Authority meeting held by teleconference

Date – 16 September 2020

Venue - Online

Agenda item	Time
1. Welcome, apologies and declarations of interest	3:00pm
2. Minutes of the Authority meeting held 17 August 2020	3:05pm
3. Performance report	3:10pm
4. Covid-19 updates	3:30pm
5. PRISM	3:45pm
6. Business planning 2020-22	4:00pm
7. Equality and diversity	4:15pm
8. Marking 30 years of the HFEA – planning for 2021	4:35pm
9. Any Other Business	4:55pm
10. Close	5:00pm

Minutes of the Authority meeting on 17 August 2020

Details:			
Area(s) of strategy this paper relates to:	Safe, ethical effective treatment/Consistent outcomes and support/Improving standards through intelligence		
Agenda item	2		
Meeting date	16 September 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 17 August 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 17 August 2020 held via teleconference

Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Anthony Rutherford Emma Cave	Jonathan Herring Ruth Wilde Yacoub Khalaf Kate Brian Anne Lampe
Apologies	Ermal Kirby Gudrun Moore	
Observers	None	
Staff in attendance	Peter Thompson Clare Ettinghausen Rachel Cutting Catherine Drennan	Joanne Triggs Helen Crutcher Debbie Okutubo

Members

There were 10 members at the meeting – six lay members and four professional members.

1. Welcome, apologies and declaration 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 the previous meeting 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. Apologies for absence were received from Ermal Kirby and Gudrun Moore.

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 extraordinary meeting

2.1. Members agreed that the minutes of the meeting held on 2 July 2020 be signed by the Chair subject to the corrections submitted prior to the meeting.

3. Covid-19 updates

Compliance and Information

3.1. The Chair invited the Director of Compliance and Information to give an update on clinics.

3.2. All licensed clinics had now opened with the exception of five small clinics previously reported at the July meeting. The continued closure of these smaller units was not of major concern as patients could choose to attend nearby licensed centres.

3.3. The Director of Compliance and Information commented that some centres were reporting that activity levels were near normal whilst others had reduced activity. Compared to 2019, NHS funded cycles were now at 66% of the activity level of 12 months ago whilst privately funded cycles were at 86%. Geographically, there were no areas where licensed centres were not carrying out treatment or where patients could not access services.

3.4. There were several reasons why levels of activity were down including reduced referrals and longer gaps between appointments due to the cleaning requirements and social distancing.

3.5. Feedback from clinics suggested that the pandemic had presented both challenges and opportunities to reconfigure services in a more efficient manner (which was of interest to Ministers as part of their wider assessment of resumption of non-covid related medical services).

3.6. On a positive note, licensed centres that were doing well included those that carry out in-house management of investigations or diagnostic services and had online consent integrated into their services.

Next steps

3.7. Members were advised that we intend to continue to monitor the number of cycles on a weekly basis, engaging with the Department of Health and Social Care (DHSC) and NHS England (NHSE) and NHS Improvement (NHSI).

Strategy and Corporate Affairs

3.8. The Director of Strategy and Corporate Affairs updated the Authority on patient and other enquiries. It was noted that general enquiries were increasing whilst Covid-19 related enquiries were reducing.

3.9. Members asked about the online petition that had been started up in relation to immunosuppressive treatments, which some licensed centres offered. The Director of Strategy and Corporate Affairs responded that the petition was started by patients and we would engage with it using the response that we published on the FAQs on our website.

Chief Executive

3.10. The Chief Executive commented that a meeting was held recently with Matt Hancock MP, Secretary of State for Health and Social Care as part of a number of meetings he was having on the resumption of non-covid related services. It was noted that the Secretary of State was trying to get a picture of what was working well and where there were still blockages in the system. Our transparency and proactive approach to reopening the fertility sector to patients was appreciated.

3.11. Another meeting had been scheduled and we would provide the Secretary of State with an update on the statistics presented last time.

3.12. The Chair commented that it was important that older women nearing the end of their eligibility to fertility treatment were provided with treatment quickly and were not disadvantaged. Members commented that there was still a backlog, and this could be detrimental to such women.

3.13. It was noted that licensed centres were increasing the number of treatments offered and working towards full capacity, whilst remaining compliant.

3.14. One member noted the strain on staff and asked if there was a way we could look into the working conditions of nursing staff at licensed centres.

3.15. The Chair concluded that we would provide a further update at the next Authority meeting in September. She thanked the Directors and the teams involved in the presentations.

4. Resuming inspections

4.1. The Director of Compliance and Information presented a paper seeking Authority approval to agree criteria that would guide the resumption of inspections.

4.2. Members were reminded that the HFEA has a statutory duty to inspect licensed clinics every two years, and that duty included a site inspection of the licensed premises. The inspection cycle involved three types of inspections: initial, interim and renewal. In the last 6 months onsite inspections have not been undertaken because of the Covid-19 pandemic. There was therefore a justifiable reason why inspections had been cancelled.

4.3. It was noted that most clinics were usually issued with a four-year licence, although the Act allowed for a licence of up to five years. Centres during the Covid-19 pandemic were assessed through a risk-based approach to determine if their licences could be extended to 5 years. Those centres where concerns were raised were noted and will be scheduled an inspection as soon as possible after inspections resume.

4.4. Continuing, the Director of Compliance and Information stated that with restrictions easing, it is now appropriate to consider when and how to recommence inspections. Since the Covid-19 pandemic, our commitment has been to keep patients, clinic staff and HFEA staff safe. With this in mind, we now believed that inspections could resume provided the following criteria are satisfied:

- An inspection resumption strategy has been agreed with SMT and the compliance directorate
- Risk assessments have been conducted for individual inspectors and each clinic
- The government restriction on social contact and travel have eased
- The inspection process has been modified to minimise onsite inspection time (including development of an appropriate Desk Based Assessment).

4.5. Members were advised that unannounced interim inspections would be suspended and would be conducted with a minimum of a 2 weeks' notice period.

4.6. Members commented that in relation to the annual conversations with persons responsible (PRs), this needed to allow for the transmission of information both ways, with space for PRs to raise any concerns and suggest better ways of working.

4.7. Staff agreed and responded that there was a framework in place for such an exchange and that conversations were frequently taking place between inspectors and PRs in licensed centres. Also, most licensed centres had quality management systems where relevant documents required for the desk-based assessments (DBA) could be viewed via screen sharing to minimise time spent onsite.

4.8. Members commented that this new way of working needed to be encouraged even after the pandemic period was over.

4.9. Members raised a concern that a number of other major corporate pieces of work were all happening within a short time period, for instance the office move, PRISM launch and resuming inspections. Members sought assurance that there were enough resources to deliver these pieces of work within the appointed timescales.

4.10. The Director of Compliance and Information commented that November had been chosen for the resumption of inspections as it is a quiet month for the inspectorate. This would provide valuable experience for when the inspection schedule gets busier in January. Those centres deemed to be higher risk and those who were granted a five-year licence will need to be prioritised for inspection.

4.11. Members commented that a good balance had been struck.

4.12. In response to a question, it was noted that the inspectors were confident about the prospect of resuming inspections and that they had played a part in developing the strategy. Also, the risk assessment would identify vulnerable staff and not all inspectors would be expected to go out on inspections immediately.

4.13. Regarding patient feedback as part of the inspection process, staff commented that we were looking into this and one way to still get feedback was to log in on zoom meetings between consultants and patients, albeit as unobtrusively as possible.

4.14. In response to a question on unannounced inspections and the number of centres on the urgent action list, staff responded that there are four clinics on the urgent list and we would schedule these from January. Lastly, inspectors were in regular contact with these centres.

4.15. The Chief Executive thanked the Director of Compliance and Information and her team and commented that resumption strategy provided a real opportunity to do things differently in the future.

4.16. The Chair commented that we were working towards a more mature inspection regime and summed up the discussion. It was noted that subject to government restrictions being lifted the inspection resumption strategy was approved. Authority members would expect feedback at the November meeting. The Chair thanked the Director of Compliance and Information, the inspection team and all teams who continued to work in the background on Authority matters, including today the Policy team and the Planning and Governance team for administrating the meetings.

Decision

4.17. Authority members considered and commented on the criteria and approved that inspections should begin to restart from November 2020.

5. Any other business

5.1. The Chair reminded everyone online that the next meeting was scheduled for 16 September 2020.

5.2. Items for the next meeting included the revised new strategy and business plan; equality and diversity; and how we might celebrate our 30th anniversary.

Chair's signature

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

Signature

Chair: Sally Cheshire

Date: 16 September 2020

Performance report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	3
Meeting date:	16 September 2020 (meeting by teleconference)
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 July 2020.

