

Authority meeting held by teleconference

Date - 2 July 2020

Venue - Online

Agenda item	Time
1. Welcome, apologies and declarations of interest	3.00pm
2. Minutes of the Authority meeting held 1 June 2020	3.05pm
3. General update	3.10pm
4. Covid-19 updates	3.30pm
5. Performance report	3.50pm
6. Fertility trends	4.05pm
7. New 2020-24 strategy revisited	4.20pm
3. Any other business	4.35pm
9. Close	4.45pm



Minutes of Authority meeting 1 June 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	2 July 2020			
Author	Debbie Okutubo, Go	vernance Manager		
Output:				
For information or decision?	For decision			
Recommendation		to confirm the minutes of the A record of the meeting	uthority meeting held on 1	
Resource implications				
Implementation date				
Communication(s)				
Organisational risk	🛛 Low	Medium	🗌 High	
Annexes				

Minutes of the Authority meeting on 1 June 2020 held via teleconference

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

Members

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

1. Welcome, apologies and declarations of interest

- 1.1. The Chair welcomed everyone present to the Authority meeting and stated that this meeting marked the beginning of a return to a more balanced agenda, combining both Covid-19 and business as usual items after a series of extraordinary meetings focussing on managing the Covid-19 pandemic and its effect on the sector.
- 1.2. To ensure that we continued to be a transparent public body she advised members that the meeting was audio recorded and the recording would be made available on our website to allow members of the public to listen to deliberations and the minutes would be issued in draft shortly after the meeting.
- **1.3.** There were no apologies for absence.
- **1.4.** 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).

2. Minutes of the meeting held on 7 May 2020

2.1. Members agreed that the minutes of the meeting held on 7 May 2020 be signed by the Chair.

3. General update

3.1. The Chief Executive (CE) introduced this item and focussed on two areas.

Staff survey

- **3.2.** Members were informed that the staff survey was now open and will be closing by mid-June. Prior to this, there was a pulse survey and responses from staff were informative. It was felt that a staff survey will also be useful.
- 3.3. It was noted that the survey would be an opportunity to further gauge how staff felt as some questions in the survey included how we will move back to an office setting and our future ways of working which could be described as the new normal. Members were advised that they would be kept abreast of the outcomes.

PRISM

3.4. The CE reminded members that regular oversight on PRISM was provided by the Audit and Governance Committee (AGC) and that progress remained on-track and we would be in a position to launch in late summer. However, following the earlier cessation of treatment at licensed centres and the gradual staggered re-opening under General Directions 0014 (relating to Covid-19), the launch strategy to introduce and train PRs would be discussed at the next AGC meeting scheduled for 5 June 2020.

Strategy and Corporate Affairs

- 3.5. The Director of Strategy and Corporate Affairs addressed members and it was noted that the Licence Committee, Statutory Approvals Committee (SAC) and Executive Licensing Panel (ELP) had all been busy over these last few months.
- **3.6.** She reported on a range of issues including Fertility Trends, our annual publication, and that it would be released later on in the month.
- **3.7.** The work on add-ons was ongoing as a key aspect of our strategy. We were also continuing our work with the Competition and Markets Authority (CMA).
- 3.8. In response to a question on horizon scanning, which usually happens at the European Society of Human Reproduction and Embryology (ESHRE) conference each year, staff commented that this would go ahead on 9 July 2020. This would be the day after ESHRE conference, which will be held online. The next SCAAC meeting is scheduled for 8 June.
- **3.9.** Members were informed that the work being done to facilitate the UK's transition process following EU exit would be brought back to a future meeting. This would include information about the impact of the Northern Ireland Protocol.
- 3.10. It was noted that the new regulations relating to the change in storage period for gametes and embryos as a result of the Covid-19 pandemic was expected soon, Members were also thanked for supporting the HFEA's response to the Department of Health and Social Care (DHSC) public consultation on the 10-year limit and this was now available to read on our website.
- **3.11.** In response to a question it was noted that there was no automatic extension for Special Directions for import and export relating to the two-year extension of the storage period.

