISM, the Register) assure us that development has appropriately considered cyber security. Clear information security guidance to HFEA staff about how identifying information should be shared, especially by the Register team, to reduce the chance of this being vulnerable.	Done – Dan Howard In place – Dan Howard
The IT support function may not provide us with the cyber security resource that we need (ie, emergency support in the case of dealing with attacks)	We have an arrangement with a third-party IT supplier who would be able to assist if we did not have enough internal resource to handle an emergency for any reason.	Contract in place until May 2021 with option to extend until May 2023 – Dan Howard
We may not effectively mitigate emerging or developing cyber security threats if we are not aware of these.	We maintain external linkages with other organisations to learn from others in relation to cyber risk.	Ongoing (such as ALB CIO network) – Dan Howard
We may have technical or system weaknesses which could lead to loss of, or inability	We undertake regular penetration testing to identify weaknesses so that we can address these.	Ongoing (last test May

Causes / sources	Controls	Timescale / owner
to access, sensitive data, including the Register.	We have advanced threat protection in place to identify and effectively handle threats. Our third-party IT supplier undertakes daily checks on our server infrastructure to monitor for any errors and to monitor for any security issues or increased threats. We regularly review and if necessary, upgrade software to improve security controls for network and data access, such as Remote Access Service (RAS) software. We regularly review and if necessary, upgrade software to improve security controls for telephony	2019) – Dan Howard In place – Dan Howard In place – Dan Howard Ongoing (Upgrade to Pulse RAS system April 2020) – Dan Howard Ongoing (Upgrade to Microsoft Teams system April 2020) – Dan Howard
Physical devices used by staff are lost, stolen or otherwise fall into malicious hands, increasing chance of a cyber-attack.	Hardware is encrypted, which would prevent access to data if devices were misplaced. Staff reminded during IT induction about the need to fully shut down devices while outside of secure locations (such as travelling) in order to implement encryption	Ongoing (regular reminders sent to staff with security best practice) – Dan Howard
Remote access connections and hosting via the cloud may create greater opportunity for cyber threats by hostile parties.	All cloud systems in use have appropriate security controls, terms and conditions and certifications (ISO and GCloud) in place. We have an effective permission matrix and password policy. Our web configuration limits the service to 20 requests at any one time. The new Register will be under the tightest security when this is migrated to the cloud.	In place – Dan Howard In place – Dan Howard In place – Dan Howard To be implemented – Dan Howard
The continued use of EDI by clinics during the extended delivery of PRISM means the end of life server version used for the EDI gateway application (which processes data from EDI or 3rd party servers into the HFEA Register) continues to be used. This may therefore be more vulnerable to attack as it becomes unsupported.	Data submitted through the EDI gateway application is encrypted in transit, which reduces the likelihood of sensitive information being accessed.	In place – Dan Howard

Causes / sources	Controls	Timescale / owner
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None. Cyber-security is an 'in-common' risk across the Department and its ALBs.		

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

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16	**3**	**3**	**9 - Medium**
Tolerance threshold:					**8 - Medium**
Status: **Above tolerance**					

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

Commentary
An internal project is in place to prepare for the office move, handle the direct impacts of the move on the organisation and ensure that we actively prepare and mitigate associated risks. This feeds into a larger programme managed by DHSC. We have made progress in reviewing working practices and policies and have launched several of these. Several cross-ALB working groups have actively defined requirements and solutions and these have fed into the HFEA internal project. Covid-19 has had significant impacts on the office move. SMT raised the risk score in April to reflect this emerging risk. Delays have been managed proactively by the overall DHSC programme which has reduced the overall impact. Remote working ensures that we are able to continue to operate despite these delays. As at November 2020 the handover of the building to DHSC, which was delayed by construction issues, has now taken place. The HFEA project team has considered the ongoing impact of the delay on our organisational preparations and put in place contingency arrangements (for instance for housing our servers) although these may not now be required, due to good progress made in recent weeks. We anticipate that the office will be ready for occupation in January, though staff working in the new office will be contingent on the Covid-19 regulations at the time.

Causes / sources	Controls	Status/Timescale / owner
The facilities provided in the Stratford office may not fulfil all HFEA requirements and desired benefits, such as ability to host key corporate meetings. Note: Covid-19 may have altered the requirements of the HFEA.	HFEA requirements were specified up front and feedback given on all proposed designs. Outline plans are in line with HFEA needs and we have staff on the working groups set up to define the detail. We will revisit our requirements and ways of working in the light of the changed circumstances we are in due to Covid-19.	Ongoing – Richard Sydee Ongoing as part of Covid-19 management

Causes / sources	Controls	Status/Timescale / owner
	If lower-priority requirements are unable to be fulfilled, conversations will take place about alternative arrangements to ensure HFEA delivery is not adversely affected. Arrangements need to be put in place to ensure that costs and access are shared equitably.	– Richard Sydee Contingency if required – Richard Sydee Discussions still underway as at October – Richard Sydee
We may be unable to recruit staff as they do not see the HFEA as an attractive central London organisation. Note: Move to Stratford noted in all job adverts. Recruitment data to date suggests we are not seeing an impact on recruitment. We will continue to monitor this to consider whether other mitigations are needed/possible.	We will continue to offer desirable staff benefits and policies, such as flexible working, and have reviewed and updated these to ensure that they support staff recruitment and retention. Other civil service and government departments are also being moved out of central London, so this is less likely to impact recruitment of those moving within the public sector.	Completed (however as per above control we will revisit in the light of Covid-19) – Yvonne Akinmodun
Stratford may be a less desirable location for some current staff due to: • increased commuting costs • increased commuting times • preference of staff to continue to work in central London for other reasons, leading to lower morale and lower levels of staff retention as staff choose to leave before the move.	We will review the excess fares policy to define the length of time and mechanism to compensate those who will be paying more following the move to Stratford. Efforts taken to understand the impact on individual staff and discuss their concerns with them via staff survey, 1:1s with managers and all staff meetings to inform controls. These have informed the policies developed. Conversely, there will be improvements to the commuting times and costs of some staff, which may improve morale for them and balance the overall effect.	Begun but to be completed (this is now subject to Covid-19 developments) – Yvonne Akinmodun, Richard Sydee Done - Yvonne Akinmodun,
The Stratford office may cost more than the current office, once all facilities and shared elements are considered, leading to opportunity costs.	Costs for Redman Place (the Stratford building) will be allocated on a usage basis which will ensure that we do not pay for more than we need or use. The longer, ten-year lease at Redman Place will provide greater financial stability, allowing us to forecast costs over a longer period and adjust other expenditure, and if necessary, fees,	Ongoing but we await confirmation of overarching procurement arrangements from central programme -

Causes / sources	Controls	Status/Timescale / owner
The Finance and procurement strand of the project has been delayed; we await final estimates of the cost to HFEA, though have been assured that calculations have been completed.	accordingly, to ensure that our work and running costs are effectively financed. The accommodation at Redman Place should allow us to reduce some other costs, such as the use of external meeting rooms, as we will have access to larger internal conference space not available at Spring Gardens.	Richard Sydee
The move to a new office will lead to ways of working changes that we may be unprepared for.	CMG will be discussing ways of working in the aftermath of Covid-19 and in relation the office move, to ensure that these changes happen by design rather than by default. Policies related to ways of working have been agreed and circulated significantly before the move, to ensure that there is time for these to bed in and be accepted ahead of the physical move. Staff have been involved and updated as appropriate.	September-November 2020 and ongoing – Richard Sydee Done and to continue as these are reviewed following Covid-19 - Richard Sydee, Yvonne Akinmodun
Owing to the different cultures and working practices of the organisations moving, there may be perceived inequity about the policy changes made.	A formal working group was in place including all the organisations who are moving to Stratford with us, to ensure that messaging around ways of working has been consistent across organisations, while reflecting the individual cultures and requirements of these. We will communicate about any differences, so that staff understand any differences in practice and that the intention is not to homogenise practices.	Ways of working group work completed, follow on communications being coordinated across all organisations – Richard Sydee
Current staff may not feel involved in the conversations about the move, leading to a feeling of being 'done to' and lower morale.	Conversations about ways of working occurring throughout the project, to ensure that the project team and HFEA staff are an active part of the discussions and development of relevant policies and have a chance to raise questions. An open approach is being taken to ensure that information is cascaded effectively, and staff can voice their views and participate. We have a separate area on the intranet and Q&A functionality where all information is being shared. Staff have had the opportunity to visit the site ahead of time so that they feel prepared. Staff engagement group established to ensure wide engagement as we approach the move.	Ongoing – Richard Sydee

Causes / sources	Controls	Status/Timescale / owner
The internal move project may be ineffectively managed, leading to oversights, poor dependency management and ineffective use of resources.	Regular reporting to Programme Board and CMG to ensure that effective project processes and approaches are followed. Assurance will be provided by regular reporting to AGC and Authority. The Director of Finance and Resources is Sponsoring the project meaning it has appropriate senior, strategic guidance. Dedicated part-time external project manager brought in to undertake ongoing project management, to ensure sufficient and effective resourcing of this as the project moves into a more advanced phase of delivery. Other key staff such as HR and representatives from other teams involved in the internal HFEA Project team.	In place – Richard Sydee
Necessary changes to IT systems and operations may not work effectively, leading to disruption to HFEA delivery.	Communications between HFEA and other organisations' IT teams to determine IT requirements, allowing more time to resolve these. Infrastructure has largely been migrated to the cloud, which will facilitate the move and reduce related risk to IT systems. It will also mean the HFEA should be able to function even if there are IT issues affecting other systems on-site.	In place - Ongoing - Steve Morris, Dan Howard Ongoing - Steve Morris, Dan Howard
The physical move may cause short-term disruption to HFEA activities and delivery, if necessary resources, such as meeting rooms or physical assets, are not available to staff. We may move to Redman Place later which could increase the chance of this disruption or extend it.	Careful planning of the move to reduce the likelihood of disruption. We will increase our focus on planning as we move closer to the move date and reprioritise as required. Staff would be able to work from home in the short-term if there was disruption to the physical move which would reduce the impact (supported by prolonged working from home due to Covid-19). Implementation of enhanced remote access security arrangements in advance of the move. Contingency plan for locating IT kit being explored to ensure smooth running in the case of further delays to building access.	Ongoing - Richard Sydee In place – Dan Howard Done - Dan Howard Planning underway – Steve Morris
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
British Council – lead on physical build – may not understand or take HFEA needs into account.	DHSC liaising directly with the British Council and managing this relationship on behalf of the other organisations, with feedback through the DHSC project board, on which the Director of Finance and Resources sits.	In place – Richard Sydee, DHSC

Causes / sources	Controls	Status/Timescale / owner
DHSC – Lead on the whole overarching project, entering into contracts on behalf of HFEA and others – HFEA requirements may not be considered/met.	Regular external programme meetings attended by the Director of Finance and Resources as HFEA Project Sponsor and other HFEA staff when delegation required.	In place – Richard Sydee
NICE/CQC/HRA/HTA – IT, facilities, ways of working interdependencies.	Regular DHSC programme meeting involving all regulators. Sub-groups with relevant IT and other staff such as HR. Informal relationship management with other organisations' leads.	In place – Richard Sydee, DHSC

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

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	5	20 – Very high	**2**	**4**	**8 - Medium**
Tolerance threshold:					**12 - High**
Status: **Below tolerance**					

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

Commentary

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

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

Legal challenge poses two key threats:

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

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

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

Causes / sources	Mitigations	Timescale / owner
We may face legal challenge about the way we have executed our core regulatory functions of inspection and licensing. For instance, clinics	Where necessary, we can draw on the expertise of an established panel of legal advisors, whose experience across other sectors can be applied to put the HFEA in the best possible position to defend any challenge.	In place – Peter Thompson