1.2. Performance was reviewed by SMT at its 3 September meeting.

2. Key trends

2.1. In July performance was generally good. There were 2 red indicators.

Red indicators

2.2. The indicators classed as red are as follows:

- Debt collection
- Debtor days (see 3.2 – 3.3 below)

2.3. Authority should note that the inspection and licencing activity reported during the Covid-19 period, during which physical inspections have been paused, includes items that would usually include an inspection but where a desk-based approach was used instead, or an inspection was not deemed necessary. This is appropriate since these still represent inspection work and a report on such centres was still prepared for committees to consider the licence (ie, renewals and interims, change of premises and initials). As such, we are continuing to capture and report on the efficiency of inspection and licensing throughput. This is in line with historic reporting, where desk-based inspections have been included in inspection data.

2.4. 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. Authority query

3.1. At its meeting in July, some Authority members asked for the data the debtor days performance indicator to be verified. This is addressed below:

Debtor days

3.2. Members queried whether the very high May figure was correct (437 days) and asked us to confirm that there were no issues with this data. Following review by the finance team, we can confirm that this was indeed correct. The methodology for the KPI is a standard finance industry approach: monthly debts/monthly sales = debtor days. For the purpose of calculating this, the finance team include all income, including grant-in-aid.

3.3. We continue to proactively chase outstanding debt, but because of the impact of Covid-19 on the sector, we anticipate that this figure will continue to be above target for some time, as the collection process has been affected by clinics' slow return to pre-Covid-19 levels. But the number of debtor days has fallen significantly since the high in May (see below).

Annex 1 HFEA Performance scorecard and management commentary – July data

Breakdown of total Red, Amber, Green and Neutral Indicators

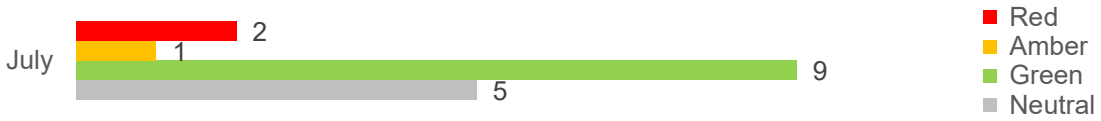


Figure 1 - Fewer red and amber indicators this month

RAG	Area	Trend and key data
Green – within target range	**People -** Employee turnover Target: between 5%-15%	9.1% Turnover 1 leaver
Green – on target	**Regulatory efficiency -** Time for end-to-end inspection and licensing process Target: 100% in 70 working days or less	100% within target. Average of 52 working days (items beginning with an inspection)
No target – down slightly this month	**Engagement -** HFEA website sessions	62,485 sessions (56,400 in same month last year)

Summary financial position – July 2020 (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	**1,080**	**2,323**	**(1,243)**	**4,542**	**7,211**	**(2,669)**
Expenditure	**(2,197)**	**(2,276)**	**(79)**	**(7,049)**	**(7,211)**	**162**
Total Surplus/(Deficit)	**(1,117)**	**47**	**(1,164)**	**(2,507)**	**0**	**(2,507)**

Commentary on financial performance to end July

The Year to date position is a deficit against budget of £1.16m and the result of the impact of the COVID19 pandemic on the sector over the 4 months of the financial year. Our expenditure is in line with budget with a small underspend of £80k, which is largely due to the profiling of expenditure in the first part of the year. The full year forecast position includes an optimistic outlook on activity increasing across the sector over the rest of this financial year. Discussions with the DHSC have provided assurance that an additional £2.4m of GIA will be provided, although it is not included in the July position. The HFEA will be able to access this funding from the end of September and although there will still likely be a shortfall this financial year, we have sufficient cash reserves to fund this.

Management commentary

In July performance was generally good. We had just two red indicators, both of which were financial. This is unsurprising given the impact of the coronavirus pandemic upon clinics and the knock-on impact on our income.

More widely, the report reflects an increasingly steadying picture, as treatment restarted and the sector begins to get back on its feet. After an exceptionally busy and disruptive period, demands are returning to more normal levels. The data suggest that the organisation is working well, and our turnover rate is now well within target and employee sickness is down.

As expected, given the Authority's earlier decisions on inspection and licensing, we have seen drops in the levels of inspectorate activity and corresponding drops in activity at committees. We expect these lower levels to continue until early next year, when items resulting from the proposed return of inspections in November will be submitted to committee. We continue to monitor sector activity closely.

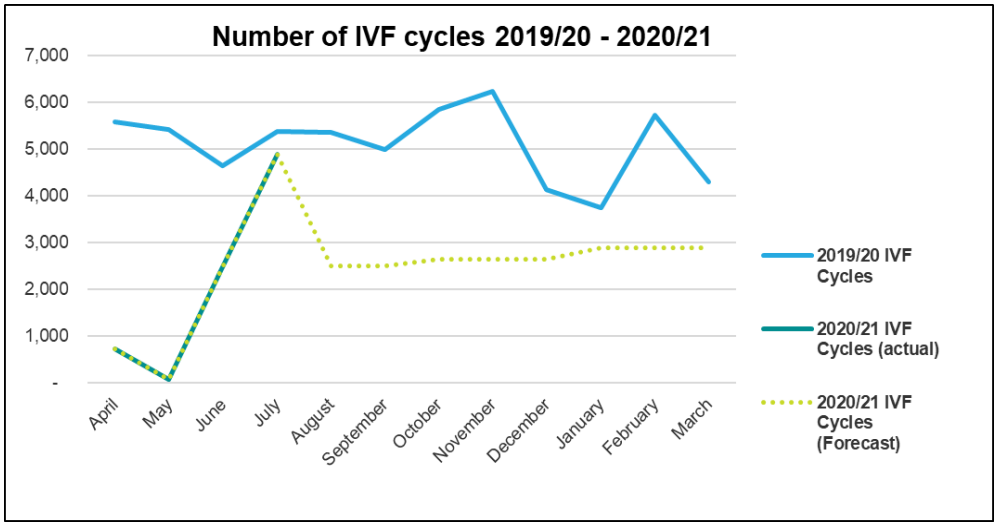
Red indicators:

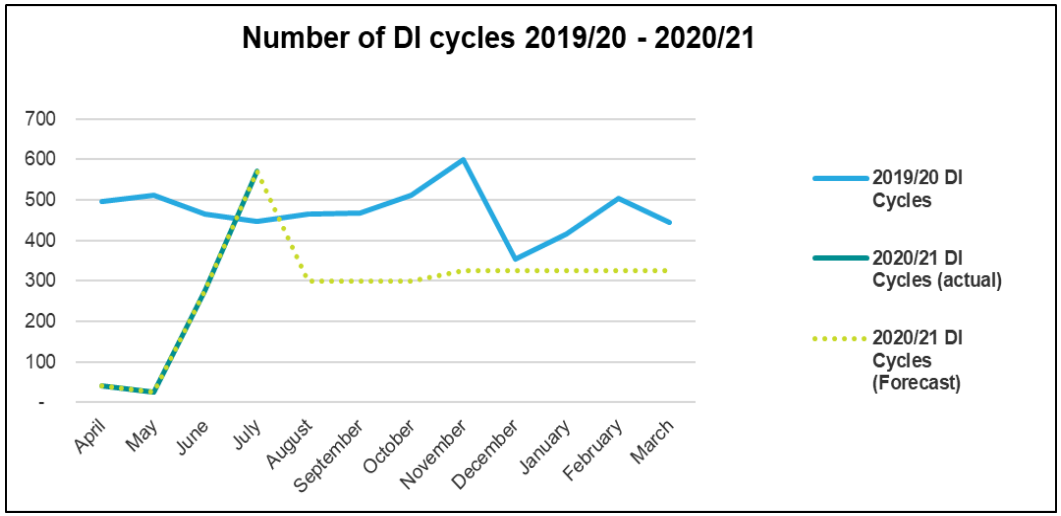
Finance

- **F1 Debt collection (% debts collected within 40 working days from billing).** Our target is 85% of debts or more collected in the month being within 40 working days from billing. In July, performance was 61%.
- **F2 Debtor days (Average days debts remain outstanding).** Our target is an average of 30 working days or less. In July, performance was an average of 53 working days.

The debtor days data is now closer to our target performance and the level of timely debt collection is increasing. In August, the Department of Health and Social Care confirmed additional Grant in Aid funding of £2.4 million, increasing the overall figure to £3.438 million. Even so, we are still forecasting a shortfall for the year, which will be funded from our cash reserves.

