Human Fertilisation & Embryology Authority

Authority meeting - agenda

08 May 2019

Church House, Deans Yard Westminster, London SW1P 3NZ

Agenda item	Time
1. Welcome, apologies and declaration of interests	1.00pm
2. Minutes of 13 March 2019 Authority meeting **HFEA (08/05/19) 913** For decision	1.05pm
3. Chair's report (verbal)	1.10pm
4. Chief Executive's report (verbal)	1.20pm
5. Committee chairs' reports (verbal)	1.30pm
6. Performance report **HFEA (08/05/19) 914** For information	1.40pm
7. EU exit update **Presentation** For information	1.55pm
Break	2.05pm
8. Fertility trends **Presentation** For information	2.20pm
9. Strategy progress update and consultation materials **HFEA (08/05/19) 915** For comment	2.40pm
10. Strategic risk register **HFEA (08/05/19) 916** For information	3.15pm
11. Any other business	3.35pm
12. Close	3.40pm

Minutes of Authority meeting 13 March 2019

Strategic delivery:	☐ Safe, ethical effective treatment	☐ Consistent outcomes and support	☐ Improving standards through intelligence

Details:	
Meeting	Authority
Agenda item	2
Paper number	HFEA (08/05/19) 913
Meeting date	8 May 2019
Author	Catherine Burwood, Licensing Manager
Output:	
For information or decision?	For decision
Recommendation	Members are asked to confirm the minutes as a true and accurate record of the meeting.
Resource implications	
Implementation date	
Communication(s)	
Organisational risk	☒ Low ☐ Medium ☐ High
Annexes	

Minutes of the Authority meeting on 13 March 2019 held at Church House, Deans Yard, Westminster, London SW1P 3NZ

Members present	Sally Cheshire Margaret Gilmore Anita Bharucha Kate Brian Emma Cave Rachel Cutting	Bobbie Farsides Jonathan Herring Anne Lampe Gudrun Moore Ruth Wilde
Apologies	Yacoub Khalaf Anthony Rutherford	
Observers	Dafni Moschidou (Department of Health and Social Care)	
Staff in attendance	Peter Thompson Clare Ettinghausen Richard Sydee Catherine Drennan	Helen Crutcher Dina Halai Dan Howard Paula Robinson

Members

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

1. Welcome, apologies and declarations of interest

1.1. The Chair opened the meeting by welcoming Authority members and members of the public to the second meeting of 2019. As with previous meetings, it was audio-recorded, and the recording would be made available on our website to enable interested members of the public who could not attend the meeting to listen to our deliberations.

1.2. Apologies were received from Yacoub Khalaf and Anthony Rutherford.

1.3. Declarations of interest were made by:

- Rachel Cutting (Clinician at a licensed centre)

2. Minutes of Authority meeting held on 30 January 2019

2.1. Members agreed the minutes of the meeting held on 30 January 2019 for signature by the Chair of the meeting.

3. Chair's report

3.1. The Chair welcomed member Jonathan Herring back, following a short illness.

3.2. The Chair announced that the Authority had recruited a new member, Reverend Ermal Kirby, whose term of office would start on 1 May 2019.

3.3. On 31 January, the Chair and Chief Executive met Jackie Doyle-Price MP, Minister in the Department of Health and Social Care, to discuss the provision of IVF in the NHS in England, including commissioning guidance and benchmark pricing.

3.4. On 27 February, the Chair, Chief Executive and Authority member Yacoub Khalaf met Siobhain McDonagh MP to discuss a private members Bill. The Chair reported that the Bill's second reading in Parliament was scheduled for late March.

3.5. On 4 March, the Chair and Chief Executive met Lord Lindsay, Chair of the United Kingdom Accreditation Service (UKAS). They discussed how to continue to build on their close working relationship and the creation of a memorandum of understanding between the HFEA and UKAS.

3.6. On 8 March, the Chair led a Remuneration Committee.

4. Chief Executive's report

4.1. On 4 February, the Chief Executive attended the Scientific and Clinical Advances Advisory Committee (SCAAC).

4.2. On 8 March, the Chief Executive attended the Remuneration Committee.

4.3. The Chief Executive reported that, along with the Chair and Head of Human Resources, he had interviewed candidates for the role of Director of Compliance and Information. Members would be updated about the outcome of this in due course.

4.4. On 13 February, the Chief Executive attended a leadership development day along with the rest of the Corporate Management Group. This was followed up with an away day on 6 March.

4.5. On 14 February, the Chief Executive spoke at a graduation event for the Health and Care Leaders Scheme for Aspiring Directors programme.

4.6. The Chief Executive advised members that much of his time had been spent on activity related to the UK's planned exit from the EU. The Chief Executive would update members on EU exit later in the meeting.

4.7. The Chief Executive finally reminded members of the new date for the HFEA's annual conference: 13 June 2019.

5. Committee Chairs' reports

Licence Committee

5.1. The Chair of the Licence Committee provided an update regarding the 10 January meeting, the minutes of which were now approved. The committee approved two licence renewal applications; noted an Executive update regarding a previous grade A incident; approved the continuation of one licence following an interim inspection and served final notices with regards to the revocation of a licence.

5.2. The Chair reported that the committee had also met on 7 March 2019 and considered five items: two licence renewal applications; one interim inspection report; one licence variation application and one grade A incident report.

5.3. The Chair advised the other members that the minutes were still being drafted.

Statutory Approvals Committee

5.4. The Chair of the Statutory Approvals Committee (SAC) reported that the committee met on 31 January and 28 February.

5.5. On 31 January the committee considered eight items: two mitochondrial donation applications; two pre-implantation genetic diagnosis (PGD) applications; three Special Directions applications and one human leukocyte antigen testing application which had previously been adjourned.

5.6. All applications were approved with the exception of one Special Directions application which was adjourned. The Chair noted that all PGD applications related to multi-type conditions.

5.7. On 28 February the committee considered five PGD applications and received a briefing from the external legal advisor on the Authority's policy position in relation to patient choice in mitochondrial donation applications.

5.8. The Chair advised the other members that the minutes were still being drafted and provided an outline of the briefing received on patient choice in mitochondrial donation applications.

Executive Licensing Panel

5.9. The Chair of the Executive Licensing Panel (ELP) advised members that the panel had met twice since the last Authority meeting, on 12 February and 26 February.

5.10. The panel considered seven items in total: two licence renewal applications; three interim inspection reports; one licence variation application and one application for Special Directions.

5.11. All applications were granted with exception of one licence renewal application, which was adjourned.

5.12. The Chair of ELP also reported that 11 Licensing Officer considerations had been completed. All were for the approval of Importing Tissue Establishment certificates.

Audit and Governance Committee

5.13. The Chair of the Audit and Governance Committee (AGC) reported that the committee had met on 5 March 2019.

5.14. Aside from the usual standing items and updates from internal and external audit, the committee received reports on: register and regulatory management; the digital programme; finance; EU exit and the anti-fraud and whistleblowing policy, an update of which was approved.

Scientific and Clinical Advances Advisory Committee

5.15. The Deputy Chair of the Scientific and Clinical Advances Advisory Committee (SCAAC) reported that the committee had met on 4 February 2019.

5.16. The committee considered items on horizon scanning and high priority standing items such as mitochondrial donation and genome editing.

6. Performance report

6.1. The Director of Strategy and Corporate Affairs provided members with information about the following areas: two private members bills currently going through Parliament; the HFEA annual conference; the Licensing Review Implementation project; EU exit; the Fertility Show; the Fertility Forum held at the Royal College of Obstetricians and Gynaecologists (RCOG); a joint British Fertility Society (BFS) study week programme on leadership; implementing the changes from the new Code Of Practice regarding treatment add-ons and patient support; and work being completed in relation to HFEA data and research support.

6.2. The Director of Finance and Resources corrected errors in the projected year end variance for IT costs which was 332K, rather than 310K, over budget, presented in the Performance Report document and then went on to provide an update on the HFEA's financial position.

6.3. The Chief Executive provided members with an update regarding the Compliance team, following the departure of the Director of Compliance and Information, and in the absence of the Chief Inspector who had been on long term sick leave. The Chief Executive thanked the team and Senior Inspectors for keeping work to a high standard.

6.4. The Chief Executive invited the Chief Information Officer to provide an update on the digital programme. Members heard that progress was good regarding to the introduction of PRISM, the new data submission system, with a completion date expected at the end of March.

6.5. Members heard that progress with data migration was slower, due to an issue relating to the tracking of data over time in the Register. Options to resolve the issue would be brought to AGC at the end of April.

Decision

6.6. The members noted the latest performance report.

6.7. The members discussed the current format of the performance report and whether it represented the risks the Authority should focus on. It was agreed that developing a performance report that could combine strategic and patient risks would be considered as part of the development of the next strategy.

7. Effective governance

7.1. The Head of Planning and Governance explained that the Authority is committed to an annual review of governance arrangements, consisting of a self-review of each committee's effectiveness, and a review of standing orders.

7.2. As minor changes to several committee terms of reference in the Standing Orders were agreed at the last Authority meeting, the Head of Planning and Governance presented a paper about the annual reviews of committee effectiveness.

7.3. Members heard that this exercise was recently conducted by the Licence Committee, SAC, ELP and SCAAC.

7.4. The Head of Planning and Governance summarised the feedback received from committees, most of which was positive. Some improvement points were raised.

7.5. Positive feedback included:

- That roles and scope were clear
- The skills and knowledge in place
- Effective decision making at meetings
- Good committee support and papers
- Good quality Chairing
- The ability to have open discussions
- That a large and varied amount of business was handled well.

7.6. The main suggestions were:

- To consider for improvement the balance of business between the Licence Committee and ELP
- Scheduling and weighting of agendas
- Committee paper structures and consistency
- Enabling videoconferencing capability (which the members heard work was underway on).

7.7. The Authority was asked to note the feedback from the annual reviews of committee effectiveness.

Decision

7.8. Members noted and discussed the feedback from the annual reviews of committee effectiveness, and the action points for each committee.

7.9. The Chair gave thanks to the committees and the staff who support them, noting the variety of work that they are presented with.

8. Finance and business plan update 2019/20

8.1. The Director of Finance and Resources presented an update on the current financial and business plans for the 2019/20 business year.

Income forecasting

8.2. The Director of Finance and Resources provided an overview of the HFEA's funding streams, stating that 80% of funding comes from treatment fees.

8.3. The Director of Finance and Resources outlined the income forecast model assumptions, and members heard that the base assumption remained that the volume growth rate of 2% per annum would remain constant in the medium term.

8.4. The Director of Finance and Resources presented members with demographic data showing changes in conception rates and an increasing population of 35-45 year old

women. It was expected that demand for fertility treatment would remain static or to increase.

8.5. Regarding economic factors, members heard that there were no directly observable economic trends that suggested a fall in demand for private IVF treatments over the next financial year.

8.6. The Director of Finance and Resources outlined the choice between basing income planning on the trend of volume growth in treatment cycles, or to plan more prudently to ensure that, should we see a drop in treatment volumes, the HFEA will be able to meet it's financial commitments.

8.7. Members heard that for planning purposes the budget was based on the lower 2018/19 assumption and that a conservative forecast had been developed.

2019/20 budget

8.8. The Director of Finance and Resources went on to outline the 2019/20 budget and the assumptions that had fed into this: pay increases; maintaining a reserve against litigation of c£300k; IT system refreshes; and inflation in key external contracts and expenditure.