Causes / sources	Mitigations	Timescale / owner
challenging decisions taken about their licence.		
We may be legally challenged if new science or technology emerges that may not be covered by the existing regulatory framework.	Scientific and Clinical Advances Advisory Committee (SCAAC) horizon scanning processes. This provides the organisation with foresight and may provide more time and ability to prepare our response to developments. Case by case decisions on the strategic handling of contentious or new issues in order to reduce the risk of challenge or, in the event of challenge, to put the HFEA in the strongest legal position.	SCAAC horizon scanning meetings annually. In place – Catherine Drennan and Peter Thompson
Our policies may be legally challenged if others see these as a threat or ill-founded. Moving to a bolder strategic stance, eg, on add-ons or value for money, could result in claims that we are adversely affecting some clinics' business model or acting beyond our powers.	Evidence-based and transparent policymaking, with risks considered whenever a new approach or policy is being developed. We undertake good record keeping, to allow us to identify and access old versions of guidance, and other key documentation, which may be relevant to cases or enquiries and enable us to see how we have historically interpreted the law and implemented related policy and respond effectively to challenge. Business impact target assessments carried out whenever a regulatory change is likely to have a significant cost consequence for clinics meaning that consideration of impacts and how these will be managed is taken into account as part of the policymaking process. Stakeholder involvement and communications in place during policymaking process (for instance via regular stakeholder meetings) to ensure that clinics and others can feed in views before decisions are taken, and that there is awareness and buy-in in advance of any changes. Major changes are consulted on widely.	In place – Laura Riley/Joanne Anton with appropriate input from Catherine Drennan Ongoing - Laura Riley, Joanne Anton In place – Richard Sydee Ongoing - Laura Riley, Joanne Anton
We may face legal challenges related to clinical implementation of regulation in terms of individual cases (ie, consent-related cases). Ongoing legal parenthood and storage consent failings in clinics and related cases are specific ongoing examples. The	We undertake good record keeping, to allow us to identify and access old versions of guidance, and other key documentation, which may be relevant to cases or enquiries and enable us to see how we have historically interpreted the law. Through constructive and proactive engagement with third parties, the in-house legal function serves to anticipate issues of this sort and prevent challenges. This strengthens our ability to find solutions that do not require legal action.	Ongoing – Catherine Drennan In place – Catherine Drennan

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

Causes / sources	Mitigations	Timescale / owner
	Measures in place to ensure consistency of advice between the legal advisors from different firms. Including: • Provision of previous committee papers and minutes to the advisor for the following meeting • Annual workshop • Regular email updates to panel to keep them abreast of any changes. Consistent and well taken decisions at licence committees supported by effective tools for committees and licensing team (licensing pack, Standard operating procedures, decision trees etc) which are regularly reviewed.	Since Spring 2018 and ongoing – Catherine Drennan In place – Paula Robinson
Any of the key legal risks may escalate into high-profile legal challenges which may result in significant resource diversion and reputational consequences for the HFEA which risk undermining the robustness of the regulatory regime. We are aware of endeavours to put some test storage consent cases to the courts which may make HFEA involvement more likely.	Close working between legal and communications teams to ensure that the constraints of the law and any HFEA decisions are effectively explained to the press and the public. The default HFEA position is to conduct litigation in a way which is not confrontational, personal or aggressive. We have sought to build constructive relationships with legal representatives who practice in the sector and the tone of engagement with them means that challenge is more likely to be focused on matters of law than on the HFEA. Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise workload should this become necessary.	In place – Catherine Drennan, Joanne Triggs In place – Peter Thompson, Catherine Drennan In place – Peter Thompson
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: HFEA could face unexpected high legal costs or damages which it could not fund. This is an interdependent risk as the Department must ensure the ability to maintain the regulatory regime.	If this risk was to become an issue then discussion with the Department of Health and Social Care would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also an interdependent risk because DHSC would be involved in resolving it.	In place – Peter Thompson
DHSC: We rely upon the Department for any legislative changes in response to legal risks or impacts.	Our regular communications channels with the Department would ensure we were aware of any planned change at the earliest stage. Joint working arrangements would then be put in place as needed, depending on the scale of the change. If necessary, this would include agreeing any associated implementation budget.	In place – Peter Thompson

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

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

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16 – High	**3**	**4**	**12 - High**
Tolerance threshold:					**12 - High**
Status: **At tolerance**					

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

Commentary
Risk management of these risk causes has necessarily become our organisational priority. All staff are working from home and a strategy to manage inspections has been put in place until November (and may need to be extended depending on the state of the pandemic and wider Government policy). Communications to the sector and patients are in place and ongoing. A business continuity group meets regularly to consider risks and ensure an effective response is developed and maintained. The Coronavirus risk has had a cascading effect across the whole risk register and will do for the foreseeable future. Where there are specific risk causes related to other core risks these are signposted as relevant. The organisation has been incredibly flexible to rapidly adapt to changed ways of working, the next step is to ensure this is sustainable and we take a flexible and appropriate response as restrictions loosen and life returns to a 'new normal'. A Covid-19 risk management review was undertaken in autumn 2020 to reflect on lessons learned during the first phase of the pandemic response. These lessons will be used to consider effectiveness of controls and a report will be presented to AGC in December.

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

Causes / sources	Controls	Status/Timescale / owner
	any developments led by them (such as guidance updates). Proactive handling of clinic enquiries and close communication with them. Careful monitoring of the need to update information and proactive handling of updates. Public enquiries about Coronavirus are being triaged, with tailored responses in place. Enquirers are being directed to information on our website, to ensure that there is a single source of truth and this is up to date. Enquiries team have additional support from Managers and Directors. We will review our approach regularly to ensure that this is fit for purpose. Close monitoring of media (including social) to identify and respond to any perceived criticism to ensure our position is clear. Regular review of communications activities to ensure they are relevant and effective.	In place and ongoing – Sharon Fensome-Rimmer, Rachel Cutting Joanne Triggs – in place In place and under regular review – Laura Riley In place – Jo Triggs
Risk of being challenged publicly or legally about the HFEA response, resulting in reputational damage or legal challenge. (This risk also therefore relates directly to LC1 above)	As above – ensuring approach is appropriate. As above – continuing to liaise with professional bodies. We may choose to put out a press release in case of public challenge. Legal advice has been sought to ensure that HFEA actions are in line with legislative powers. Further advice available for future decisions. Ability to further engage legal advisors from our established panel if we are challenged.	In place – Richard Sydee Ongoing - Rachel Cutting If required - Joanne Triggs Done – Peter Thompson If required – Peter Thompson, Catherine Drennan
Gaps in HFEA staffing due to sickness, caring responsibilities etc	Possible capability gaps have been reviewed by teams to ensure that these are identified and managed. Other mitigations as described under the C1 risk.	In place – Yvonne Akinmodun
Risk of disproportionate impact of coronavirus on staff from black and ethnic minority backgrounds.	Decision taken not to return to Spring Gardens site so no office-working will occur until at least January 2021, reducing work-related risk. We will consider the impact as part of planning for a return to inspections and office working.	In progress – Yvonne Akinmodun

Causes / sources	Controls	Status/Timescale / owner
	We are engaging with other similar organisations to consider possible approaches to managing this risk.	
Clinics stop activity during the epidemic and so we are unable to inspect them within the necessary statutory timeframes.	Extending of licences (noted above) should remove this risk by ensuring that the licence status of clinics is maintained.	In place - Paula Robinson
Ineffective oversight of those clinics that are continuing to practice as clinics may not abide by professional body and HFEA guidance. Since GD0014 version 2 was issued, clinics have been able to reopen where it is safe to do so. Meanwhile, HFEA do not plan to restart physical inspections until November. This creates a potential oversight gap.	We put in place a new General Directions for clinics to follow. Clinics who do not follow General Directions 0014 would be subject to serious regulatory action. Inspection team are in active communication with all of their clinics to ensure oversight and understanding of risks. Activity of centres is being monitored through the register submission system. Effective desk-based approach to oversight of clinics. Those clinics (who have resumed treatment services and/or are open) where Interim inspections were due during the period of no inspections will still be asked to complete the Self-Assessment Questionnaire, in the same way that they would have done before an inspection. This gives us oversight of all areas of practice. A methodology for a wholly virtual inspection is being developed. In discussion with the Department about statutory duty to physically visit licensed premises every two years.	In place – Rachel Cutting In place – Sharon Fensome-Rimmer In place with methodology development in progress as at October 2020– Sharon Fensome-Rimmer, Rachel Cutting Underway as at October 2020 – Rachel Cutting, Catherine Drennan
Precipitous decrease in funding due to large reductions in treatment undertaken because of Coronavirus. Note: as per FV1 this is a live issue. Note: this risk may be both short and longer-term if clinics close down as a result.	As per FV1 risk - We have sufficient cash reserves to function normally for a period of several months if there was a steep drop-off in activity (contingency). The final contingency would be to seek additional cash and/or funding from the Department, we have agreed support for the remainder of 2020/21 and we will resume discussions about the likely impact on us in 2021/22 in the coming months (further contingency).	In place – Richard Sydee Ongoing discussions as impact becomes clearer – Richard Sydee
We have had to cancel events and meetings and cannot run them as planned which may delay some strategic delivery.	Conversations ongoing with Authority and Corporate Management about options for management of individual risk impacts and review key milestones where needed.	In place – Peter Thompson

Causes / sources	Controls	Status/Timescale / owner
	Routine stakeholder meetings occurring virtually and revised arrangements to allow for virtual meetings and committees.	
Negative effects on staff wellbeing (both health and safety and mental health) caused by extended working from home (WFH), may mean that they are unable to work effectively, reducing overall staff capacity.	Provided equipment for staff who have to WFH without suitable arrangements in place. Temporary use of desks at another ALB's office site from October – December. Mental Health resources provided to staff, such as employee assistance programme and links to other organisations' resources. Mental Health First Aiders in place to increase awareness of need to care for mental health. Available to discuss mental health concerns confidentially with staff. Regular check-ins in place between staff and managers at all levels, to support staff, monitor effectiveness of controls and identify need for any corrective actions. Additional support for Managers in place. Corrective actions could include discussions about workload, equipment, reallocation of work or resource dependent on circumstance.	In place – Richard Sydee In place – Yvonne Akinmodun In place – Yvonne Akinmodun In place and ongoing – Yvonne Akinmodun
Inability of staff to return to office working may negatively impact organisational culture, reduce collaboration, or hamper working dynamics and productivity. Note: This risk is linked to the E1 risk due to inability to return to Spring Gardens and delay to accessing Redman Place. This risk will affect the organisation for some time including when we return to the office, while social distancing is in place and office working is significantly reduced due to Covid-19 restrictions.	Discussion about return to work at CMG to ensure that this is planned effectively, and impacts considered. Online solutions to maintain collaboration and engagement, such as informal team engagement and 'teas', Microsoft teams etc.	September-November CMG meetings – Peter Thompson In place – Heads
Risk that we miss posted financial, OTR or other correspondence.	While the office remains open, we have an arrangement to securely store, collect and distribute post. Though we would need to reconsider this control should the office be closed. Updated website info to ask people to contact us via email and phone. We have notified all suppliers about the change in arrangements. Although this is unlikely to stop all post as some have automated systems.	In place – Richard Sydee In place – Jo Triggs In place – Morounke Akingbola

Causes / sources	Controls	Status/Times cale / owner
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
In common risk		
DHSC: HFEA costs exceed annual income because of reduced treatment volumes. Live issue as at October – captured under FV1	Use of cash reserves, up to appropriate contingency level available. The final contingency would be to seek additional cash and/or funding from the Department. (additional Grant in Aid has been provided for the 2020/2021 business year).	Richard Sydee

Reviews and revisions

21/10/2020 – SMT review - July 2020

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

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

23/06/2020 – AGC review – October 2020

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

- AGC discussed board member recruitment, noting that interviews had taken place for four new Authority members and we were waiting for these appointments to be completed by the DHSC. The DHSC representative confirmed that the advert for the appointment of the Chair position was progressing.
- The Deputy Chair of the Authority commented that she was willing and able to step in as Authority Chair should there be a gap before the new chair is appointed following the departure of the current Chair.
- Members asked the executive to ensure that risks related to the Opening the Register service were effectively reflected in the Register and controlled.