Annex 2 Financial management information





IVF Cycles	YTD		YE Position	
	Volume	£	Volume	£
2019/20 IVF Cycles	21,030	1,682,400	61,386	4,910,880
2020/21 IVF Cycles (actual)	8,197	655,760	29,847	2,387,760
Variance	12,833	1,026,640	31,539	2,523,120

DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2019/20 DI Cycles	1,918	71,925	5,676	212,850
2019/20 DI Cycles	913	34,238	3,438	128,925
Variance	1,005	37,688	2,238	83,925

The graph on the left illustrates the significant reduction in IVF treatment cycles (61%) in the period ended 31 July 2020. We are currently forecasting a c50% reduction in activity across the year, but this is based on continuous increased activity over the next three quarters.
Whilst DI treatments (graph on the right) do not follow IVF activity patterns exactly we are still experiencing a significant reduction in volumes. We are again forecasting a c50% reduction but will continue to monitor throughout the year.

HFEA Income & Expenditure Jul-20

	Year to Date				Full Year		
	Actual £'000	Budget £'000	Variance £'000	Variance YTD %	Forecast £'000	Budget £'000	Variance £'000
Income							
Grant-in-aid	234	310	76	24	1,238	1,238	-
Non-cash (Ring-fenced RDEL)	170	170	-	0	510	510	-
Grant-in-aid - PCSPS contribution	33	33	0	0	100	100	-
Licence Fees	594	1,771	1,177	66	2,539	5,209	(2,670)
Interest received	1	3	2	70	10	10	-
Seconded and other income	48	36	(11)	-32	144	144	-
Total Income	1,080	2,323	1,243	54	**4,542**	**7,211**	**(2,670)**
Revenue Costs							
Salaries (excluding Authority)	1,571	1,651	80	(5)	4,521	4,629	108
Staff Travel & Subsistence	1	0	(1)		97	161	64
Other Staff Costs	31	19	(12)	63	126	121	(4)
Authority & Other Committees costs	67	58	(9)	15	276	284	8
Facilities Costs incl non-cash	225	305	79	(26)	930	928	(2)
IT Costs	184	163	(21)	13	533	517	(16)
Legal / Professional Fees	96	65	(31)	48	379	388	8
Other Costs	21	16	(5)	34	187	183	(3)
Total Revenue Costs	**2,197**	**2,276**	**80**	**(4)**	**7,049**	**7,211**	**166**
TOTAL Surplus / (Deficit)	**(1,117)**	**47**	**(1,164)**	2,502	**(2,507)**	**(0)**	**(2,507)**
Adjusted for non-cash income/costs	**(1,117)**	**4**	**(1,122)**		**(2,507)**	**(0)**	**(2,507)**

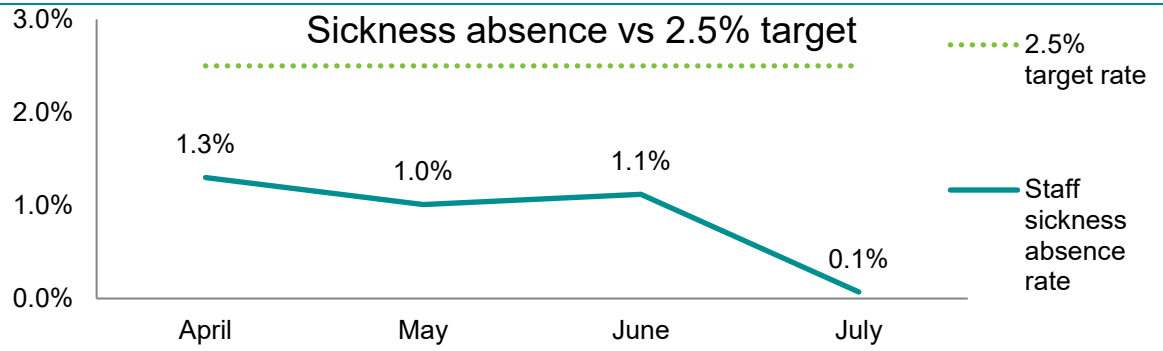
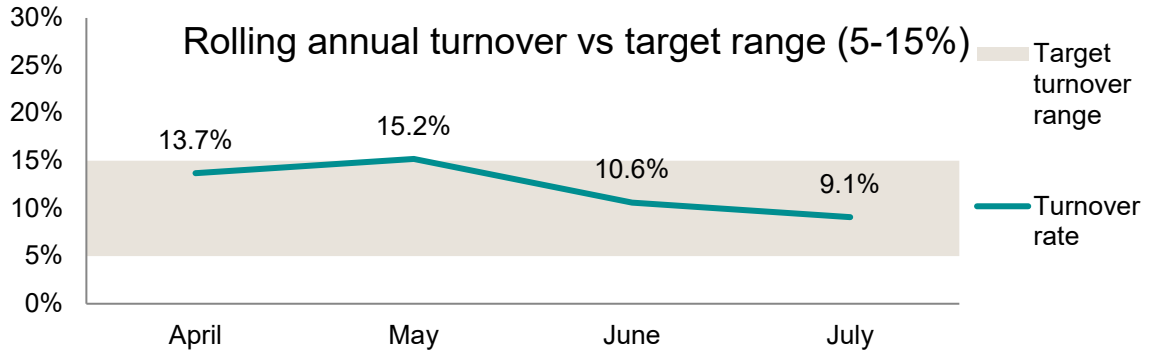
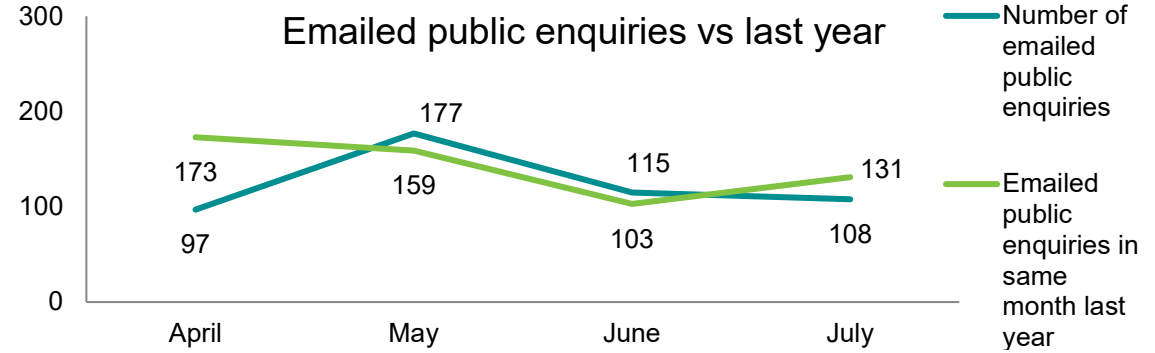
Management commentary