8.9. Members heard that in budget planning the HFEA had chosen not to factor in a planned increase in employer pension contributions to the Civil Service Pension Scheme at this time, as this remained an area of ongoing negotiation between the Department of Health and Social Care (DHSC) and HM Treasury. However, the Director of Finance and Resources advised members that on the preceding Monday, it had been confirmed that HFEA contributions would increase by 2.5%, leaving a shortfall in budget of £70k.

8.10. The Director of Finance and Resources presented members with the draft budget for 2019/20 which met all planned business delivery assumptions for the year and provided a buffer should treatment volumes drop.

Business plan 2019/20

8.11. The Risk and Business Planning Manager explained that the content of the business plan for 2019/20, agreed in draft at the November 2018 meeting, had been further developed to add a looking back section, reviewing what had been achieved in 2018/19. In addition, year-end and EU exit content would also be added imminently.

8.12. The Risk and Business Planning Manager noted that the activities related to our EU exit role would be reflected in the business plan, so that it was clear the HFEA would be maintaining the same standards and objectives following EU exit.

8.13. Members heard how, due to wider uncertainties, the final business plan and budget was not brought to this Authority meeting for sign off. Confirmation was being sought from DHSC regarding the process for departmental sign-off.

8.14. Given these circumstances, it was proposed that we await the remaining content, add year-end data, and circulate for Authority sign off via email.

8.15. The Authority was asked to:

- Note the assumptions behind the 2019/20 income and expenditure forecasts.
- Note the unusual circumstances around business plan sign-off this year and the imminent addition of further content related to EU exit and year-end.
- Agree to review and sign off further content via email, though any major revisions to previously agreed content will be brought before the Authority at its May meeting.
- Agree that DHSC sign-off of the business plan and the associated budget according to their timetable, after which the business plan will be published on our website.

Decision

8.16. Members noted the assumptions behind the 2019/20 income and expenditure forecasts but expressed concerns that too cautious an approach was being taken. Members discussed the possibility that any underspend be used to fund patient focused projects and to recruit a limited amount of new staff to help with capacity issues. The Chief Executive would discuss resources with the DHSC in the immediate term.

8.17. The members noted the unusual circumstances around business plan sign-off and the imminent addition of further content related to EU exit and year-end, and agreed to approve the draft business plan via email, or to consider further information in May if there were any further developments.

8.18. Members also agreed to DHSC sign-off of the business plan and the associated budget according to their timetable, after which the business plan would be published on the HFEA website.

9. EU Exit

9.1. The Chief Executive presented members with a verbal update regarding the UK's exit from the EU, providing an overview of activity to date and the different legal and operational preparations taking place.

Decision

9.2. Members noted the update on EU exit.

10. Strategy development

10.1. The Head of Planning and Governance presented a paper about the emerging shape of the 2020-2023 strategy, due to be launched in April 2020, and proposals for consultation and engagement during 2019.

10.2. Members heard that being ambitious and working with others to achieve results were key aims. The Head of Planning and Governance also summarised the operating landscape which would influence the strategy.

10.3. The Head of Planning and Governance went on to talk about the proposed strategic themes of the strategy.

10.4. The theme of ethical and effective care would include work on treatment add-ons; consent; treatment of partners; research and intelligence.

10.5. The theme of reaching people before treatment would include work with GPs and practice nurses; educating GPs and prospective patients; looking at access to treatment options and supporting initial choices.

10.6. The theme of being future ready would include work on legislative reviews; Opening the Register requests and the impact of the first donor conceived people turning 16 and 18 during the strategy period and considering developments in genetics.

10.7. The Head of Planning and Governance then outlined the overall strategic approach, including proposals on who the HFEA would work with and how, as well as possible consultation channels.

10.8. The Authority was asked to comment on the:

- Context and themes set out in this paper, with a view to further shaping our aims and the broad tactics we should adopt to achieve those aims.
- Broad approach outlined for consulting stakeholders and the general public.

Decision

10.9. Members agreed with the overall proposed themes of the strategy and approach to consultation.

10.10. Members discussed the use of the word 'ethical' and the proposal to specifically reach people before treatment. Members proposed wording suggestions that the Head of Planning and Governance would take away in order to prepare the strategy for consultation in such a way that would be appropriate for the remit of the HFEA.

11. The use of electronic consent

11.1. The Scientific Policy Manager presented a paper on the use of electronic consent in clinics, explaining that recent interest in the sector required the HFEA to consider whether to provide explicit Code of Practice guidance on the use of new technology.

11.2. Members heard that current guidance for centres only envisaged paper-based consenting using HFEA consent forms, and that it was therefore not explicitly applicable to the various methods of electronic consenting.

11.3. The Scientific Policy Manager talked about legal advice that had been sought. This included whether, for the purposes of Schedule 3 of the HFE Act 1990 which relates to consent, a consent form completed electronically and with an electronic signature would satisfy the requirement for consent to be "in writing". Legal advisers confirmed that electronic signature capture would be lawful. Additionally, advice was sought on practical and operational issues that research had uncovered.

11.4. If the Authority approved the recommendation to develop guidance on electronic consent, the Scientific Policy Manager confirmed that draft wording would be brought to the Authority for approval.

11.5. The Authority was asked to consider:

- current practice and use of electronic consent and
- the need for the HFEA to provide guidance on the safe and effective use of electronic consent.

Decision

11.6. Members expressed interest in this topic, and the area of consent in general. Concerns were expressed about electronic consenting, including ensuring that consent is always informed and provided by the person in question.

11.7. It was agreed that the executive would continue to look into ways to provide guidance in this area and report back to the Authority for consideration.

12. Any other business

12.1. There was no further business to discuss.

13. Chair's signature

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

Signature

Chair

Date

Performance report

Strategic delivery:	☒ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☒ Improving standards through intelligence

Details:	
Meeting	Authority
Agenda item	6
Paper number	HFEA (08/05/2019) 914
Meeting date	8 May 2019
Author	Helen Crutcher, Risk and Business Planning Manager
Output:	
For information or decision?	For information
Recommendation	The Authority is asked to note and comment on the latest performance report.
Resource implications	In budget
Implementation date	Ongoing
Communication(s)	The Senior Management Team (SMT) reviews performance in advance of each Authority meeting, and their comments are incorporated into this Authority paper. The Authority receives this summary paper at each meeting, enhanced by additional reporting from Directors. Authority's views are discussed in the subsequent SMT meeting. The Department of Health and Social Care reviews our performance at each DHSC quarterly accountability meeting (based on the SMT paper).

Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: HFEA performance scorecard		

1. Introduction

1.1. The attached paper summarises our performance up to the end of March 2019.

1.2. Further updates on performance and trends since this point will be provided verbally in the meeting.

2. Reviewing performance

2.1. SMT reviewed March performance data at its 15 April 2019 meeting.

2.2. Overall performance is good. Five indicators are currently classified as red. There is a full discussion of these in the performance report, provided in the annex to this paper.

3. Recommendation

3.1. The Authority is asked to note the latest performance report.

HFEA performance scorecard

Dashboard – March data

Overall performance – RAG status (all indicators)

People – capacity

Establishment leavers per month
(% turnover for the year).
KPI: 5 - 15% establishment turnover

⇧ Leavers: 1 (26.8%)

Engagement – Website traffic

Website sessions this month
Arrow tracks performance since last month

⇧ 60,344

Licensing end-to-end

Length of the whole inspection and licensing process
KPI: ≤ 70 working days

★ 60 working days

Summary Financial Position - 31 March 2019

	Year to Date		
	Actual £'000	Budget £'000	Variance £'000
Income	**6,870**	**6,490**	**(379)**
Expenditure	**6,746**	**6,269**	**(477)**
TOTAL Surplus / (Deficit)	**124**	**222**	**(98)**

Commentary

At the end of the financial year we are reporting a surplus of **£124k**, this is **£98k lower than budgeted.** We have incurred much higher expenditure in relation to agency staff and IT spend than was forecast at quarter 3 and this has reduced the surplus we anticipated.
This position may change as we review the accounts prior to the final audit that will commence in May 2019.

Overall performance – March 2019

SMT reviewed the overall performance picture on 15 April. There were five red indicators. Overall, March performance was generally good. Looking back across the business year as a whole, the vast majority of our KPIs have been consistently met, suggesting an organisation that is functioning well. The 2018/19 year saw us deal with a busy inspection programme, a significant increase in licensing activity, and a substantial increase in OTR requests, a threefold increase in PQs and an increase of nearly 50% in the number of unique visits to our website.

Red indicators
The five red key performance indicators (KPIs) shown in the 'overall status - performance indicators' bar chart on the dashboard are as follows:

People

- Establishment ('unplanned') leavers per month. Our target is to remain within 5 - 15% headcount turnover for the year. Performance in March was 26.8%. The overall planned and unplanned leavers for the year is 28.4%. This was a slight increase from February.

As a small organisation there is limited room for staff to develop their roles once they have been in post a while and so we are likely to experience a higher than average level of turnover going forward. However, an analysis of those leaving the organisation shows that they have worked for the HFEA for a reasonable period of time and therefore we should not be too surprised that they decided to move on. More positively, we have recruited very strong candidates to join the HFEA in recent months and continue to work on improving our offer to staff. Looking ahead we need to develop further our resilience as an organisation to cope with what is likely to be a continued period of stretched staff resources while recognizing that after several years of public sector austerity there is no spare capacity to call on.

Licensing decisions approved and finalised

- Average number of working days between Licence Committee (LC) date and minutes being finalised (signed by the Chair). The target for LC minutes is 100% in 15 working days but in March average performance was 20 working days. This month's LC minutes were particularly complex.

Reviewing the year as a whole, the licensing decision KPI has been met more often than not. The recent additions to the Governance team will provide greater resilience.

PGD processing

Although we have red indicators in this area, performance improved in February and March.

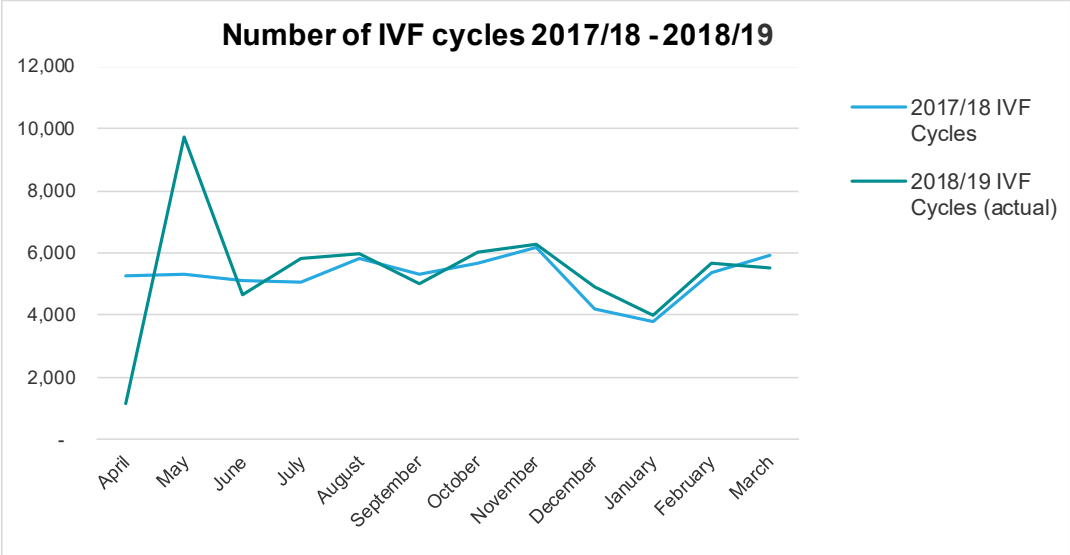
- Percentage of PGD applications processed within three months – Although this is still below our target of 100%, in March we saw an improvement in PGD processing times, 71% (5/7) of applications were completed within 66 working days, with an average processing time for those completed of 62 working days.
- 3 month rolling average figure – Percentage of all PGD applications processed within 3 months for the three months to date. Our target is 100% within 66 working days. In the five months to March this remained at 0% but in the 3 months to March we achieved 28% (five of the 18 due for completion were done on time), with an average processing time for those that had been completed of 75 working days.