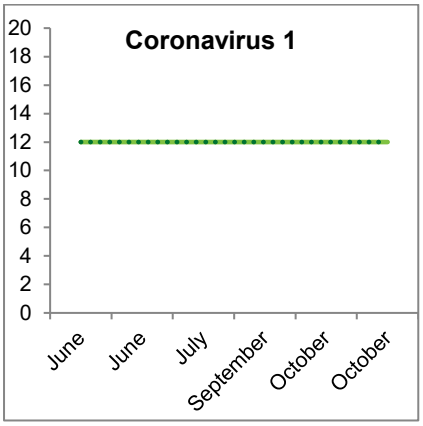
07/09/2020 – SMT review – September 2020

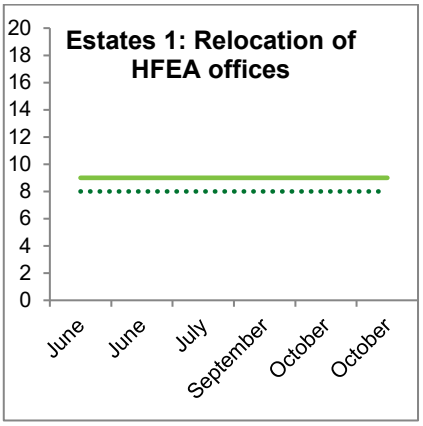
SMT reviewed all risks, controls and scores and made the following points:

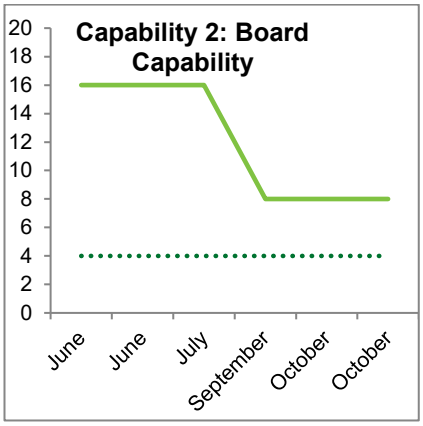
- SMT agreed that the following risks and their scores remained appropriate, IP1, RF1, I1. Authority discussions to follow would prompt further reconsideration.
- FV1 – SMT discussed the recent assurance provided for financial cover through to the end of this financial year. SMT reflected that the score had therefore decreased in the short to medium term. However, future treatment volumes were uncertain and there was also significant uncertainty for 2021/2022. The risk would need careful monitoring over the coming months.
- C2 – as recruitment was now in hand and discussions were underway regarding targeted extensions to terms, SMT agreed to reduce this risk, although it remains above tolerance.
- E1 – SMT discussed current delays to the project and noted that this does not increase this risk further at the current time, since the organisation had proven effective ways of working remotely.
- CV1 – SMT reflected that a further risk source emerged the longer the organisation worked entirely from home, negative impacts on organisational culture and close working. CMG would discuss further control options shortly.
- CS1 – clarity on progress of some controls being sought from the Chief Information Officer.
- LC1 – no matters of strategic significance, no change to this risk.

Risk trend graphs (last updated October 2020)

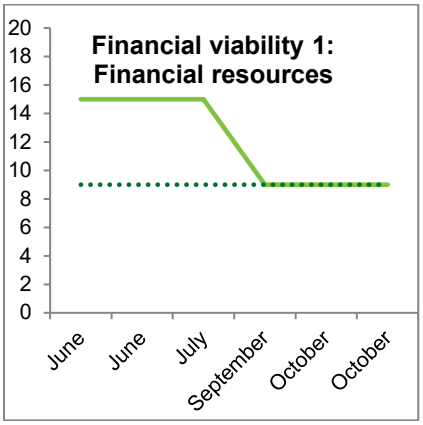
High and above tolerance risks

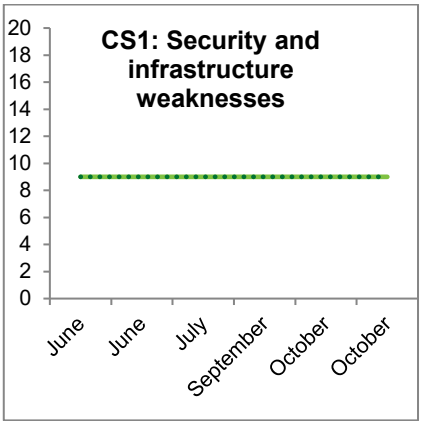


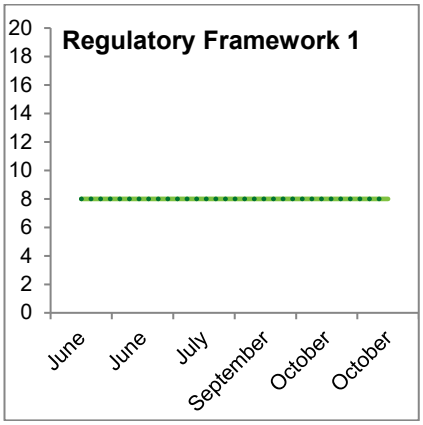


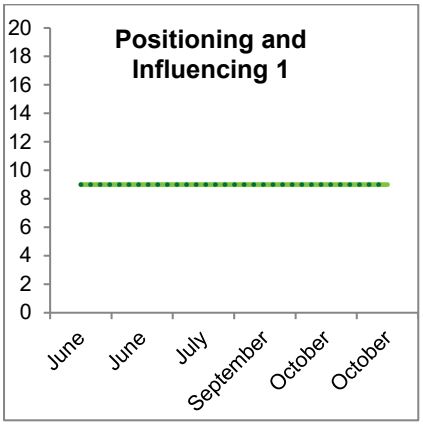


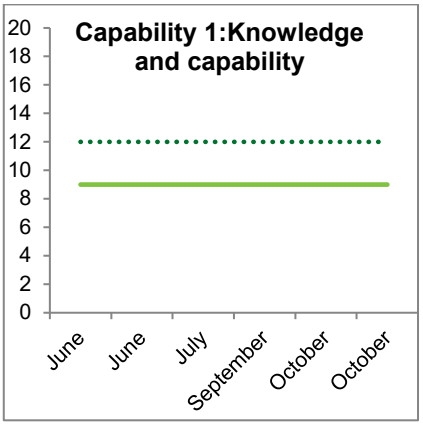
Lower and below tolerance risks

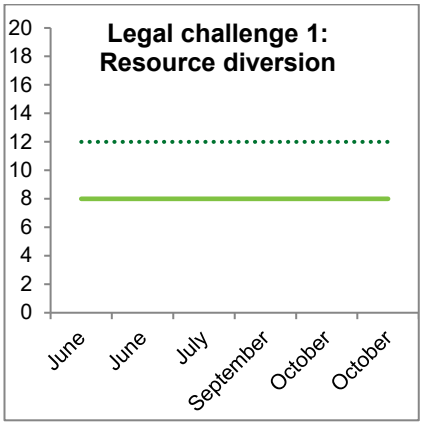


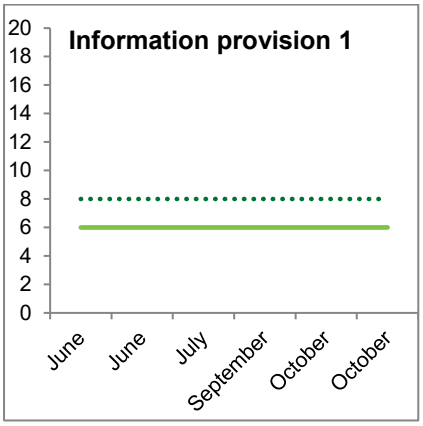












Criteria for inclusion of risks

Whether the risk results in a potentially serious impact on delivery of the HFEA's strategy or purpose.

Whether it is possible for the HFEA to do anything to control the risk (so external risks such as weather events are not included).

Rank

The risk summary is arranged in rank order according to the severity of the current residual risk score.

Risk trend

The risk trend shows whether the threat has increased or decreased recently. The direction of the arrow indicates whether the risk is: Stable ⇔ , Rising ⇧ or Reducing ⇩.

Risk scoring system

We use the five-point rating system when assigning a rating to the likelihood and impact of individual risks:

Likelihood:	1=Very unlikely	2=Unlikely	3=Possible	4=Likely	5=Almost certain
Impact:	1=Insignificant	2=Minor	3=Moderate	4=Major	5=Catastrophic

Risk scoring matrix

Impact	1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
5.Very high	5 Medium	10 Medium	15 High	20 Very High	25 Very High
4. High	4 Low	8 Medium	12 High	16 High	20 Very High
3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
1. Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium
Risk Score = Impact x Likelihood	Likelihood				

Risk appetite and tolerance

Risk appetite and tolerance are two different but related terms. We define risk appetite as the willingness of the HFEA to take risk. As a regulator, our risk appetite will be naturally conservative and for most of our history this has been low. Risk appetite is a general statement of the organisation's overall attitude to risk and is unlike to change, unless the organisation's role or environment changes dramatically.

Risk tolerance on the other hand is the willingness of the HFEA to accept and deal with risk in relation to specific goals or outcomes. Risk tolerance will vary according to the perceived importance of particular risks and the timing (it may be more open to risk at different points in time). The HFEA may be prepared to tolerate comparatively large risks in some areas and little in others. Tolerance thresholds are set for each risk and they are considered with all other aspects of the risk each time the risk register is reviewed

Assessing inherent risk

Inherent risk is usually defined as 'the exposure arising from a specific risk before any action has been taken to manage it'. This can be taken to mean 'if no controls at all are in place'. However, in reality the very existence of an organisational infrastructure and associated general functions, systems and processes introduces some element of control, even if no other mitigating action were ever taken, and even with no particular risks in mind. Therefore, for our estimation of inherent risk to be meaningful, we define inherent risk as:

'the exposure arising from a specific risk before any additional action has been taken to manage it, over and above pre-existing ongoing organisational systems and processes.'

System-wide risk interdependencies

We explicitly consider whether any HFEA strategic risks or controls have a potential impact for, or interdependency with, the Department or any other ALBs. There is a distinct section beneath each risk to record any such interdependencies, so we identify and manage risk interdependencies in collaboration with relevant other bodies, and so that we can report easily and transparently on such interdependencies to DHSC or auditors as required.

Contingency actions

When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation must achieve balance between the costs and resources involved in limiting the risk, compared to the cost of the risk translating into an issue. In some circumstances it may be possible to have contingency plans in case mitigations fail, or, if a risk goes over tolerance it may be necessary to consider additional controls.

When a risk exceeds its tolerance threshold, or when the risk translates into a live issue, we will discuss and agree further mitigations to be taken in the form of an action plan. This should be done at the relevant managerial level and may be escalated if appropriate.

PRISM update

Details about this paper

Area(s) of strategy this paper relates to:	The right information – to ensure that people can access the right information at the right time
Meeting:	Authority
Agenda item:	5
Meeting date:	11 November 2020
Author:	Dan Howard, Chief Information Officer Kevin Hudson, PRISM Programme Manager
Annexes	None

Output from this paper

For information or decision?	For information
Recommendation:	To note
Resource implications:	Within budget
Implementation date:	From 13 October 2020 to 31 March 2021
Communication(s):	
Organisational risk:	High

1. PRISM launch – a summary

1.1. Since the last update to Authority on 16 September progress has been made across all areas of the programme. This paper sets out the progress made and the remaining steps of our launch process.

1.2. Authority will recall that in response to clinic feedback, we agreed with AGC in September a 'PRISM / CaFC reprofiling plan'. The reprofile will include included extended clinic engagement and enhanced training, additional clinic support, integrated testing and data cutover, development of additional functionality for staff, and in addition will include a full CaFC verification later in 2020 underpinned by EDI system migration.

1.3. We have sought to be flexible in our approach for the launch of PRISM. Over recent months we have changed our plans in response to Covid-19 and as we set out in September, the launch of PRISM is a process consisting of key stages rather than a single event.

1.4. The PRISM build was completed at the end of September. On 13 October 2020, we shared the 'Release Candidate' with clinics as planned. This commenced the process of PRISM launch.

1.5. Our reprofiling of the PRISM launch and CaFC allows clinics to spend more time to ensure their 2020 CaFC data is as accurate as possible, as well as providing an easier introduction for both clinics and HFEA staff to familiarise themselves with PRISM.

1.6. We anticipate that PRISM will go live for new data on 25 January 2021. PRISM represents a significant change from the legacy EDI system which has been in place since 2005:

1. Data submissions from clinics will be highly structured and automatically validated.
2. There is a far greater onus on clinics to submit correct data in the first instance, and the PRISM system itself helps the clinic identify where data is missing and how it needs to be corrected
3. Conversely, we expect the level of 'post submission corrections' that clinics need to conduct to be substantially reduced, saving significant time for clinics and HFEA support staff.

1.7. This paper sets out the remaining work that we are conducting as part of the launch process to support both clinics and staff, ensuring all are bedded in and supported to become experts in PRISM, allowing HFEA and the sector to realise the benefits of the new system and register.

1.8. We expect that PRISM will be embedded by 31 March 2021.

2. Extended Clinic Engagement and Training

2.1. The Release Candidate is a fully featured version of PRISM that clinics can use to familiarise themselves with the new system.