Finance and Resources

- 3.12. The Director of Finance and Resources reported on the office move to Stratford later in the year. It was noted that increased activity on site had brought the project back on track and the new premises should be ready for occupation from November 2020. However this would be subject to adherence to government guidance relating to social distancing and Covid-19 compliance.
- 3.13. Regarding our finances, it was noted that the auditors were currently auditing our 2019/2020 accounts and the interim report was suggesting that we were bordering on a small overspend but at this stage it did not appear to be material. For the 2020/21 financial year we continue to await confirmation of our grant in aid.

4. Covid-19/sector/patient updates

- 4.1. The Director of Compliance and Information provided an update on the number of clinics that had re-opened and treatment numbers undertaken. She stated that as of 29 May, 88 out of 106 licensed centres had applied to resume treatment services and these included both private and NHS centres.
- 4.2. Members were advised that even though centres had applied and received the permission to reopen not all licensed centres will resume treatment due to various reasons including lack of PPE, Trust policy decisions and other locally based reasons, which meant that they were not actively treating patients.
- **4.3.** The Director of Compliance and Information commented that work with licensed centres was ongoing and that members would be sent updates on a weekly basis.
- **4.4.** Members provided insight and suggested that new referrals were delayed due to GP services not yet back to their full scale. Another reason was that to adhere to social distancing guidance, some Trusts had introduced a policy of operating at 30% delivery of fertility services which would be increased incrementally in a managed way. Patient appointments had also been scaled down in hospitals, and this included diagnostic and other investigations.
- 4.5. It was noted that we had feedback from patients that some centres were over-charging patients for Covid-19 tests and for Personal Protective Equipment (PPE) usage at very high prices with no justification. Members commented that in terms of PPE some licensed centres were encouraging patients to bring their own as health services might have to ration supplies otherwise.
- **4.6.** Staff responded that Covid-19 and PPE charges were not directly within our remit but as the regulator we should comment on matters that appear to over-step the bounds of ethical treatment.
- **4.7.** The CE responded that he will be writing to all PRs later in the week about this.
- **4.8.** Members commented that Clinical Commissioning Groups (CCGs) had been advised that they could refer patients to other providers where their centres were not yet open. The DHSC representative commented that this was the intention and work was ongoing in this area.
- **4.9.** Members were concerned that the information passed on to patients from various clinics differed greatly in terms of content. Members advised that we should communicate with licensed centres about the benefits of giving detailed information to patients as this would ensure that no one was at a disadvantage due to incomplete information. The Chair commented that we might have to look

into passing the information to patients in other ways via our own website or HFEA communications.

- 4.10. The Director of Strategy and Corporate Affairs gave an update and informed members that there was recently an Association of Fertility Patient Organisations (AFPO) meeting where attendees had commented that the information we had published on our website relating to the pandemic and the reopening of the sector was very useful.
- **4.11.** There had been over 200 individual Covid-19 related patient enquiries and the types of issues raised had changed over the last three months.
- 4.12. Media interest had also reduced in relation to Covid-19 and fertility treatment and enquires were back to more general ones. In relation to social media, members commented that it was positive that the public could communicate directly with the regulator.
- **4.13.** Members were also informed that there had been lots of research/data enquiries and we were looking at how to manage this through the Register Research Panel (RRP) and SCAAC.
- 4.14. Members asked how staff responding to enquiries were being supported. Members heard that training was provided annually, there were regular team meetings and regular one-to-ones with the relevant staff.
- 4.15. The Chair also responded that the CE should pass on to staff the Authority's appreciation. The CE also commented that staff in the organisation were very well supported and there were mental health first aiders as part of that support package.