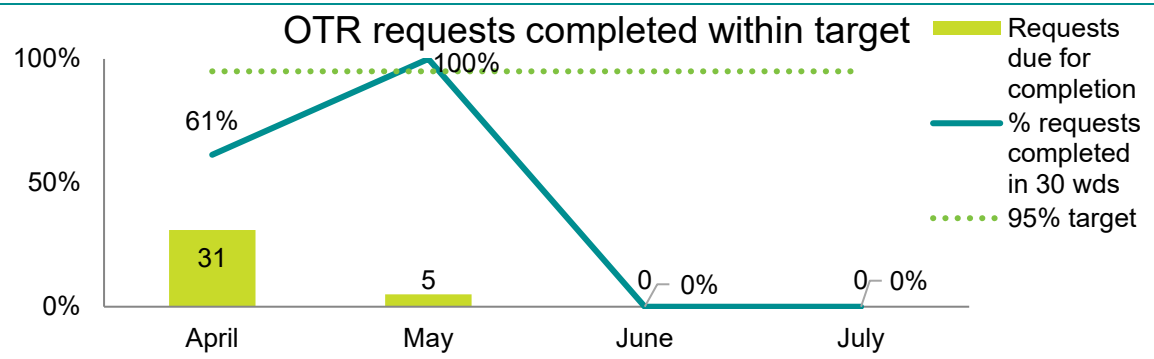
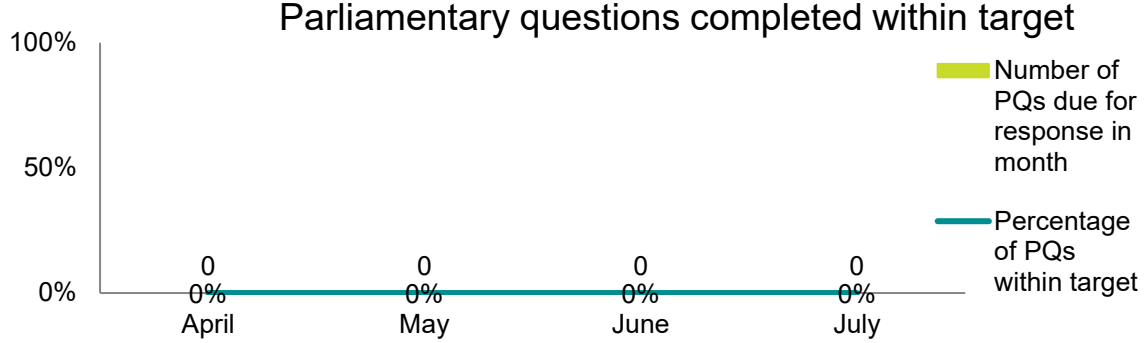
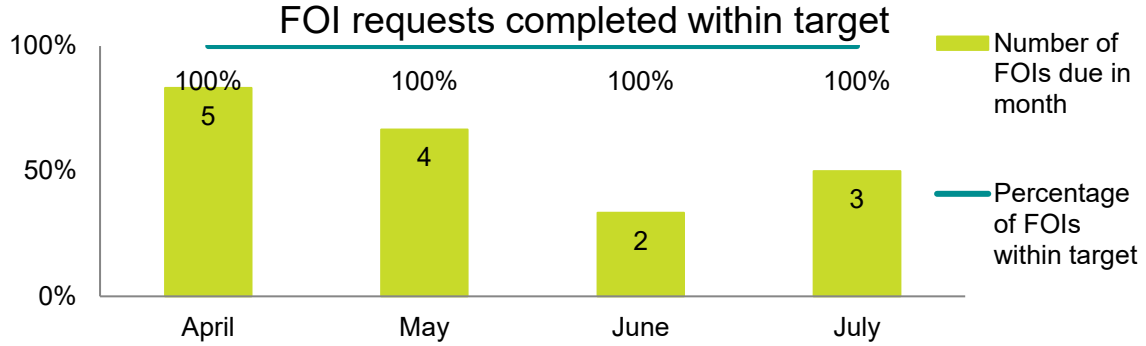
Income.
For the four months ended 31 July 2020, we are under budget by £1.2m which is largely due to the reduction in our treatment fee income of (67%). Volumes of both IVF and DI have increased from June by 97% and 100% however, it is too early to say if this will continue.

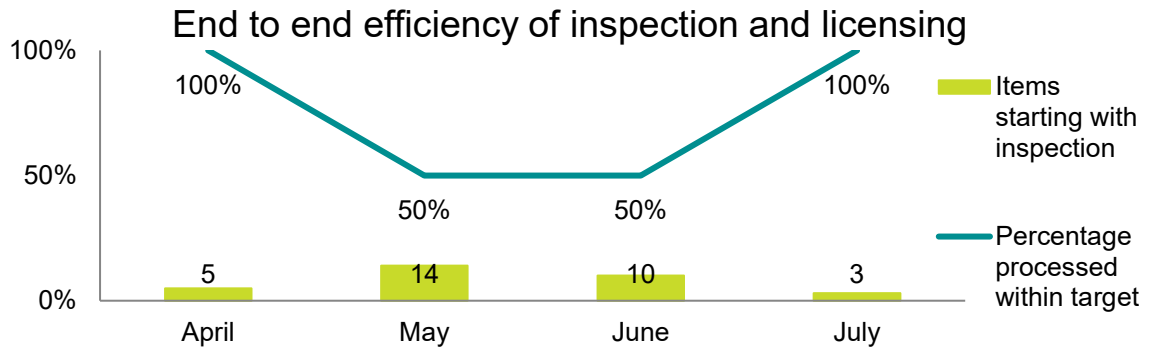
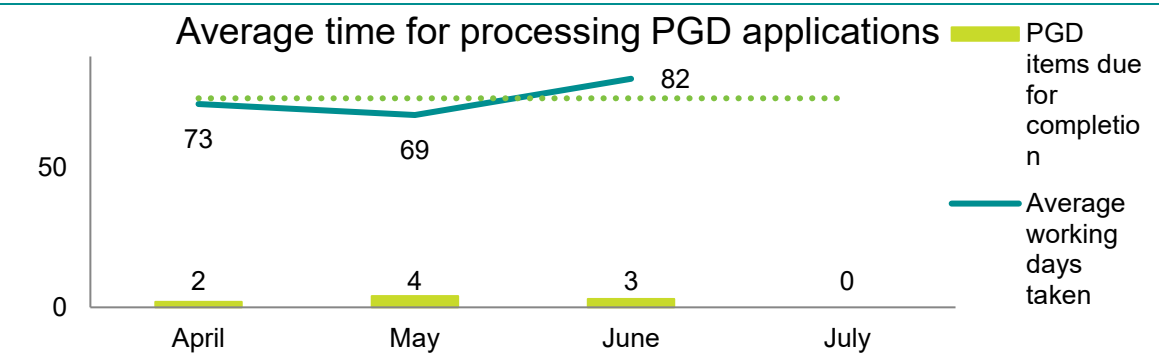
Expenditure by exception. Year to date we are underspent by £80k down £10k from June.
Salary costs - currently running under budget by £80k which is due to vacancies carried and associated on-costs.
Other staff costs - over budget by £12k represented by £18k in training and staff welfare, offset by underspends in recruitment and pension processing costs of £6k.
Authority & Other Committee costs - overspend of £9k due to profile of budget. The actual costs relate to Appeals (£6k) and cancellation cost for meetings (£3k).
Facilities costs - include our non-cash costs of depreciation/amortisation (£76k). The underspend here is due to the timing of the capitalisation of IfQ and PRISM. These costs are covered by Ring-fenced RDEL receive from the DHSC. Also costs associated with COVID-19 £3k not budgeted for.
IT costs - show an overspend of £21k, due to costs associated with Alscient (support contract) higher than expected and in part the profiling of the budget.
Legal/Professional Fees - legal fees are overspent against budget (£50k) due to profiling - spend weighted towards Q3 onwards. This is offset by underspends within audit and contingency (£19k).

Forecast.
We are currently forecasting an overspend against budget of £2.5m which is the short-fall in income we anticipate following reduced clinic activity due to impact of the COVID-19 pandemic. The £2.6m income forecast is a first estimate and represents an optimistic view of the likely increase in sector activity over the next three quarters .
A more detailed review of plans will be undertaken at the end of Q2 when we will have a clearer picture of how clinics are operating and the effect on our income. This review will also include a detailed look at our business plan for the reminder of the year which will impact on our forecast expenditure.

Annex 3 – Key performance indicators – Authority summary

Key performance indicator name and description	Graph showing performance trend for last 5 months (only two months available in June)	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 rates are significantly down from this time last year (2.5% in July 2019). Reasons are unclear but this may be a result of homeworking.	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 (only two months available in June)	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.		Service has been paused since late April.	Neutral
RI1 – PQs responded to within deadline set (Based on deadlines agreed with DHSC) **Target:** 100% within deadlines set.		None received.	Neutral
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 (only two months available in June)	Commentary (if any)	RAG rating
C1 - Efficiency of end to end inspection and licensing process. **Target:** 100% within 70 working days (wds). % processed in 70 working days, for items where minutes were sent in month. Measured from inspection date to date minutes sent.		Average working days taken –.52 Most days taken: 60 working days Least days taken: 45 working days	Green
C4 – Average PGD processing **Target:** average processing time of 75 working days. Average number of working days taken for those due in month. Note: Target changed from 66 to 75 in April 2020.		Most days taken: N/A Least days taken: N/A	Neutral

Business planning 2020-22

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	6
Meeting date:	16 September 2020 (meeting by teleconference)
Author:	Paula Robinson, Head of Planning and Governance
Annexes	Annex 1: Six month business plan for 2020/21

Output from this paper

For information or decision?	For decision
Recommendation:	
Resource implications:	In budget
Implementation date:	1 October 2020 (subject to DHSC sign-off)
Communication(s):	For publication on the website
Organisational risk:	Low

1. Overview

1.1. Since the 2020/21 business year began, during the Covid-19 lockdown, the Authority has discussed the strategy and our associated business plans several times. We have agreed to publish a six month business plan in October, setting out our plans for the remainder of the current business year, alongside the new strategy.

1.2. In August, the Corporate Management Group (CMG) met and discussed how best to modify our original three year delivery plan for the strategy, in light of our response to the Covid-19 pandemic and the associated work.