2.2. We have created a four-stage process for ensuring that clinics maximise their PRISM expertise by 25 January 21 (our data 'go live' date)

1. From 13 October: **Basic training** on the Release Candidate
2. From mid-November: **Advanced training** on complex fertility scenarios
3. During early Dec: **Specialist training** on functions not offered by all clinics (e.g. surrogacy)
4. From early January 2021: **Live training** on the clinics' own data before go-live

2.3. Since the launch of the Release Candidate we have been holding weekly drop-in sessions with clinics to capture feedback, for clinics to ask questions about PRISM, hear the questions that other clinics are asking, and discuss the use of PRISM with each other.

2.4. More than 50% of the clinics that will use PRISM have been represented on the drop-in sessions so far and over the coming weeks we will work to ensure all clinics take part. This 'user group' will be very valuable for HFEA in the longer term and is a key component of our plan for the ongoing evolution of PRISM. We hope it will cross pollinate expertise and ideas and will help reduce the ongoing burden for HFEA itself to have to keep training and supporting the sector on PRISM.

2.5. Clinics are also free to contact the PRISM team directly with queries or recommendations at any time. We have received a steady stream of communications from clinic staff ranging from PRs and embryologists to administrators.

2.6. We are continuing to respond to all queries rapidly to provide reassurance to clinics. So far, the general feedback has been that the system has been 'easy to use', and any issues that the clinics have encountered, we have been able to advise them easily and quickly.

2.7. We are also tracking closely clinics in large NHS trusts where the PR and their staff might be reliant on large (but potentially remote) IT teams to ensure that their internal support needs are met as they move to using PRISM.

2.8. For those clinics that appear not to be progressing through the training at the pace of their colleagues, we will proactively engage with them to understand any issues and agree individual action plans as appropriate to ensure all clinic staff are expert on PRISM by 25 January 2021.

2.9. We have also launched our final API package to the three system suppliers that will automatically send data into PRISM. Over the weeks before go-live we will liaise closely with them to make sure they are completing their final preparatory steps.

2.10. Mellowood, which operates the IDEAS system used by 38 clinics and is bar far the largest system suppler, has recruited an ex HFEA inspector to support them in the PRISM roll out. This is a hugely encouraging step by this system suppler.

2.11. The programme will continue to keep the Senior Management Team and AGC fully informed of the ongoing response from the sector as we progress through the developing stages of PRISM engagement and training.

3. Integrated Testing and Data Cutover

3.1. We have agreed with AGC three stages of sign off for PRISM before we complete the cutover, and the system goes live:

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

3.2. We have already conducted penetration testing of PRISM and we can provide assurance the register data in PRISM is secure.

3.3. PRISM has already passed its functional tests. This means the system works as we expect, which is reinforced by the positive feedback we are now getting from clinics as they use and explore the Release Candidate.

3.4. We have also already imported data into PRISM and conducted tests on how HFEA legacy data appears in PRISM and ensuring it reports data as expected. Those initial data tests have identified no major issues, although have shown some refinements in data migration we would like to make.

3.5. We will be using this reprofiling period to make further refinements in our data migration and as a further precaution we will conduct further tests to check that our original findings are sustained. Due to the nature of data migration and the fact that data errors are generally systematic (and not episodic), we are therefore not expecting to find any new issues from this exercise.

3.6. To ensure that all HFEA Business Processes are ready for the PRISM go live, we have a detailed cutover plan and our data migration lead has met with all the HFEA teams, understood their sign-off criteria, and built this into the cutover plan.

3.7. Our cutover plan is currently as follows:

1. **13 January 2021:** EDI switches off to clinics and we take a final copy of the legacy system.
2. **15 January 2021 weekend:** We run the 'live' Extract/Transform/Load (ETL) programme and bring the EDI data into PRISM. Over the past 18 months, we have conducted over 40 trial runs of the ETL.
3. **Week from 18 January 2021:** We perform extensive checks that the data has migrated successfully with multiple sign off and roll back points during that week:
4. **25 January 2021:** If all checks are passed then PRISM is made live for clinic data entry.

4. Additional Functionality for HFEA staff (RITA System)

4.1. This work, called the RITA (Register Information Team Administration) System, delivers extra functionality for staff and was a known programme of work, which through the reprofiling we are bringing forward so that essential parts can be addressed before 'go-live'.

4.2. We have identified two phases of this work:

1. RITA Phase 1: Essential functionality required ahead of go live to query the register and provide reporting (for Register and OTR teams).
2. RITA Phase 2: Additional functionality to support internal teams and the sector.

4.3. Now PRISM is built, we are proceeding immediately to develop RITA phase 1 and we anticipate completing this by 23 December 2020.

4.4. However, we will take more time to develop the requirements for phase 2 and allow these to be informed by the actual experiences of PRISM by both staff and clinics once the system goes live.

4.5. Alongside, we are also working to confirm the new HFEA reporting structure that will support functions such as the 2021 CaFC process. This work will start after go-live in February 2021.

5. CaFC verification and EDI migration

5.1. In response to clinic feedback we have extended the 2020 CaFC verification process to allow clinics to ensure their data is as accurate as possible before CaFC is published.

5.2. In October 2020 we issued new verification reports to clinics which they are required to complete and sign off by mid-December

5.3. This CaFC verification process will complete before Christmas and we expect to publish the 2020 CaFC in February 2021, shortly after PRISM go live.

5.4. To facilitate this, we have also undertaken to migrate the legacy EDI system from being based on servers in Spring Gardens to 'the cloud'. This work will complete in early November 2020 and is required because of the fixed end date of HFEA's occupancy of Spring Gardens.

5.5. Whilst we had hoped to avoid this cost, Authority should note that migrating EDI also provides an extended safety net and fallback option for PRISM beyond November to deal with any future unforeseen events either related to PRISM or wider circumstances such as those related to Covid-19.

6. Finances

6.1. We expect the cost of PRISM build and cutover to be delivered on budget as per our January 2020 Completion Plan

6.2. Nevertheless, as agreed with AGC, reprofiling the programme to deliver the further components set out in section 1.2 results in additional costs of £230,380. The funding was identified earlier in October 2020 and will not impact on any other HFEA activities planned for the 2020-21 business year.

6.3. These costs specifically relate to:

1. Cover for the departure of HFEA's PRISM Development Manager
2. Extended Clinical Engagement
3. Developing RITA
4. EDI migration from Spring Gardens

7. Next steps

7.1. Authority are asked to note that:

1. PRISM has been built and the launch process has commenced.
2. We have a detailed plan for delivering an improved PRISM launch, a full CaFC verification process and EDI migration concurrently.
3. We expect the launch of PRISM to be the start of a major change for clinics and staff alike.

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:	6
Meeting date:	11 November 2020
Author:	Paula Robinson, Head of Planning and Governance Helen Crutcher, Business Planning and Risk Manager
Annexes	Annex A: Draft activities section of 2021/22 business plan Annex B: Three year overview of planned strategic delivery

Output from this paper

For information or decision?	For decision
Recommendation:	The Authority is asked to approve the draft activities section of the 2021/22 business plan, for further development over the coming months, and for submission to the Department for review, on request.
Resource implications:	In budget
Implementation date:	1 April 2021 – 31 March 2022
Communication(s):	HFEA website
Organisational risk:	Low

1. Planning progress since the last Authority meeting

1.1. At the September Authority meeting, members approved the 6 month business plan for the remainder of 2020/21, and an outline plan for 2021/22 and beyond.

1.2. The 6 month business plan is with the Department of Health and Social Care (DHSC) for final approval, and will then be published on our website.

1.3. This paper presents two documents – a first detailed draft of the activities section of the 2021/22 business plan (Annex A), for comment and approval, and, for context, an overview of the whole three year strategy delivery period from April 2021 through to March 2024 (Annex B).

1.4. The three year plan has been refined following earlier Authority and CMG discussions about priorities and sequencing, particularly in light of the adjustments we have made to our workplans to enable us to respond to the Covid-19 pandemic. In addition, some pieces of work that include engagement with other bodies has been moved back a year, since the ability of other organisations to engage with us on new issues will be limited in 2021/22. The last time the Authority was given a three year overview was prior to the pandemic, in November 2019. At that stage members suggested it would be useful to see this again at a future meeting.

2. Recommendation

2.1. The Authority is asked to comment on, and approve, the draft activities section of next year's business plan, as set out in Annex A. Further work on the business plan and review by colleagues at DHSC will take place over the next few months.

2.2. The Authority is also asked to note the updated overall three year delivery plan shown in Annex B.

Annex A (Business plan 2021/22 – activities section)

Activities for 2021/2022

This business plan represents the first full year of our 2020 - 2024 strategy which launched in October 2020.

[General introductory text will be added here prior to publication.]

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 October 2020 to March 2021

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 Roll out of • revised inspection reports • 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.

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
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 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
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 four 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

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
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.	Throughout the year
Completion 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 patient information and traffic lights.	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. 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.	Summer 2021 with further work to be planned for subsequent years of strategy delivery.
Delivery of a project to build on success rates work from 2019/2020.	We use our data to understand variations between clinics and collaboratively define best practices.	Throughout the year
Improved Register data analysis tools to improve reporting and analysis	Realisation of a post-PRISM reporting database. Increased ability to analysis data and report from the Register.	Throughout the year

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
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 review the application process for researchers to use HFEA data, or human embryos. Anonymised Register dataset available for researchers. 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

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
Effective handling of and communication about: • clinical incidents and adverse events, including publication of 2020/21 'State of the Sector' report and quarterly compliance reports • complaints about clinics	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. Patients' experiences used to make improvements and prevent recurrence. Better understanding of factors contributing to particular types of adverse event.	Throughout the year, with the state of the sector report 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

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
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: • 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.	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
Review of information provided on HFEA website about: • routine treatments for instance 'standard' IVF • greater clarity about the costs of treatment	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.	Throughout the year

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
• testing of new information using the pilot patient forum.		
Implementing any 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 any 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

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 October 2020 to March 2021

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 October 2020 to March 2021

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 October 2020 to March 2021.

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
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 in 2019. The Clinic Portal remains useful and easy to use for clinic staff and meets their updated requirements.	Throughout the year
Update to the data available in Choose a Fertility Clinic (CaFC) and continuation of scoping work to consider how clinic data will be published in future.	Completion of project to integrate performance data from the new register into the CaFC website, to allow up to date CaFC data to be published. Patients have access to regularly updated data on clinic performance to inform their treatment decisions.	Throughout the year
Follow on work from the Competition and Markets Authority (CMA) project on self-funded IVF and consumer law guidance.	We communicate and embed the CMA guidance so that clinics understand their obligations under consumer law in relation to self-funded treatment. Review any recommended changes to our Code of Practice as part of this activity and support clinics to implement any changes as a result of the CMA guidance.	March-October 2021

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Understanding first hand patient experiences of the clinics we regulate.	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. We are committed to gathering patient views and will consider the best ways to do this, either in a similar way to the 2018 national survey pilot or by other appropriate means.	Summer 2021
Data review board established	Clear methodology and process for considering any future additions to the Register.	First meeting Autumn 2021
Make use of patient feedback and our pilot patient forum to ensure that information is fit for purpose.	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 an insight into the patient experience in clinics and encourage good practice based on feedback.	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

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
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), parliamentary question (PQ), and subject access requests.	We comply with FOI, PQ and DPA requirements. Requesters have access to accurate information in a timely fashion. 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.	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
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

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
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. Greater knowledge about the efficacy and safety of fertility treatment.	Throughout the year
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

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Responding to external consultations and reviews including from the Department of Health and Social Care, other 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
Continued participation in the collaborative regulatory advice service for regenerative medicine, to provide advice to those working in the life sciences industry.	Ensuring we're an effective collaborator and partner in the interests of the efficiency of the wider Department of Health and Social Care group of arm's length bodies (ALBs) and other health organisations. 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.	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
Continuing 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
Early life support of 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 October 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 October 2020 to March 2021.

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**
Activity to monitor the use of AI and data-driven new technologies in fertility clinics and the wider sector.	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. We understand any developments and are responsive to these. We ensure that our regulatory regime is fit for purpose.	Throughout the year

Table 6 - Strategic objective 6. Preparing for future legislative and operational changes. Table outlining planned activities for October 2020 to March 2021.