5. Revised licence fee model - development and consultation process

- 5.1. The Director of Finance and Resources presented this item and commented that at this stage members are being asked to consider and agree the proposed options and how we will consult with the sector going forward.
- **5.2.** The suggested models below were presented
 - **Introduce new variable charges.** This would maintain a full activity-based charging regime but would consider increasing the number of chargeable activities under the licence, which could result in different charges for freeze all, fresh embryo transfer and frozen embryo transfer.
 - **Inspection fee +**. The cost of inspection would be recovered in the year of an inspection taking place and there would be a different charge for a renewal and interim inspection. The remainder of HFEA licence fees would be derived from activity levels at each clinic which was similar to current our approach.
 - Semi fixed, some differentiation. This would be a combination of fixed "minimum" annual fee plus an activity-based charge. Fixed charge bandings would be based on clinic size in terms of activity with a different fee based on number of IVF cycles for example 0 99, 100 249, 250 599, 600 999, 1000 1499, 1500 2249, 2500 +. A further direct activity-based charge would also apply per cycle.
 - **Fully fixed, some differentiation.** This would be a single fixed annual fee with the annual licence fee being based on clinic size using historic activity levels and weighted against

agreed activity bands for example the number of IVF cycles - 0 - 99, 100 - 249, 250 - 599, 600 - 999, 1000 - 1499, 1500 - 2249, 2500 +.

- **5.3.** Following the presentation, members were invited to comment.
- 5.4. Members asked what the chances of litigation were if we moved to a different modelling proposal. Staff responded that we could not rule out litigation completely but consultation with the sector would take place and the outcome would be communicated extensively to avoid misunderstandings.
- **5.5.** Members felt that detailing what the charges were based on would be a positive way forward and would be clearer to the sector. Charging an inspection fee once every 2 to 4 years might not be received positively, especially in the NHS clinics. Therefore, the semi-fixed third option above might be a solution to this. Some members felt that there should be an inspection fee as it was the norm in other sectors including the education sector. Therefore, having a less frequent inspection fee could be seen as a reward for compliance.
- **5.6.** Regarding consultation, members cautioned against limiting it to patient groups only and suggested that it should be extended to the wider audiences in the sector. Ensuring there was fairness in terms of size and volume of activity was a fairer way forward.
- **5.7.** The representative from the DHSC commented that timings needed to be factored in especially as other government departments would be involved in signing off the change to fees.
- **5.8.** Staff commented that the Treasury would be expecting the proposal to demonstrate fairness and that time for this had been built into the plan.

Decision

- **5.9.** Members considered and agreed the proposed modelling options for wider consultation.
- **5.10.** Members agreed the proposed timetable for approval of a new fees model in November 2020.

6. New strategic risk register

- **6.1.** The Risk and Business Planning Manager presented the new strategic risk register to the Authority.
- **6.2.** Members were advised that three new risks aligning to the new strategy for 2020-2024 had been drafted. They were
 - RF1 Regulatory framework (the best care)
 - I1 Information provision (the right information)
 - P1 Positioning and influencing (shaping the future)
- **6.3.** Three risks which were all above tolerance had been identified and they were
 - Board capability
 - Financial viability
 - Relocation of HFEA offices in 2020.
- **6.4.** Coronavirus was a new high risk that has been added to the register, but it was at tolerance level.

- **6.5.** The Chair commented that it was a sensible risk register but there were concerns around the above tolerance risks. Regarding the board capability risk, the Chair commented that we continued to carry two vacancies and nine members would be coming to the end of their terms of office (be it first or second term) within the next few months. She stated that we were working with DHSC to try and stagger finishing dates for the purposes of continuity and invited other members to comment.
- **6.6.** Members asked if it was felt that the risk register adequately prepared us for our current position. Also, if the risk appetite for the board was appropriate for the current situation.
- **6.7.** Members suggested that some of the causes, sources and controls in the risk register be revisited so that they reflected strategic high-level points.
- **6.8.** Members felt that it was an excellent risk register. In particular, members welcomed the approach taken, responsiveness to information provision and how the register aligned with the strategy.
- 6.9. Regarding Heads of service considering what work to prioritise, especially if income should fall below projected expenditure, members asked staff to ensure that the Authority was sighted on the proposals.
- 6.10. In response to a question, it was noted that PRISM plans and the launch and roll-out to clinics remained under review and the PRISM report to AGC would include our underlying assumptions and management of risks.
- 6.11. The Chair commented that there was pressure all around in doing business as usual and addressing the new normal due to the impact of Covid-19 but she felt that we were getting the balance right.