Debts collected within 60 working days

- Our target is for 85% of all debts to be collected within 60 working days. In March performance was 80% (96/120). We missed the KPI in February and March, partly due lack of access to the portal/invoices by the clinics which has now been resolved.

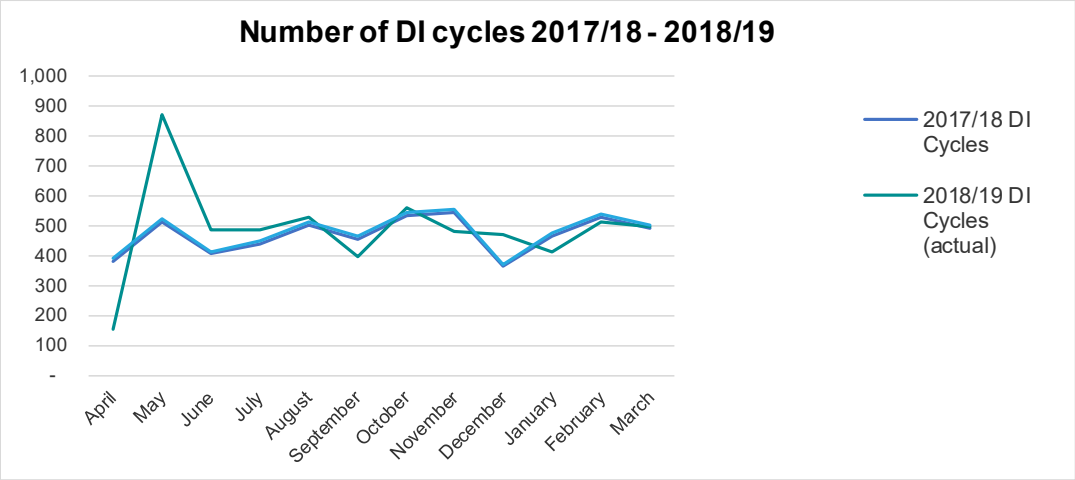
Budget status – March data

2018/19 Income



IVF Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2017/18 IVF Cycles	62,969	5,037,520	62,969	5,037,520
2018/19 IVF Cycles	64,720	5,177,600	64,720	5,177,600
Variance	1,751	140,080	1,751	140,080

Our year end position reports billable IVF acitivty levels at 2.8% above our budget. Our budget for 2018/19 anticipated a 2% increase on 2017/18 volumes, actual volumes tranlate to year end income from IVF fees of £5,178k - £48k higher than budgeted and £140k higher than 2017/18.



DI Cycles	YTD		YE / Forecast	
	Volume	£	Volume	£
2017/18 DI Cycles	5,607	210,263	5,607	210,263
2018/19 DI Cycles	5,845	219,188	5,845	219,188
Variance	238	8,925	238	8,925

At the end of the 2018/19 financial year, the volume of DI treatment cycles reported is 4.2% higher than for the 2017/18 financial year. This increased level of activity has led to £9k of additional income.

HFEA Income & Expenditure — Mar-2019

	Year to Date		
	Actual £'000	Budget £'000	Variance £'000
Income			
Grant-in-aid	934	934	-
Licence Fees	5,446	5,416	(30)
Other Income	15	-	(15)
Seconded Salary reimbursed	476	141	(335)
Total Income	6,870	6,490	(379)
Revenue Costs			
Salaries (excluding Authority)	4,265	3,911	(354)
Staff Travel & Subsistence	157	162	5
Other Staff Costs	160	126	(35)
Authority & Other Committees costs	263	280	18
Facilities Costs incl non-cash	692	709	16
IT Costs	600	211	(389)
Legal / Professional Fees	317	585	268
Other Costs	292	285	(7)
Total Revenue Costs	**6,746**	**6,269**	**(477)**
TOTAL Surplus /(Deficit)	**124**	**222**	**(98)**

Management commentary

Income.

We have ended the year with income from Treatment and licence fees exceeding budget by **£30k.** This is represented by an increase of **£44k** treatment fees and net reduction of **£14k** in Licence fees (renewals, storage and research) and EUTD fees. Ring-fenced income is the non-cash cover provided by DHSC of **£336k** with balance being income from seconded staff.

Expenditure.

The year end position shows that expenditure is above our budget by **£477k** (7.6%). Below are details of material variances:

Staff costs including Temporary staff - £354k above budget - a result of overspends on agency staff (£618k) offset by underspends in salary and on-costs (national insurance and pension) of £266k. Agency staff costs within the Compliance and Information Directorate are significant due to additional data migration and other work resulting from the delay in completing the PRISM project.

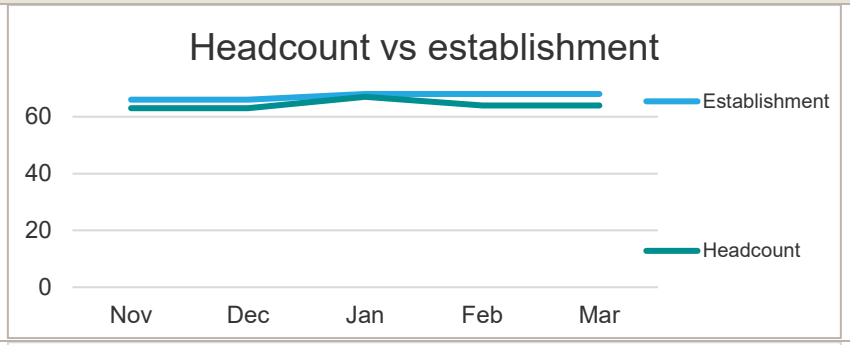
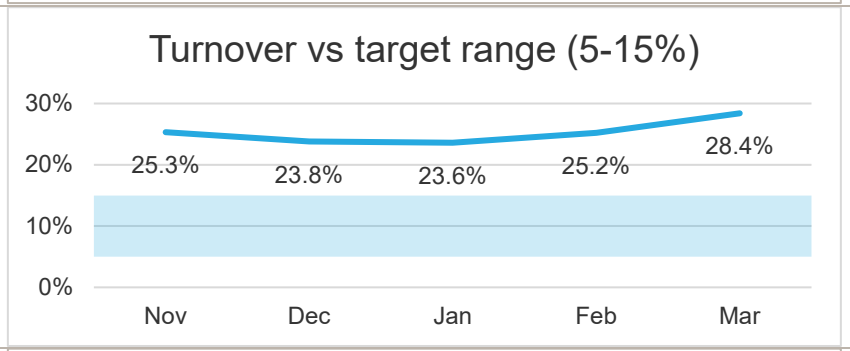
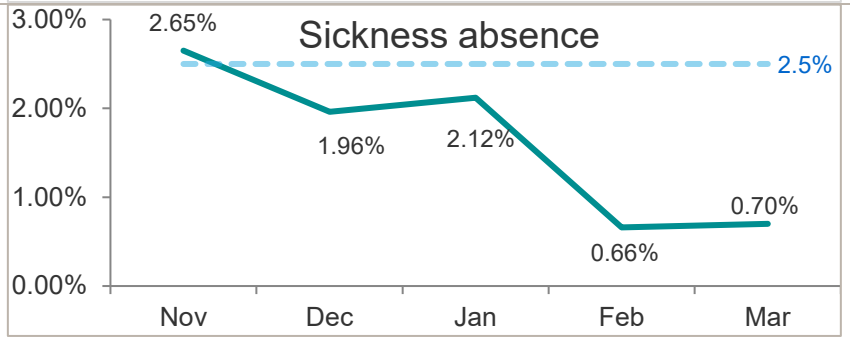
Other staff costs - overspends within the staff training budget (£19k) and recruitment (£20k).

IT Costs - £389k over budget - due to significant overspends within IT Consultancy/Support costs (£244k), IT subscriptions (£25k) and Consumables (£118k). The IT Consultancy spend is the cost of IT support through to the completion of a tendering exercise to procure third party support from 2019/20.

Legal and Professional fees - **£268k under budget** - The overall underspend in this area relates to the litigation contingency funds that were held to meet a Court of Appeal hearing. Legal spend for the year is on budget at £262k.

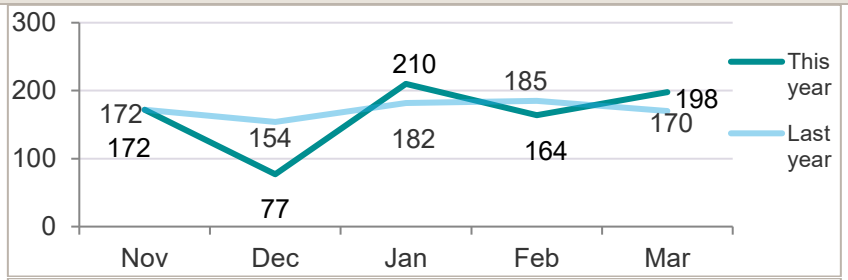
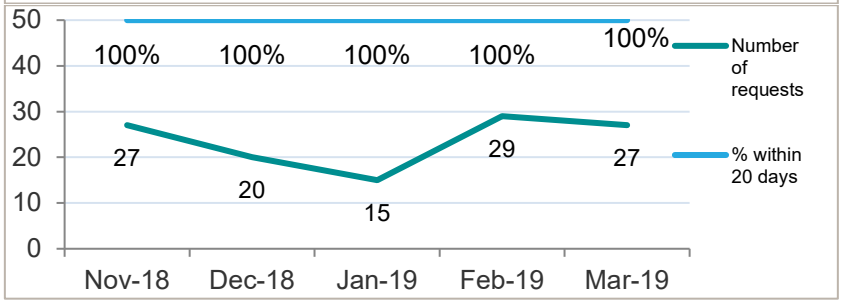
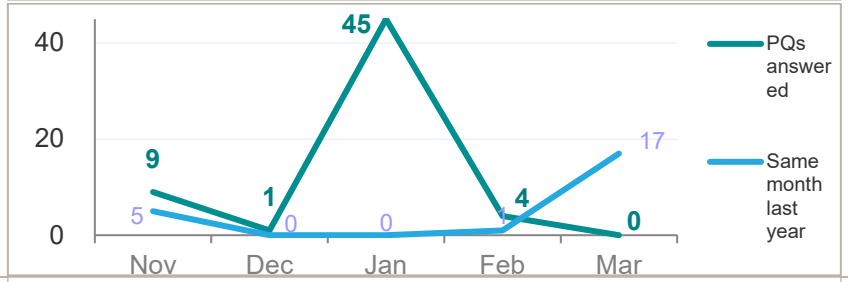
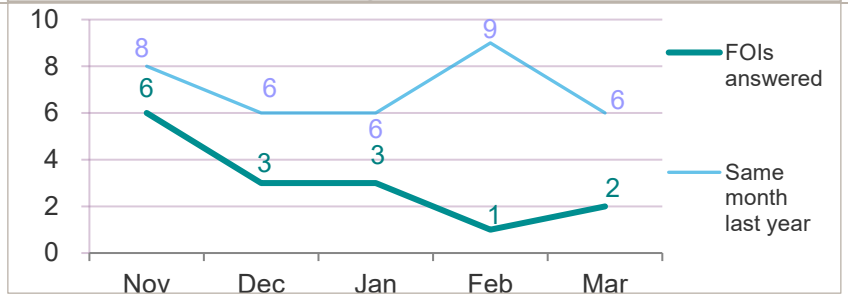
Other Costs - £6k - underspends are within the Strategy directorate totaling (£26k) offset by overspend of £26k within Compliance.