1.3. This paper presents a six month business plan for 2020/21, for Authority approval (Annex 1), and outlines the intended content for our new 2021/22 business plan, which will be drafted in full in the coming months.

1.4. Both business plans will require Department of Health and Social Care (DHSC) approval, in the normal way, prior to publication.

2. Prioritising our plans

2.1. CMG's discussions have taken into account the new strategy and the Authority's previous discussions on the prioritisation of work. We have also considered our core work, our resources and the dependency, in some areas, on collaborating with other organisations to deliver the work successfully.

2.2. Alongside our strategic priorities and our ongoing core statutory work, there are a number of other specific pieces of work that need to be addressed in the second half of the current business year:

- Office move to Stratford and establishment of Covid-19 safe working conditions
- Resumption of inspections and ongoing monitoring of Covid-19 risks
- Development of fees options for future consultation
- PRISM completion and associated work on Choose a Fertility Clinic
- EU Exit and the Northern Ireland Protocol
- Code of Practice updates
- Work with the Competition and Markets Authority (CMA)
- Management of significant Authority member turnover and associated recruitment, induction and training
- Planning ahead for the celebration of the 30th anniversary of the HFEA, and associated future scoping work (see separate agenda item)
- Establishing a pilot patient forum
- Work on accessibility requirements for published documents.

2.3. Since this is an unusually long list of notable additional pieces of work, we need to take care to ensure that our plans can be successfully delivered within our resources.

3. Six month business plan for 2020/21

3.1. The six month business plan attached at Annex 1 includes the list of activities above, and all of our core work, as well as starting to address elements of the new strategy.

3.2. Our strategic work for the next six months includes:

- Completion of the in-progress review of the compliance and enforcement policy.
- A project to build on our earlier work on success rates in 2019/20.
- Continuation of our in-progress work on add-ons.
- Re-planning of our work on supporting and encouraging research, in light of Covid-19 practicalities.
- Positioning and promoting our information for patients, partners, professionals, surrogates, donors, donor-conceived people and their families.
- Reviewing the statutory framework and identifying areas for improvement.
- Scoping future operational needs for our Opening the Register (OTR) service.

3.3. The Authority is invited to comment on, and approve, the draft six month business plan. This will then be passed to the Department for approval prior to publication.

3.4. The six month plan omits some of the sections we normally include in our business plans, including the looking back section, performance measures and the 'other required information' section. It is our intention to include a two year overall picture in the next full business plan, for 2021/22.

4. Full business plan for 2021/22

4.1. Having reviewed the three year plan for delivery of the whole strategy, CMG believes that the following areas of work should be started, or continued from this year's work, in the first full year of delivery, in addition to our core statutory functions:

Additional areas of work in 2021

- Continued adaptations as needed for Covid-19.
- Preparation of future fees options in readiness for consultation.
- EU Exit work, if there is an implementation phase following the end of the transition period.
- Continued management of member turnover throughout 2021.
- Celebration of the 30th anniversary of the HFEA.

Best care

- Code of practice update (October 2021).
- Scoping for a future review of consent form content and presentation.
- Inspection changes linked to the review of the compliance and enforcement policy.

- Improved register data tools.
- Success rates.
- Establishment of a data review board to consider additions to the Register.
- Gathering patient views.
- Work on supporting and encouraging research.

Right information

- Positioning and promoting our latest information.
- Developing new information about any new treatment or evidence.
- Clinic portal and website technical updates.

Shaping the future

- Providing up to date information on developments such as genome research, DNA tests and AI.
- Add-ons project.
- Preparing for future changes in the fertility field, and potential future changes to our Act.
- Prepare for any legislative changes relating to storage limits.
- Following scoping work in the current business year, ensure we are organisationally ready for an increase in our OTR operations, from 2021 onwards.

4.2. The Authority is invited to comment on and approve this outline, so that the full business plan for 2021/22 can be prepared in the coming months.

5. Business plans beyond 2022

5.1. CMG looked at the whole range of work to deliver the strategy, and in the course of our prioritisation discussions, we agreed that work would begin on the following areas of the strategy in year two or three (from April 2022 through to March 2024):

- A further Code of Practice update.
- Consent form review (following a scoping exercise in 2021).
- Completion of the review of the compliance regime.
- Review of donor compensation levels.
- Further work on success rates (following work in 2021).
- Review of our information and guidance on partners' involvement in treatment.
- Development of more information for partners and donors.
- Review of our signposting information on male fertility.
- Partnership work with primary care organisations to better support people in their early decision-making.
- Further work on add-ons.

- Follow-on work as needed on any future legislative changes or review of the Act.
- Follow-on work in response to the anticipated increases in OTR operations in 2021 and again in 2023.

6. Recommendations

6.1. The Authority is asked to:

- Approve the six month business plan for the second half of 2020/21.
- Approve the outline plan for 2021/22, so that this can be drafted in full.
- Note the activities that will be scheduled in more detail later, for the final two years of strategy delivery.

Annex 1

Six month business plan for 2020/21

[Title page and end page to be added in new accessible template]

Contents

Our role and strategic aims

Who we are

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

Our vision for 2020-2024 is:

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

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

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

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

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

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

The best care

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

The right information

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

Shaping the future

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

In March 2020 Covid-19 led to restrictions in the United Kingdom. As a result, the first six months of the 2020/2021 business year were spent ensuring that the risks that emerged were managed well and the fertility sector and patients were supported effectively. We suspended inspections for a six-month period, with alternative arrangements in place to ensure that statutory compliance and licensing arrangements could continue in the absence of physical clinic visits. Treatments were necessarily suspended under a new General Direction (0014) for a period of several weeks. Clinics subsequently began to re-open in mid-May, when wider restrictions were somewhat eased. Although we were able to continue to

work towards some of our strategic goals during this period, we did not publish an external business plan during this time, as we focused on ensuring that we effectively supported the sector and reprioritised our work.

This business plan sets out how we will work towards our vision in the second six months of 2020/2021.

Our legislation and functions

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

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

Under this legislation, our main statutory functions are to:

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

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

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

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

Following the UK's exit from the EU, the Human Fertilisation and Embryology Authority has continued to work closely with the Department of Health and Social Care (DHSC) and its arm's-length bodies to understand the opportunities available to the UK and our health and care system. This includes supporting the cross-organisational work on the UK's future relationships with the EU and the rest of the world. The United Kingdom will seek a broad free trade agreement covering goods and services, and cooperation in other areas. We will work with the Department to ensure that this includes consideration of the regulation of human reproductive tissues and cells, and to contribute to delivering the future relationship with the European Union and implementing the Northern Ireland Protocol.

We will continue to work closely with DHSC to ensure preparations are in place throughout the transition period and assess any implications this may have on the regulation of human reproductive tissues and cells. Following the end of the transition period, the UK will be classified as a third country under the EU Directives. The relevant EU Directives allow for reproductive tissue and cell exchange between member states and third countries. We will work with the Department to ensure that agreements can be put in place, if necessary, so the movement of reproductive tissues and cells between the UK and other countries can continue.

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

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

Delivering our strategy in 2020/2021

The publication of our new strategy was delayed from April 2020 in light of the Covid-19 pandemic, and the Authority agreed we should publish it instead in the autumn, at the same time as this business plan. During the UK lockdown period, and beyond, our work has focused on the operational changes required to manage the effects of Covid-19 to ensure that patients, clinic staff and our inspectors are safe. The strategy itself has been extended by one year, to March 2024, to acknowledge the fact that so much of the current business year has been, and will continue to be, dominated by Covid-19 and its impact on fertility services. Our strategy remains clearly focused on achieving the very best care, ensuring the right information is available to people at the right time, and shaping the future.

Our strategic vision for the three and a half years from October 2020 to March 2024 is:

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

We aim to achieve our vision through delivering the following strategic objectives:

Table 1 - Outline of our strategic objectives and aims for 2020 to 2024

In this area…	We will…
The best care	1. Treatment that is effective, ethical and scientifically robust. Our aims: • To ensure the HFEA and clinics are prepared for future changes in the fertility field, and for any legislative changes. • Clinics that are well led and see compliance and the provision of high quality care, including excellent support, as good business. • 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.
	2. Improved recognition of partners' importance (of the same or opposite sex) in the care process. Our aims: • Partners to be involved in care and treatment choices throughout the process. • Clinics to recognise that partner care is a core part of the service they provide.