Decision

6.12. Members noted and agreed the new strategic risks for the 2020 – 2024 strategy subject to the comments above.

7. Any other business

- 7.1. The Chair commented that she had nearly completed all member appraisals and would be sending them on to the DHSC when completed. It was noted that members whose terms of office were affected by the current discussions would be contacted directly by the Chair.
- **7.2.** The 30th anniversary of the HFEA and the Act was coming up and Lord Bethell, Parliamentary Under Secretary of State at the DHSC supported the idea of marking this key milestone.
- **7.3.** The Chair advised members that the date of the next meeting would be 2 July 2020.

Chair's signature

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

Signature

Minutes of Authority meeting 1 June 2020

Human Fertilisation and Embryology Authority

Chair: Sally Cheshire Date: 2 July 2020



Performance report

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	5
Meeting date:	2 July 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:	The Authority is asked to note and comment on the latest performance report and upon the changes to the content of the 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 May 2020.
- **1.2.** Performance was reviewed by SMT at its 22 June meeting.

2. Key trends

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

Red indicators

- **2.2.** The indicators classed as red are as follows:
 - C1 Efficiency of end to end inspection and licensing process
 - F1 Debt collection
 - F2 Debtor days (which is a new KPI from April 2020)
- 2.3. C1 can be explained by a range of factors, none of which suggest a wider structural problem with the administration of the licensing process. F1 and F2 can be explained by the impact of the Covid-19 pandemic.
- **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. Annex 2 lays bare the very significant impact that Covid-19 has had on our financial position. We recently received assurance from the DHSC that appropriate financial support would be provided and both AGC and the NAO are satisfied with that assurance.

3. Review of performance targets and report format

- **3.1.** A review of all performance measures was undertaken from February to April 2020. This is the first month Authority have seen the revised report.
- 3.2. In reviewing our performance management metrics, we have been mindful of a few key principles. Measures should be meaningful, actionable and reliable and we should maintain the smallest number of measures that will allow Authority to undertake its strategic oversight role effectively. Having more metrics does not ensure better management. Key will always be acting on what they are telling us. Having a focused approach to performance measurement will ensure that what is reported is meaningful to both executive management and the Authority.
- **3.3.** The vast majority of measures have remained as they were, though a few key indicators were changed to make them more meaningful and to reflect appropriate targets for our work. We are mindful of the need to maintain consistency for some cross-year reporting, but our priority is that measures should be informative, and changes have been proposed for that reason. The following is a high-level summary of the changes from the standard Authority performance data reported during the 2017-2020 strategic period:

3.4. Scorecard, summary financial position and finance data

- Mainly presentational changes.
- Overall RAG status of all indicators we have stopped counting trackers that are reported to SMT as neutral RAGs.
- Average working days taken for licensing end-to-end processing (RAG rated) we have changed the methodology for tracking the end to end compliance and licensing indicator, so this will now track one set of licensing events from the date of the inspection through to

Performance report

Human Fertilisation and Embryology Authority

decisions being made in the reporting month. This will mean the data is not a composite indicator, so shows 'real' items.