People – key performance and volume indicators

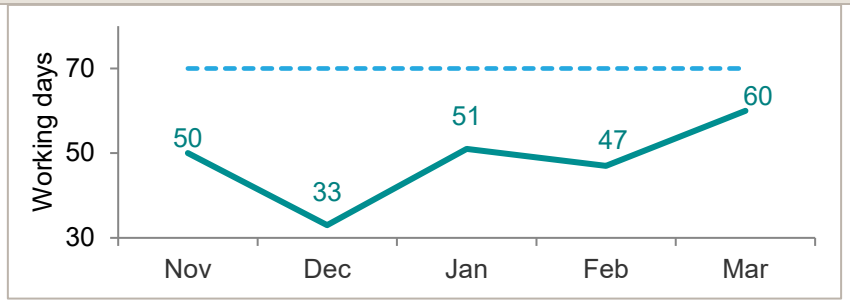
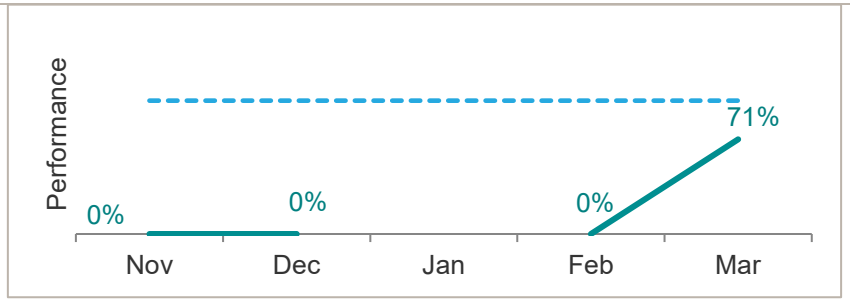
Indicator	Score	RAG	Recent trend[1]	Notes
Current headcount by month Staff in post/headcount	64/68	⇩		Overall volume (capacity) indicator.
Turnover: Establishment ('unplanned') leavers (% establishment turnover for the year). This is done monthly for the rolling year to date.	28.4%	⇧		KPI range: 5-15% turnover for the rolling year The public-sector average is 10.9% (Xpert HR 2017) on which we base our target.
Staff sickness absence rate (%) per month.	0.7%	★		KPI: Absence rate of ≤ 2.5%. Average rate of public sector sickness absence is 2.6% versus 1.7% for the private sector. (Source: ONS data 2017)

Information – key performance and volume indicators

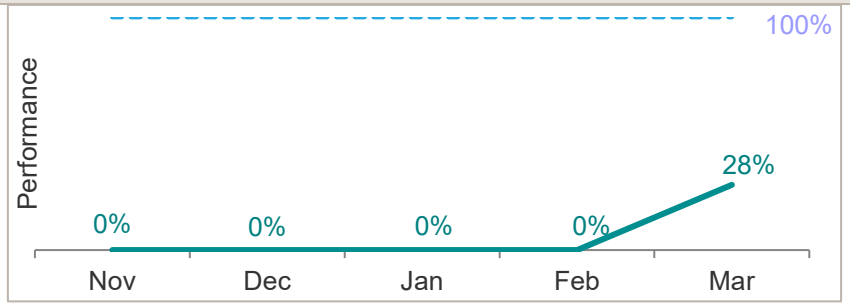
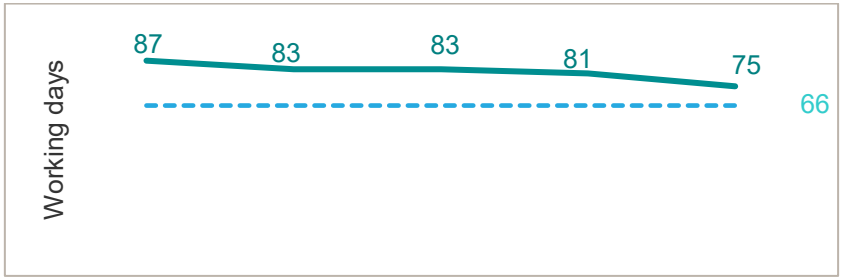
[1] KPIs, where applicable, are shown as a blue dashed line in graphs. This line may be invisible when performance and target are identical (eg, 100%). Our establishment turnover KPI is a range, which is shown as a blue band in the graph.

Indicator	Score	RAG	Recent trend	Notes
Number of emailed public enquiries received (compared with same month last year)	198	⇧		Volume indicator.
Percentage of Opening the Register requests responded to within 20 working days	100%	★		KPI: 100% of complete OTR requests to be responded to within 20 working days (excluding counselling time)
Number of requests for contributions to Parliamentary questions	0	⇩		Volume indicator.
Number of Freedom of Information (FOI) requests	2	⇧		Volume indicator.

Inspection and licensing process – key performance and volume indicators

Indicator	Score	RAG	Recent trend[2]	Notes
Average number of working days taken for the whole licensing process, from the day of inspection to the decision being finalised (signed off by the chair)	60	★		KPI: Less than or equal to 70 working days.
Monthly percentage of PGD applications processed within three months (66 working days).	71% (5/7)	⇧		KPI: 100% processed (i.e. considered by SAC) within three months (66 working days) of receipt of completed application. No applications were due to be completed in January, so there is no data to report.
Average number of working days taken (in the month).	62	★		As above, there was no data to report for January.

[2] KPIs, where applicable, are shown as a blue dashed line in graphs. This line may be invisible when performance and target are identical (eg, 100%). Our establishment turnover KPI is a range, which is shown as a blue band in the graph.

Indicator	Score	RAG	Recent trend[2]	Notes
Cumulative 3 month (rolling average) percentage of PGD applications processed within three month KPI (66 working days)	28% (5/18)	⇧		KPI: As above.
Average number of working days taken (cumulative 3 month picture).	75	⇩		

Strategy progress update

Strategic delivery:	☒ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☒ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	9		
Paper number	HFEA (08/05/2019) 915		
Meeting date	08 May 2019		
Author	Paula Robinson, Head of Planning and Governance Helen Crutcher, Risk and Business Planning Manager		
Output:			
For information or decision?	For decision		
Recommendation	The Authority is asked to approve the draft outline of the strategy, and the plans for consultation.		
Resource implications			
Implementation date	May to October 2019		
Communication(s)	We will use our website and social media to promote the survey, as well as existing channels with stakeholders. When the strategy has been finalised, it will be published on our website.		
Organisational risk	☒ Low	☐ Medium	☐ High
Annexes	Annex: Draft outline of the 2020-2023 HFEA strategy		

1. Introduction

1.1. Following an earlier Authority workshop, and further discussion at the March Authority meeting, an outline strategy has been created, for consultation purposes. This is attached at Annex 1.

1.2. We have also prepared a consultation plan and a survey, which the Authority is invited to comment on.

1.3. Our goal is to create a strategy which is succinct and powerful, to set a framework for the more detailed operational business plans which will be created later. As before, our intention is to focus our organisational energies and resources around three key areas.

1.4. At this stage, we need to reach agreement on the ideas in the strategy rather than the drafting.

2. Outline strategy

2.1. At this stage, the outline sets out the overarching aims and objectives we have agreed to date.

2.2. At a later stage (post-consultation), the Authority will wish to agree a vision statement as well as the detail of the strategy. We have previously agreed that our vision will continue to entail a strong focus on quality. Our current vision is for high quality care for everyone affected by fertility treatment.

2.3. We have also discussed our ways of working to deliver the next strategy. In particular, we have recognised the benefits of working collaboratively, in partnership with our stakeholders and other bodies. In this way, we can extend our reach to patients, GPs, and other groups, and maximise our impact.

2.4. In line with earlier comments from members, we now propose the following strategic aims and objectives:

The best care

- **Aim -** That patients, partners and donors receive high quality care, informed by evidence
- **Objectives**
  - Treatment that is ethically and scientifically robust
  - Improved recognition of partners' importance in the care process

The right information

- **Aim -** To ensure that people can access the right information at the right time
- **Objectives**
  - Improved access to information at the earliest stage of the treatment journey
  - Patients have the right information to support them in making choices

Being future-ready

- **Aim -** To ensure the HFEA is ready to respond to changes in law and society
- **Objectives**
  - Preparedness for future legislative and operational changes

- Responsiveness to scientific and social changes, particularly in the fields of genetics and artificial intelligence (AI)

2.5. The above aims and objectives are accompanied by an outline set of statements entitled 'we want' and 'we will', to indicate our aspirations and tactics for addressing each area.

3. Consultation

3.1. We want to consult widely to ensure that we gather views and ideas from a range of stakeholders, including patients and the public. The consultation will fall into two parts. In early summer, we will open a survey to all stakeholders and promote this, as well as talking directly to our existing stakeholder groups. Then later in the summer into the early autumn, we will begin to target our conversations, to follow up on the ideas and issues raised, concluding at the PR event in October, before finally presenting findings to Authority in November.

3.2. A key strand of the consultation will be a short survey which will be open to all stakeholders. This will be no more than five questions and will focus on the key areas of the draft strategy, with free text boxes to give respondents the option to provide more information on what they would like to see and what is most important to them. There will be some tailoring so that we can ask slightly different questions to:

- Patients and their partners
- Donors, donor conceived people and the families of donor conceived people
- Professionals, including researchers, and those working in UK clinics
- Other respondents.

3.3. The survey will be one key way of gathering views, but we intend to supplement this through a wide range of methods. Below is a table setting out the consultation activities we are planning:

Timing	Channel
May - August	Engagement with HFEA staff including intranet posts and all staff meetings
May	Website – publish information about the survey and the purpose of the consultation
May - August	Consultation survey live
May - August	Twitter – a targeted campaign to boost the reach of the survey
May - August	Facebook – posts promoting the survey
May - August	Social media through stakeholder bodies (tbc)
June/July	Clinic Focus article(s) to reach clinic staff
May	Association of Fertility Patient Organisations meeting (based on today's discussion)
May	Professional Stakeholder Group meeting (based on today's discussion)
May	Licensed Centres Panel meeting (based on today's discussion)
June	Scientific and Clinical Advances Advisory Committee meeting
June	HFEA Conference - possibly kiosk for clinic staff to complete the survey (tbc)

Timing	Channel
July – October	Direct engagement with the Department and wider stakeholders, for example ESHRE, royal colleges and others as appropriate
October	PR leadership event – sharing direction of travel
September – October	Follow up on earlier survey findings as necessary to explore what they might mean and what we might do

3.4. We are keen for members to be able to participate in the consultation if they would like to, be that through attending stakeholder meetings to help present ideas and listen to feedback, reaching out to networks to encourage them to complete the survey (or publish a link for us), or through other means.

3.5. In November we will bring the results of the consultation, including a survey analysis, back to you, alongside a more worked up draft of the strategy for discussion.