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
Implementation of any legislative changes that occur, for example on storage limits.	Any legislative changes are successfully implemented as required.	September 2021 onwards
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 the year

Objective 6 Preparing for future legislative and operational changes - methods and channels	Benefits and outcomes	Timescale
Delivery of a project to scope future 'opening the Register' (OTR) demand and logistics.	To put the groundwork in place for a subsequent project to operationally prepare for a growth 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
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.	Early 2021
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

Objective 6 Preparing for future legislative and operational changes - methods and channels	Benefits and outcomes	Timescale
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. Training run to ensure that HFEA leaders are equipped to deliver effectively. Staff feel valued and motivated to deliver our strategic aims. 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
Undertake a fee review informed by our income forecasting model.	We ensure that we meet the financial needs for regulation.	By March 2022

Annex B (Three year overview of strategy delivery)

Strategy delivery outline - 2021-2024

Key:	
	Core work (mixed bag of sizes)
	Large piece of work
	Medium piece of work
	Small piece of work

General workload:	2021/22				2022/23				2023/24			
	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar
All core work	CORE WORK											
Follow-on work from office move.	SNAG GING	COVID SECURE ARRANGEMENTS REMAIN IN PLACE AS LONG AS NECESSARY										
Covid-19 - inspection strategy	COVID MONITORING & INSPECTIONS											
Supporting the PRISM data submission system and the Register Information Team Application (RITA)	PRISM & RITA SUPPORT	PRISM & RITA MAINTENANCE (BUSINESS AS USUAL)										
Fees review	FEES REVIEW											
CaFC update and scoping.	CaFC UPDATE AND SCOPING											
EU Exit / NI protocol	EU EXIT - TRANSITION AND BEYOND											
Code of Practice updates	COP UPDATE						COP UPDATE					
CMA work	IMPLEMENT CMA GUIDANCE											
Management of member turnover and induction / training	MANAGING MEMBER INDUCTION AND TURNOVER											
Activities to mark the 30th anniversary of the HFEA	30TH ANNIVERSARY OF THE HFEA											
Accessibility	ACCESSIBILITY REQUIREMENTS MET				ACCESSIBILITY REQUIREMENTS MAINTAINED							

Strategy Areas: Outcomes sought:	2021/22 Apr - Jun	2021/22 Jul - Sep	2021/22 Oct - Dec	2021/22 Jan - Mar	2022/23 Apr - Jun	2022/23 Jul - Sep	2022/23 Oct - Dec	2022/23 Jan - Mar	2023/24 Apr - Jun	2023/24 Jul - Sep	2023/24 Oct - Dec	2023/24 Jan - Mar
Best care												
Objective 1: Treatment that is effective, ethical and scientifically robust.												
Individualised treatment and care that is safe, responsible, consistent and based on clear values.	C&E POLICY											
	INSPECTION REPORT CHANGES											
					COMPLETION OF REVIEW OF COMPLIANCE REGIME							
									COMPENSATION FOR OVERSEAS DONORS			
					CONSENT FORMS - SCOPING				REVIEW OF CONSENT FORMS			
Clinics that are well led and see compliance and the provision of high quality care, including excellent support, as good business.	DEVELOP PREVIOUS SUCCESS RATES WORK				POSSIBLE FURTHER WORK - TBD							
	SCOPING - 10-FAMILY LIMIT				POTENTIAL FURTHER WORK							
A transparent and accurate evidence base, to ensure that patients can make informed choices about their treatment. More research and innovation to improve the evidence base and outcomes.	REVIEW WEBSITE INFORMATION ON TREATMENTS				KEEP WEBSITE UP TO DATE AND CONTINUE OUR FOCUS ON SUPPORT							
	COMPLETION OF CURRENT ADD-ONS PROJECT				FURTHER WORK ON ADD-ONS							
	REGISTER INFORMATION TOOLS											
	SUPPORTING RESEARCH											
Objective 2: Improved recognition of partners' importance (of the same or opposite sex) in the care process.												
Partners to be involved in care and treatment choices throughout the process.								GUIDANCE AND INFORMATION ABOUT INVOLVING PARTNERS				
Clinics to recognise that partner care is a core part of the service they provide.									SIGNPOSTING TO ACCURATE INFORMATION ABOUT MALE FERTILITY			

Strategy Areas: Outcomes sought:	2021/22 Apr - Jun	2021/22 Jul - Sep	2021/22 Oct - Dec	2021/22 Jan - Mar	2022/23 Apr - Jun	2022/23 Jul - Sep	2022/23 Oct - Dec	2022/23 Jan - Mar	2023/24 Apr - Jun	2023/24 Jul - Sep	2023/24 Oct - Dec	2023/24 Jan - Mar
Right information												
Objective 3: Improved access to information at the earliest (pre-treatment) stage.												
Right-moment information provision from the outset for patients, partners, donors and surrogates.					PARTNERSHIP WORKING ON PRIMARY CARE INFORMATION							
	SOCIAL MEDIA & OTHER CHANNELS								MATERIALS TO SUPPORT PEOPLE AT THE START OF THEIR JOURNEY			
Objective 4: High quality information to support decision-making during and after treatment or donation.												
Patients, partners, professionals, surrogates, donors, donor-conceived people and their families all to have access to relevant and impartial information.	POSITIONING AND PROMOTING INFORMATION											
		ENGAGE-MENT										
	PILOT PATIENT FORUM											
	DATA REVIEW BOARD											
	TECHNICAL UPDATES TO WEBSITE AND CLINIC PORTAL											
Shaping the future												
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												
Diverse fertility service users and professionals to have information that is up to date and relevant on developments such as genome research and editing, DNA tests and screening, home genetic testing and AI.	MONITOR AI & OTHER NEW TECHNOLOGIES				FURTHER POLICY WORK TO PREPARE FOR ANY CHANGES RELATED TO NEW TECHNOLOGIES.							
Clinics to assess innovative treatments (including add-ons), and to encourage responsible innovation that improves current practice.					FUTURE WORK TO FOLLOW FROM CURRENT WORK ON THE ACT							
Objective 6: Preparing for future legislative and operational changes.												
To ensure the HFEA and clinics are prepared for future changes in the fertility field, and for any legislative changes.	RESPOND TO POSSIBLE LEGISLATIVE CHANGES				AS YET UNKNOWN							
		IMPLEMENTATION - STORAGE LIMITS							IMPLEMENTATION - SURROGACY (?)			

Strategy Areas: Outcomes sought:	2021/22				2022/23				2023/24			
	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar	Apr - Jun	Jul - Sep	Oct - Dec	Jan - Mar
To be a modern effective regulator and continue to respond to changes in our operating environment. Respond to changes such as the growth in donor-conceived people eligible to make 'opening the register' (OTR) requests from 2021 and 2023.	OPERATIONAL READINESS FOR GROWTH IN OTR REQUESTS								EMBEDDING OF NEW PROCESSES			

Treatment add-ons progress report 2020

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time
Meeting	Authority
Agenda item	7
Meeting date	11 November 2020
Author	Dina Halai, Scientific Policy Manager
Annexes	Annex 1: Summary findings of the website add-ons information survey

Output from this paper

For information or decision?	For decision
Recommendation	The Authority are asked to consider : • The approach to information provision for holistic/alternative therapies on the HFEA website: and • the best way forward on green rated 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. The Authority last discussed treatment add-ons in September 2019 and agreed next steps. The aim of this important work is to encourage and facilitate a culture change towards the responsible supply of treatment add-ons in fertility services, in line with the consensus statement agreed by 11 professional and patient bodies[1] in March 2018.

1.2. The aims of this paper are to:

- set out the work completed (sections 2 and 3) since the last Authority discussion;
- seek agreement on the way forward on two policy issues (holistic therapies, section 4 and 'green' rated add-ons, section 5); and
- summarise future activity on add-ons to September 2021 (section 6).

1.3. Addressing treatment add-ons is a key feature of our new organisational strategy for 2020-24. As far as we are aware, we are the first regulatory body in the world to attempt to tackle issues around unevidenced fertility treatment add-ons and we are at the forefront in developing unbiased information and tools to help patients make important decisions about their fertility treatment. This pioneering work is complex and is developing over time as we refine our policy approach in response to its impact on the ground.

1.4. To recap, treatment add-ons are extra to 'routine' fertility treatment and often claim to improve a patients' chances of having a baby. The evidence base for many add-ons is weak; there are few (if any) randomised controlled trials (RCT, the gold standard of clinical effectiveness) and few high-powered retrospective studies of effectiveness either. Yet despite this, add-ons are frequently being offered to patients at a charge.

1.5. The potential regulation of add-ons in the UK is complex. The HFEA does not have explicit regulatory powers that would allow it to control the introduction and uptake of treatment add-ons. We do, however, have powers that relate to the information that clinics must provide to patients so that they can make an informed choice, we also have some limited powers over the introduction of novel treatments and we can work with other regulatory bodies in respect of drugs, medical devices and advertising.

2. New treatment add-ons audit tool to improve clinic practice

2.1. In August 2020 the HFEA introduced a new audit tool for use by clinics and HFEA inspectors. The audit tool will be used 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.

2.2. The tool was tested in some clinics before introduction and received positive feedback, especially about its usefulness for the development of compliant practice. All clinics are now required to use

[1]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)

the audit tool. Where its specifications are not met, an action plan should be developed and documented by the clinic to ensure they are met within a reasonable time period.

2.3. Clinics were required to return their completed audit tool and action plan to address any non-compliances to their inspector by 1 October 2020. To date, 67 clinics have completed the audit (out of the 91 clinics that undertake relevant treatment activities) and inspectors are engaged with those that have yet to respond. These audits are active inspection documents which inspectors will be reviewing to prepare for upcoming inspections. The audit will allow inspectors to address non compliances and any items of significant concern with the centres on inspection.

2.4. An analysis of the completed audit tools will be undertaken shortly 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.

3. Update of our website add-ons information

3.1. A key element of our work on add-ons is the information we provide for patients on our website. First introduced in 2017, we provide a 'traffic light' assessment of the state of the evidence base for a number of the most widely available treatment add-ons. We have made a number of minor revisions since then, but in the last few months have undertaken a substantial update of all of the information on this part of our website. Throughout our aim has been to make the HFEA website information on treatment add-ons more accessible and informative for patients, key improvements include:

- Greater clarity of presentation - reducing the volume of information on the treatment add-ons main page and giving each treatment add-on its own separate page. This will allow space for more detailed information on each treatment add-on going forward. We have also made it easier to access the information by adding the treatment add-ons webpages to the 'Treatments' dropdown menu.
- Greater clarity on which add-ons will be considered for our list and how we allocate traffic light ratings - the revised information includes the criteria for add-ons to which we allocate traffic light ratings and to make it clear that the ratings indicate whether the evidence, in the form of *high-quality randomised control trials (RCTs)*, shows that a treatment add-on can safely improve the *live birth rate* for someone undergoing fertility treatment.
- Greater transparency about the process by which traffic light ratings are decided - the new text provides links to the Scientific and Clinical Advances Advisory Committee (SCAAC) webpage which lists the minutes and research papers used to make these decisions. This will inform patients and support clinicians when discussing the evidence base for effectiveness and risks of add-ons.
- A new process to allow medical professionals, academics or patients to propose that add-ons are added to the HFEA website – the aim is to provide greater consistency around how treatments are added to the traffic-light rated list of add-ons. The new form will trigger a HFEA review of the evidence for a treatment add-on where there is a concern that a treatment add-on is being irresponsibly offered to patients in a UK licensed clinic.

3.2. The website update was highlighted in the August Clinic Focus, the HFEA's newsletter for clinics, resulting in views for the main add-ons page rising by 8% (1,384) in the first week following the update. There were also an additional 1,066 page views (combined) on the individual treatment add-ons webpages. In the first month following the update, the page views were up by 85% in comparison with the same period in the previous year. This is clearly encouraging, and we will continue to follow the trends in page views.

3.3. Since its introduction there has been considerable debate about the information on the HFEA website about treatment add-ons. Some professionals like the traffic light ratings; others think they run the risk of being too simplistic. While that expert debate is healthy what matters most is the response of patients. We therefore conducted user testing to determine patients' understanding of the new information around treatment add-ons and the traffic light ratings. A summary of findings from the survey are at Annex 1. In essence, over 80% of patients surveyed found the information clear and useful, and majority understood the key elements of the traffic light rating system. However, it is also clear that some of the subtleties are not always understood and it is clear that we have more to do.

3.4. In addition to the survey findings, we will also consider the recent feedback from SCAAC about whether the traffic light assessment on our website should be drawn from an assessment of both effectiveness (at increasing live birth rate) and risk. Where there is no evidence to suggest a particular add-on is safe or it is unsafe there is an argument that this may be confusing. The SCAAC also recommended we consider whether the information we provide on reproductive immunology should be expanded as it covers a number of treatments which raise different issues for prospective patients.