The right information	3. Improved access to information at the earliest (pre-treatment) stage. Our aim: • Right-moment information provision from the outset for patients, partners, donors and surrogates.
	4. High quality information to support decision-making during and after treatment or donation. Our aim: • Patients, partners, professionals, surrogates, donors, donor-conceived people and their families all to have access to relevant and impartial information.
Shaping the future	5. Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI). Our aims: • 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. • Clinics to assess innovative treatments (including add-ons), and to encourage responsible innovation that improves current practice.
	6. Preparing for future legislative and operational changes. Our aim: • To ensure the HFEA and clinics are prepared for future changes in the fertility field, and for any legislative changes.

Although we are a specialist regulator, there are broad priorities that will be important across the health and care system which are relevant to us, and our programme of work is well aligned to these.

Activities for 2020/2021

This six-month business plan represents the first six-months of our 2020 - 2024 strategy which launches in October 2020.

Because of the work that was required during the first six months of the business year, to respond to the Covid-19 pandemic, our main focus for the remainder of the year will be on recovery, supporting the sector to re-establish normal services to patients and building a solid foundation for future strategic delivery.

A period of recovery has already started for our sector, and we plan to recommence inspections of licensed premises in November 2020. Careful plans have been put in place to manage this safely, minimising the duration of site visits.

We begin our new strategy looking firmly ahead, to the 30th anniversary of the HFEA in 2021, future developments in the fertility sector and an upcoming period of change for the organisation, as the Government recruits several new Authority members, including a new Chair. During the UK's period of lockdown, we reviewed our intended plans, and have reprioritised some activities, and delayed others. But our overall vision remains the same – to regulate for excellence, and to shape the future of fertility care and treatment. Like all organisations, we will continue to work closely with the sector we regulate, and consider the best ways to achieve our aims while Covid-19 continues to be a factor in all our lives.

The activities set out over the next few pages will help us to deliver our strategic objectives in the remaining two quarters of 2020/2021, and beyond.

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 2 - 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 of: • compliance and enforcement policy • inspection priorities • our use of intelligence gained from inspections • information in reports • roll out and use of the revised PREP test. Develop plans for quality improvements. Readiness for next steps to ensure the HFEA's compliance regime is more aligned to strategic priorities	Throughout the year with further work falling into subsequent years.
Maintenance of Inspection Resumption Strategy and ongoing monitoring of Covid-19 risks and impacts on fertility sector and the HFEA. Clear	Clear ongoing recovery plan and assistance for clinics as treatments recommence. Risk-based approach for the resumption of inspection activity. Clinics effectively respond to Covid-19 related risks.	Throughout the year

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
actions and communication as the situation develops.	We effectively adapt and respond to any changes in Covid-19 circumstances, such as any local lockdowns, and also assist the sector to do so.	
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
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	Throughout the year, with further work planned for subsequent years of strategy delivery.

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	**Benefits and outcomes**	**Timescale**
Initiating 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.	Autumn 2020
Effective handling of and communication about: • clinical incidents and adverse events, including publication of 2019/20 '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 events.	Throughout the year, with the state of the sector report published in Autumn 2020
Ensuring governance tools underpinning licensing and other decisions are in place and effective.	Ensure that licensing decisions and other approvals are well governed. Efficient and effective decision-making is maintained. Decisions are evidenced, transparent and consistent. Committee governance arrangements and effectiveness reviewed annually.	Throughout the year
Processing applications for the licensing of preimplantation genetic diagnosis (PGD), human leukocyte antigen (HLA) and mitochondrial donation.	Applications handled effectively, efficiently and transparently and processed according to performance indicator timelines. Decisions on whether to authorise such treatments made, and communicated, in a proper and timely manner for the direct benefit of patients waiting for treatment. Mitochondrial donation and PGD approvals taken in an accountable and transparent way.	Throughout the year
Ongoing review of guidance for clinics to ensure this	Guidance for clinics is up to date and reflects latest scientific developments, legal advice and policy decisions.	Throughout the year.

Objective 1 Treatment that is effective, ethical and scientifically robust - methods and channels	Benefits and outcomes	Timescale
remains fit for purpose, including: • preparation of updates to the Code of Practice including further guidance on electronic and storage consent. • other clinic-facing resources such as patient support pathways.	A clear Code of Practice and other guidance for clinics.	Preparatory Code work this year with revised Code of Practice to be published in 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 and enforcement policy.	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	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
• typical prices for treatment • including testing of this information using the pilot patient forum.		
Ensure that the HFEA and licensed clinics are ready for any changes as a result of the end of the EU exit transition period, so that they 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.	Throughout the year
We review and update business continuity plans regularly, in line with the UK's future relationship with the EU.	Gain assurance that clinics and suppliers have robust business continuity plans in place and continue to seek further engagement on any risks and issues identified relating to the end of the transition period.	Throughout the year

Table 3 - 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 year one, work to follow in years two and three.	None in year one.	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 4 - 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 5 - 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.	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
Consideration of Clinic portal and website updates (subject to budget) to: • increase stability • deliver additional functionality • enhance search functionality.	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

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
Update to the data available in Choose a Fertility Clinic (CaFC) and scoping work to consider how clinic data will be published in future.	A 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 and into 2021/22
Working with the Competition and Markets Authority (CMA) on their project on self-funded IVF and consumer law guidance.	We support the CMA to produce guidance so that clinics understand their obligations under consumer law in relation to self-funded treatment.	March 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
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.	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**
	We continue to be active members of the UK health data research alliance to encourage widespread and responsible access to data	
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
Planning the reintroduction of effective Opening the Register (OTR) and counselling services after the Covid-19 pause and the completion of follow-on work related to PRISM.	Planning to ensure that Opening the Register requests will continue to be met in a sensitive manner and within agreed time limits when it resumes. Counselling support is offered when appropriate for any Opening the Register (OTR) applicants (those seeking non-identifying information) and for donor-conceived applicants receiving donor-identifying information.	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

Objective 4 High quality information to support decision-making during and after treatment or donation - methods and channels	**Benefits and outcomes**	**Timescale**
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
To publish good quality statistical and other reports, including the Fertility Trends report.	We provide the public, patients, clinic staff and others with up-to-date, high quality information about treatment outcomes, trends and the performance of clinics. We provide important information to those affected by donor conception, including patients seeking treatment. We make use of our data to help us to enhance the quality of care that patients and donors receive in clinics through our regulatory work.	Throughout the year
Effective handling of enquiries, complaints about the HFEA and whistleblowing.	These are handled efficiently and appropriately. Learning gained and actions identified where necessary to secure improvements.	Throughout the year
Maintaining the Register of Treatments and Outcomes and working with clinics to ensure they are accurately reporting their data.	Register data and forms continue to be processed and quality assured through liaison with clinics on errors and omissions and through validation and verification of Register entries. High quality data available to develop patient information and respond to information requests.	Throughout the year
Information provision for researchers requesting access to Register data, including ongoing review of the processes that support this.	Running the Register Research Panel to oversee applications for data release and ensure approved data is released effectively and securely to researchers. Information for researchers is provided within specified timeframes. Register information is used to best effect, to increase understanding and facilitate good research and ultimately benefit patients.	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**
	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.	
Ongoing compliance with government information requirements, including: • reporting in our annual report on the growth duty and compliance with the regulators' code • complying with the business impact target by identifying and reporting any 'in-scope activity'.	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. Compliance with the business impact target for any activities that may be in scope.	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
Recruitment of new Authority and other committee members, in liaison with the Department of Health and Social Care.	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
Full realisation of the benefits of our improved Register function and processes, including early life support for the PRISM data submission system and ongoing	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. Stable system. Stable register.	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
engagement with and feedback from clinics.	'Right first time' data quality and reduction in effort by clinics submitting the data.	
Building and realising the benefits 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 March 2021

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 6 - 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 in fertility clinics and the wider sector.	We understand any developments and are responsive to these. We ensure that our regulatory regime is fit for purpose.	Throughout the year

Table 7 - 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
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.	As these occur
Project to scope future 'opening the Register' (OTR) demand and logistics.	To understand, through analysis, the likely future demand on the OTR service. 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.	By March 2021
HFEA Office relocation to Stratford.	Continue to implement a project to coordinate work for the HFEA to prepare for new accommodation in Stratford and engage with a wider DHSC project, managing the infrastructure and logistics of the move. HFEA have the space and facilities needed to operate effectively within the new office and for staff working remotely. HFEA successfully move in 2020 with minimal disruption to HFEA operations during the move.	Winter 2020
Ensuring that our working arrangements are suitable for maintaining appropriate Covid-19 safe working conditions.	We have reviewed our ways of working, including relevant policies. Our office-based staff is able to return to working in an office environment when it is safe to do so.	Throughout the year
Ensuring that we retain and recruit the staff we need in	We are able to maintain the staff capacity and capability to deliver our strategy and our core statutory duties.	Throughout the year

Objective 6 Preparing for future legislative and operational changes - methods and channels	**Benefits and outcomes**	**Timescale**
order to operate a good quality service and implement our People Strategy for 2020-2024.	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. Staff feel valued and motivated to deliver our strategic aims.	
Scope a fee review informed by our income forecasting model.	Develop options for a fee review in 2021-22.	By March 2021
Planning for activities to mark the 30th anniversary of the HFEA.	We develop plans to mark this historic milestone, and take a forward view as to the future of the fertility sector.	Throughout the year

Financial picture

Our finances and high-level budget

We receive funding from two main sources: the majority, around 80%, from clinics and the balance from our sponsors, the Department of Health and Social Care, as grant-in-aid (GIA).