3.5. High-level Authority KPIs

- Some presentational changes.
- Percentage of OTRs responded to by deadline (RAG rated) we revised RAG thresholds, so our target is now to complete these in 30 working days rather than 20 and we changed target performance from 100% to 95%. This reflects the reality that we are now handling a greater number of requests without having yet identified any additional resource and that given the sensitivity of the information involved it is more important that we are correct than quick. We will add the number of requests that came in as a further reflection of workload in the month, as we begin work on these from the moment they arrive. While the service is on hold due to Covid-19 the clock will be paused on in-progress applications.
- FOI and PQs we now include the RAG status for these measures.
- PGD applications average number of working days will be used as the RAG indicator, alongside the range (rather than percentage delivered within the target). This reflects the fact that although we want to process these applications in a timely manner, for complex items it may not always be possible to achieve 100%, and this is not in itself a performance issue. A commentary will be provided and by including a range the outliers will be clearer. A new target for processing PGD applications of 75 working days (replacing the earlier 66 working day target) reflects the reality that applications are more complex and so we can expect these to routinely take longer to process. It also brings the end to end KPI into line with the additional days that were allowed for SAC minutes many months before.
- We removed:
 - Percentage of PGD applications processed within 66 working days (RAG KPI) replaced by average working days as noted above.
 - 3 months rolling average PGD data These measures do not add value for the purposes of monthly reporting.
- **3.6.** Authority should note that in the first year of a new report, some indicators may be reviewed and possibly revised. In addition, we will need to review the performance data that will be tracked for the PRISM system, once this is launched, and it will take some time to bed this in. If there are changes to the methodology or content of the report, we will share this in the management commentary.
- **3.7.** We would welcome any views from the Authority on any other KPIs or pieces of performance data it feels it is lacking.

Annex 1 HFEA Performance scorecard and management commentary - May data



Figure 1 - Fewer red indicators this month

RAG	Area	Trend and key data
Amber – just above	People - Employee turnover	15.2% Turnover
target	Target: between 5%-15%	1 leaver
Red – not at target	Regulatory efficiency - Time for end-to-end inspection and licensing process	50% within target. Average of 72wds
	Target: 100% in 70 working days or less	(items beginning with an inspection)
No target – more than double last month	Engagement - HFEA website sessions	148,372 sessions (61,192 in same month last year)

Summary financial position – May 2020 (Figures in thousands – £'000s)

Туре	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	199	1,028	(829)			
Expenditure	(1,117)	(1,106)	(11)			
Total Surplus/(Deficit)	(918)	78	(840)			

Commentary on financial performance to end May

Year to date is a deficit against budget of £840k and is represented by: a shortfall in our income due to the COVID-19 pandemic. The cessation of treatments implemented at the end of March has and will continue to impact our income. The majority of the year-to-date income relates to GIA funding and secondments (£125k). The second component is our expenditure which is higher than budget by £11k. This is due to the profiling of the budget of non-staff costs taking effect from the end of Q1.

There are no figures for the forecast. A detail review of planned expenditure will be undertaken at the end of Q1 and the results reflected in the first reforecast.

Management commentary

In May performance is generally good. We had 3 red indicators.

May saw the organisation continue to adapt to new ways of working required by Covid-19. In spite of this disruption, we saw good performance in most areas, including licensing which managed a significant amount of business, including 21 ELP items. Licence Committee minutes were amber rated, but only missed the target by a single day, despite members of the team juggling caring responsibilities.

Although the majority of treatments were paused following the implementation of General Direction 0014 on 23 March 2020, this was varied on 11 May to allow clinics to begin to reopen when safety requirements had been met. The Register team has been monitoring reported treatments to ensure that these are in line with Directions. We are pleased to report that they are: in April, the forms submitted were almost exclusively outcomes forms, or treatments that took place before the shutdown; in May, we saw an increase in the number of forms received, explained by an increase in activity in the sector and a number of other centres working on clearing reporting backlogs created by technical issues.

Covid-19 has had a significant impact on our finances. As a result of clinics' closure there have been delays in us collecting debts and a significant increase in debtor days. This poor performance will continue until clinics are working at pre-lockdown levels. We have reserves to cover our outgoings for a period but have recently received assurance from the Department that we will receive support enable us to manage these financial risks.

The risk-based approach to inspections undertaken by Compliance has been proceeding well. Desk-based interims have been undertaken, with visits scheduled for when physical inspections are possible, if there are concerns. Renewals have also been assessed using a risk-based approach, those licences considered low risk have been extended by 1 year. For those with concerns, a desk-based assessment has been conducted. Where necessary we have scheduled visits for as soon as we restart physical inspections (currently planned for September 2020).