3.5. The work set out above will be undertaken before March 2021. This will conclude the first substantial update of our add-ons information since it was published. Going forward, the website information will continue to be reviewed annually alongside the review of evidence and traffic light ratings to ensure that it continues to serve its purpose.

4. Should holistic/alternative therapies be part of our traffic light rated list of add-ons?

4.1. In recent years the range of holistic/alternative therapies that are marketed to fertility patients has increased. In response, the Authority requested in September 2019 that the Executive consider whether the most commonly opted for holistic/alternative therapies should be added to the list of treatment add-ons.

4.2. Although some fertility patients may choose to use holistic/alternative therapies, they are not a licensable activity and are often not offered in a licensed fertility clinic. However, occasionally patients do come to us for advice about the use of holistic/alternative therapies in fertility treatment and there is therefore an argument that it would be appropriate for us to publish information about them on our website. Furthermore, if holistic/alternative therapies were being offered with the claimed benefit of increased live birth rate, that would additionally support the need to have such therapies as part of our traffic light rated list of add-ons.

4.3. In July 2020 we looked at which holistic/alternative therapies are offered within licensed clinics and which of these are offered with the claimed benefit of increased live birth rate. We conducted

a survey of 214 clinic websites (106 licensed centres and 108 satellite centres). The results were as follows:

- Most licensed and satellite clinics did not offer any holistic/alternative therapies on their websites (65.4%, n=140), although that still leaves a significant minority that do.
- The holistic/alternative therapy most offered on clinic websites was acupuncture (25.7%, n=55), followed by reflexology (6.5%, n=14), yoga (6.1%, n=13) and nutrition/supplements (4.2%, n=9). There were six other holistic/alternative therapies mentioned on the surveyed websites, however these were not commonly offered with less than 1% of websites mentioning them.
- Only two websites made any claims of an increased chance of live birth after using a holistic/alternative therapy (ie for acupuncture and nutrition/supplements). HFEA inspectors will speak to these in line with their compliance processes.
- Most licensed clinics and satellite centres that highlight holistic/alternative therapies suggested that they could be used in addition to routine treatment to help with the stress of treatment.

4.4. We have not gathered information on holistic/alternative therapies offered with the claim of increasing live birth rate within clinics and during consultations.

4.5. In the light of our findings, the Authority are asked to consider the following approach to information provision for holistic/alternative therapies on the HFEA website

- Not to include holistic/alternative therapies as part of our traffic light rated list of add-ons for now because the majority of clinic websites (99%) do not offer them with the claimed benefit of increased live birth rate. Going forward if a medical professional, academic or patient organisation feels that there is a holistic/alternative therapy being offered at a UK licensed clinic with the unevidenced claim that it will increase live birth rate, then they are able to apply to propose that treatment for inclusion in the HFEA's traffic-light rated list.
- However, with a third of clinics offering holistic/alternative therapies on their website, there is a need for the HFEA to provide information for patients on holistic/alternative therapies that are most commonly offered during fertility treatment on the HFEA website. This information would be published separately to the treatment add-ons information.

4.6. Should the Authority agree with this approach, going forward we will add information on holistic/alternative therapies to the HFEA website without traffic light ratings, and will carry out communication activities to inform clinics and patients of the update.

5. Should green rated treatment add-ons be listed as part of our traffic light rated list of add-ons?

5.1. The HFEA website classifies treatment add-ons as either red, amber or green. A green symbol for an add-on would be awarded where there is more than one good quality RCT which shows that the procedure is effective at improving live birth rates and is shown to be safe for patients to use. At present, none of the add-ons reviewed by the HFEA are rated green.

5.2. The absence of a green rated add-on has led to a debate about whether it is even appropriate to think of an add-on in those terms. If a particular treatment, drug or piece of equipment can be shown to improve the chances of a live birth, there is a good argument that it should be part of routine treatment, rather than something that patients have to choose separately. In a majority private sector market any such choice involves additional cost to the patient.

5.3. Others argue that the absence of any green add-ons in the current traffic light ratings may mean that some patients look more favourably than the evidence suggests they should on add-ons rated as amber, seeing them as the 'best' add-on available. Moreover, the evidence base for some add-ons may vary with different categories of patients so that in say, younger women, a particular treatment may be classified as green, but amber in older women. Without a green rating that difference in outcomes would be lost.

5.4. This is clearly a complex issue and one which is made more difficult by the absence of any agreed definition as to constitutes an add-on treatment. The original policy intention of our work on add-ons was to provide patients with an independent assessment of the evidence of effectiveness of the most commonly available add-ons. Given the continuing availability of add-ons and the varying claims made for their effectiveness, that remains a valid and necessary policy objective for the HFEA.

5.5. However, in thinking about the traffic light ratings it is important not to lose sight of the primary purpose of this work: to provide patients with an assessment of those add-ons where there is no robust evidence of their effectiveness. In other words, the red and amber ratings matter more than the green. Viewed through this lens the current absence of a green add-on is not a significant issue.

5.6. In the light of this brief discussion the Authority is asked for a steer on how best to take forward the issue of green rated add-ons; should we:

a) Continue, for the time being, with the current position which assumes that the primary purpose of the traffic light rating system is to highlight where the evidence for effectiveness is not robust. Under this approach, should an add-on be rated green it would then be considered part of routine treatment; or

b) Decide that where an add-on is rated green it should be listed as part of our traffic light rated list of add-ons. That might mean, for example, that a green add-on was listed for a period of time to show how the evidence had changed. Were we to take this approach, we would seek to limit the consideration of the list of add-ons to those currently listed on the HFEA website.

6. Additional future work planned (until September 2021)

6.1. The Treatment Add-ons Working Group (TAG) made up of the 11 signatories of the consensus statement will next meet on 24 November 2020. At that meeting the HFEA will propose the following priority work areas:

- Develop information to empower patients to ask questions e.g. a checklist of what questions patients should be asking their clinician before accepting a treatment so that they are informed about the risks involved and possible outcomes before consenting.

- Create guidance and/or policy and/or training for clinicians, nurses, embryologists about understanding the evidence base around treatment add-ons so that there is consistency in how clinicians make judgements about the quality of the evidence and whether it supports the use of that treatment. This work could also support clinicians in explaining the evidence base to their patients.

6.2. Review the HFEA's existing information on the legal requirements for informed consent under Montgomery2 and carry out communication activities to re-reiterate the principles about informed consent for treatment add-ons. This will include encouraging provision of information on the financial and psychological impact of treatment as part of the consenting process.

6.3. Consider what data we would need to collect to establish an understanding of the use of treatment add-ons in the sector. That work would start by collating the existing data which is currently part of the PRISM data dictionary (assisted hatching and PGS) to assess the quality of data collected. The second stage would be to assess what data points we would want to collect for treatment add-ons as a whole and what we could use them for. Any decision to go forward on this work would require Authority decision.

[2] https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf. The Montgomery decision redefined the standard for informed consent and disclosure in the UK to a new, patient-focused standard: revolving around whether "a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it."

7. Annex 1: Summary findings of the website add-ons information survey

7.1. Introduction - The online survey was aimed at patients who have recently undergone or are planning to undergo fertility treatment. The survey was publicised on our website and through social media channels. We also sent the survey link to our professional stakeholder and patient groups to share on their social media platforms and websites. The survey closed on 11 October 2020 with 122 people having completed it.

7.2. Cohort - The survey was fully completed by 122 participants. Almost nine in ten (87%) had undergone treatment within the last two years, and 8% within the last three to five years. Just 2% had received treatment more than five years ago, with 2% not having yet started. Around two-thirds of those surveyed (65%) had received one to three cycles of treatment, with a quarter receiving four to six cycles (25%). Just seven percent had received more than six cycles.

7.3. Findings:

7.3.1. Four in five (83%) participants found the content easy to understand. A similar proportion (80%) thought that the content was helpful for patients who are thinking about, or are going through, fertility treatment (including fertility preservation) in making an informed choice about treatment add-ons. Around two-thirds (64%) thought the website had the right amount of detail, with slightly fewer (57%) considering the site to be clear about what type of evidence is used to allocate a traffic light rating.

7.3.2. Over three-quarters (77%) correctly stated that HFEA's traffic light rated list of add-ons related to additional treatment to routine IVF, DI or IUI. However, only two in five (44%) correctly attributed it to treatments that carry risk and are unproven at increasing the chances of having a baby.

7.3.3. Two in five (43%) incorrectly stated that the traffic light process related to every treatment add-on that a patient could be offered in a UK clinic – the same proportion as the correct answer, which was that they related to add-ons for which there is not enough evidence to show an increase in the chances of having a baby (43%). Only 12% correctly stated that they referred to treatment add-ons that are not proven to be safe.

7.3.4. Most participants (93%) correctly stated that the ratings gave an indication of the strength of evidence to show that a treatment could increase the chances of having a baby.

7.3.5. When looking at understanding around red traffic lights specifically, the majority (87%) correctly stated that there is no evidence to show that the treatment can improve the chances of having a baby.

7.3.6. Looking at amber ratings, around three-quarters (76%) agree that this means the evidence is not conclusive for this treatment. However, only around a quarter (27%) think that it means treatment should not be recommended for routine use for increasing the chances of having a baby.

7.3.7. For green ratings, four in five (83%) agree that it means there is robust scientific evidence to support the use of this treatment. However, less than half (48%) thought that the rating meant that treatment was proven to be safe for patients to use.

Compliance and Enforcement report

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:	8
Meeting date:	11 November 2020
Authors:	Rachel Cutting, Director of Compliance and Information Catherine Drennan, Head of Legal
Annexes	Annex A – draft Compliance and Enforcement Policy

Output from this paper

For information or decision?	For decision
Recommendation:	That members approve the revised draft version of the Compliance and Enforcement Policy to go out for consultation and the proposed timeline for the consultation and implementation
Resource implications:	N/a
Implementation date:	April 2021
Communication(s):	
Organisational risk:	High

1. Introduction

1.1. It is good practice that all regulatory bodies have a public policy setting out how they regulate. The specifics will vary depending on the sector regulated and the statutory or policy framework in place, but essentially the aim of any such policy is to provide a public statement of *when* and *how* regulatory action will be taken. The current HFEA Compliance and Enforcement Policy (C&E) was approved by the Authority in 2016.

1.2. The proposed new HFEA C&E policy (at Annex A) is a public statement of the process that will be followed by inspectors to determine *when* regulatory action is necessary and crucially, in those cases where regulatory action is necessary, it provides a clear statement of what action clinics can expect us to take. The policy aims to provide a clear framework to guide the compliance team when difficult decisions need to be made when non-compliances found on inspection or from incidents, or indeed that might arise in other circumstances, raise concern. The policy is an overarching document which refers to other operational procedures in the licensing process.

1.3. Whilst implicit in all our regulatory activity, the new C&E policy provides for the first time a public statement of our regulatory aims i.e. what it is that we wish to achieve through our regulatory activities. The policy can best be described as a route that will be followed to achieve those regulatory aims in various scenarios. The policy importantly also reflects the principles of best regulatory practice under which regulatory activities should be transparent, accountable, proportionate, consistent, and targeted only at cases in which action is needed.

1.4. The policy aims to provide clarity as to when regulatory action will be taken, what regulatory action will be recommended and achieves greater transparency and drives a more consistent and proportionate approach to regulatory action.

1.5. This paper sets out the rationale for updating the C&E policy and highlights where this new draft policy has been developed and changed from the previous version.

1.6. The Authority is asked to approve the regulatory aims, comment and advise on the proposed policy and approve a focussed consultation with the sector before a final version is agreed at Authority in March 2021 with a planned implementation date of 1st April 2021.

2. Background

2.1. The C&E policy is used to guide the compliance team when evidence of regulatory non-compliance at a licenced centre is found or when information we have received suggests that there may be non-compliance.

2.2. In most cases non-compliances identified on inspection are low risk and do not pose immediate or direct risk to patients, gametes, or embryos. Such non-compliances can usually be addressed through informal engagement, or what will from now on be referred to as ‘standard actions’, between inspectors and clinic staff and improvements can be quickly implemented.

2.3. Non-compliances posing more serious risk may warrant a recommendation to licence committee, for more stringent regulatory action. The escalation of concerns should be undertaken through a

process which is managed consistently, fairly, and transparently. The process must be able to stand up to legal challenge. This revised policy will mitigate the risk that centres feel they have been treated unfairly or disproportionately.