The vast majority of fee income arises from individual IVF treatments in regulated clinics. In aggregate, together with licence fees, these cover the costs of regulation including:

- evaluating licence applications
- making licensing decisions and issuing licences
- managing licences
- site visit inspections
- managing statutory information flows, and
- providing advice and guidance to licensed establishments.

We maintain a model to predict the likely activity in future years. This is based on a combination of historic trend data and Office for National Statistics population forecasts. We monitor how closely actual activity follows our projections including a formal review of the model annually.

Over the years, we have managed our expenditure to ensure we spend within our annual budget and expect to do so moving forward. We continue to maintain a cash reserve to ensure we can manage fluctuations in our monthly income and provide a buffer should we see a material deviation from our forecast income levels.

Income

Table 8 - HFEA high-level income for 2020/2021

Income	Budget £000s	Forecast £000s (as at end July)
Department of Health and Social Care funding	1,338	3,438
Non-cash income	510	510
Treatment and licence fees	5,209	2,539
Other income	154	154

Income	Budget £000s	Forecast £000s (as at end July)
Total income	7,211	6,641

Expenditure

Table 9 – breakdown of HFEA operating costs

Operating costs	Budget £000s	Forecast £000s (as at end July)
Staff costs	4,791	4,675
Other operating costs	1,910	1,864
Total operating costs	6,701	6,539

Table 10 - HFEA high-level expenditure for 2020/2021

Overall expenditure	Budget £000s	Forecast £000s (as at end July)
Total operating costs	6,701	6,539
Capital charges	510	510
Total revenue expenditure	7,211	7,049

The Department of Health and Social Care have provided additional Grant in Aid funding of £2.4 million, increasing the overall figure to £3.438 milllion. Even so we are still forecasting a shortfall which will be funded from our cash reserves.

Equality and diversity

Details about this paper

Area(s) of strategy this paper relates to:	Safe, ethical effective treatment/Consistent outcomes and support/Improving standards through
Meeting:	Authority
Agenda item:	7
Meeting date:	16 September 2020
Author:	Yvonne Akinmodun, Head of Human Resources Peter Thompson, Chief Executive
Annexes	Annex 1: Name Annex 2: Name

Output from this paper

For information or decision?	For information and decision
Recommendation:	The Authority asked to note and comment on: a. The actions in train to further support the work underway on equality and diversity in the workplace b. Consider whether we should sign up to Race at Work Charter (section 4)
Organisational risk:	Medium

1. Introduction

1.1. Like most public sector bodies, the HFEA has long had a range of policies in place designed to promote equality and diversity (see section 3 below). Aspects of equality and diversity have come into particular focus in recent months following the tragic death of George Floyd in America in May. The subsequent protests and the formation of the Black Lives Matter (BLM) movement, has led many organisations, including the HFEA, to review our current approach to equality and diversity.

1.2. In doing this work we have approached equality and diversity widely, looking at questions of race, gender and disability. Throughout we use the term 'BAME' to describe our staff or our audiences who come from a black or minority ethnic background – though widely in use we recognise that the term may hide as much as it reveals. This paper begins with a brief overview of the composition of the HFEA (section 2). It then provides an account of the key existing employment practices within the HFEA which support an equality and diversity culture and summarises the discussions we have been having with staff and Authority members over the summer (section 3). The paper also identifies a range of new processes which will be adopted to further embed a best practice approach to equality in the workplace and seeks Authority approval that we should sign up to the Race at work Charter (section 4). Lastly, the paper notes how our data can illuminate a range of equality a diversity issues going forward (section 5).

2. Context

2.1. The HFEA is a small public body with a full-time staffing (FTE) complement of usually between 60-70. The key equality and diversity data for the HFEA is set out below.

Organisation	Gender		BAME	Disability	Approximate staffing figures (as at 2018/19 reporting)
	Female	Male			
Civil Service Average	53.9%	46.1%	12.5%	11.7%	N/A
Core DHSC only	59.9%	40.1%	12.3%	7.4%	1762
Human Fertilisation and Embryology Authority (HFEA)	80.0%	20.0%	26.0%	7.5%	63

2.2. The table shows that in June 2020 the HFEA compares favourably when measured against both the DHSC and the Civil Service in all areas other than disability. The HFEA is a significantly more female organisation and has twice the number of staff from a BAME background.

2.3. Since this data was submitted to the DHSC, the HFEA has seen a slight increase in the number of male employees and those with disabilities. However, a word a caution is required, as in any

small organisation the overall percentages of staff with a particular characteristic at a particular grade can change significantly with one or two staff leaving or joining.

2.4. The HFEA Board presents a similar pattern to the staff. Of the current 12 members, 66% are female, and 25% come from a BAME background. We do not have comparative figures from other public bodies to make a comparison, but anecdotal evidence suggests that the Board is fairly diverse compared to many others.

3. Our current equality and diversity policies

3.1. The HFEA has an equality and diversity policy which is included in the standard policies published on our staff intranet. The policy reaffirms the HFEA's commitment to promoting equality and diversity and promoting a culture that actively values difference. The policy, like all HFEA policies, is reviewed at regular intervals to ensure it continues to reflect best practice.

3.2. The HFEA also provides equality training to all staff as part of our induction program.

3.3. In addition to our equality policy, we are also members of the '2 Ticks' program. The criteria for receiving this badge is that we demonstrate a positive approach to the employment of people with disabilities. The '2 Ticks' logo is on all of our job adverts.

3.4. Our recruitment policy states that those who declare a disability in their job application and who meet the minimum requirements for the job role are guaranteed an interview for the job.

3.5. We also gather diversity data at recruitment stage on all candidates so that we can monitor and track appointment outcomes based on this data.

3.6. While these policies are essential, we want to use the Black Lives Matters movement as an opportunity to ask whether there is more that we can do to ensure that we are a truly diverse organisation. To that end, the Chief Executive spoke to all staff in June and issued a statement on our intranet and the Head of HR met BAME staff members in the organisation. The feedback from that meeting was broadly positive. BAME staff also made some suggestions for action which have been fed into this paper.

3.7. In addition, the Chief Executive and Head of HR met with Anita Bharucha and Ermal Kirby in July to discuss this issue. Their helpful comments have also been incorporated in this paper.

4. Future actions to support equality in the workplace

4.1. Following a review of our current recruitment and equality and diversity policies, we have identified the following actions, which we believe will further support the work we have already put in place to promote equality and diversity in the workplace:

- **Awareness training** - we will conduct a rollout of a new mandatory equality, diversity and inclusion, unconscious bias awareness course for all staff from September. HR will track and monitor the program to ensure all staff complete the course as part of their continuing learning and development. It will be important to ensure that we view such training as a way of embedding a culture, rather than viewing it as a tick box exercise.

- **Induction** – the awareness course will also form part of future induction programs so that staff are able to complete the course as early into their employment with the HFEA as possible. Again, we need to view induction as an opportunity to 'set the tone' as to the behaviours we expect from HFEA employees.
- **Recruitment** - we will make a commitment, wherever possible and within the constraints of our budget, to work with organisations that can support us in reaching a wider section of the community when advertising our job and board vacancies (it should be noted that the appointment of Board members is led by the DHSC; however public appointments are made within the provisions of the Equalities Act 2010, which places a requirement on all public bodies to adhere to the principles of equality and diversity in all aspects of employment, including recruitment practices. It could be argued this is evidenced by the profile and make up of our members.)
- **Staff diversity group** - we are also looking into the possibility of introducing a diversity group which will be a self-managed group supported by a member of our senior management team
- **Race at work charter** - the DHSC has suggested that all its ALBs consider signing up to the Race at Work Charter. We have conducted initial enquires into this charter and believe we can meet the 5 criteria for this program. Which are:

a) Appoint an Executive Sponsor for race
b) Capture ethnicity data and publicise progress
c) Commit at Board level to zero tolerance of harassment and bullying
d) Make clear that supporting equality in the workplace is the responsibility of all leaders and managers
e) Take action that supports ethnic minority career progression

- **Staff mentoring** the HFEA is part of a new mentoring program which will be launched in October of this year. The program provides opportunities for middle and junior managers to have access to a mentor from one of the 14 health ALBs who form part of the program. All mentors in the first round of the program are either at CEO or Director level
- The potential mentors will be able to express an interest in working directly with someone from one of the protected characteristics such as race, gender, disability or sexual orientation. We believe this approach will enable us to address criteria (e) set out in the race charter above. The intention is that the first generation of mentees will then have training to become mentors so that they can in tun provide mentoring to more junior members of staff
- We will report on diversity and inclusion data broken down by gender, disability, ethnicity and grade as part of the bi-annual HR report presented to AGC.