Red indicators:

Compliance

• **C1 – Efficiency of licensing process.** Average days taken from date of inspection to decision communicated (minutes sent) to centre for those where minutes sent in month. Target is 100% within 70 working days. In May performance was 50% within target (7/14), with an average of 72 working days. The average hides a significant discrepancy between items, 14 items were completed, with the longest taking 123 working days (25 weeks) and the shortest 21 (4 weeks). Reasons for delays included busy workload, additional follow up needed, scheduling of items to sync with related papers, complexity of reports and actions. One item missed the target by only one day.

Finance

- **F1 Debt collection.** Percentage of debts collected within 40 working days from billing. Target is 85% of debts or more collected in the month within 40 working days from billing. In May our performance was 70% (based on number of debts).
- F2 Debtor days. Average days debts remain outstanding. Target is 30 working days or less. In May our performance was 437 days.

Annex 2 Financial management information



		-		-			~			
2019/20 IVF Cycles	10,996	879,680	61,386	4,910,880	2019/20 DI Cycles	5,676	212,850	5,676	212,850	
2020/21 IVF Cycles (actual)	818	65,440	27,983	2,238,640	2019/20 DI Cycles	66	2,475	2,550	95,625	
Variance	10,178	814,240	33,403	2,672,240	Variance	5,610	210,375	3,126	117,225	

The data shows the significant reduction in IVF and DI treatments as expected during the COVID-19 pandemic. When extrapolated, shows a potential year end position of a shortfall against last year's income of 54%(IVF) and 55% (DI). A review of clinic activities will be undertaken at the end of the first quarter which will inform our forecast.

May-20

Year to Date				
			Variance	
Actual	Budget	Variance	YTD	
£'000	£'000	£'000	%	
		Actual Budget	Actual Budget Variance	

Income

Grant-in-aid	-	-	-	0%
Non-cash (Ring-fenced RDEL)	85	85	-	0%
Grant-in-aid - PCSPS contribution	17	17	0	0%
Licence Fees	73	927	853	92
Interest received	0	-	(0)	-
Seconded and other income	24	-	(24)	-
Total Income	199	1,028	829	81

Revenue Costs

Adjusted for non-cash income/costs	(957)	(78)	(878)	
TOTAL Surplus / <mark>(Deficit)</mark>	(919)	(78)	(840)	(1,071)
Total Revenue Costs	1,118	1,107	(11)	1
Other Costs	9	8	(1)	12
Legal / Professional Fees	60	17	(42)	242
IT Costs	75	68	(7)	10
Facilities Costs incl non-cash	115	152	37	(24)
Authority & Other Committees costs	31	28	(3)	10
Other Staff Costs	17	8	(10)	125
Staff Travel & Subsistence	1	-	(1)	-
Salaries (excluding Authority)	811	826	15	(2)

Management commentary

Income.

Our income for the first two months of the financial year is down due to the impact of the COVID-19 pandemic which has seen activity at clinics halter. The variation of our Directions (GD0014) to allow the conditional reopening of clinics, does mean that some clinics will start to increase their activity, however our income will not reflect this for at least another three months.

Expenditure.

We have overspent against budget year-to-date by £11k which is the result of profilng budgeted expenses towards the end of Q1..

Forecast - a detailed review will be conducted at the end of Q1 of planned expenditure with the results being reflected in our forecast.

Annex 3 – Key performance indicators – Authority summary









New 2020-24 strategy revisited

Details about this paper

Area(s) of strategy this paper relates to:	Whole strategy
Meeting:	Authority
Agenda item:	7
Meeting date:	2 July 2020 (meeting by teleconference)
Author:	Paula Robinson, Head of Planning and Governance
Annexes	Annex 1: Strategy 2020-2024

Output from this paper

For information or decision?	For decision
Recommendation:	
Resource implications:	In budget
Implementation date:	1 October 2020 (tentative)
Communication(s):	For publication on the website
Organisational risk:	Low

1. Overview

- **1.1.** At the extraordinary Authority meeting on 21 April 2020, we agreed to delay the publication of our strategy and business plan, owing to the Covid-19 pandemic, until October or later. We also agreed to extend the strategy by one year, to 2024.
- **1.2.** That paper also set out the range of continuing and new work we would be undertaking during the 'lockdown' period, and beyond. Since then, alongside the measures we have taken to respond to the pandemic, we have put in place internal service delivery plans setting out the work we are doing in the first half of this unusual business year.
- **1.3.** The next step will be to move towards publishing a half-year business plan alongside our new strategy, in the autumn.