2.4. The proposed new C&E policy will not place any new or additional requirements on licenced centres, instead, as stated above, it establishes a clear framework for addressing non-compliances or suspected non-compliances to ensure a more consistent approach to regulatory action.

2.5. The policy has been developed in consultation with the compliance team and has been used to work through previous inspection reports to check for consistency and ease of application.

2.6. Throughout this paper references to the current inspection methodology do not consider the impact of the Covid-19 pandemic. Due to Covid-19 a change of inspection methodology has been necessary. Currently an upfront desk-based analysis approach and a shortened but more focussed on-site inspection are utilised to highlight where improvements are required. This approach, as part of the wider compliance strategy, will be monitored and reviewed as part of the wider project to improve and modernise the inspection process.

3. The Revised Policy

3.1. The proposed new C&E policy has been developed so it can be used for any aspect of compliance activity: scheduled and unscheduled clinic inspections, clinic visits (other than 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.

3.2. 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 step by step approach to determining what regulatory action to take. This is the principle innovation in this policy and one that should result in greater consistency for clinics.

3.3. The proposed policy has a risk-based approach to regulatory action and ensures consistency by following 5 steps:

1. assessing likelihood

2. assessing impact

3. using the defined levels of likelihood and impact to determine the risk score

4. working through a series of mitigating and aggravating factors, or at least those relevant in the particular circumstances, to determine whether the initial risk score reflects the broader context in which the clinic operates

5. determine what regulatory action should be recommended by using the Regulatory Action table (RAT)

3.4. The first three steps use a classic risk scoring matrix system which will result in a score. The matrix looks at impact and the likelihood of the issue arising if no action is taken. Having determined the risk score, one proceeds to the fourth step where the broader context within which the clinic operates is considered.

3.5. In step 4 the PR's actions as well as any mitigating and aggravating factors will be taken into account. Having considered these factors, the inspector will then form a view on whether, or to what extent, he or she is concerned and may adjust their initial risk score accordingly. The mitigating and aggravating factors are not exhaustive but will aid the inspectorate in making fair and reasonable judgements and assist in reaching a proportionate outcome. Examples of mitigating and aggravating factors are detailed in the policy.

3.6. The inspector will then plot the risk score on the RAT. The higher the score the more serious the action that will be taken. The RAT will indicate whether Standard, Formal or Statutory Enforcement is appropriate or should be recommended.

3.7. Regulatory action has been grouped into Standard, Formal and Statutory Enforcement Action representing an escalating scale proportionate to the risk score. The RAT details what regulatory action should be taken and in the context of licensing matters, recommends the length of licence which should be granted. This is so as to ensure that there is a distinction between the Standard Regulatory action that will be taken in the case of a clinic which is very low risk and very low concern as compared to a clinic which is very high risk.

4. Next Steps

4.1. Following integration of comments and advice from Authority members the proposal is to consult for a period of 4 weeks in January 2021 through seeking feedback on the draft policy through clinic focus, members of the Licenced Centres Panel and principal professional stakeholders.

4.2. Once feedback has been reviewed and incorporated into the policy members will be asked to review and agree the final policy to be issued from 1st April 2021.

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 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 principles of best regulatory practice, including the principles under which regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed.

3. This policy and the procedures set out in this document aim to ensure fairness and consistency in the Authority's compliance and enforcement activities and will 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 standard and formal regulatory actions that may be taken by an inspector, some of which may be taken without recourse to a licensing committee i.e. during post-inspection monitoring or other informal engagement with clinics. The Authority's inspection activities are a statutory requirement. The reports produced by inspectors following an inspection or clinic visit are usually considered by the Authority's licensing committee which has delegated authority to make a range of licensing decisions. This policy sets out the range of statutory enforcement action that may be recommended by an inspector in a report submitted to the Authority's licensing committee.

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 procedures set out in this policy will be followed by inspectors 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 be followed.

7. 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.

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

7.2. Is regulatory action necessary to ensure the quality and safety of gametes or embryos;

7.3. Is regulatory action necessary to maintain public confidence in the regulatory scheme; and

7.4. 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.

8. If one or more of the questions at paragraph 7 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

9. 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 thus what the most proportionate regulatory action will be.

10. 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.

11. 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 clearly documented on each occasion.

Risk Grading

12. 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:

12.1. risk of harm to patients, partners, donors, gametes or embryos, or any child(ren) that may be born as a result of proposed treatment.

12.2. risk of harm to staff.

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

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

13. 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 materialise. 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.

14. 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 and is a qualitative assessment.

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

Very unlikely – meaning rare, something that will probably never happen or recur;

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

Possible – might happen or recur occasionally;

Likely – will happen or recur but it is not a persisting issue or set of circumstances;

Almost certain – will undoubtedly happen or recur more than once or on a frequent basis.

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.

STEP 2: Assessing Impact

17. Impact refers to the consequences or harm that will be caused if a risk materialises; 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 24 below) and harm may include physical, psychological or emotional injury or trauma.

18. Inspectors will consider how a risk factor has affected or may affect patients, partners, donors, recipients, the quality and safety of gametes or embryos, the unborn child and/or clinic staff.

19. **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 of a short-term or non-permanent nature requiring support of any sort or other remedial action (e.g. informing the patient of the incorrect date for egg collection or frozen embryo transfer, failure to screen patients and partners within the specified timeframes);

A moderate impact causes semi-permanent 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 long-term permanent 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 permanent harm or damage to patients, partners, donors, 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:	Impact the risk has had or may have:
1. **Very unlikely** – meaning rare, something that will probably never happen or recur 2. **Unlikely** - not expected to happen or recur but it may 3. **Possible** - might happen or recur occasionally 4. **Likely** - will happen or recur but it is not a persisting issue or set of circumstances 5. **Almost certain or has already materialised** - will undoubtedly happen or recur more than once or on a frequent basis	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 of a short-term or non-permanent nature requiring support of any sort or other remedial action (e.g. informing the patient of the incorrect date for egg collection or frozen embryo transfer, failure to screen patients and partners within the specified timeframes) 3. **Moderate** - causes semi-permanent 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 long-term permanent 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 permanent harm or damage to patients, partners, donors, recipients 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		**Very unlikely**	**Unlikely**	**Possible**	**Likely**	**Almost certain/has materialised**
		Likelihood of risk materialising if action is not taken				

STEP 4

20. 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 23 and 24 below). Aggravating and mitigating factors may be both directly and indirectly related to the likelihood of the risk materialising and the impact that it may have. Any aggravating and mitigating factors considered will be documented.

21. By section 17 of the 1990 Act, the Person Responsible (PR) has overall statutory responsibility and must ensure among 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 PRs by statute, the inspector, in determining a clinic's final 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 25 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, and any professional codes of conduct they are bound by.

22. This step is an opportunity for the inspector to reassess and if necessary, adjust the initial 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 initial risk score and the factors considered in making the adjustment will be documented.

Mitigating 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. Whether the PR has demonstrated insight i.e. has the PR reflected on the issue, recognised the shortcomings and accepted that things should have been done differently to avoid the scenario arising; has the PR taken timely and appropriate remedial action;

23.2. Whether the PR has recognised the impact or potential impact on patients or donors and done the right thing in response (this may include making full disclosure to patients or donors, offering an apology, offering appropriate support, financial remediation, or further treatment at no or low cost).

Understanding requirements

23.3. Whether the PR understands the requirements or standards that they are expected to meet and recognised where or in what way the clinic has fallen short; has the PR taken responsibility for the non-compliances or for enabling a situation or circumstances that resulted in the non-compliance(s);

23.4. Is the PR taking remedial action or establishing an action plan; did the PR do so proactively and within reasonable timescales or has the PR shown reluctance to act at all or within reasonable timescales;

Cooperation

23.5. Whether the PR has fully co-operated with inspectors regarding the current issue i.e. has the PR answered questions honestly and provided information freely; made full disclosure regarding the circumstances of any non-compliances; has the PR encouraged his or her staff to be cooperative and open with inspectors; has the PR provided information within the timescales agreed or specified;

Aggravating factors

24. 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

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

24.2. Failure to investigate patient complaints and 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 or donors.

Compliance with and understanding of requirements

24.3. The number and seriousness of any non-compliances identified i.e. other, critical, or major failure to take the initiative to address non-compliances or the consequences of non-compliances.

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

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

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

24.7. 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.

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

24.9. Disregard for the system of regulation including repeated or ongoing breaches of the statutory framework and repeated or ongoing failure to comply with recommendations for remedial action within the specified timescales or at all.

Co-operation

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

24.11. Failure to respond to inspector's reasonable requests including requests made during an inspection, investigation or another clinic visit.

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

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

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

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

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

24.17. Abuse of trust or position.

The Person Responsible

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

25.1. fulfilled their duties under section 17 of the 1990 Act;

25.2. acted with integrity and shown insight;

25.3. been cooperative, fully engaged and responsive in their dealings with inspectors and any affected patients or donors;

25.4. taken responsibility for what has happened;

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

25.6. demonstrated that they will embed and sustain the required improvement or changes;

25.7. been open, transparent and honest in their dealings with inspectors and affected patients, partners, or donors;

25.8. been proactive in ensuring compliance and implementing corrective actions.

Step 5: Regulatory Action Table (RAT)

26. The final risk score calculated in Step 4 will, by reference to the Table below, determine what regulatory action is required and in the context of licensing matters, will determine what length of licence is recommended in any report to be presented to the licensing committee. Actions may include standard action, formal action or statutory enforcement action. These actions are defined below in paragraphs 27 and 28, and at paragraph 29, a summary of the range of statutory enforcement actions that may be taken under the 1990 Act are set out.

Risk score 1-4	**Risk score 5-9**	**Risk score 10-12**	**Risk 15-16**	**Risk 20 - 25**
Standard action(s) requiring response within reasonable timeframes	Standard action(s) requiring more intensive scrutiny or shorter response timeframes (e.g. additional audits, seeking legal advice)	Standard and Formal action(s) requiring urgent and/or immediate interventions or actions	Formal action(s) requiring immediate interventions or actions	Statutory enforcement 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; recommendation that PR not suitable	Revocation or immediate/ongoing suspension of licence

27. Standard 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 time frames agreed to by the PR.

27.3. Promoting awareness of requirements and the need for appropriate remedial action.

28. Formal 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 undertakes to take certain prescribed actions or agrees to cease prescribed activities within a specified time (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 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 time.

28.6. Referring the case for consideration by the Licence Committee1 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 the Licence Committee1 with a recommendation for a licence in accordance with the Authority's Guidance on Licensing.

28.8. Where professional codes of conduct may have been breached or where the regulatory requirements or standards of another regulatory body may have been breached, a recommendation that the individual 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.

29. Statutory Enforcement action:

29.1. The Authority's statutory enforcement powers are limited to revocation of licences (section 18), variation of licences otherwise on application of the PR or licence holder (section 18A) and immediate suspension of licenses (section 19C).

29.2. In any case in which the RAT indicates statutory enforcement action, a management review will be held before further steps are taken. Statutory enforcement will only be

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* The licensing committee considering any matter has full discretion as to its decision and may or may not follow the recommendation made by the inspector. The committee's decision may result in greater or lesser regulatory or statutory enforcement action being taken.

recommended following a management review at which a Senior Inspector, the Chief Inspector and/or the Director of Compliance are in attendance.

29.3. A minute will be kept of any management review meeting where statutory enforcement 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 the relevant statutory tests can be met.

29.5. Statutory Enforcement may include referring the case for consideration by a licensing committee* with a recommendation that:

29.5.1. the PR has failed to fulfil their section 17 duties and is not suitable to remain PR and recommending the appointment of someone else as PR;

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

29.5.3. 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.

29.5.4. 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;

29.5.5. with a recommendation that the licence should be revoked under section 18(2) of the 190 Act.

30. Procedure where recommendations for statutory enforcement action are made

30.1. In cases in which a recommendation for statutory enforcement action has been made and the 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 timeframe 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 and 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.