4. Recommendations

4.1. The Authority is asked to:

- Comment on and approve the outline draft aims and objectives, as the basis for consultation in the coming months.
- Comment on and approve the approach to consultation outlined above, and let us know if you would like to attend particular stakeholder meetings.

Annex (draft outline strategy 2020-2023 – aims and objectives)

The best care

Aim: That patients, partners and donors receive high quality care, informed by evidence.		
Objectives	**We want**	**We will**
Treatment that is ethically and scientifically robust.	Care that is safe, responsible and consistent.	Regulate transparently and collaboratively.
	A transparent and accurate evidence base, to inform patients' treatment choices.	Publish more information about the evidence-base for treatments and add-ons.
	Clinics that are well led and operate to a 'gold standard', and see compliance as good business.	Use our intelligence data to explore variations between clinics (eg for success rates, and levels of compliance) and define a 'gold standard' clinic.
	More research and innovation to improve outcomes.	Continue our leadership conversation with PRs, engaging with a representative cross-section of the sector (NHS and private clinics, including groups).
		Work collaboratively to encourage more clinical and data research, including the usage of our Register data.
		Support people to do research, and encourage funding for fertility research.
Improved recognition of partners' importance in the care process.	Partners to be involved in care and treatment choices throughout the process, on an equal footing with patients.	Focus strongly on the provision of improved information for, and care of, partners by clinics.
	Clinics to recognise that partner care is a core part of the service they provide.	Provide information about male fertility issues.

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 stage of the treatment journey.	Right-moment information provision. People to be supported all the way through their journey and their choices, including at the very beginning. Information about accessing fertility services to be transparent at the outset.	Create new information flows to educate GPs, practice nurses and patients. Work in partnership with key organisations such as the Royal Colleges. Develop a toolkit for GPs to help them access key knowledge to help them guide patients. Develop materials to support people in making early treatment decisions.
Patients have the right information to support them in making choices.	Informed patient choice. Patients to feel supported to make difficult treatment decisions.	Position and promote our information so it is easy to find. Keep our information up to date so that it explains any new treatment options. Continue to focus on the support patients and their partners receive at all stages of their treatment.

Being future-ready

Aim: To ensure the HFEA is ready to respond to changes in law and society.		
Objectives	**We want**	**We will**
Preparedness for future legislative and operational changes.	To be prepared for future changes in the fertility field, and for a possible future review of our Act. To be prepared for a growth in donor-conceived people eligible to make 'opening the register' (OTR) requests from 2021 and 2023.	Prepare to inform any future Parliamentary and public debate and implement any agreed changes. Ensure we are organisationally ready for an increase in our OTR operations.
Responsiveness to scientific and social changes, particularly in the fields of genetics and artificial intelligence (AI).	Patients 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. To be ready to respond to increasing numbers of complex PGD applications, and potentially new types of patients being treated in clinics.	Lead debates within the fertility sector on emerging topics, work in partnership with relevant bodies, and provide up-to-date information. Raise awareness about issues such as the impact of social media on anonymity. Recognise scientific and societal changes, and integrate these into our work and the information we publish.

Strategic risk register

Strategic delivery:	☒ Safe, ethical, effective treatment	☒ Consistent outcomes and support	☒ Improving standards through intelligence
Details:			
Meeting	Authority		
Agenda item	10		
Paper number	HFEA (08/05/2019) 916		
Meeting date	08 May 2019		
Author	Helen Crutcher, Risk and Business Planning Manager		
Output:			
For information or decision?	For information		
Recommendation	The Authority is asked to note and comment on the latest edition of the strategic risk register.		
Resource implications	In budget		
Implementation date	Ongoing		
Communication(s)	The risk register is reviewed monthly by the Senior Management Team (SMT) and presented at every Audit and Governance Committee (AGC) meeting. AGC last reviewed the risk register at its meeting on 5 March and will review it again at its meeting on 18 June.		
Organisational risk	☐ Low	☒ Medium	☐ High
Annexes	Annex 1: Strategic risk register		

1. Latest reviews

1.1. The Authority's strategic risk register sets out the key strategic risks that the organisation faces and the mitigating actions that are required to ensure that the risks remain at or below tolerance. The risk register is a live document and is reviewed on a monthly basis by SMT, with input from Heads as needed. SMT last reviewed all risks, controls and scores in the strategic risk register at its meeting on 15 April. One of the six risks was above tolerance.

1.2. The risk register was last discussed at AGC on 5 March. No changes were made to the risk scores at that time, although the committee requested the Executive considered additions related to the vacant Director post. Any comments from the Authority will be fed into the Committee's next review on 18 June.

1.3. SMT and AGC's comments are summarised on page 24 of the risk register, at Annex 1.

1.4. Looking ahead, the Authority will wish to revisit the strategic risk register in the light of its new three-year strategy for 2020-2023, once it is agreed.

2. Recommendation

2.1. The Authority is asked to

- note and comment on the latest edition of the strategic risk register

Latest review date – 15/04/2019

Strategic risk register 2018/19

Risk summary: high to low residual risks

Risk area	Strategy link*	Residual risk	Status	Trend**
C1: Capability	Generic risk – whole strategy	**12 – High**	At tolerance	⇔⇔⇔⇔
RE1: Regulatory effectiveness	Improving standards through intelligence	**9– Medium**	Above tolerance	⇔⇔⇧⇔
CS1: Cyber security	Generic risk – whole strategy	**9 – Medium**	At tolerance	⇔⇔⇔⇔
LC1: Legal challenge	Generic risk – whole strategy	**8 – Medium**	Below tolerance	⇔⇔⇔⇔
ME1: Effective communications	Safe, ethical effective treatment Consistent outcomes and support	**6 – Medium**	At tolerance	⇔⇔⇔⇔
FV1: Financial viability	Generic risk – whole strategy	**6 – Medium**	Below tolerance	⇔⇔⇔⇔

* Strategic objectives 2017-2020:

Safe, ethical effective treatment: Ensure that all clinics provide consistently high quality and safe treatment

Safe, ethical effective treatment: Publish clear information so that patients understand treatments and treatment add-ons and feel prepared

Safe, ethical effective treatment: Engender high quality research and responsible innovation in clinics

Consistent outcomes and support: Improve access to treatment

Consistent outcomes and support: Increase consistency in treatment standards, outcomes, value for money and support for donors and patients

Improving standards through intelligence: use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce

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

Recent review points are: SMT 28 January 2019 ⇨ AGC 5 March 2019 ⇨ SMT 18 March 2019 ⇨ 15 April 2019

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

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	4	12 – High	**2**	**3**	**6 – Medium**
Tolerance threshold:					**9 - Medium**

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

Commentary
Below tolerance. Indications to date are that income is in line with the predictive income model and there has been a small increase in treatment cycles from last year; this risk is therefore stable. While planning our draft 2019/20 budget, we have taken a prudent approach, utilising our predictive model, planning based on 2% growth on the current budget rather than against the recent trend, which is higher. This should ensure that should we see a drop in treatment volumes, the HFEA will be able to meet its financial commitments from its annual receipts. Should we find ourselves in a position of surplus we would consider additional projects to utilise this underspend effectively. Increases of 6% have been confirmed to the civil service pension employer contributions, of which we must fund 2.5% within the HFEA budget with the remainder centrally funded. This will be budgeted for and does not pose a particular risk to financial viability. There is uncertainty about the costs of completing the data migration element of the digital projects. If more money was needed for the completion of data migration, then in order to ensure that we do not exceed our control totals with DHSC we would reprioritise expenditure in other areas of the organisation.

Causes / sources	Mitigations	Timescale / owner
There is uncertainty about the annual recovery of treatment fee income – this may not cover our annual spending.	Heads see quarterly finance figures and would consider what work to deprioritise or reduce should income fall below projected expenditure. We have a model for forecasting treatment fee income and this reduces the risk of significant variance, by utilising historic data and future population projections. We will refresh this model quarterly internally and review at least annually with AGC.	Quarterly, ongoing, with AGC model review at least annually - next review due in 2019 - Richard Sydee

Our monthly income can vary significantly as: • it is linked directly to level of treatment activity in licensed establishments • we rely on our data submission system to notify us of billable cycles.	Our reserves policy takes account of monthly fluctuations in treatment activity and we have sufficient cash reserves to function normally for a period of two months if there was a steep drop-off in activity. The reserves policy was reviewed by AGC in December 2018. If clinics were not able to submit data and could not be invoiced for more than three months we would invoice them on historic treatment volumes and reconcile this against actual volumes once the submission issue was resolved and data could be submitted.	Ongoing – Richard Sydee In place – Richard Sydee
Annual budget setting process lacks information from directorates on variable/additional activity that will impact on planned spend. There is uncertainty about the costs of completing the data migration element of the digital projects.	Annual budgets are agreed in detail between Finance and Directorates with all planning assumptions noted. Quarterly meetings with Directorates flag any shortfall or further funding requirements. All project business cases are approved through CMG, so any financial consequences of approving work are discussed. If more money was needed for the completion of data migration, then in order to ensure that we do not exceed our control totals with DHSC we would reprioritise other expenditure in other areas of the organisation.	Quarterly meetings (on-going) – Morounke Akingbola Ongoing – Richard Sydee Ongoing – Richard Sydee
Inadequate decision-making leads to incorrect financial forecasting and insufficient budget.	Within the finance team there are a series of formalised checks and reviews, including root and branch analyses of financial models and calculations. The organisation plans effectively to ensure enough time and senior resource for assessing core budget assumptions and subsequent decision making.	In place and ongoing - Richard Sydee Quarterly meetings (on-going) – Morounke Akingbola
Project scope creep leads to increases in costs beyond the levels that have been approved.	Finance staff present at Programme Board. Periodic review of actual and budgeted spend by Digital Projects Board (formerly IfQ) and monthly budget meetings with finance. Any exceptions to tolerances are discussed at Programme Board and escalated to CMG at monthly meetings, or sooner, via SMT, if the impact is significant or time-critical.	Ongoing – Richard Sydee or Morounke Akingbola Monthly (on-going) – Olaide Kazeem
Failure to comply with Treasury and DHSC spending controls and finance policies and guidance leads to serious reputational risk and a loss of financial autonomy or goodwill for securing future funding.	The oversight and understanding of the finance team ensures that we do not inadvertently break any rules. The team's professional development is ongoing and this includes engaging and networking with the wider government finance community. All HFEA finance policies and guidance are compliant with wider government rules. Policies are reviewed annually, or before this if required. Internal	Continuous - Richard Sydee Annually and as required –

	oversight of expenditure and approvals provides further assurance (see above mitigations).	Morounke Akingbola
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: Legal costs materially exceed annual budget because of unforeseen litigation.	Use of reserves, up to contingency level available. The final contingency for all our financial risks would be to seek additional cash and/or funding from the Department.	Monthly – Morounke Akingbola
DHSC: GIA funding could be reduced due to changes in Government/policy.	A good relationship with DHSC Sponsors, who are well informed about our work and our funding model.	Accountability quarterly meetings (on-going) – Richard Sydee
	Annual budget has been agreed with DHSC Finance team. GIA funding has been provisionally agreed through to 2020.	December/January annually, – Richard Sydee

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

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

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

Commentary
At tolerance. This risk and the controls are focused on business as usual capability, rather than capacity, though there are obviously some linkages between capability and capacity. Since we are a small organisation, with little intrinsic resilience, it seems prudent to retain a low tolerance level. Turnover has been high for many months but the organisation continues to attract high-quality staff. Evidence suggests that the two main drivers of high turnover are the continuing constraints on public sector pay and the relatively few development opportunities in small organisations like the HFEA. Following the 2018 staff survey and the December 2018 staff awayday, an action plan has been shared with staff and this is being reviewed on a regular basis to ensure that progress continues. As part of this, in April 2019 we ran the first of several more frequent, shorter surveys to get a sense of the concerns of staff at regular intervals. Work has taken place to improve the organisational learning and development offer, with several courses planned throughout the first quarter of 2019/20 to target training needs identified by staff and the corporate management group. AGC received a paper on HR data in December 2018, to consider the situation in the round, including ongoing strategies for the handling of these risks, and further updates will be provided to allow them to track progress, the next being in June. Looking further ahead, we need to find ways to tackle the issues of pay and development opportunities, to prevent this risk increasing further. An idea we are keen to explore is whether we can build informal links or networks with other public sector or health bodies, to develop clearer career paths between organisations.