5. Looking externally

5.1. Taking equality and diversity seriously is about more than ensuring that our organisation is well run and that we are a regulator who is inclusive. We already publish data on the background and groupings of patients for example, whether of a particular ethnic background or family partnership as part of our annual Fertility Trends report. And our Code of Practice has long met the requirements of the Equality Act and other relevant legislation. We will continue to develop insights into this data over the coming months with planned in-depth looks at different types of family formations and access/outcomes of fertility treatment and a similar in-depth study on patients from a BAME background in early 2021.

6. Recommendations

The Authority is asked to:

6.1. Note and comment on the actions set out in sections 4 and 5 of this paper.

6.2. Approve the proposal to sign up for the Race Charter.

Marking 30 years of the HFEA – Planning for 2021

Details about this paper

Area(s) of strategy this paper relates to:	Safe, ethical effective treatment/Consistent outcomes and support/Improving standards through
Meeting:	Authority
Agenda item:	8
Meeting date:	16 September 2020
Author:	Clare Ettinghausen, Director of Strategy and Corporate Affairs
Annexes	Annex 1: Name Annex 2: Name

Output from this paper

For information or decision?	For information
Recommendation:	That Authority review plans for marking the 30th anniversary of the HFEA
Resource implications:	Resources needed for external events (subject to Covid restrictions) and potential
Implementation date:	1 October 2020
Communication(s):	Communications to be planned with patients, clinics, key stakeholders and wider public.
Organisational risk:	Medium

Introduction

The HFEA will mark its 30th anniversary in 2021. This is a significant milestone that should be celebrated, but it also offers an exciting opportunity to recast the place of the HFEA as a regulator and to set in train thinking on the future of fertility treatment in the UK. The HFE Act is now 30 years old, and despite a revision in 2008, is in many respects, fundamentally unaltered. Given the changes in technology, clinical practice and societal attitudes over that time, it is inevitable that this work will give rise to proposals to change the Act. Our aim is to begin a public conversation about where changes might be most beneficial; in a contested area of public policy like this, experience suggests that it is better to try to develop a consensus over time. It is important to note that changes to the HFE Act is a matter for the Government and Parliament.

Planning for events and activities in 2021 is taking place during the ongoing Covid-19 pandemic and any activities may have to be adapted as the situation changes.

Background to the HFEA at 30

The UK has long been a leader in fertility treatment and embryo research. When looking back at the birth of the first IVF baby over 40 years ago, comments are often made about the experimental nature of the work at that time with those involved taking measured risks to achieve success. It can be argued that the mixture of innovation and ethical responsibility, which was a feature of that early work, became a central feature of the regulatory regime that followed some years later.

In thinking about the future, it is helpful to remind ourselves as to why the Warnock Committee, which led to the HFE Act and the establishment of the HFEA, thought that regulation was vital in the first place.

REGULATING INFERTILITY SERVICES AND RESEARCH

13.1 Public concern about the techniques we have discussed needs to be reflected in public policy. We believe that all the techniques require active regulation and monitoring, even though, as we realise, such restrictions may be regarded by some as infringing clinical or academic freedom. It is not our intention to interfere with the duty of the doctor to exercise clinical judgement in treating patients. Indeed we accept and expect the doctor to be the person who makes the final decision about whether a treatment is likely to succeed, and whether it should be used. Similarly we accept that scientists must not be unduly restricted in pursuing their research interests especially when this may produce direct therapeutic benefits.

13.2 But doctors and scientists work within the moral and legal framework determined by society. They do not and should not depart radically from that framework. Our intention is that activities which have evolved in an unstructured and unmonitored way should be placed on a properly organised basis, within a framework broadly acceptable to society. The interests of those directly concerned, as well as those of society in general, demand that certain legal and ethical safeguards should be applied.

13.3 The protection of the public, which we see as the primary objective of regulation, demands the existence of an authority independent of Government, health authorities, or research institutions. The authority should be specifically charged with the responsibility to regulate and monitor practice in relation to those sensitive areas which raise fundamental ethical questions. We therefore recommend the establishment of a new statutory licensing authority to regulate both research and those infertility services which we have recommended should be subject to control.

Report of the Committee of Inquiry into Human Fertilisation and Embryology; 1984

Although what is medically and scientifically possible has moved on considerably since then, and the nature of the family looks very different, the need for some form of regulation remains. Indeed, it is crucial that the HFEA remains at the forefront of these debates. It is also necessary for us to be able to have the powers to regulate effectively to encourage responsible innovation and best practice in patient care going forward.

Where next?

Our day-to-day work at the HFEA is largely focused on implementing our core statutory functions and it is in these areas that the age of the legislation shows the most. The fertility sector in the UK is very different from that envisaged at the time of Warnock. Today, the fertility sector is ‘big business’ and is now estimated to be worth over £320m p.a. Fertility treatment in the UK is often taking place in private clinics, with some parts of England having less than 30% of treatments funded by the NHS. Many private clinics are grouped into larger corporate entities owned by private companies. When the Act came into force 30 years ago, consideration was not given to patients having to fund treatment themselves and the consequences of this. Nor were the regulatory powers designed for this sort of treatment model.

When looking at whether our core set up is fit for purpose in 2021, there are some areas which look more out of date than others. For example, powers to ensure that innovation is undertaken through appropriately designed medical trials. At the moment, patients can be offered any treatment at any stage as long as it is not unsafe. Such treatment does not have to be shown to be effective and we are unable to stop very many patients every year from being charged for treatments that may be potentially harmful, will not increase their chances of having a baby and may cost many thousands of pounds.

There are other example of where the law is out of date in its language, not recognising the many family types that are now formed as a result of fertility treatment, or simply, regulatory powers that are out of step with more modern regulatory models.

Plans for 2020/2021

The annual **PR event** takes place on 3 November and will be an opportunity for the Chair to talk to PRs about some of the issues and challenges outlined here. We will also be discussing the position and response to the Covid-19 pandemic, and the Competition and Markets Authority's work on the fertility sector.

The **30th anniversary** will be marked in a number of ways through a planned communication strategy to include events (with the current and new Chair), media opportunities, and our own channels to talk about successes over the last 30 years.

We will use a 30th anniversary brand pack to mark all our external communications and social media during 2021. We will use opportunities to mark the current Chair's term of office as a way to celebrate the anniversary and all that has been achieved, as well as looking to the future.

The arrival of the new Chair will be promoted through the media in May and June 2021 as a way to further open up discussions about the future.

Key **topics** to be covered over the year will include:

- How the patient has changed over 30 years
- What's different? IVF then and now
- Ethnic minority fertility patients
- CMA guidance – the fertility sector and consumer protection law
- Fertility trends – 30th anniversary angle to be included
- Research enabled – scientific and data driven
- Patient care – putting the patient at the heart of our work
- Donors – where are we now – working to 2023 and questions of anonymity
- Treatment add-ons – a regulator who encourages responsible innovation

A key issue for the HFEA is to mark what needs to change in the **HFE Act** to bring it in line to where we are in 2021 as well as looking to 'future-proof' it. As noted above, it is rare to have a UK regulator reliant on a law that is 30 years old and there are parts that need to be updated.

We will look at these areas in terms of:

- Regulatory powers and principles

  Consideration of a range of enforcement powers with a broad range of sanctions, including perhaps economic regulatory powers, as well as the principles of regulation being brought up to date.

- Patient safety

  Consideration of patient safety and our ability to consider activities and novel processes

- Societal changes
  Consideration of terms of consent and anonymity and whether they reflect wider healthcare practice
- Scientific changes

  Consideration of where artificial gametes or embryo like entities may fit and whether the 14 day rule is still appropriate

For discussion

The Authority are asked to consider the areas outlined above as priority issues for highlighting during 2021.

Further updates on events and activities will be shared with the Authority in due course.