33. 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

EU exit: HFEA preparations for the end of the transition period

Details about this paper

Area(s) of strategy this paper relates to:	The best care – effective and ethical care for everyone The right information – to ensure that people can access the right information at the right time Shaping the future – to embrace and engage with changes in the law, science and society
Meeting:	Authority
Agenda item:	9
Meeting date:	11 November 2020
Author:	Emily Tiemann, Regulatory Policy Manager Andrew Leonard, Senior Inspector Catherine Drennan, Head of Legal
Annexes	Annex 1: Imports and Exports to or from clinics in Northern Ireland Annex 2: Background information on General Directions, Licence conditions

Output from this paper

For information or decision?	For decision
Recommendation:	Approve arrangements relating to the Authority's preparedness for the end of the Transition Period including delegating authority to the Chair to make decisions in relation to practical implications of EU Exit.
Resource implications:	Allocated budget to allow for expenditure relating to the end of the transition period and external legal advice when required.
Implementation date:	31 December 2020
Communication(s):	As set out in the paper primarily to licensed treatment and storage centres.
Organisational risk:	Medium

Background

1.1. The United Kingdom (UK) officially left the European Union (EU) on 31 January 2020. The Withdrawal Agreement with the EU came into force and the UK entered a transition period (TP) which will end on 31 December 2020. Arrangements at the end of the TP will either be based on the Withdrawal Agreement only, or also on a Free Trade Agreement concluded with the EU, negotiations for which are ongoing at the time of writing.

1.2. The Withdrawal Agreement contains the Northern Ireland Protocol (NIP) which will respect the fact that Northern Ireland (NI) is an integral part of the customs territory of the UK and respect the need to bear as lightly as possible on the everyday life of NI. Although there will be some new administrative requirements, the government's aim is for these to be streamlined and simplified to the maximum extent. Under the NIP, NI will continue to enforce EU customs rules and follow its rules on product standards. Under the Withdrawal Agreement the rest of the UK will stop following those rules, meaning some new processes on movements between Great Britain (GB, i.e. England, Scotland and Wales) and NI. The government aims to reduce them to the absolute minimum so that the integrity and smooth functioning of the UK internal market is protected.

1.3. This paper sets out the preparations the HFEA is making for the end of the TP, particularly for the implementation of the NIP and The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020. These preparations will ensure that at the end of the TP, the regulatory framework reflects the legal and practical reality of the country having left the EU, and ensure that clinics understand the regulatory framework. These changes are required regardless of whether a Free Trade Agreement between the UK and the EU is concluded.

1.4. Section 2 below on the legal impact outlines specific changes to our regulatory framework as a result of new regulations and their impact on existing General Directions, Licence Conditions and other matters. Given the focus of the NIP, the changes will primarily affect movement of gametes and embryos, traceability and reporting. Section 3 outlines the impact on regulation, and looks at how the HFEA will continue to regulate clinics in Northern Ireland after the end of the TP. Though this will require changes to the way that the HFEA carries out elements of its work, it is important to note that most of our regulatory framework will remain the same. Finally, section 4 outlines how we will communicate these developments.

1.5. There are currently four HFEA licensed clinics in NI providing approximately 2,300 cycles per year.

2. Legal impact

2.1. The **EU Tissues and Cells Directives** (EUTCDs) have been transposed into domestic UK law, meaning licensed fertility clinics in the UK will continue to meet the EU standards of quality and safety after the end of the TP.

2.2. The **Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020**: The 2020 Statutory Instrument (SI) is the means by which the NIP is implemented in so far as it relates to reproductive tissues and cells (gametes and embryos).

2.3. The **Human Fertilisation and Embryology Act 1990** will continue to apply UK wide, with certain provisions applying in relation to NI only and, in some instances, to GB only. To reflect this, certain changes have been made to General Directions, Licence Conditions, and to the Special Direction decision tree, as well as to relevant application forms and templates. These can be found in the Annexes to this paper. Any necessary changes will also be made to the Code of Practice at the time of the next update (October 2021), including a new dedicated 'Guidance Note' specific to regulation in Northern Ireland (NI).

2.4. **Movement of gametes and embryos into and from NI and GB:** After the end of the transition period] countries within the EEA will become 'third countries' to the UK but will not be treated as 'third countries' to NI due the provisions of the NIP. The EEA includes the EU Member States, Iceland, Liechtenstein and Norway.

Previously, an Importing Tissue Establishment (ITE) import certificate was needed if a clinic in the UK wished to import gametes or embryos from outside the EEA or Gibraltar (i.e. from a third country). After the end of the TP, the definition of what a third country is will change depending on whether a clinic is in GB or NI, and therefore the need for an import certificate will also change.

We have amended the ITE import certificate application form which clinics will find in the clinic portal and have produced a flow chart that clinics can use to identify whether an ITE import certificate application is required. These will be provided to clinics in advance of the end of the TP so they can start to plan. After the end of the TP the need for an import certificate will be as follows:

- For clinics in Great Britain: Imports of gametes and embryos from all countries outside the UK (GB and NI) will be third country imports and will need an ITE import certificate from the HFEA.
- For clinics in Northern Ireland: Imports from all countries outside the EEA will be third country imports and will need an ITE import certificate from the HFEA. This will include movements from GB into NI.
- The NIP ensures unfettered access for Northern Ireland to the UK market.

See annex 1 for more detailed information about imports and exports to and from NI, and movements to and from GB.

To account for the different arrangements, we have produced two versions of General Direction 0006 on Import and Export of Gametes and Embryos, one for clinics in NI and one for clinics in GB. Where clinics seeking to import or export cannot satisfy the requirements of the relevant schedule under GD0006, as has always been the case, application can be made to the Authority for a Special Direction (SD) authorising the import or export. The SD application form and associated 'Further Information Sheet', as well as the decision tree for SD applications for import/export used by the Statutory Approvals Committee, have been/will be revised to account for changes to General Direction 0006. For more information on changes to other General Directions and changes to Licence Conditions, see annex 2.

2.5. **Reporting functions:** The requirements for the HFEA to report to the EU as the Competent Authority in NI (CA-NI) will remain for the activities of centres in NI. The UK and EU have agreed that for the purposes of the NIP, we will continue to have access to relevant EU databases. The HFEA will have no responsibility to report data to the EU concerning the activities of centres in GB after the TP.

3. HFEA regulation in Northern Ireland

3.1. After the TP the HFEA will remain the CA-NI and will continue to regulate licensed clinics and embryo research in NI in line with the requirements of the HFE Act 1990 (as amended) to reflect the provisions of the NIP. Some HFEA staff will have roles specific to the CA-NI function of the HFEA, in addition to their roles for the HFEA in GB.

3.2. The regulatory scheme that we currently follow will be applied across GB and NI equally, apart from the differences discussed in this paper specific to The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020.

3.3. After the TP there will be some changes to this legislation which mean that provisions which apply in NI will not apply in GB and vice versa. Other than to the extent dictated by these changes, the same regulatory scheme will be applied consistently across all clinics regardless of

location. Regulatory changes in GB and the EU will be reviewed on an ongoing basis so that the regulatory scheme applied in NI remains compliant with the terms of the NIP. Over time, there may be more significant differences should EU and GB rules diverge.

3.4. The HFEA will be the CA for Northern Ireland and use common staff and committees to inspect and licence clinics in both Great Britain and Northern Ireland.

4. Communication

4.1. We have periodically updated licensed clinics with information relating to EU exit as well as passing on information we have received from the Department of Health and Social Care and had a dedicated area on the Clinic Portal with relevant information. The changes outlined in the revised General Directions and licence conditions will be communicated to centres via a Chair's Letter and we will also issue a 'special edition' Clinic Focus on the changes resulting from the end of the TP.

4.2. To understand changes to guidance brought about by EU Exit, clinics will need to read and adhere to the guidance and information set out in the Chair's letter and the requirements in the revised versions of General Directions and Licence Conditions specific to their jurisdictions, notably concerning movement of materials and traceability. The flowchart will help clinics navigate the changes in relation to import and export, and movements from GB to NI.

4.3. At the end of the TP, the UK is leaving the Single Market and Customs Union, meaning that there will be significant changes at the GB-EU border. The HFEA wrote recently to ask all treatment and/or storage centres to undertake an 'End of the Transition Period risk assessment' in preparation for the end of the transition period. We asked that control measures are in place to mitigate, as much as is feasible, all the risks identified in these risk assessments. The HFEA will be seeking confirmation from clinics that the 'End of the Transition Period risk assessment' has been undertaken, and all risks identified have been controlled.

4.4. We take part in periodic meetings with other ALBs and the relevant minister to update on the situation as the end of the TP nears. We are also in regular communication with DHSC officials and other health ALBs regarding overriding risks relating to the end of the transition period, the Covid-19 pandemic and the winter season. We have been asked for reassurances relating to the readiness of the organisation and those we regulate for the end of the TP.

5. Recommendation

5.1. The Authority is asked to:

- Note the arrangements relating to the Authority's preparedness for the end of the transition period.
- Delegate to the Chair the power to make any decisions in relation to the end of the transition period and practical implications of this including General Directions, Licence Conditions and any other matters.

Annex 1

Table 1, Imports 2018-19: Total number of imports of sperm, eggs and embryos into all centres in NI from third country providers inside and outside the EU (each import may comprise several straws or vials of a provider's gametes). Approximate numbers.

EU/Non-EU	Sperm 2018	Sperm 2019	Eggs 2018	Eggs 2019	Embryos 2018	Embryos 2019	Total 2018	Total 2019
NI total (EU)	58	69	0	0	0	0	**58**	**69**
NI total (non-EU)	8	1	3	0	0	0	**11**	**1**

Table 2, Exports 2018-19: Total number of exports of sperm, eggs and embryos from all centres in NI, to tissue establishments inside and outside the EU (each export may comprise several straws or vials of a provider's gametes). Approximate numbers.

EU/non-EU	Sperm 2018	Sperm 2019	Eggs 2018	Eggs 2019	Embryos 2018	Embryos 2019	Total 2018	Total 2019
NI total to EU	1	1	0	0	0	1	**1**	**2**
NI total to non-EU	0	0	0	1	1	0	**1**	**1**

Annex 2

Background information on GD 0013 and GD 0009

In 2018 we implemented the Single European Code (SEC) based on requirements set out in EU Directive 2015/565 (the Coding Directive) which amended the Second Technical Directive (2006/86/EC) in 2015. After the TP, to ensure compliance with section 24(12) of the Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020, clinics in Great Britain (GB) will no longer need to apply a SEC while clinics in NI will still need to do so. In GB, Directive 2006/86/EC will be applied as it was before it was amended by Directive 2015/565, while in NI, the 2015 amended version of Directive 2006/86/EC will be applied. We have therefore produced two versions of General Direction 0013 on Traceability of Gametes and Embryos, one with reference to the SEC, which will apply to clinics in NI, and one without reference to the SEC which will apply in GB. Clinics in GB will need to implement procedures to ensure that all gametes and embryos, and all relevant data relating to anything coming into contact with those gametes or embryos are traceable from procurement of gametes to patient treatment or disposal and vice versa. The information needed is listed in the new GB version of GD0013. Centres in GB must also ensure that all containers (dishes, vials, ampoules, tubes etc.) used in the course of procurement, processing, use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier.

We have also produced new versions of General Direction 0009 on Keeping Gametes and Embryos in the Course of Carriage Between Premises, to reflect the changes brought about to Sections 24 of the HFE Act in relation to GB.

Revised Licence Conditions

Clinics in GB will be required to comply with revised versions of Licence Conditions T100 and T101 which exclude reference to the SEC but include the need for a unique and accurate identification of each

patient/donor, date and place of procurement, type of treatment, and a description of any products associated with and all processing steps applied to the procurement, use and storage of any gametes and embryos.

For clinics in GB we have also revised Licence Conditions T20 and R49 to remove reference to Directive 2003/94/EC, as well as License Conditions T31 and R60 to remove reference to Council Directive 93/42/EEC and Directive 98/79/EC of the European Parliament, and replace these with Medical Devices Regulation 2002 (UK MDR 2002), which were amended by the 2019 EU Exit Regulations and further by the 2020 EU Exit Regulations.

Another change for clinics in GB is the introduction of the UKCA (UK Conformity Assessed) marking, which is a new UK product marking that will be used for goods being placed on the market in GB. This covers most goods which previously required the CE marking, meaning that T30, T51, T53, R59 and R67 will be amended for clinics in GB.

Background note:

Under the Human Fertilisation and Embryology Act 1990, we have the power to issue Directions – or rules. Directions can be 'general' which apply to all clinics and centres, or 'special' which apply to individual licensed clinics/centres. These can be found on our website here.

We also grant licences to fertility clinics and human embryo research centres and provide a list of Licence Conditions which must be followed to allow continuation of a clinic's licence. These can be found on our website here.

We are in the final process of reviewing the General Directions and Licence Conditions that will be amended for fertility clinics and they are currently undergoing a legal check.