Causes / sources	Mitigations	Timescale / owner

High turnover, sick leave etc., leading to temporary knowledge loss and capability gaps.	Organisational knowledge captured via documentation, handovers and induction notes, and manager engagement. We have developed corporate guidance for all staff for handovers. A checklist for handovers is circulated to managers when staff hand in their notice. This checklist will reduce the risk of variable handover provision.	In place – Yvonne Akinmodun Checklist in use – Yvonne Akinmodun
	Vacancies are addressed speedily, and any needed changes to ways of working or backfill arrangements receive immediate attention. CMG and managers prioritise work appropriately when workload peaks arise.	In place – Yvonne Akinmodun In place – Peter Thompson
The vacant Director of Compliance and Information is being covered by other staff, this creates a risk that key pieces of work are unable to be delivered due to resource pressures and unforeseen capability gaps.	Appointment made and due to start in June, meanwhile, other staff are covering elements of this role and work is being re-prioritised as required.	Underway – Peter Thompson
Poor morale could lead to decreased effectiveness and performance failures.	Communication between managers and staff at regular team and one-to-one meetings allows any morale issues to be identified early and provides an opportunity to determine actions to be taken. The new intranet, which launched in October 2018 has enabled more regular internal communications.	In place, ongoing – Peter Thompson In place – Jo Triggs
	Work continues to implement actions in the people plan which launched in April 2018 and reflected staff feedback. Further actions have been identified through the 2018 staff survey and awayday. An action plan is in place from January 2019 and is being regularly reviewed to ensure that actions are effective. In 2018 new benefit options were implemented, including PerkBox and a buying and selling of annual leave policy (launched July 2018).	Annual survey and staff conferences – Yvonne Akinmodun In place - Peter Thompson
Increased workload either because work takes longer than expected or reactive diversions arise.	Careful planning and prioritisation of both business plan work and business flow through our Committees. Regular oversight by CMG – standing item on planning and resources at monthly meetings.	In place – Paula Robinson
	Oversight of projects by both the monthly Programme Board and CMG meetings, to ensure that projects end through due process (or closed, if necessary). We are re-launching our interdependencies matrix, which supports the early identification of	In place – Paula Robinson Matrix relaunching early 2019/20 –

	interdependencies in projects and other work, to allow for effective planning of resources.	Paula Robinson
	Learning from Agile methodology to ensure we always have a clear 'definition of done' in place, and that we record when products/outputs have met the 'done' criteria and are deemed complete.	Partially in place – further work to be done in 2019/20 - Paula Robinson
	Team-level service delivery planning for the next business year, with active involvement of team members. CMG will continue to review planning and delivery. Requirement for this to be in place for each business year.	In place – Paula Robinson
	Planning and prioritising data submission project delivery, and therefore strategy delivery, within our limited resources.	In place until project ends – Dan Howard
Future increase in capacity and capability needed to process and assess licensing activity including mitochondrial donation applications. Since Summer 2017, we have experienced resource pressures relating to the Statutory Approvals Committee, caused in part by mitochondrial donation applications and also the increasing complexity and volume of PGD conditions.	Licensing processes for mitochondrial donation are in place (decision trees etc). An external review of the HFEA licensing processes was carried out to assess current capabilities and processes and make changes for the future. We are in the process of implementing the relevant proposals. To mitigate the present capacity and capability issues, the executive has signed up more experienced mitochondria peer reviewers, have received feedback on the process and have made administrative changes to improve it. This includes improvements to the application form, to prevent additional administration and/or unnecessary adjournments. We have increased staffing capacity in the licensing team to address the capacity and capability issues. We hope that this will enable us to accommodate our existing level of demand, increasing our capacity to support the licensing function as we handle more business and ensure our committees are supported effectively.	Licensing review implementation underway from September 2018 – Paula Robinson / Clare Ettinghausen
We may not be able to find time to implement the People Plan to maximise organisational capability given our small organisational capacity and ongoing delivery of business as usual.	A leadership awayday in November 2017 and an all staff awayday in January 2018 focused on building an HFEA culture following organisational changes. Small focus groups have since been utilised to make the most of staff time and involve wider staff in developing proposals.	Ongoing – Yvonne Akinmodun

A number of staff are simultaneously new in post. This carries a higher than normal risk of internal incidents and timeline slippages while people learn and teams adapt.	Recognition that a settling in period where staff are inducted and learn, and teams develop new ways of working is necessary. Formal training and development are provided where required. Knowledge management via records management and documentation and the HR team has revised onboarding methods to make them clearer and more effective.	In progress – Peter Thompson In place – Yvonne Akinmodun
The future office move, occurring in 2020, may not meet the needs of staff (for instance location), meaning staff decide to leave sooner than this, leading to a significant spike in turnover, resulting in capability gaps.	We will consult with staff, to ensure that their needs are taken into account, where possible, when planning for the move. We plan to explore possible knowledge and capability benefits arising from the office move, such as the potential to open up closer working and career progression with other health regulators.	Early engagement with staff and other organisations underway and ongoing – Richard Sydee
The new organisational model may not achieve the desired benefits for organisational capability Delay in completing our digital projects means that elements of the new model have not been fully implemented. It will therefore take more time for us to validate whether the changes have been effective.	The model will be kept under review following implementation to ensure it yields the intended benefits. The staff survey provided an opportunity for staff to reflect on whether change has been well managed. The results will help to inform any further actions related to the model.	A review of the new model was presented to AGC in June 2018. Staff survey in October 2018 – Peter Thompson
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
Government/DHSC: The government may implement further cuts across all ALBs, resulting in further staffing reductions. This would lead to the HFEA having to reduce its workload in some way.	We were proactive in reducing headcount and other costs to minimal levels over a number of years. We have also been reviewed extensively in the past eg, the Triennial Review in 2016.	In place – Peter Thompson
Government/DHSC The UK leaving the EU may have unexpected operational consequences for the HFEA which divert resource and threaten our ability to deliver our strategic aims.	The department has provided guidance about the impact of a no-deal EU exit on the import of gametes and embryos. We continue to work closely to ensure that we are prepared and can provide detailed guidance to the sector at the earliest opportunity, to limit any impact on patients. We have provided ongoing updates to the sector. In December 2018, we commenced an EU exit project to ensure that we fully consider implications and are able to build enough knowledge and capability to handle the effects of the UK's exit from the EU, as a third country in relation to import and export of gametes. This project includes our role in communicating with the sector on the effects of EU	Communications ongoing – Peter Thompson

	exit, to ensure that clinics are adequately prepared in terms of staffing and access to equipment and materials. We have continued to engage with the DHSC and clinics to prepare for a 'no deal' scenario. As of early April 2019 immediate 'no deal' plans have been stepped down by the DHSC and we have informed clinics accordingly.	

CS1: There is a risk that the HFEA has unsuspected system vulnerabilities that could be exploited, jeopardising sensitive information and involving significant cost to resolve.

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

Risk area	Risk owner	Links to which strategic objectives?	Trend
Cyber security CS1: Security and infrastructure weaknesses	Peter Thompson, Chief Executive (pending start of new Director of Compliance and Information)	Whole strategy	⇔⇔⇔⇔

Commentary
Above tolerance. We have undertaken further cyber security (penetration) testing of the new digital systems such as PRISM and the Register, to ensure that these remain secure. The results have not revealed any significant issues. The third and final test is scheduled ahead of go-live. Go-live has been delayed owing to issues with data migration which are being investigated so that revised deployment plans can be developed. The delay poses no increased cyber risk. We continue to assess and review the level of national cyber security risk and take action as necessary to ensure our security controls are robust and are working effectively. The results of a cyber security audit were received in in December 2018, the rating of this audit was moderate with no significant weaknesses found.

Causes / sources	Mitigations	Timescale / owner
Insufficient governance or board oversight of cyber security risks (relating to awareness of exposure, capability and resource, independent review and testing, incident preparedness, external linkages to learn from others).	AGC receives reports at each meeting on cyber-security and associated internal audit reports. The Vice Chair of the Authority is regularly appraised on actual and perceived cyber risks. Internal audit report on data loss (October 2017) gave a 'moderate' rating, recommendations have been actioned, one final recommendation is being reported at each AGC meeting. A further cyber security internal audit report was finalised in December 2018. A final report on cyber security will be signed off by AGC before any decision is made to go live with PRISM.	Ongoing regular reporting – Director of Compliance and Information/ Dan Howard Ongoing – Dan Howard Deployment date of project to be confirmed once ongoing

		data migration issue resolved – Dan Howard
Changes to the digital estate open up potential attack surfaces or new vulnerabilities. Our relationship with clinics is more digital, and patient identifying information or clinic data could therefore be exposed to attack.	The website and Clinic Portal are secure and we have been assured of this. The focus now is on obtaining similar assurance through penetration testing report to the SIRO in relation to the remaining data submission deliverables (PRISM). The second of three rounds of penetration testing has been completed and there have been no significant issues found so far.	Penetration testing underway throughout development and ongoing – Peter Thompson/ Dan Howard
There is a risk that IT demand could outstrip supply meaning IT support doesn't meet the business requirements of the organisation and so we cannot identify or resolve problems in a timely fashion. We do not currently have a developer in post.	We continually refine the IT support functional model in line with industry standards (ie, ITIL). We undertook an assessment of our ticketing systems and launched a new system in November 2018. Following implementation, we will introduce ways to capture user feedback and this functionally will be introduced in May 2019. Following the completion of an earlier short-term cover arrangement, we have agreed to engage the third-party supplier again to provide further short-term cover, from November 2018 for a period of 4/5 months. Our vision is to have an internal team working in partnership with a third-party software development provider. Our strategy was to recruit to the in-house software development team following a workload review. This has now concluded and so we plan to start the recruitment process during April 2019. The tender for the third-party contract (Infrastructure support and Development support) was approved by CMG in March 19 and went live on 01 April 2019. We expect to award the contract in early June 2019 with a contract start date during July 2019. The service is based on the ITIL framework (IT service standard).	Approved per the ongoing business plan – Dan Howard Short-term arrangement in place from November 2018 for 4/5 months. Tender process underway to procure a longer-term support arrangement – Dan Howard Recruitment to internal development team underway from April 2019 – Dan Howard
Confidentiality breach of Register or other sensitive data by HFEA staff.	Staff are made aware on induction of the legal requirements relating to Register data. All staff have annual compulsory security training to guard against breaches of confidentiality although we are now due to refresh this. Updated information risk training has been identified and staff are expected to complete this during April / May 2019. Relevant and current policies to support staff in ensuring high standards of information security.	In place – Peter Thompson A review of current IT