2. Revisiting our strategy and plans

- **2.1.** The situation we find ourselves in with Covid-19 has highlighted the importance of the best care and the right information, and of proactively preparing well for the future.
- **2.2.** Our response to the pandemic has largely been well received, and indeed the fertility sector was the first health service to re-open. But now, life is different. Our new strategy represents a significant step forward from our last strategy and focuses strongly on collaborating with other bodies to achieve the most positive impact. In the current context, some of those bodies may not be ready to begin to engage until a year or more from now.
- 2.3. Before the pandemic we had agreed a broad three-year plan for delivering the new strategy. It would be timely now to consider how Covid-19 might affect, or re-order, the delivery of our strategic priorities, to inform our consideration of the three-year plan. For instance, we had planned to collaborate with primary care professionals and Royal Colleges in year one, in relation to 'Improved access to information at the earliest (pre-treatment) stage'. It seems unlikely that the next business year would now be the ideal time to engage with those groups.
- 2.4. The Corporate Management Group (CMG) will hold its annual business planning meeting in August. We plan to discuss the reprioritisation of our future business plans at that meeting. The Authority's views on priorities and timing would therefore be very helpful, to inform that discussion.
- **2.5.** Our pre-publication version of the strategy is attached at Annex 1. Minor changes made to reflect the current situation are highlighted in the document.

3. Strategic priorities

- **3.1.** The strategy itself is as relevant and ambitious as ever. But our practical approach, and the order in which we address the strategic objectives, may need to be modified.
- **3.2.** The Authority's views are invited on the following key questions:
 - Has Covid-19, and our response to it, altered our relationship with patients, the public, and the sector?

- If so, how does this affect our approach to delivering our strategy, particularly in relation to collaborative working, or the timing of some of the objectives between later this year and March 2024?
- Are our strategic goals still the right ones?
- Does the 'shaping the future' area now come into focus sooner, rather than later?
- **3.3.** The upcoming 30th anniversary of the HFE Act and the establishment of the HFEA itself, may provide an opportunity to begin a wider discussion about 'shaping the future'. Quite properly, the 2020-24 strategy is focused on achievable outcomes within the medium term, but the Board may feel that this is also the time to look longer term, resources permitting.

4. Recommendations

- **4.1.** The Authority is asked to:
 - Discuss strategic priorities and our approach to strategy delivery, in light of the Covid-19 pandemic.
 - Confirm that the strategic vision and aims agreed previously remain valid and relevant.





HFEA Strategy 2020-2024

www.hfea.gov.uk



Our vision

Our vision is...

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

As we approach the 30th anniversary of the HFEA's creation, 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. The importance of this has been highlighted during the Covid-19 pandemic, when safe high quality care, good information and support have been paramount.

People's experiences differ, based on their individual circumstances. Our 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 change, 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.

The best care	O The right information	Shaping the future
Effective and ethical care that is scientifically robust, accompanied by excellent support, and provided by well-led clinics.	Accurate and useful information that is provided at the right time.	Proactively embracing new developments in the changing fields of modern family creation, genetics, and artificial intelligence.
A transparent evidence base so that patients can make informed choices, and more research and innovation to improve the evidence base.	Improved information at the earliest (pre-treatment) stage, with new information flows to support primary care professionals and patients.	Engaging with and facilitating debates on changes in science, law and society, integrating new developments into our work.
Improved recognition by clinics of partners' importance in the care process.	Access to relevant and impartial information for all – particularly about the evidence base, add-ons and treatment options.	Preparing for future legislative and operational changes, to ensure we remain a modern, effective and responsive regulator.