	There are secure working arrangements for all staff both in the office and when working at home (end to end data encryption via the internet, hardware encryption) Further to these mitigations, any malicious actions would be a criminal act.	policies is ongoing – Dan Howard
There is a risk that technical or system weaknesses lead to loss of, or inability to access, sensitive data, including the Register.	Back-ups of the data held in the warehouse in place to minimise the risk of data loss. Regular monitoring takes place to ensure our data backup regime and controls are effective. We are ensuring that a thorough investigation takes place prior, during, and after moving the Register to the Cloud. This involves the use of third party experts to design and implement the configuration of new architecture, with security and reliability factors considered.	In place – Dan Howard Results of penetration testing have been positive. The new Register will be deployed once ongoing data migration issue is resolved, date TBC – Dan Howard
Business continuity issue (whether caused by cyber-attack, internal malicious damage to infrastructure or an event affecting access to Spring Gardens).	Business continuity plan and staff site in place. The BCP information cascade system was tested in March 2019 and recommendations for improvement will be made to CMG in April. Existing controls are through secure off-site back-ups via third party supplier. A cloud backup environment has been set up to provide a further secure point of recovery for data which would be held by the organisation. The cloud backup environment for the new Register has been successfully tested. Once the final penetration tests are complete we will utilise this functionality as we go live with our new Register and submission system.	BCP in place, regularly tested and reviewed – Director of Compliance & Information/ Dan Howard Undertaken monthly – Dan Howard The new Register cloud backup environment will be deployed once ongoing data migration issue is resolved – date TBC – Dan Howard
The corporate records management system (TRIM) is unsupported and unstable and we are carrying an increased risk of it failing. The organisation may be at risk of poor records management	A formal project to replace our electronic document management system is underway, for delivery of a new system in May 2019. We are continuing to manage the existing risk with the TRIM system by minimising changes and monitoring performance regularly. All staff have	Project to be delivered in May 2019 – Dan Howard

until the new system is functioning and records successfully transferred.	been reminded to continue to use TRIM to ensure records are complete.	
Cloud-related risks.	Detailed controls set out in 2017 internal audit report on this area. We have in place remote access for users, appropriate security controls, supply chain security measures, appropriate terms and conditions with Microsoft Azure, Microsoft ISO 27018 certification for cloud privacy, GCloud certification compliance by Azure, a permission matrix and password policy, a web configuration limiting the service to 20 requests at any one time, good physical and logical security in Azure, good back-up options for SQL databases on Azure, and other measures.	In place – Dan Howard
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None. Cyber-security is an 'in-common' risk across the Department and its ALBs.		

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

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

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

Commentary
Below tolerance. We accept that in a contested area of public policy, the HFEA and its decision-making will be legally challenged. Legal challenge poses two key threats: • that resources are substantially diverted • that the HFEA's reputation is negatively impacted by our participation in litigation. These may each affect our ability to regulate effectively and deliver our strategy. Both the likelihood and impact of legal challenge may be reduced, but it cannot be avoided entirely. For these reasons, our tolerance for legal risk is high. We have not had any active legal action since October 2018.

Causes / sources	Mitigations	Timescale / owner
Assisted reproduction is complex and controversial and the Act and regulations are not beyond interpretation. This may result in challenges to the way the HFEA has interpreted and applied the law.	Evidence-based and transparent policy-making and horizon scanning processes. Horizon scanning meetings occur with the Scientific and Clinical Advances Advisory Committee on an annual basis.	In place – Laura Riley with appropriate input from Catherine Drennan
	Through constructive engagement with third parties, the in-house legal function serves to anticipate issues of this sort and prevent challenges or minimise the impact of them. Where necessary, we can draw on the expertise of an established panel of legal advisors, whose experience across other sectors can be applied to put the HFEA in the best possible position to defend any challenge.	Ongoing – Catherine Drennan In place – Peter Thompson

	Case by case decisions on the strategic handling of contentious issues in order to reduce the risk of challenge or, in the event of challenge, to put the HFEA in the strongest legal position.	In place – Catherine Drennan and Peter Thompson
	We undertake good record keeping, to allow us to identify and access old versions of guidance, and other key documentation, which may be relevant to cases or enquiries and enable us to see how we have historically interpreted the law.	In place – Catherine Drennan
Committee decisions or our decision-making processes may be contested. ie, Licensing appeals and/or JRs.	Panel of legal advisors in place to advise committees on questions of law and to help achieve consistency of decision-making processes. The Head of Legal has put measures in place to ensure consistency of advice between the legal advisors from different firms. These include: • Provision of previous committee papers and minutes to the advisor for the following meeting • Annual workshop (next due April 2019) • A SharePoint site for sharing questions, information and experiences is in development	In place – Peter Thompson Since Spring 2018 and ongoing – Catherine Drennan
	Maintaining, keeping up to date and publishing licensing SOPs, committee decision trees etc. to ensure we take decisions well. Consistent decision making at licence committees supported by effective tools for committees. Standard licensing pack distributed to members/advisers (refreshed in February 2019). Project underway to implement changes in the light of the findings of an external licensing review, to make the licensing process more efficient and robust.	In place, further development underway as part of the licensing review implementation project – Paula Robinson
	Well-evidenced recommendations in inspection reports mean that licensing decisions are adequately supported and defensible.	In place – Sharon Fensome-Rimmer
High-profile legal challenges have reputational consequences for the HFEA which risk undermining the robustness of the regulatory regime and affecting strategic delivery.	Close working between legal and communications teams to ensure that the constraints of the law and any HFEA decisions are effectively explained to the press and the public. The default HFEA position is to conduct litigation in a way which is not confrontational, personal or aggressive.	In place – Catherine Drennan, Joanne Triggs In place – Peter Thompson, Catherine Drennan

	The Compliance team stay in close communication with the Head of Legal to ensure that it is clear if legal involvement is required, to allow for effective planning of work. The Compliance management team monitor the number and complexity of management reviews to ensure that the Head of Legal is only involved as appropriate.	In place – Sharon Fensome Rimmer, Director of Compliance & Information
Moving to a bolder strategic stance, eg, on add-ons or value for money, could result in claims that we are adversely affecting some clinics' business model or acting beyond our powers. Any changes could be perceived as a threat – not necessarily ultimately resulting in legal action, but still entailing diversion of effort.	Risks considered whenever a new approach or policy is being developed. Business impact target assessments carried out whenever a regulatory change is likely to have a significant cost consequence for clinics. Stakeholder involvement and communications in place to ensure that clinics can feed in views before decisions are taken, and that there is awareness and buy-in in advance of any changes. Major changes are consulted on widely.	In place – Clare Ettinghausen
The Courts approach matters on a case by case basis and therefore outcomes can't always be predicted. So, the extent of costs and other resource demands resulting from a case can't necessarily be anticipated.	Scenario planning is undertaken with input from legal advisors at the start of any legal challenge. This allows the HFEA to anticipate a range of different potential outcomes and plan resources accordingly.	In place – Peter Thompson
Legal proceedings can be lengthy and resource draining and divert the in-house legal function (and potentially other colleagues) away from business as usual.	Panel in place, as above, enabling us to outsource some elements of the work.	In place – Peter Thompson
	Internal mechanisms (such as the Corporate Management Group, CMG) in place to reprioritise workload should this become necessary.	In place – Peter Thompson
HFEA process failings could create or contribute to legal challenges, or weaken cases that are otherwise sound,	Licensing SOPs were improved and updated in Q1 2018/19, committee decision trees in place. Advice sought through the Licensing review on specific legal points, so that improvements can be identified and implemented. A project to implement these is underway.	In place – Paula Robinson From October 2018 – Paula Robinson
	Up to date compliance and enforcement policy and related procedures to ensure that the Compliance team acts consistently according to agreed processes.	In place but in the process of being reviewed – Catherine Drennan
Legal parenthood consent cases are ongoing and some are the result of more recent failures (the mistakes occurred	The Head of Legal continues to keep all new cases under review, highlighting any new or unresolved compliance issues so that the	In progress and ongoing – Catherine Drennan,

within the last year). This may give rise to questions about the adequacy of our response when legal parenthood first emerged as a problem in the sector (in 2015).	Compliance team can resolve these with the clinic(s).	Sharon Fensome-Rimmer, Director of Compliance & Information
Storage consent failings at clinics are leading to a significant diversion of legal resource and additional costs for external legal advice.	We have taken advice from a leading barrister on the possible options for a standard approach for similar cases. We are in the process of considering how the advice can be interpreted in guidance which can be applied broadly across the sector. The Head of Legal made significant amendments to guidance in the Code of Practice dealing with consent to storage and extension of storage. This guidance should mean that clinics are clearer about their statutory responsibilities and thus prevent issues arising in the future.	Done in Q1 2018/19 – Catherine Drennan Revised version of the Code launched January 2019 – Laura Riley
GDPR requirements require a large number of changes to practice. If we fail to comply with the requirements, this could open the HFEA up to legal challenge and possible fines from the Information Commissioner's Office.	The GDPR project introduced a number of new and updated policies and processes, to ensure that the HFEA complies with the requirements. These will now be bedded into BAU to ensure that they are effective. The project was handled proactively, with a joint HFEA and HTA project team and sponsored directly by the Director of Finance and Resources to ensure senior oversight. Although the project was closed in October, ongoing actions are being closely monitored to ensure effective compliance. AGC have regular updates on progress.	Ongoing-Richard Sydee
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
DHSC: HFEA could face unexpected high legal costs or damages which it could not fund.	If this risk was to become an issue then discussion with the Department of Health and Social Care would need to take place regarding possible cover for any extraordinary costs, since it is not possible for the HFEA to insure itself against such an eventuality, and not reasonable for the HFEA's small budget to include a large legal contingency. This is therefore an accepted, rather than mitigated risk. It is also an interdependent risk because DHSC would be involved in resolving it.	In place – Peter Thompson
DHSC: Legislative interdependency.	Our regular communications channels with the Department would ensure we were aware of any planned change at the earliest stage. Joint working arrangements would then be put in place as needed, depending on the scale of the change. If necessary, this would include agreeing any associated implementation budget.	In place – Peter Thompson

	The Department are aware of the complexity of our Act and the fact that aspects of it are open to interpretation, sometimes leading to challenge. Sign-off for key documents such as the Code of Practice in place	

RE1: There is a risk that planned enhancements to our regulatory effectiveness are not realised, in the event that we are unable to make use of our improved data and intelligence to ensure high quality care.

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	4	16 - High	**3**	**3**	**9 – Medium**
Tolerance threshold:					**6 - Medium**

Risk area	**Risk owner**	**Links to which strategic objectives?**	**Trend**
Regulatory effective-ness RE 1: Inability to translate data into quality	Peter Thompson, Chief Executive (pending start of new Director of Compliance & Information)	Improving standards through intelligence: use our data and feedback from patients to provide a sharper focus in our regulatory work and improve the information we produce	⇔⇔⇧⇔

Commentary
Above tolerance. Data submission work continues although delivery has been somewhat delayed owing to complexities. As of mid-April, development work on PRISM is nearly complete, data migration is progressing but more slowly than anticipated. A discussion at AGC in March put forward five outline options to migrate the data and fully developed options will be taken to AGC in May at which point the plan for deployment will be agreed. This obviously causes a delay to accessing improved data and we consequently raised this risk in March 2019.

Causes / sources	**Mitigations**	**Timescale / owner**
IfQ has taken longer than planned, and there will be some ongoing development work needed leading to delays in accessing the benefits.	Data Submission development work is now largely complete, however decisions related to data migration must be taken before clinic implementation is possible. Oversight and prioritisation of remaining development work will be through the IT development programme board with oversight from AGC.	Deployment date of data submission project to be confirmed once ongoing data migration issue resolved – Director of Compliance & Information
Risks associated with data migration to new structure, compromises record accuracy and data integrity.	Migration of the Register is highly complex. IfQ programme groundwork focused on current state of Register. There is substantial high-level oversight including an agreed migration strategy	Deployment date to be confirmed once ongoing

	which is being followed. The migration will not go ahead until agreed data quality thresholds are met. AGC will have final sign off on the migration.	data migration issue resolved, with regular reporting on progress prior to this – Director of Compliance & Information /Dan Howard
We could later discover a barrier to meeting a new reporting need, or find that an unanticipated level of accuracy is required, involving data or fields which we do not currently focus on or deem critical for accuracy.	IfQ planning work incorporated consideration of fields and reporting needs were agreed. Decisions about the required data quality for each field were 'future proofed' as much as possible, through engagement with stakeholders to anticipate future needs and build these into the design. Further scoping work would occur periodically to review whether any additions were needed. The structure of the new Register makes adding additional fields more straightforward than at present.	In place regular reviews to occur once the Register goes live – Director of Compliance & Information
Risk that existing infrastructure systems – (eg, Register, EDI, network, backups) which will be used to access the improved data and intelligence are unreliable.	Maintenance of desktop, network, backups, etc. core part of IT business as usual delivery. In March 2018 CMG agreed to a new approach, including some outsourcing of technical second and third line support, this provides greater resilience against unforeseen issues or incidents. As noted above under CS1, we have a further temporary arrangement in place for ongoing external support for 4/5 months from November 2018 and are in the process of tendering for ongoing support.	In place – Dan Howard
Insufficient capability and capacity in the Compliance team to enable them to act promptly in response to the additional data that will be available.	Largely experienced inspection team. Two vacancies in the inspection team were filled in November 2018 and there will be a period of bedding in now that they have joined. A further inspector will be joining in May.	In place – Director of Compliance & Information
Failure to integrate the new data and intelligence systems into Compliance activities due to cultural silos.	Work has been undertaken to bed in systems, such as the patient feedback mechanism, and this is now a part of compliance business as usual.	Ongoing - Yvonne Akinmodun
Regulatory monitoring may be disrupted if Electronic Patient Record System (EPRS) providers are not able to submit data to the new Register structure until their software has been updated.	Earlier agreements to extend part of 'IfQ' delivery help to address this risk by extending the release date for the data submission project. Plan in place to deal with any inability to supply data. The Compliance management team will manage any centres with EPRS systems who are not ready	Ongoing - Director of Compliance & Information

	to provide Register data in the required timeframe. Centres will be expected to use the HFEA's PRISM if they are unable to comply. Early engagement with EPRS providers means the risk of non-compliance is slim.	
Data migration efforts are being privileged over data quality leading to an increase in outstanding errors	The Register team uses a triage system to deal with clinic queries systematically, addressing the most critical errors first.	In place – Director of Compliance & Information
	We undertake an audit programme to check information provision and accuracy.	In place – Director of Compliance & Information
Excessive demand on systems and over-reliance on a few key expert individuals – request overload – leading to errors	PQs and FOIs have dedicated expert staff to deal with them although they are very reliant on a small number of individuals. We have systems for checking consistency of answers.	In place – Clare Ettinghausen
	There is a dedicated team for responding to OTRs and all processes are documented to ensure information is provided consistently	In place – Dan Howard
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
None	-	-

ME1: There is a risk that patients and our other stakeholders do not receive the right information and guidance from us.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	4	12 High	**2**	**3**	**6 - Medium**
Tolerance threshold:					**6 - Medium**

Risk area	Risk owner	Links to which strategic objectives?	Trend
Effective communications ME1: Messaging, engagement and information provision	Clare Ettinghausen Director of Strategy and Corporate Affairs	Safe, ethical effective treatment: Publish clear information so that patients understand treatments and treatment add-ons and feel prepared Safe, ethical effective treatment: Engender high quality research and responsible innovation in clinics. Consistent outcomes and support: Increase consistency in treatment standards, outcomes, value for money and support for donors and patients.	⇔⇔⇔⇔

Commentary
At tolerance. Authority discussed our communications strategy in January 2019 and agreed that good progress had been made. Communications should be derived from the strategy and aligned with the key organisational objectives. This included the approach to building relationships with political and other stakeholders and developing a wider public affairs approach. Conversations about messaging and engagement are central to early discussion about the new 2020-2023 strategy to ensure that we take a joined-up approach that takes full advantage of our channels and a public affairs approach.

Causes / sources	Mitigations	Timescale / owner
Some of our strategy relies on persuading clinics to do things better. This is harder to put across effectively, or to achieve firm outcomes from.	When there are messages that need to be conveyed to clinics through the inspection team, staff work with the team so that a co-ordinated approach is achieved and messages that go out to the sector through other channels (eg clinic focus) are reinforced. When there are new or important issues or risks that may impact patient safety, alerts are produced collaboratively by the Inspection, Policy and Communications teams.	In place - Sharon Fensome-Rimmer, Laura Riley, and Jo Triggs
Patients and other stakeholders do not receive the correct guidance or information.	Communications strategy in place, including social media and other channels as well as making full use of our new website. Stakeholder meetings with	In place and reviewed periodically

	the sector in place to help us to underline key campaign messages. Our new publications use HFEA data more fully and makes this more accessible. Policy team ensures guidance is created with appropriate stakeholder engagement and is developed and implemented carefully to ensure it is correct. Ongoing user testing and feedback on information on the website allows us to properly understand user needs. We have internal processes in place which meet The Information Standard. Procurement of new providers for the Donor Conceived Register undertaken and successful. The executive is facilitating interim arrangements to ensure that there is a smooth transition of the service to the new supplier and effective information and support continues to be in place for donor conceived people.	(review underway Jan 2019) – Jo Triggs Ongoing – Nora Cook-O'Dowd In place – Laura Riley, Jo Triggs In place –Jo Triggs Certification in place, although the assessment and certification scheme is being phased out – Jo Triggs Contract awarded and transition arrangements in place – Dan Howard
We are not able to reach the right people with the right message at the right time.	We have an ongoing partnership with NHS.UK to get information to patients early in their fertility journey and signpost them to HFEA guidance and information. Planning for campaigns and projects includes consideration of communications channels. When developing policies, we ensure that we have strong communication plans in place to reach the appropriate stakeholders. Extended use of social media to get to the right audiences. The communications team analyse the effectiveness of our communications channels at Digital Communications Board meetings, to ensure that they continue to meet our user needs.	In place – Jo Triggs In place and ongoing – Jo Triggs In place - Laura Riley, Jo Triggs In place– Jo Triggs Ongoing – Jo Triggs
Risk that incorrect information is provided in PQs, OTRs or FOIs and this may lead to misinformation and misunderstanding by patients, journalists and others.	PQs and FOIs have dedicated expert staff to manage them and additional staff are being trained to ensure there is not over-reliance on individuals. We have systems for checking consistency of answers and a member of SMT must sign off every PQ response before submission.	In place - Clare Ettinghausen Clare Ettinghausen /SMT - In place

	There is a dedicated OTR team and all responses are checked before they are sent out to applicants to ensure that the information is accurate.	In place - Dan Howard
Some information will be derived from data, so depends on risk above being controlled.	See controls listed in RE1, above.	
There is a risk that we provide inaccurate information and data on our website or elsewhere.	All staff ensure that public information reflects the latest knowledge held by the organisation. The Communications team work quickly to amend any factual inaccuracies identified on the website. The Communications publication schedule includes a review of the website, to update relevant statistics when more current information is available.	In place - Nora Cook-O'Dowd, Laura Riley, and Jo Triggs In place – Jo Triggs In place – Jo Triggs
Risk interdependencies (ALBs / DHSC)	**Control arrangements**	**Owner**
NHS.UK: The NHS website and our site contain links to one another which could break	We maintain a relationship with the NHS.UK team to ensure that links are effectively maintained.	In place – Jo Triggs
DHSC: interdependent communication requirements may not be considered	DHSC and HFEA have a framework agreement for public communications to support effective co-operation, co-ordination and collaboration and we adhere to this.	In place – Jo Triggs

Reviews and revisions

SMT review – April 2019 (15/04/2019)

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

- RE1 – SMT discussed the changes relating to the delay to data migration delivery. Discussions would be occurring with AGC in May.
- C1 – SMT discussed the progress made in recruiting to the licensing function and reflected this in the register.

SMT review – March 2019 (18/03/2019)

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

- FV1 –SMT discussed the impact of increased pensions contributions on the budget and agreed that this did not materially impact the level of this risk or affect financial viability. SMT reflected that there was uncertainty as to the costs of completing the data migration, however work would be reprioritised as necessary to ensure that we did not exceed control totals.
- C1 – SMT agreed to an additional risk area being included, reflecting the particular risk related to the vacant Director of Compliance post. This was being proactively managed and did not increase the overall risk score.
- CS1 RE1 – SMT discussed the impact of the digital projects delays and noted that all timeframes should be updated. The primary implication was on the RE1 risk, since this was about taking advantage of improved systems. SMT agreed to raise the risk score from six to an above tolerance score of nine.

The risks were being proactively managed as part of discussions on the options for data migration, which would be considered by AGC.

- SMT discussed when the right time would be to expand on the estates/office move risk and agreed this this could be added as a separate risk area in this register once the scoping of the internal project had progressed and the business case agreed.

AGC review – March 2019 (05/03/2019)

AGC reviewed the risk register and scores and did not change any of these. The committee made the following points in discussion of the register and other items:

- C1 – Capability. AGC discussed the vacant Director of Compliance and Information post, the effects of this and current arrangements to cover the gap while a successor is recruited. The committee heard that possible interim arrangements were being considered and asked the Executive to consider how these risks and mitigations were reflected in the risk register.
- FV – AGC heard that there were emerging risks in this area related to the delay to sign off of the budget and the recent announcement of an increase to employer pension contributions. These would be reflected in the register as relevant.
- Under other items AGC discussed digital projects and estates and heard that these would be updated in the Register.

SMT review – January 2019 (28/01/19)

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

- CS1 – SMT noted that various controls needed updating and that a review of this risk would therefore be done following the meeting with the Chief Information Officer.
- EU Exit – SMT noted that the Director of Strategy and Corporate Affairs would be the main contact on this once the Director of Compliance and Information leaves the organisation. The Chief Executive remained the overall risk owner.
- SMT agreed that the Chief Executive would be the overall risk owner for the strategic risks owned by the Director of Compliance and Information following the departure of Nick Jones and until his successor started.

Criteria for inclusion of risks

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

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

Rank

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

Risk trend

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

Risk scoring system

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

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

Risk scoring matrix

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

Risk appetite and tolerance

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

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

Assessing inherent risk

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

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

System-wide risk interdependencies

As of April 2017, we explicitly consider whether any HFEA strategic risks or controls have a potential impact for, or interdependency with, the Department or any other ALBs. A distinct section to record any such interdependencies beneath each risk has been added to the risk register, so as to be sure we identify and manage risk interdependencies in collaboration with relevant other bodies, and so that we can report easily and transparently on such interdependencies to DHSC or auditors as required.

Contingency actions

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

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