Our ambitions for 2020-2024 are summarised in the figure below:

3

Engagement, partnering and collaboration

As a public body, we value working collaboratively with organisations and professional bodies with whom we have shared interests.

We have well-established relationships with stakeholder groups and professional bodies, and we plan to build further partnerships with other organisations over the coming years.

Engagement with fertility clinics is about much more than satisfying the requirements of the compliance regime. We know we are most successful when we involve the sector and the professional bodies working within and around it, and when we listen to patients.

Partnership working helps us to have the most positive effect on the quality of care in clinics, and to magnify our impact, even though we work with limited resources.

Through dialogue and partnership, we want to improve the accessibility and positioning of accurate and timely information about fertility issues and treatment.

The best care



Aim: Effective and ethical care for everyone.				
Objectives	We want	We will		
Treatment that is effective, ethical and scientifically robust.	Individualised treatment and care that is safe, responsible, consistent and based on clear values.	Regulate effectively, transparently and consistently, and provide clinics with more comparative information about performance to encourage improved care.		
		Use our data to reduce variations between clinics (eg, for success rates, and levels of compliance) and collaboratively define best practices.		
	Clinics that are well led and see compliance and the provision of high quality care, including excellent support, as good business.	Continue our dialogue with clinic leaders, engaging with a representative cross-section of the sector (NHS and private clinics, including groups).		
		Continue to ensure clinics are compliant and offer good support.		
	A transparent and accurate evidence base, to ensure that patients can make informed choices about their	Work collaboratively to encourage and support more clinical and data research, including the usage of our Register data.		
	treatment. More research and innovation to improve the evidence base and outcomes.	Encourage clinics to use add-ons responsibly.		
Improved recognition of partners' importance (of the same or opposite sex) in the care process.	Partners to be involved in care and treatment choices throughout the process. Clinics to recognise that partner care is a core part of the service they provide.	Focus strongly on the care of partners and the provision of improved information for them by clinics. Highlight accurate information and encourage dialogue about male (as well as female) fertility issues.		

4

The right information []

Aim: To ensure that people can access the right information at the right time.				
Objectives	We want	We will		
Improved access to information at the earliest (pre-treatment) stage.	Right-moment information provision from the outset for patients, partners, donors and surrogates.	Create new information flows to support and engage with GPs, practice nurses and patients.		
		Work in partnership with key organisations such as the Royal Colleges to develop or link to materials for primary care professionals to help them access key knowledge and learning to help them guide patients.		
		Develop materials to support people in making early decisions about treatment, donation and surrogacy.		
High quality information to support decision- making during and after treatment or donation.	Patients, partners, professionals, surrogates, donors, donor-conceived people and their families all to have access to relevant and impartial information.	Position and promote our information so it is easy to find by everyone including professionals.		
		Publish more information about the evidence-base for treatments and add-ons.		
		Keep our information up to date so that it explains new treatment options.		

Shaping the future



Aim: To embrace and engage with changes in the law, science and society.				
Objectives	We want	We will		
Responding to scientific and social changes, particularly in modern family creation and the fields of genetics and artificial intelligence (AI).	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.	Engage with and facilitate debates within the fertility sector on emerging topics, working in partnership with relevant bodies, and providing up-to- date information. Recognise scientific evidence and societal changes, integrate these into our work, and encourage take-up of effective new techniques into clinical practice.		
Preparing for future legislative and operational changes.	To ensure the HFEA and clinics are prepared for future changes in the fertility field, and for any legislative changes.	Prepare to inform any future Parliamentary and public debate and implement any agreed changes. Be responsive to the changing nature of patient and public concerns. Work with the sector to ensure preparedness for ensuing changes.		
	To be a modern effective regulator and continue to respond to changes in our operating environment.	Respond to changes such as the growth in donor-conceived people eligible to make 'opening the register' (OTR) requests from 2021 and 2023.		

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